Comparative Effectiveness Review
Number 245

Breast Reconstruction After Mastectomy: A Systematic Review and Meta-Analysis

AHRQ
Agency for Healthcare
Research and Quality

Comparative Effectiveness Review

Number 245

Breast Reconstruction After Mastectomy: A Systematic Review and Meta-Analysis

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 75Q80120D00001

Prepared by:
Brown Evidence-based Practice Center
Providence, RI

Investigators:
Ian J. Saldanha, M.B.B.S., M.P.H., Ph.D.
Wangnan Cao, Ph.D.
Justin M. Broyles, M.D.
Gaelen P. Adam, M.L.I.S., M.P.H.
Monika Reddy Bhuma, B.D.S., M.P.H.
Shivani Mehta, M.P.H.
Laura S. Dominici, M.D.
Andrea L. Pusic, M.D.
Ethan M. Balk, M.D., M.P.H.

AHRQ Publication No. 21-EHC027
July 2021
Revised October 2021

Errata

The original systematic review reported that autologous reconstruction (AR) with deep inferior epigastric perforator (DIEP) compared with latissimus dorsi (LD) flaps may result in comparable patient satisfaction with breasts (low strength of evidence [SoE]), based on two studies. Upon re-review of the studies, we found that only a single study reported relevant data for this comparison. The SoE was downgraded from low to insufficient based on a single study with high risk of bias and imprecise effect size. Based on this, a conclusion cannot be made for this comparison. This change is reflected in the Abstract, Main Points, Key Points for Key Question 6, and in Tables 8 and 9 and Appendix Tables E-6.4 and G-6.

This report is based on research conducted by the Brown Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 75Q80120D00001). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

Suggested citation: Saldanha IJ, Cao W, Broyles JM, Adam GP, Bhuma MR, Mehta S, Dominici LS, Pusic AL, Balk EM. Breast Reconstruction After Mastectomy: A Systematic Review and Meta-Analysis. Comparative Effectiveness Review No. 245. (Prepared by the Brown Evidence-based Practice Center under Contract No. 75Q80120D00001.) AHRQ Publication No. 21-EHC027. Rockville, MD: Agency for Healthcare Research and Quality; July 2021. Revised October 2021. DOI: https://doi.org/10.23970/AHRQEPCCER245. Posted final reports are located on the Effective Health Care Program search page.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new healthcare technologies and strategies.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see https://effectivehealthcare.ahrq.gov/about/epc/evidence-synthesis.

AHRQ expects that these systematic reviews will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the website (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

David Meyers, M.D.
Acting Director
Agency for Healthcare Research and Quality

Arlene S. Bierman, M.D., M.S.
Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Christine Chang, M.D., M.P.H.
Acting Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Jill Huppert, M.D., M.P.H.
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Associate Editor Timothy Wilt, M.D., M.P.H., from the Minnesota Evidence-based Practice Center, Minneapolis, MN; Task Order Officer Jill Huppert, M.D., M.P.H., from AHRQ; and Acting EPC Program Director Christine Chang, M.D., M.P.H., from AHRQ.

Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of Key Informants who provided input to this report follows:

Binita Ashar, M.D.
Center for Devices and Radiological Health
Food and Drug Administration
Silver Spring, MD

Katelyn Donnelly, M.P.H.[†]
American Society of Plastic Surgeons
The Plastic Surgery Foundation
Arlington Heights, IL

Phyllis Greenberger, M.S.W.
HealthyWomen
Middletown, NJ

Priscilla McAuliffe, M.D., Ph.D.
Department of Surgery
University of Pittsburgh School of Medicine
Pittsburgh, PA

Terence Myckatyn, M.D.
Department of Surgery
Washington University School of Medicine
in St. Louis
St. Louis, MO

Anne Taylor, M.D.
Aesthetica Surgery & Spa
Worthington, OH

Myelin Torres, M.D. [*†]
Department of Radiation Oncology
Emory University School of Medicine
Atlanta, GA

[*]Also provided input on Draft Report.
[†]Also a Technical Expert Panel member.

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

The list of Technical Experts who provided input to this report follows:

Michele Manahan, M.D.
Department of Plastic and Reconstructive Surgery
Johns Hopkins University School of Medicine
Baltimore, MD

Steven Nagel, M.D.*
Center for Devices and Radiological Health
Food and Drug Administration
Silver Spring, MD

William Sikov, M.D.*
Department of Medicine
Warren Alpert Medical School of Brown University
Providence, RI

Edwin Wilkins, M.D.
Department of Plastic Surgery
University of Michigan School of Medicine
Ann Arbor, MI

Sung Yoon, M.D.*
Center for Devices and Radiological Health
Food and Drug Administration
Silver Spring, MD

*Also provided input on Draft Report.

Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO

and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

The list of Peer Reviewers follows:

Melissa Camp, M.D., M.P.H.
Department of Surgery
Johns Hopkins University School of Medicine
Baltimore, MD

Olivia Ho, M.D., M.S.
Department of Plastic and Reconstructive Surgery
Mayo Clinic
Rochester, MN

Sameer Nath, M.D.
Department of Radiation Oncology
University of Colorado Anschutz Medical Campus
Aurora, CO

Kilian Salerno, M.D.
Radiation Oncology Branch, Center for Cancer Research
National Cancer Institute
Bethesda, MD

Jean Wright, M.D.
Department of Radiation Oncology and Molecular Radiation Sciences
Johns Hopkins University School of Medicine
Baltimore, MD

Breast Reconstruction After Mastectomy: A Systematic Review and Meta-Analysis

Structured Abstract

Objectives. This systematic review evaluates breast reconstruction options for women after mastectomy for breast cancer (or breast cancer prophylaxis). We addressed six Key Questions (KQs): (1) implant-based reconstruction (IBR) versus autologous reconstruction (AR), (2) timing of IBR and AR in relation to chemotherapy and radiation therapy, (3) comparisons of implant materials, (4) comparisons of anatomic planes for IBR, (5) use versus nonuse of human acellular dermal matrices (ADMs) during IBR, and (6) comparisons of AR flap types.

Data sources and review methods. We searched Medline®, Embase®, Cochrane CENTRAL, CINAHL®, and ClinicalTrials.gov from inception to March 23, 2021, to identify comparative and single group studies. We extracted study data into the Systematic Review Data Repository Plus (SRDR+). We assessed the risk of bias and evaluated the strength of evidence (SoE) using standard methods. The protocol was registered in PROSPERO (registration number CRD42020193183).

Results. We found 8 randomized controlled trials, 83 nonrandomized comparative studies, and 69 single group studies. Risk of bias was moderate to high for most studies. **KQ1:** Compared with IBR, AR is probably associated with clinically better patient satisfaction with breasts and sexual well-being but comparable general quality of life and psychosocial well-being (moderate SoE, all outcomes). AR probably poses a greater risk of deep vein thrombosis or pulmonary embolism (moderate SoE), but IBR probably poses a greater risk of reconstructive failure in the long term (1.5 to 4 years) (moderate SoE) and may pose a greater risk of breast seroma (low SoE). **KQ 2:** Conducting IBR either before or after radiation therapy may result in comparable physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts (all low SoE), and probably results in comparable risks of implant failure/loss or need for explant surgery (moderate SoE). We found no evidence addressing timing of IBR or AR in relation to chemotherapy or timing of AR in relation to radiation therapy. **KQ 3:** Silicone and saline implants may result in clinically comparable patient satisfaction with breasts (low SoE). There is insufficient evidence regarding double lumen implants. **KQ 4:** Whether the implant is placed in the prepectoral or total submuscular plane may not be associated with risk of infections that are not explicitly implant related (low SoE). There is insufficient evidence addressing the comparisons between prepectoral and partial submuscular and between partial and total submuscular planes. **KQ 5:** The evidence is inconsistent regarding whether human ADM use during IBR impacts physical well-being, psychosocial well-being, or satisfaction with breasts. However, ADM use probably increases the risk of implant failure/loss or need for explant surgery (moderate SoE) and may increase the risk of infections not explicitly implant related (low SoE). Whether or not ADM is used probably is associated with comparable risks of seroma and unplanned repeat surgeries for revision (moderate SoE for both), and possibly necrosis (low SoE). **KQ 6:** AR with either transverse rectus abdominis (TRAM) or deep inferior epigastric perforator (DIEP) flaps may result in comparable patient satisfaction with breasts (low SoE), but TRAM flaps probably increase the risk of harms to the area of flap harvest (moderate SoE).

Conclusion. Evidence regarding surgical breast reconstruction options is largely insufficient or of only low or moderate SoE. New high-quality research is needed, especially for timing of IBR and AR in relation to chemotherapy and radiation therapy, for comparisons of implant materials, and for comparisons of anatomic planes of implant placement.

Contents

Tables

Figures

Appendixes

Evidence Summary

Main Points

- **Implant-Based Reconstruction (IBR) Versus Autologous Reconstruction (AR)**
  - Compared with IBR, AR is probably associated with clinically better sexual well-being and patient satisfaction with breasts, but comparable general quality of life and psychosocial well-being (Moderate strength of evidence [SoE], all outcomes).
  - Compared with IBR, AR probably poses a greater risk of deep vein thrombosis or pulmonary embolism but comparable risk of unplanned repeat hospitalization (both Moderate SoE).
  - Compared with AR, although results in the short term (1 to 1.3 months) are inconsistent, IBR probably poses greater risk of reconstructive failure in the long term (1.5 to 4 years) (Moderate SoE). IBR may also pose a greater risk of breast seroma (Low SoE).
- **Timing of IBR and AR in Relation to Chemotherapy and Radiation Therapy**
  - Conducting IBR either before or after radiation therapy may result in comparable physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts (Low SoE for all).
  - Conducting IBR either before or after radiation therapy probably results in comparable risk of implant failure/loss or need for explant surgery (Moderate SoE).
  - We found no evidence comparing timing of IBR or AR before or after chemotherapy or timing of AR before or after radiation therapy.
- **Comparisons of Implant Materials for IBR**
  - Silicone or saline implants may result in clinically comparable patient satisfaction with breasts (Low SoE).
  - There is insufficient evidence to make conclusions about surgical complications when comparing silicone and saline implants.
  - There is insufficient evidence regarding double lumen implants.
- **Comparisons of Anatomic Planes of Implant Placement During IBR**
  - Whether the implant is placed in the prepectoral or total submuscular plane may not impact the risk of infections that are not explicitly implant-related (Low SoE).
  - There is insufficient evidence for all outcomes comparing prepectoral versus partial submuscular planes and partial versus total submuscular planes.
- **Use Versus Nonuse of Acellular Dermal Matrices (ADMs) During IBR**
  - The evidence is inconsistent regarding whether human ADM use during IBR impacts patient physical well-being, psychosocial well-being, or satisfaction with breasts.
  - ADM use probably increases the risk of implant failure/loss or need for explant surgery (Moderate SoE) and may increase the risk of infections not explicitly related to the implants or ADM (Low SoE). The risks of seroma or of unplanned repeat surgery for revision probably are comparable with or without ADM use (Moderate SoE); the risk of necrosis may be comparable (Low SoE).
- **Comparisons of Flap Types for AR**
  - AR with either transverse rectus abdominis (TRAM) or deep inferior epigastric perforator (DIEP) flaps may result in comparable patient satisfaction with breasts (Low SoE); however, TRAM flaps probably increase the risk of harms to the area of flap harvest (Moderate SoE).
  - There is insufficient evidence regarding other flap types.

Background and Purpose

Breast cancer is the most common new cancer diagnosis among women in the United States and the second most common cause of cancer death. For women who choose to undergo breast reconstruction surgery (more than 40% of women in the United States who undergo mastectomy), various decisions must be made related to the timing and type of reconstruction. Based on the type of procedure and composition of the newly reconstructed breast, reconstruction is categorized into IBR and AR. Implants are prosthetic devices that replace the surgically removed breast tissue. With AR, breast reconstruction is done with the patient's own tissue, thereby obviating the need for implants (except for latissimus dorsi [LD] flaps, which usually require an implant).

This systematic review (SR) aims to inform plastic surgeons, breast surgical oncologists, medical oncologists, radiation oncologists, other care providers, patients, policymakers, and developers of clinical guidance about surgical breast reconstruction options after mastectomy for breast cancer (or breast cancer prophylaxis). The SR addresses six Key Questions (KQs): (1) IBR versus AR, (2) timing of IBR and AR in relation to chemotherapy and radiation therapy, (3) comparisons of implant materials for IBR, (4) comparisons of anatomic planes of implant placement during IBR, (5) use versus nonuse of human ADMs during IBR, and (6) comparisons of flap types for AR.

Methods

We used methods consistent with those outlined in the Agency for Healthcare Research and Quality Evidence-based Practice Center Program Methods Guidance (https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview). Our searches targeted comparative studies and single group studies (i.e., studies without a comparison group) from database inception to March 23, 2021. We extracted study data into the Systematic Review Data Repository Plus (SRDR+). Our conclusions about comparative effectiveness and harms are based solely on the comparative studies. Single group studies provided additional information about incidence of surgical complications. Where there was sufficient evidence with an acceptable amount of heterogeneity, we conducted pairwise meta-analyses. In the Results section of this Evidence Summary, we provide numeric estimates of summary treatment effects only where meta-analyses were feasible for prioritized outcomes. We assessed the risk of bias and evaluated the SoE using standard methods. The PROSPERO protocol registration number is CRD42020193183. This Evidence Summary incorporates SoE ratings into the Main Points through qualifying language to communicate SoE of conclusions: "probably" for Moderate SoE and "may" for Low SoE.

Results

We found 160 primary studies comprising 478,650 patients in total. These included 8 randomized controlled trials (N = 570 patients), 83 nonrandomized comparative studies (i.e., observational studies that compared 2 or more interventions; N = 202,862), and 69 single group studies (N = 275,218).

IBR versus AR: Compared with IBR, AR is probably associated with clinically significant better sexual well-being (summary adjusted mean difference [adjMD] 5.8, 95% confidence interval [CI] 3.4 to 8.2; 3 studies) and satisfaction with breasts (summary adjMD 8.1, 95% CI 6.1 to 10.1; 3

studies) but comparable psychosocial well-being (summary adjMD 3.1, 95% CI 1.3 to 5.0; 3 studies) and general quality of life (Moderate SoE, all outcomes) (Table A). Compared with IBR, AR may be associated with greater risks of deep vein thrombosis or pulmonary embolism (Moderate SoE) but comparable risk of unplanned repeat hospitalizations (Moderate SoE). On the other hand, IBR may be associated with greater risk of seroma (Low SoE). Results were inconsistent regarding whether the choice of IBR versus AR impacts physical well-being, satisfaction with surgical outcome, or risks of reconstructive failure, infections that are not explicitly implant-related, pain, analgesic use, or unplanned surgeries for revision or for complications.

Timing of IBR and AR in relation to chemotherapy and radiation therapy: Whether IBR is conducted before or after radiation therapy may result in comparable physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts (Low SoE for each). We found that IBR probably results in comparable risk of implant failure/loss or need for explant surgery whether conducted before or after radiation therapy (summary adjusted odds ratio [adjOR] 0.87, 95% CI 0.62 to 1.24; 3 studies) (Moderate SoE). We found no evidence addressing timing of AR in relation to radiation therapy. We did not find any studies comparing timing of IBR or AR before or after chemotherapy.

Comparisons of implant materials for IBR: Silicone and saline implants may result in clinically comparable assessments of satisfaction with breasts (Low SoE). We found insufficient evidence addressing surgical complications when comparing silicone and saline implants. We found insufficient evidence addressing double lumen implants.

Comparisons of anatomic planes of implant placement for IBR: Prepectoral and total submuscular placements of implants may result in comparable risks of infections that are not explicitly implant-related (Low SoE). We found insufficient evidence for clinical outcomes for this comparison. We found insufficient evidence for all outcomes when comparing prepectoral versus partial submuscular placements and partial versus total submuscular placements.

Use versus nonuse of human ADMs during IBR: ADM use probably increases the risk of implant failure/loss or need for explant surgery (summary adjOR 1.28, 95% CI 0.97 to 1.70; 6 studies) (Moderate SoE) and may increase the risk of infections not explicitly related to the implants or ADM (summary adjOR 1.56, 95% CI 0.96 to 2.53; 7 studies) (Low SoE). However, ADM use and nonuse groups probably experience comparable risks of seroma (summary adjOR 1.52, 95% CI 0.62 to 3.71; 4 studies) (Moderate SoE) and unplanned repeat surgeries for revision (Moderate SoE). ADM use and nonuse groups may experience comparable risks of necrosis (summary adjOR 0.89, 95% CI 0.63 to 1.25; 4 studies) (Low SoE). The results are inconsistent regarding whether ADM use impacts physical well-being, psychosocial well-being, satisfaction with breasts, pain, or risks of wound dehiscence or capsular contracture.

Comparisons of flap types for AR: *TRAM versus DIEP flaps*: These two flap types may result in clinically comparable patient satisfaction with breasts (Low SoE) and risk of necrosis (Low SoE), but TRAM probably poses greater risk of harms to the area of flap harvest (abdominal bulge/hernia and need for abdominal hernia surgery) (Moderate SoE). *Other flaps*: We found insufficient evidence addressing LD, lateral thoracodorsal (LTD), superficial inferior epigastric artery (SIEA), and thoracodorsal artery perforator (TAP) flaps.

Limitations

Although we found a large body of evidence, it included many single group studies and relatively few studies reported the same outcomes pertaining to similar comparisons. Thus, evidence regarding surgical breast reconstruction options is largely insufficient or of only low or moderate SoE. Nonrandomized comparative studies often did not report adjusted effect sizes or omitted confidence intervals and P values. When subgroup data were reported, statistical analyses evaluating heterogeneity of treatment effects were not reported. The included studies were mostly at moderate to high risk of bias. Several prioritized outcomes, including general quality of life and risk of animation deformity, were infrequently reported.

Implications and Conclusions

Our analysis of all surgical choices examined as KQs in this review finds no clear winners when all outcomes are considered. We encourage clinicians to inform patients about the limitations of existing research and to help patients make decisions regarding options for breast reconstruction based on their values and preferences, together with the clinician's expertise and experience. Research is needed to address various questions related to breast reconstruction, particularly the timing of IBR and AR in relation to chemotherapy and radiation therapy, and the choices of implant materials, anatomic planes of implant placement during IBR, and flaps used for AR. Future studies should either randomize patients or adequately account for important confounders and evaluate key outcomes, especially those in the existing core outcome set for breast reconstruction after mastectomy.

Table A. Summary of evidence identified in this systematic review

Category	Outcomes	KQ 1	KQ 2*	KQ 3	KQ 4	KQ 5	KQ 6
Clinical outcomes	General quality of life	~~	nd	?	nd	nd	nd
	Physical well-being	↑↓	~	?	?	↑↓	?
	Psychosocial well-being	~~	~	?	?	↑↓	?
	Sexual well-being	▲▲ AR clinically better	~	?	nd	?	?
	Patient satisfaction with breasts	▲▲ AR clinically better	~	~	?	↑↓	~
	Patient satisfaction with outcome	↑↓	?	?	nd	nd	?
	Planned surgeries for reconstruction	N/P	N/P	nd	nd	nd	nd
	Duration of initial hospitalization	.	.	.	.	.	?
	Mortality	?	nd	?	nd	?	?
Surgical complications	Unplanned repeat hospitalization	~~	nd	nd	nd	nd	nd
	Duration of unplanned repeat hospitalization	nd	nd	nd	nd	nd	nd
	Unplanned repeat surgery for revision	↑↓	?	nd	?	~~	?
	Unplanned repeat surgery for complications	↑↓	nd	nd	nd	?	nd
	Pain	↑↓	?	nd	↑↓	↑↓	?
	Analgesic use	?	nd	nd	?	?	nd
	Necrosis	?	?	nd	?	~	~
	Harms to area of flap harvest	.	.	.	.	.	◆◆ Increased abdominal bulge/hernia, hernia repair surgery with TRAM than DIEP
	Animation deformity	nd	nd	nd	nd	nd	.
	Implant-related infections	.	nd	nd	nd	nd	.
	Implant rupture	.	nd	nd	nd	?	.
	Implant deflation	.	nd	nd	nd	nd	.
	Implant malposition	.	nd	nd	nd	?	.
	Implant failure/loss or needing explant	.	~~	?	?	◆◆ with ADM	.
	Capsular contracture	.	N/P	?	?	↑↓	.
	New neoplasms	.	.	nd	nd	nd	.
	Complications delaying other cancer treatments	nd	nd	nd	nd	nd	nd
	Thromboembolic events	◆◆ DVT or PE with AR	nd	nd	nd	?	?
	Infections not explicitly implant-related	↑↓	N/P	.	~	◆ with ADM	?
	Wound dehiscence	N/P	N/P	N/P	N/P	↑↓	?
	Delayed healing	N/P	N/P	N/P	N/P	?	nd
	Seroma	◆ with IBR	?	nd	?	~~	nd
	Chronic conditions	N/P	N/P	nd	nd	N/P	.
	Reconstructive failure	◆◆ with IBR in the long term	.	.	.	.	.

* KQ 2 data refer only to IBR before versus after radiation [KQ 2b]

Abbreviations: ADM = acellular dermal matrix, AR = autologous reconstruction, DIEP = deep inferior epigastric perforator, DVT = deep vein thrombosis, IBR = implant-based reconstruction, KQ = Key Question, LD = latissimus dorsi, N/P = not prioritized (for strength of evidence assessment), nd = no data (no evidence identified), PE = pulmonary embolism, SoE = strength of evidence, TRAM = transverse rectus abdominis myocutaneous. ▲ = Low SoE of better clinical outcomes, ▲▲ = Moderate SoE of better clinical

outcomes, ▲▲▲ = High SoE of better clinical outcomes (no instances in this table)
◆ = Low SoE of increased complications, ◆◆ = Moderate SoE of increased complications, ◆◆◆ = High SoE of increased complications (no instances in this table)
~ = Low SoE of comparable outcomes, ~~ = Moderate SoE of comparable outcomes, ~~~ = High SoE of comparable outcomes (no instances in this table)
? = Insufficient SoE due to sparse evidence, ↑↓ = Insufficient SoE due to inconsistent or conflicting results, . = not applicable (i.e., outcome not applicable to KQ)

Colors: Insufficient SoE, Low SoE, Moderate SoE, High SoE (no instances). The colors do not add unique information.

Introduction

Background

Breast cancer is the most common new cancer diagnosis among women in the United States and the second most common cause of cancer death.[1] Approximately 268,600 new breast cancer diagnoses and 41,760 cancer-related deaths in the U.S. were estimated for 2019.[2] Surgery is a standard component of the treatment strategy for most patients with breast cancer. Surgical options include mastectomy (where the entire breast is removed) and lumpectomy or segmental mastectomy (where a portion of the breast is removed). Radiation is generally recommended following lumpectomy, but less frequently following mastectomy. The indications for post mastectomy radiation therapy (PMRT) include four or more positive axillary lymph nodes, axillary nodal involvement that persists after systemic therapy, and stage T3 breast tumors.[3] The evidence to support PMRT in patients with one to three positive lymph nodes, younger age, tumor margins less than 1 mm, lymphovascular tumor invasion, and high nuclear grade or negative nodal disease is less clear. Mastectomy is chosen or recommended for approximately 50 percent of women in the U.S. with breast cancer.[4] Nonsurgical treatments that are used in conjunction with surgery include radiation therapy as well as chemotherapy and endocrine (hormonal) therapy with a range of pharmacologic agents.

Breast reconstruction is commonly offered to women receiving mastectomy for breast cancer. (In this report, we use the term "women" to refer to phenotypic females, regardless of gender.) Women are increasingly choosing to undergo breast reconstruction, although some women are not considered candidates and some choose to avoid reconstruction.[5, 6] As of 2016, more than 40 percent of women in the U.S. who underwent mastectomy for breast cancer had reconstruction.[4] According to the American Society of Plastic Surgeons/Plastic Surgery Foundation, approximately 107,200 women in the U.S. underwent breast reconstruction in 2019.[7] Federal regulations require that health insurance policies that cover mastectomy also cover breast reconstruction.[8] Breast reconstruction is also offered to women who undergo mastectomy for prophylaxis against breast cancer, such as women with high-risk gene mutations such as BRCA1 and BRCA2.[9-11]

For women who choose breast reconstruction surgery, two main considerations must be made: timing and type of reconstruction. Breast reconstruction can be initiated either at the time of mastectomy (immediate reconstruction) or at a later date (delayed reconstruction). Immediate reconstruction is the most common practice in the U.S., selected for approximately 75 percent of patients.[7] Immediate reconstruction is believed to be associated with better aesthetic results, lower overall costs, and better patient psychological well-being than delayed reconstruction.[12] This is at least in part related to the fact that both mastectomy and reconstruction are done during the same surgery, thus reducing the number of surgeries and exposures to anesthesia. Although immediate reconstruction has traditionally been thought to be associated with more postoperative complications than delayed reconstruction in the setting of PMRT, a recent systematic review suggested found that complication rates were comparable.[13] Immediate reconstruction may impact the planning and delivery of radiation therapy in a negative fashion, particularly in regard to chest wall and/or nodal coverage and heart/lung minimization.[14, 15]

Based on the type of procedure and composition of the newly reconstructed breast, reconstruction can be categorized into either implant-based reconstruction (IBR) or autologous reconstruction (AR). Most reconstruction procedures in the U.S. (81%) are implant-based. Implants are prosthetic devices that replace the surgically removed breast tissue or, in the case of

breast augmentation, are intended to increase the size of the intact breast. IBR can occur in either one or two stages. In planned single-stage implant placement, also known as direct-to-implant placement, IBR is accomplished through a single implantation procedure. In planned two-stage implant placement, a tissue expander is placed as a first procedure, followed by permanent implant placement at a later date. Direct-to-implant placements comprise 16 percent and tissue expander-based reconstructions 84 percent of IBR procedures.[7] IBR can be further divided based on the physical design of the implant (silicone, saline, or double lumen [e.g., may contain both silicone and saline[16]]), the anatomic plane in which the device is placed (prepectoral, partial submuscular, or total submuscular), and whether or not an adjunctive human acellular dermal matrix (ADM) is incorporated into the reconstruction. Regardless of these factors, IBR poses potential risks, such as infection, rupture, deflation, and malposition.[17]

Approximately 95 percent of implants for breast reconstruction used in the U.S. are silicone-filled because of the more natural feel and appearance and greater patient satisfaction than with saline implants.[7, 18] A 2015 systematic review concluded that the evidence remained inconclusive about any association between silicone implants and long-term cancer or rheumatologic health outcomes.[19] However, there have been continued reports of systemic symptoms, such as joint pains, muscle aches, and chronic fatigue. Additionally, breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare type of non-Hodgkin's lymphoma, may occur, especially with textured implants (regardless of fill type). The risk of BIA-ALCL led the U.S. Food and Drug Administration to request a recall of one manufacturer's textured implant and tissue expander in 2019[20] and to recommend a boxed warning for all breast implants in 2020.[21]

The anatomic plane in which the implant is placed during breast reconstruction can have implications on complications, aesthetics, and cost. The most common anatomic plane has traditionally been total submuscular placement, where the implant is placed beneath the pectoralis major muscle. It provides vascularized soft tissue coverage of the implant. However, total submuscular placement has challenges, such as limits to the possible size of the breast reconstruction and incidence of "animation deformity" (i.e., distortion of the reconstructed breast during contraction of the pectoralis major muscle). Animation deformity is experienced by as many as 80 percent of patients who receive total submuscular placement of the implant.[22] To overcome these challenges, another option is partial submuscular placement with ADM use (which creates a musculofascial pocket to leave the rib cage covered by a portion of the muscle[23]) or prepectoral placement with ADM (in front of, or superficial to, the muscle). Prepectoral placement also obviates the need for pectoralis muscle dissection and may cause less pain.[24] However, the prepectoral technique currently used is relatively novel, and evidence regarding comparative effectiveness, aesthetics, and harms of the various anatomic planes of implant placement is lacking.

ADMs can be derived from human (allografts), animal (xenografts), or synthetic sources. They represent a heterogeneous group of biologic scaffolds that are used in reconstructive surgery to hold the implant in place. ADMs allow for repopulation, revascularization, and integration of the host's cells into the implanted tissue.[25] Use of ADMs may reduce the incidence of capsular contracture and may improve the aesthetic definition of the inframammary fold (where the lower breast meets the chest wall) and the medial (i.e., midline) border of the breast. However, ADMs may lead to postoperative complications, such as infection and seroma.[26-29]

In AR, breast reconstruction is done with the patient's own tissue, thereby generally obviating the need for implants. In 2018, AR represented approximately 19 percent of breast reconstruction procedures performed in the U.S.[7] AR is generally described by the anatomic

region from which the tissue flap is sourced. These include deep inferior epigastric perforator (DIEP; 52% of ARs), latissimus dorsi (LD; 22%), transverse rectus abdominis myocutaneous (TRAM; 21%), and others (5%).[7] DIEP flaps use fat and skin from the patient's abdomen. LD flaps use muscle, fat, and/or skin from the patient's back and are often accompanied by implant placement ("hybrid" reconstruction[30]). TRAM flaps include muscle, fat, and skin from the patient's abdomen. The options regarding source of the AR flap are limited by the patient's body habitus, prior surgery, medical comorbidities, and preference. Different flap types vary in their associated types and frequencies of complications. In contrast to IBR, AR can have several advantages, including: (1) AR is intended to be completed in a single, albeit multi-site, surgery (as opposed to most IBRs, which require two-stage implant placements) and (2) AR is intended to be life-long although some patients require small revision surgeries of the breast and/or the donor site (implants, even when single-stage, are recommended to be replaced every 10 years). However, AR requires a larger operation and may have more major complications, such as deep vein thrombosis, abdominal bulge or hernias, wound dehiscence, delayed healing, and scarring. The long-term sequelae of AR, especially patient-reported clinical outcomes, such as satisfaction, psychosocial well-being, and sexual well-being, as well as long-term harms, e.g., harms to the area of flap harvest, remain unclear.

Purpose of the Review

This systematic review assesses the surgical breast reconstruction treatments for women who are undergoing (or have undergone) mastectomy for breast cancer (or breast cancer prophylaxis). The review does *not* address the choice of *whether* patients who have undergone mastectomy should undergo breast reconstruction.

Specifically, the review addresses the (comparative) benefits and harms of:

- IBR versus AR (Key Question [KQ] 1)
- Timing of IBR and AR in relation to chemotherapy and radiation therapy (KQ 2)
- Various options for IBR, including implant materials (KQ 3), implant placement planes (KQ 4), and use of human ADMs (KQ 5)
- Various flap types for AR (KQ 6).

The intended audience for this systematic review includes plastic surgeons, breast surgical oncologists, medical oncologists, radiation oncologists, other care providers for women undergoing mastectomy for breast cancer, guideline developers, healthcare policy makers, and patients. It is expected that the findings will inform clinical guidance for breast reconstruction after mastectomy.

Methods

Review Approach

For all Key Questions (KQs), the systematic review followed Evidence-based Practice Center (EPC) Program methodology, as laid out in its Methods Guide, particularly as it pertains to reviews of comparative effectiveness, diagnostic tests, and complex meta-analyses.[31] As described below, the Contextual Questions were addressed using a nonsystematic approach. We registered the protocol for this systematic review in PROSPERO (registration number CRD42020193183).

Key Questions

KQ 1: For adult women who are undergoing (or have undergone) mastectomy for breast cancer, what are the comparative benefits and harms of **implant-based (IBR) versus autologous (AR) breast reconstruction**?

KQ 2: For adult women undergoing IBR or AR after mastectomy for breast cancer that requires chemotherapy or radiation therapy,

> **KQ 2a**: What is the **optimal time** for IBR or AR with respect to chemotherapy?
>
> **KQ 2b:** What is the **optimal time** for IBR or AR with respect to radiation therapy?

KQ 3: For adult women undergoing IBR after mastectomy for breast cancer, what are the comparative benefits and harms of **different types of implants** (e.g., silicone, saline)?

KQ 4: For adult women undergoing IBR after mastectomy for breast cancer, what are the comparative benefits and harms of **different anatomic planes of implant placement** (prepectoral, partial submuscular, and total submuscular)?

KQ 5: For adult women undergoing IBR after mastectomy for breast cancer, what are the comparative benefits and harms of IBR **with versus without the use of a human acellular dermal matrix (ADM)** in the reconstruction procedure?

KQ 6: For adult women undergoing AR after mastectomy for breast cancer, what are the comparative benefits and harms of **different flap types for AR**?

Contextual Questions

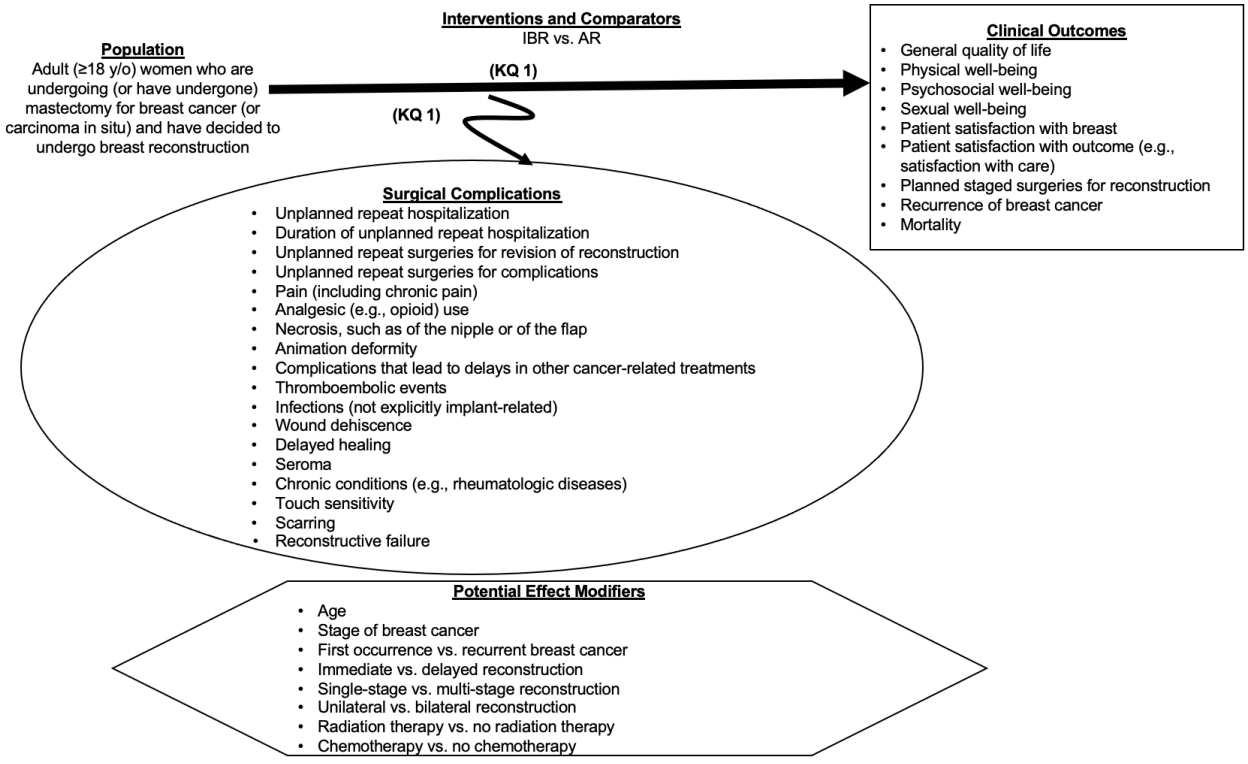
Contextual Question 1: What patient preferences and values inform decision making about breast reconstruction after mastectomy for breast cancer? This includes the initial choice to undergo reconstruction, as well as the type and timing of surgery.

Contextual Question 2: What strategies or tools (including shared decision making) are available to help women make informed choices about breast reconstruction after mastectomy for breast cancer?

Analytic Framework and Criteria for Inclusion and Exclusion

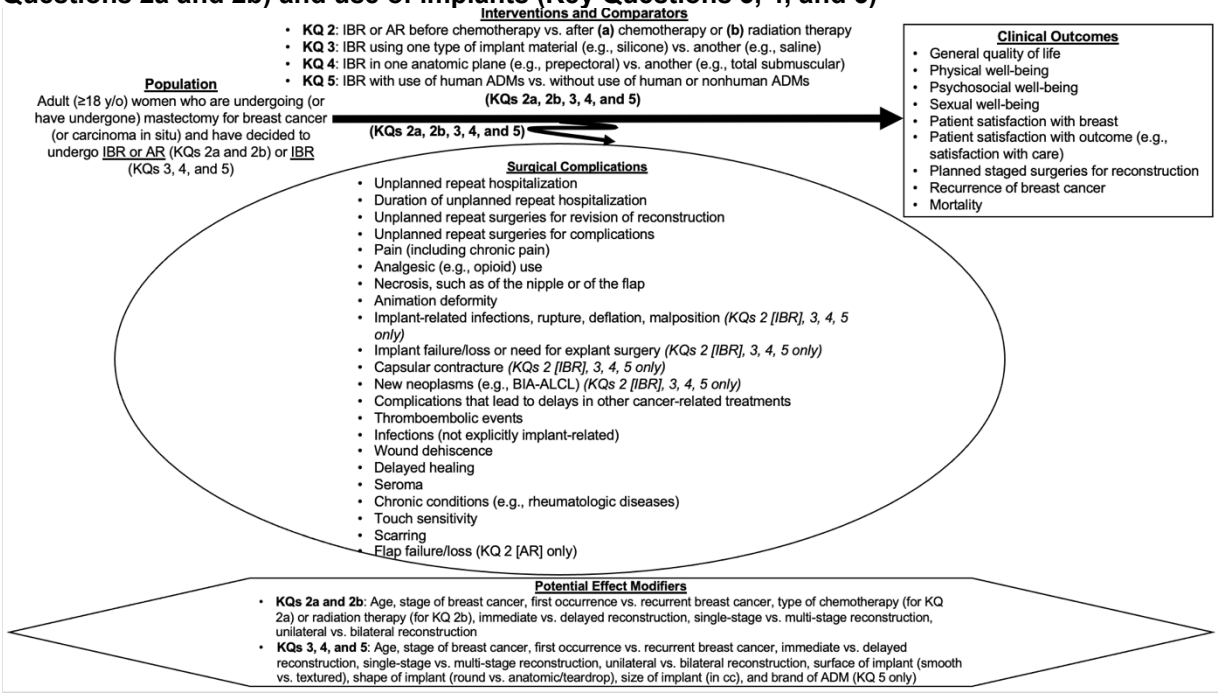
Based on discussions with Key Informants and Technical Expert Panel members, we developed three analytic frameworks for the six KQs (Figures 1 to 3).

Figure 1. Analytic framework for Key Question 1: Implant-based versus autologous breast reconstruction



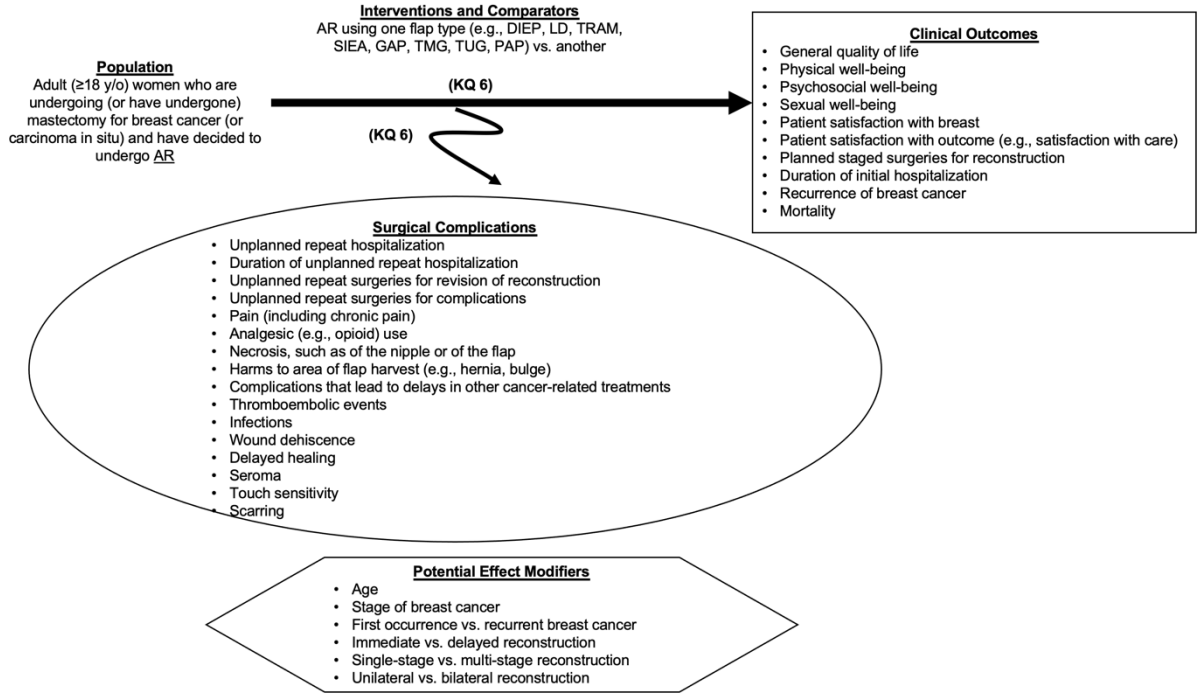
Abbreviations: AR = autologous reconstruction, IBR = implant-based reconstruction, KQ = Key Question.

Figure 2. Analytic framework for Key Questions focusing on timing of reconstruction (Key Questions 2a and 2b) and use of implants (Key Questions 3, 4, and 5)



Abbreviations: ADM = acellular dermal matrix, AR = autologous reconstruction, BIA-ALCL = breast implant-associated anaplastic large cell lymphoma, IBR = implant-based reconstruction, KQ = Key Question.

Figure 3. Analytic framework for Key Question 6: Comparisons of flap types for autologous reconstruction



Abbreviations: AR = autologous reconstruction, DIEP = deep inferior epigastric perforator, GAP = gluteal artery perforator, KQ = Key Question, LD = latissimus dorsi, PAP = profundal artery perforator, SIEA = superficial inferior epigastric artery

perforator, TMG = transverse musculocutaneous gracilis, TRAM = transverse rectus abdominis myocutaneous, TUG = transverse upper gracilis.

Study Selection

Appendix A provides full details on all search strategies, inclusion and exclusion criteria, and screening processes. Briefly, we searched for published studies for all KQs in Medline® (via PubMed®), Embase®, the Cochrane Central Register of Clinical Trials, and CINAHL®, and for unpublished studies in ClinicalTrials.gov from database inception through March 23, 2021. We included controlled vocabulary terms, along with free-text words, related to breast, cancer, mastectomy, implants/implantation, and autologous reconstruction. We did not employ any date or language restrictions to the search but included filters to remove nonhuman studies and articles not describing primary studies.

Table 1 summarizes the eligibility criteria for all KQs (Appendix A provides detailed inclusion and exclusion criteria). For KQ 1 (IBR versus AR) and KQ 2 (IBR or AR before versus the same type of reconstruction after [a] chemotherapy or [b] radiation therapy), the population of interest was all women who had decided to undergo breast reconstruction after mastectomy. For KQs 3, 4, and 5, we were specifically interested in women undergoing IBR: KQ 3 compared different types of implant materials (of any kind), KQ 4 compared different anatomic planes of implant placement (of any kind), and KQ 5 compared use versus nonuse of human ADMs. For KQ 6, we were specifically interested in women undergoing AR; the comparisons of interest were different flap types (of any kind).

For all KQs, we examined various clinical outcomes (such as psychosocial well-being, sexual well-being, and general quality of life) and surgical complications (such as necrosis, seroma, and reconstructive failure) at any followup time-point.

We included randomized controlled trials (RCTs), nonrandomized comparative studies (NRCSs; prospective or retrospective cohort studies comparing two or more treatments), case-control studies, and single group studies (prospective or retrospective, without a comparison group).

Table 1. Eligibility criteria for each Key Question

Element	Eligibility Criteria	KQ 1	KQ 2	KQ 3	KQ 4	KQ 5	KQ 6
Population	Adult (≥18 years old) women who are undergoing (or have undergone) therapeutic or prophylactic mastectomy for breast cancer (or carcinoma in situ) and have decided to undergo Any breast reconstruction	X	X	.	.	.	.
	Implant-based breast reconstruction	X	X	X	X	X	
	Autologous breast reconstruction	X	X	.	.	.	X
Interventions and Comparators	Implant-based reconstruction (any)	X	X	.	.	.	.
	Implant-based reconstruction before or after chemotherapy	.	X	.	.	.	.
	Implant-based reconstruction before or after radiation therapy	.	X	.	.	.	.
	Implant-based reconstruction with specific materials	.	.	X	.	.	.
	Implant-based reconstruction with specific anatomic placements	.	.	.	X	.	.
	Implant-based reconstruction with vs without human ADMs	.	.	.	.	X	.
	Autologous reconstruction (any)	X	X	.	.	.	X

Element	Eligibility Criteria	KQ 1	KQ 2	KQ 3	KQ 4	KQ 5	KQ 6
	Autologous reconstruction before or after chemotherapy	.	X	.	.	.	.
	Autologous reconstruction before or after radiation therapy	.	X	.	.	.	.
	Autologous reconstruction with specific flap types	X	X	.	.	.	X
Outcomes – Clinical	General quality of life	X	X	X	X	X	X
	Physical, psychosocial, or sexual well-being	X	X	X	X	X	X
	Patient satisfaction with breasts or with outcome	X	X	X	X	X	X
	Planned surgeries for reconstruction	X	X	X	X	X	X
	Recurrence of breast cancer	X	X	X	X	X	X
	Duration of initial hospitalization	.	.	.	.	.	X
	Mortality	X	X	X	X	X	X
Outcomes – Surgical Complications	Unplanned repeat hospitalization	X	X	X	X	X	X
	Duration of unplanned repeat hospitalization	X	X	X	X	X	X
	Unplanned repeat surgery for revision of reconstruction	X	X	X	X	X	X
	Unplanned repeat surgery for complications	X	X	X	X	X	X
	Pain	X	X	X	X	X	X
	Analgesic use	X	X	X	X	X	X
	Necrosis	X	X	X	X	X	X
	Harms to area of flap harvest	.	.	.	.	.	X
	Animation deformity	X	X	X	X	X	.
	Implant-related infection, rupture, deflation, or malposition	.	X	X	X	X	.
	Implant failure/loss or need for explant surgery	.	X	X	X	X	.
	Capsular contracture	.	X	X	X	X	.
	New neoplasms	.	.	X	X	X	.
	Complications that lead to delay in cancer-related treatment	X	X	X	X	X	X
	Thromboembolic events	X	X	X	X	X	X
	Infections	X	X	.	X	X	X
	Wound dehiscence	X	X	X	X	X	X
	Delayed healing	X	X	X	X	X	X
	Seroma	X	X	X	X	X	X
	Chronic conditions	X	X	X	X	X	.
	Touch sensitivity	X	X	X	X	X	X
	Scarring	X	X	X	X	X	X
	Red breast syndrome	.	.	X	X	X	.
	Flap failure/loss	.	X	.	.	.	X
	Reconstructive failure	X	.	.	.	.	.
Study Designs	Randomized controlled trials, N≥10 patients per group	X	X	X	X	X	X
	Nonrandomized comparative studies, N≥30 patients per group, provided adjusted analyses	X	X	X	X	X	X
	Case-control studies, N≥100 patients per group	X	X	X	X	X	X
	Single group studies, N≥500 patients (for complications only)	X	X	X	X	X	X
	Prospective or retrospective	X	X	X	X	X	X
Timing	Any	X	X	X	X	X	X
Setting	Any, including single- and multi-center studies	X	X	X	X	X	X

Abbreviations: ADM = acellular dermal matrix, KQ = Key Question, X = relevant to KQ, . = not relevant to KQ.

Data Extraction and Data Management

We extracted data into the Systematic Review Data Repository Plus (SRDR+) software (https://srdrplus.ahrq.gov). Each eligible study was extracted and assessed for risk of bias/quality by one researcher, and extracted data were confirmed by a second, independent researcher.

Assessment of Risk of Bias in Individual Studies

We evaluated each study for risk of bias and methodological quality.

Because we included a variety of study designs, we incorporated items from three different existing commonly used tools and tailored the set of items for each study design. The three tools include the Cochrane Risk of Bias Tool,[32] the Risk of Bias in Nonrandomized Studies (ROBINS-I) Tool,[33] and the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool.[34]

For RCTs, we used all the items from the Cochrane Risk of Bias Tool,[32] which addresses issues related to randomization and allocation concealment methodology; blinding of patients, study personnel/care providers, objective outcome assessors, and subjective outcome assessors; completeness of outcome data; selective outcome reporting; and other issues that could be related to bias. We also used items from the NHLBI Tool focusing on the adequacy of descriptions of study eligibility criteria, interventions, and outcomes.[34]

For NRCSs, we used the specific sections of the ROBINS-I Tool[33] that pertain to confounding and selection bias. ROBINS-I requires the identification of specific confounders of interest for the systematic review. To assess the presence of potential confounding in studies, we considered age, body mass index, and stage of breast cancer as potential confounders for all KQs. In addition, we considered history of abdominal surgeries as a potential confounder for KQ 6. Because NRCSs, like RCTs, can be impacted by the lack of blinding and by participant loss to followup, we also used the items from the Cochrane Risk of Bias Tool[32] that focus on issues related to blinding of patients, study personnel or care providers, objective outcome assessors, and subjective outcome assessors; incomplete outcome data; selective outcome reporting; and other issues that could be related to bias. We also used items from the NHLBI Tool that pertain to the adequacy of descriptions of study eligibility criteria, interventions, and outcomes.[34]

No case-control studies were identified.

For single group studies, we used items from the Cochrane Risk of Bias Tool[32] that pertain to issues of participant loss to followup, specifically, incomplete outcome data, selective outcome reporting, and other issues that could relate to bias. We also used items from the NHLBI Tool focusing on the adequacy of descriptions of eligibility criteria, interventions, and outcomes.[34]

Data Synthesis

We summarized the evidence both qualitatively and, when feasible and appropriate, quantitatively. Each study included in the systematic review is described in summary and evidence tables presenting study design features, study participant characteristics, descriptions of interventions, outcome results, and risk of bias/methodological quality. Summary tables briefly describe the studies and their findings.

For all KQs, we compared interventions with their comparators for their effects, preferentially with odds ratios for dichotomous outcomes (e.g., recurrence of breast cancer), net mean differences (between-intervention comparison of within-intervention changes) for continuous outcomes with both pre- and post-intervention data (e.g., pain or general quality of life scales), and mean differences (between interventions) in continuous outcome data evaluated only postintervention (e.g., patient satisfaction with breasts). Other effect sizes were included (e.g., hazard ratio) when the preferred effect sizes could not be elicited. For continuous outcomes, we used published estimates of minimal clinically important differences as a guide for interpreting whether differences between groups were clinically significant. Adjusted analyses

were preferentially included over unadjusted (crude) comparisons. Unadjusted analyses from observational studies (NRCSs) were extracted but are not included in our findings.

Where there were at least three studies reporting results from sufficiently similar analyses, we conducted meta-analyses using random-effects models. In the key points sections of the text and the evidence profile tables for each KQ, we provide numeric estimates of summary treatment effects only where meta-analyses were feasible for prioritized outcomes; these are denoted as "summary" estimates. The data did not allow for network meta-analyses.

Grading the Strength of Evidence for Major Comparisons and Outcomes

We graded the strength of the body of evidence (SoE) as per the Agency for Healthcare Research and Quality (AHRQ) Methods Guide on assessing SoE.[31, 35] We evaluated SoE for each major comparison or evaluation within each KQ.

We assessed SoE for each outcome that was deemed to be important prior to compiling the evidence. We determined the relative importance of the outcomes with input from the Technical Expert Panel, which included experts in plastic surgery, medical oncology, radiation oncology, breast reconstructive device regulation, and clinical practice guideline development. Examples of prioritized clinical outcomes include:

- General quality of life
- Physical, psychosocial, and sexual well-being
- Patient satisfaction with breasts
- Mortality.

Examples of prioritized surgical complications include:

- Repeat hospitalization
- Duration of repeat hospitalization
- Unplanned repeat surgeries
- Pain.

For specific KQs, we also prioritized certain additional surgical complications, for example:

- Animation deformity
- Implant-related infections (KQ 3, types of implants for IBR)
- Harms to area of flap harvest (KQ 6, flap types for AR).

The prioritized outcomes are consistent with the outcomes in a "core outcome set" published in 2015 for research on breast reconstructive surgery.[36] Core outcome sets are agreed minimum sets of outcomes that should be reported in research in a given topic area.[37]

For each SoE assessment, we considered the number of studies, their study designs, the study limitations (i.e., risk of bias and overall methodological quality), the directness of the evidence to the KQs, the consistency of study results, the precision of any estimates of effect, the likelihood of reporting bias, other limitations, and the overall findings across studies. Based on these assessments, we assigned a SoE rating as being either high, moderate, low, or insufficient evidence to estimate an effect.

Outcomes with highly imprecise estimates (with a 95% confidence interval that extends beyond both 0.50 and 2.0 for categorical outcomes), highly inconsistent findings across studies, or with data from only one study were deemed to have insufficient evidence to allow for a conclusion (with the exception that a particularly large and generalizable single study could provide at least low SoE). This approach is consistent with the concept that for imprecise

evidence "any estimate of effect is very uncertain," the definition of Very Low quality evidence per the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) approach.[38]

We summarize the data sources, study characteristics, and each SoE dimensional rating in an evidence profile table. This table details our reasoning for arriving at the overall SoE rating.

In accordance with AHRQ guidance for describing treatment effects,[39, 40] we have incorporated qualifying language regarding SoE when communicating conclusions (e.g., in Key Points sections of the text) as follows: "probably" for conclusion statements with Moderate SoE and "may" for conclusion statements with Low SoE.

Results

Literature Search Results

The electronic literature search, combined with a hand search of existing systematic reviews, yielded 15,936 unique citations. A total of 160 primary studies met criteria. Appendix B provides a list of excluded studies. Appendix Figure C-1 summarizes the results of the search and screening processes.

The 160 included studies were reported in 202 articles that were published between 1989 and 2021. Across studies, patients were enrolled and followed between 1977 and 2020. The 160 studies comprised eight randomized controlled trials (RCTs), 83 nonrandomized comparative studies (NRCSs), and 69 single group studies. The 160 included studies enrolled a total of 478,650 patients. The 160 studies comprised eight RCTs with 570 patients (ranging from 34 to 150 patients each), 83 NRCSs with 202,862 patients (ranging from 70 to 32,897 patients), and 69 single group studies with 275,218 patients (ranging from 501 to 56,522 patients).

Table 2 summarizes the number of studies that addressed each Key Question (KQ), by study design. Most (69%) of the studies (111/160) addressed KQ 1 (implant-based reconstruction [IBR] versus autologous reconstruction [AR]); in some of these studies, IBR was further categorized into direct-to-implant IBR- and tissue expander IBR-specific groups, and AR was further categorized into specific flap types. KQ 2 was addressed by five NRCSs, each of which addressed the timing of reconstruction before or after radiation therapy (none before or after chemotherapy). All five NRCSs addressing KQ 3 (comparisons of implant materials for IBR) compared silicone versus saline implants, and one NRCS also included a third group of women who received double lumen silicone implants. The RCT and seven NRCSs addressing KQ 4 compared prepectoral, total submuscular, and partial submuscular planes of implant placement. KQ 5 (human acellular dermal matrix [ADM] use versus nonuse during IBR) was addressed by 22 studies and KQ 6 (comparisons of flap types for AR) was addressed by 20 studies. KQ 6 studies compared six flap types.

Table 2. Number of studies addressing each Key Question, by study design

Design	KQ 1	KQ 2	KQ 3	KQ 4	KQ 5	KQ 6	Total
Randomized controlled trials	2	0	0	1	2	3	**8**
Nonrandomized comparative studies	40	5	5	7	20	16	**83***
Single group studies	69	0	0	0	0	0	**69**
Total	**111**	**5**	**5**	**8**	**22**	**19**	**160***

* Some nonrandomized comparative studies addressed multiple Key Questions (KQs).

For all 160 included studies, Appendix Tables C-1 to C-7 summarize the design, arm, and patient characteristics (separate subtables for each KQ, with two tables for KQ 1: one for comparative studies [RCTs and NRCSs] and another for single group studies) and Appendix Tables D-1 to D-4 summarize the risk of bias assessments (separate subtables by study design, with two tables for NRCSs: one for selection bias and confounding and the other for other types of bias). Further details about the literature search, included studies, and excluded studies (with reasons for their exclusion) are in Appendixes A and B.

Description of Included Evidence

Detailed findings are in the appendixes. These include tables describing study designs, groups, and sample characteristics (Appendix C); risk of bias (Appendix D); all outcomes

(Appendixes E and F); and evidence profiles (Appendix G). Appendix H includes the references cited in the rest of the appendixes. Where relevant, we call attention to specific appendix table numbers in the relevant subsections of this main report.

Key Question 1: Implant-Based Reconstruction Versus Autologous Reconstruction

Key Points

- Compared with patients who undergo IBR, those who undergo AR probably experience clinically significant better sexual well-being (summary adjusted mean difference [adjMD] 5.8, 95% confidence interval [CI] 3.4 to 8.2; 3 studies) and satisfaction with breasts (summary adjMD 8.1, 95% CI 6.1 to 10.1; 3 studies) (Moderate strength of evidence [Moderate SoE], both outcomes). However, IBR and AR are probably associated with clinically comparable psychosocial well-being (summary adjMD 3.1, 95% CI 1.3 to 5.0; 3 studies) and general quality of life (Moderate SoE, both outcomes).
- Because of inconsistent results, evidence is insufficient regarding whether the choice of IBR versus AR impacts physical well-being, satisfaction with nipples, satisfaction with surgical outcome, or risks of unplanned repeat surgeries for revision, unplanned repeat surgeries for complications, pain, analgesic use, or infections that are not explicitly implant-related.
- Compared with patients who undergo IBR, those who undergo AR probably are at a greater risk of deep vein thrombosis or pulmonary embolism (Moderate SoE).
- Compared with patients who undergo AR, although results were inconsistent in the short-term (1 to 1.3 months), those who undergo IBR probably are at greater risk of reconstructive failure in the long-term (1.5 to 4 years) (Moderate SoE). Those who under IBR may also be at greater risk of breast seroma (Low SoE).
- IBR and AR are probably associated with comparable risks of unplanned repeat hospitalizations (Moderate SoE).
- Because of sparse data, there is insufficient evidence to compare IBR and AR in terms of risks of mortality or necrosis.

We found 109 eligible studies. We found two RCTs and 38 NRCSs (with adjusted analyses) for the comparison between IBR and AR. An additional 69 single group studies of either IBR or AR (with 500 or more patients) provided data on surgical complications. An additional two NRCSs did not report adjusted effect sizes or P values.[41, 42] The IBR and AR groups in these two NRCSs did not meet the sample size threshold of 500 patients, so we could not consider them as single group studies. They are thus not discussed further in this section. Appendix Tables C-1, D-2, D-3, and F-1.1 to F-1.26 include full data for all RCTs and NRCSs, irrespective of whether they reported adjusted effect sizes. Details of the 69 single group studies are in Appendix Tables C-2, D-4, and F-1.13 to F-1.26.

Randomized Controlled Trials

The two RCTs[43, 44] compared IBR and AR in a total of 223 patients in Sweden. We rated one RCT to be at overall high risk of bias and the other at overall moderate risk of bias. Average ages of patients were similar in the RCTs, with mean ages ranging from 52 to 56 years. Average body mass indices (BMIs) ranged from 25 to 26 kg/m^2. Neither RCT reported the racial distribution of patients.

The RCT result summaries are in Appendix Tables E-1.1 to E-1.7 and Appendix Table F-1.26.

Nonrandomized Comparative Studies

The 38 adjusted NRCSs, reported in 53 articles,[45-97] compared IBR and AR in a total of 121,302 patients. Among the 38 NRCSs, 10 (26%) were prospective and 28 (74%) were retrospective. We rated 25 of the 38 NRCSs to be at overall high risk of bias, mostly related to serious risk of confounding and the lack of blinding of participants, study personnel, and/or outcome assessors. We rated the remaining 13 NRCSs to be at overall moderate risk of bias.

The 38 NRCSs enrolled between 70 and 32,897 women each. More than half (n=22; 58%) were conducted in North America (19 in the U.S., 2 in Canada, and 1 in both). The remaining NRCSs were conducted in China (n=5), the Netherlands (n=3), South Korea (n=3), and Finland, France, Italy, Japan, and Portugal (1 each). Average ages of patients were similar across NRCSs, ranging from 43 to 53 years. Average BMIs ranged from 22 to 35 kg/m^2. In the only eight NRCSs that reported patient races, between 63 and 89 percent were White and between 4 and 7 percent were Black.

The NRCS result summaries are in Appendix Tables E-1.1 to E-1.7 and Appendix Table F-1.26.

Single Group Studies

The 69 single group studies, reported in 86 articles,[98-183] evaluated IBR (n=30) or AR (n=39) in a total of 275,245 patients. We rated one single group study to be at overall high risk of bias, 14 at moderate risk of bias, and 54 at low risk of bias. Note that because these studies only involved a single group, issues of confounding are not relevant. High and moderate risks of bias were mostly related to eligibility criteria not being clearly described, interventions not being clearly described or consistently delivered, and/or selective outcome reporting.

The 69 single group studies included between 501 and 56,522 women each. Most (n=44; 64%) were conducted in North America (43 in the U.S. and 1 in Canada). Other studies were conducted in South Korea (n=5), the U.K. (n=4), Germany (n=4), Belgium (n=3), Sweden (n=2), and in seven other countries (n=1 each). Average ages of patients were similar across studies, ranging from 46 to 54 years. Average BMIs ranged from 22 to 29 kg/m^2. Only 17 of the 69 studies reported patient races: between 42 and 98 percent were White and between 2 and 15 percent were Black.

The single group study results are in Appendix Tables F-1.13 to F-1.26.

Summary of Comparison of IBR Versus AR

Table 3 summarizes the evidence for the comparison of IBR versus AR. There is low to moderate SoE for all conclusions. (We did not make any conclusions based on insufficient evidence.) AR is probably associated with clinically better experiences for some patient-reported clinical outcomes (e.g., sexual well-being, satisfaction with breasts) but not others (e.g., general quality of life). In terms of surgical complications, patients who undergo AR may be at greater risks of deep vein thrombosis or pulmonary embolism. However, although results are inconsistent in the short-term (1 to 1.3 months), patients who undergo IBR probably are at greater risk of reconstructive failure in the long-term (1.5 to 4 years). Additionally, patients who undergo IBR may be at greater risk of breast seroma. Risks of some other surgical complications (e.g., unplanned repeat hospitalizations) may be comparable between IBR and AR. For others, the evidence is sparse (e.g., necrosis) and/or the results are inconsistent (e.g., infections, pain).

Table 3. Evidence profile for Key Question 1: IBR versus AR

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Clinical outcomes	General quality of life	3 (709)	Moderate	Consistent	Precise	Direct	None	Moderate	Comparable in both groups
	Physical well-being	6 (5717)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Psychosocial well-being	5 (2760)	Moderate	Consistent	Precise	Direct	None	Moderate	Clinically comparable in both groups: summary adjMD 3.14 (95% CI 1.26, 5.02); 3 studies
	Sexual well-being	4 (3307)	Moderate	Consistent	Precise	Direct	None	Moderate	Clinically significant better with AR: summary adjMD 5.83 (95% CI 3.44, 8.23); 3 studies
	Patient satisfaction with breasts	7 (4557)	Moderate	Consistent	Precise	Direct	None	Moderate	Clinically significant better satisfaction with breast with AR: summary adjMD 8.08 (95% CI 6.11, 10.1); 3 studies.
	Patient satisfaction with surgical outcome	5 (1432)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Mortality	1 (4061)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Unplanned repeat hospitalization	3 (50675)	High	Consistent	Precise	Direct	None	Moderate	Comparable in both groups
	Unplanned repeat surgeries for revision	3 (3138)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Unplanned repeat surgeries for complications	3 (14313)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Pain	5 (3173)	Moderate	Inconsistent	Precise	Direct	None	Low	None (Inconsistent results)
	Analgesic use	1 (90)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Necrosis	4 (2176)	High	Inconsistent	Imprecise	Direct	None	Insufficient	None (Inconsistent results)
	Thromboembolic events	4 (34742)	High	Consistent	Precise	Direct	None	Moderate	Increased risk of deep vein thrombosis or pulmonary embolism with AR
	Infections	4 (17246)	Moderate	Inconsistent	Imprecise	Direct	None	Insufficient	None (Inconsistent results)
	Seroma	2 (1300)	Moderate	Consistent	Unclear	Direct	None	Low	Increased risk of breast seroma with IBR
	Reconstructive Failure	5 (21090)	Moderate	Consistent	Precise	Direct	None	Moderate	Increased risk with IBR in the long-term (1.5 to 4 years of followup)

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, MD = mean difference, N/A = not applicable, NR = not reported, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SoE = strength of evidence, TRAM = transverse rectus abdominis myocutaneous.

For continuous outcomes, clinical significance is based on published estimates of minimal clinically important differences (MCIDs), where available.
Colors: Header rows are shaded orange. The color does not add unique information.

Appendix Table G-1 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified.

Clinical Outcomes

One RCT and 13 NRCSs reported on clinical outcomes comparing IBR and AR (Appendix Tables E-1.1 to E-1.5). Note that we did not evaluate single group studies for clinical outcomes.

General Quality of Life

Three NRCSs (Kouwenberg 2019, Kouwenberg 2020, and Roth 2007) reported on **general quality of life** (Appendix Table E-1.1). Kouwenberg 2019 and Kouwenberg 2020 used the EuroQoL Group 5-dimension 5-level scale (EQ-5D-5L). The EQ-5D-5L includes two components: (1) a visual analog scale (VAS) that ranges from 0 to 100, with higher scores indicating better quality of life and (2) a utilities score that ranges from 0 to 1, with higher scores indicating better preference-weighted quality of life. The minimum clinically important differences (MCIDs) have been estimated to be 7 points for the VAS component and 0.06 points for the utilities component.[184] Kouwenberg 2019 reported that patients who underwent IBR and AR had comparable utilities scores (P=0.7; adjusted effect size not reported). Kouwenberg 2020 also reported that patients who underwent IBR and AR had comparable utilities scores as well as VAS scores (P=NS; adjusted effect size not reported).

Kouwenberg 2020 also used the global health status component of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30), which was designed to measure changes (or differences) in health-related quality of life in patients with cancer. The score ranges from 0 to 100, with higher scores indicating better quality of life. The MCID has been estimated to be 4 to 10 points.[185] Patients who underwent IBR and AR had comparable scores (P=not significant [NS]; adjusted effect size not reported).

Roth 2007 reported on quality of life using five measurements: the **functional well-being** component of the Functional Assessment of Cancer Therapy (FACT-B); the **role emotional**, **vitality**, and **general mental health** components of the Short Form-36 (SF-36); and a score evaluating **body image** (9 to 45; higher is better). The functional well-being component of the FACT-B ranges from 0 to 28 (higher is better; MCID 2 points[186]). Each of the SF-36 component scores ranges from 0 to 100 (higher is better; MCID not available for component scores). Although adjusted effect sizes were not reported, Roth 2007 reported that, at 2 years of followup, scores for each of the five measurements were comparable between patients who underwent IBR and AR ($P \geq 0.05$).

Physical Well-Being

One RCT (Tallroth 2020) and five NRCSs (Eltahir 2015, Kouwenberg 2020, Kulkarni 2017, McCarthy 2014, and Nelson 2019) reported on **physical well-being** (Appendix Tables E-1.2 and E-1.3).

The RCT (Tallroth 2020) and four NRCSs (Eltahir 2015, Kouwenberg 2020, Kulkarni 2017, and McCarthy 2014) reported physical well-being as continuous data using seven different measurement instruments. Data were inconsistent across studies. All five studies used the **BREAST-Q**, an instrument designed to evaluate changes (or differences) in patient-reported outcomes in patients who have undergone breast surgery. Scores range from 0 to 100, with higher scores indicating better well-being. The MCID for physical well-being has been estimated to be 3 points.[187]

Tallroth 2020 (the RCT) reported that patients randomized to AR had clinically significant higher BREAST-Q **physical well-being: chest and upper body scores** at 5.3 years of followup

(mean difference [MD] 7.6, 95% CI 0.30 to 14.9). Among the NRCSs, Eltahir 2015 reported comparable BREAST-Q **physical well-being: overall scores** between IBR and AR groups, at 2.2 years of followup (adjMD −2.60, 95% CI −9.77 to 4.57). However, McCarthy 2014 reported that, at 1 to 5 years of followup, patients who underwent AR had higher physical well-being scores (P<0.05; adjusted effect size not reported). Similarly, Kouwenberg 2020 reported that patients who underwent AR had higher **chest** scores beyond 6 months of followup (P<0.05; adjusted effect size not reported). Kulkarni 2017 reported data only for the chest- and upper body-specific BREAST-Q scores. For the **chest**, scores at 1 and 2 years of followup were comparable between IBR and AR overall as well as within subgroups of women who had unilateral or bilateral reconstructions. For the **chest and upper body** scores, however, the group of women who specifically underwent AR with pedicled transverse rectus abdominis myocutaneous (TRAM) flaps had clinically important poorer well-being than patients who underwent IBR.

One NRCS (Kulkarni 2017) also used the **pain interference** and **physical function** components of the Patient-Reported Outcomes Measurement Information System (PROMIS) (scores 0 to 100; higher is worse; MCID 3 to 4.5 points[188]) and reported comparable scores between IBR and AR groups at 1 year of followup. Eltahir 2015 also used the **physical functioning** component of the SF-36 (scores 0 to 100; higher is better) and reported comparable scores between IBR and AR groups (adjMD 2.13, 95% CI −4.20 to 8.46). Kouwenberg also used the EORTC QLQ-C30 (0-100; higher is better; MCID 3 points[187]) and reported comparable scores between IBR and AR beyond 6 months of followup.

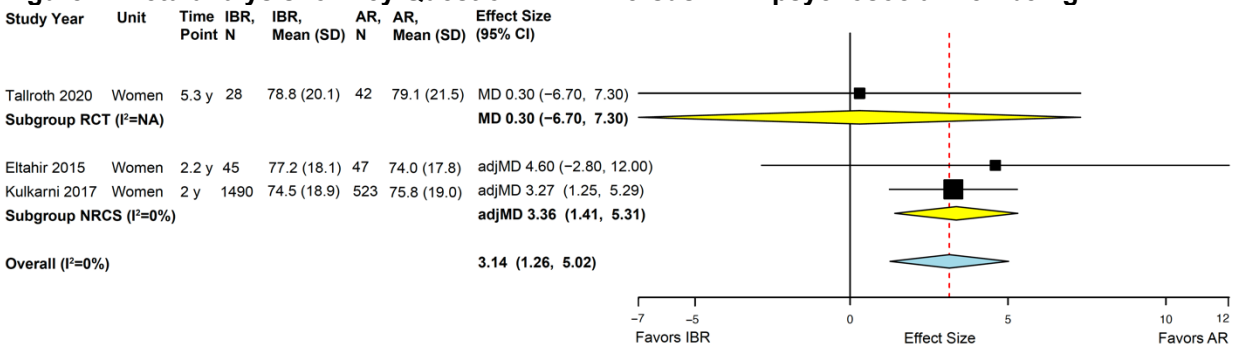
One NRCS (Nelson 2019) reported categorical data for the likelihood of patients having **higher BREAST-Q physical well-being: chest scores** (Appendix Table E-1.3). Although the likelihoods at 1 and 3 years of followup were comparable between IBR and AR groups, patients who underwent AR were more likely to have higher (versus unchanged) scores at 5 years (adjusted odds ratio [adjOR] 4.52, 95% CI 2.03 to 10.1) and at 7 years (adjOR 3.08, 95% 1.03 to 9.15).

Psychosocial Well-Being

One RCT (Tallroth 2020) and four NRCSs (Eltahir 2015, Kouwenberg 2020, Kulkarni 2017, and Roth 2007) reported on **psychosocial well-being** using six different measurement instruments (Appendix Table E-1.1). Psychosocial well-being was generally comparable between IBR and AR groups.

The RCT (Tallroth 2020) and three NRCSs (Eltahir 2015, Kouwenberg 2020, and Kulkarni 2017) reported data using the BREAST-Q questionnaire (0-100; higher is better; MCID 4 points[187]) (Figure 4 and Appendix Table E-1.1). Only two of the NRCSs (Eltahir 2015 and Kulkarni 2017) reported adjusted effect sizes, and therefore we combined their estimates and the RCT's estimate at average followup durations ranging from 2 to 5.3 years (Figure 4). Effect sizes ranged from 0.30 to 4.60 across these studies. The meta-analysis provided evidence that patients who underwent IBR or AR experienced clinically comparable psychosocial well-being (adjMD 3.14, 95% CI 1.26 to 5.02; I^2=0%).

Figure 4. Meta-analysis for Key Question 1: IBR versus AR – psychosocial well-being



Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), MD = mean difference, NA = not applicable, NRCS = nonrandomized comparative study, RCT = randomized controlled trial, SD = standard deviation, y = years.

Kulkarni 2017, which was included in the meta-analysis, reported additional data regarding psychosocial well-being. At 2 years, scores were comparable even within the subgroups of women who had unilateral reconstruction or bilateral reconstruction.

Psychosocial well-being data were also comparable between IBR and AR groups in studies that used other measurement instruments. Kulkarni 2017 also used the PROMIS **anxiety** and **depression** components (scores 0 to 100; higher is worse; MCID 3 to 4.5 points for each[188]) and reported comparable scores between IBR and AR groups at 1 year of followup.

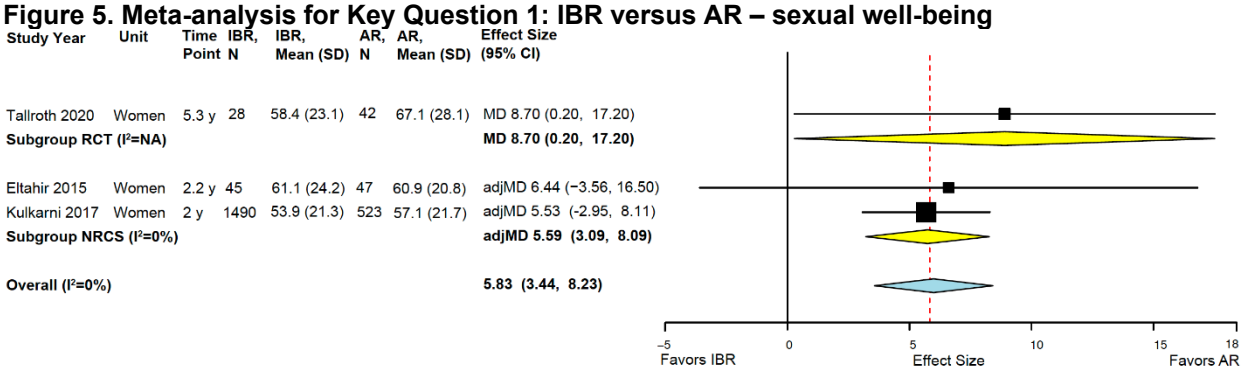
Two NRCSs (Eltahir 2015 and Roth 2007) reported on the **social functioning** component of SF-36 (scores 0 to 100; higher is better; MCID not available). Both NRCSs reported that IBR and AR groups had comparable scores. Eltahir 2015 reported an adjMD of –1.21 (95% CI, –8.44 to 6.02), while Roth 2007 reported that the P value was ≥0.05 (adjusted effect size not reported). Roth 2007 also reported on the **social/family well-being** component of the FACT-B (0-28; higher is better; MCID 2 points[186]). Although an adjusted effect size was not reported, at 2 years of followup, patients who underwent IBR and AR had comparable FACT-B scores (P=0.24).

One NRCS (Kouwenberg 2020) reported on the **social**, **emotional**, **cognitive**, and **role function** components of the EORTC QLQC30 (each scored from 0 to 100; higher is better; MCIDs not available). Only the role function component scores were statistically significantly different between IBR and AR groups; patients who underwent IBR had higher scores (P<0.05; adjusted effect size not reported).

Sexual Well-Being

One RCT (Tallroth 2020) and three NRCSs (Eltahir 2015, Kouwenberg 2020, and Kulkarni 2017) reported on **sexual well-being** using the BREAST-Q questionnaire (0-100; higher is better; MCID 5[187]) (Figure 5 and Appendix Table E-1.1). Only two of the NRCSs (Eltahir 2015 and Kulkarni 2017) reported adjusted effect sizes, and therefore we combined their estimates and the RCT's estimate at average followup durations ranging from 2 to 5.3 years (Figure 5). Effect sizes ranged from 5.53 to 8.70 across these studies. The meta-analysis provided evidence that patients who underwent AR experienced clinically better sexual well-being than patients who underwent IBR (adjMD 5.83, 95% CI 3.44 to 8.23; I^2=0%).

Figure 5. Meta-analysis for Key Question 1: IBR versus AR – sexual well-being



Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), MD = mean difference, NA = not applicable, NRCS = nonrandomized comparative study, RCT = randomized controlled trial, SD = standard deviation, y = years.

Kulkarni 2017, which was included in the meta-analysis, reported additional data regarding sexual well-being. At 2 years, the clinically better sexual well-being advantage of AR over IBR existed within the subgroup of women who had unilateral reconstruction (adjMD 11.4; P<0.001) but not bilateral reconstruction (adjMD 4.2; P<0.001).

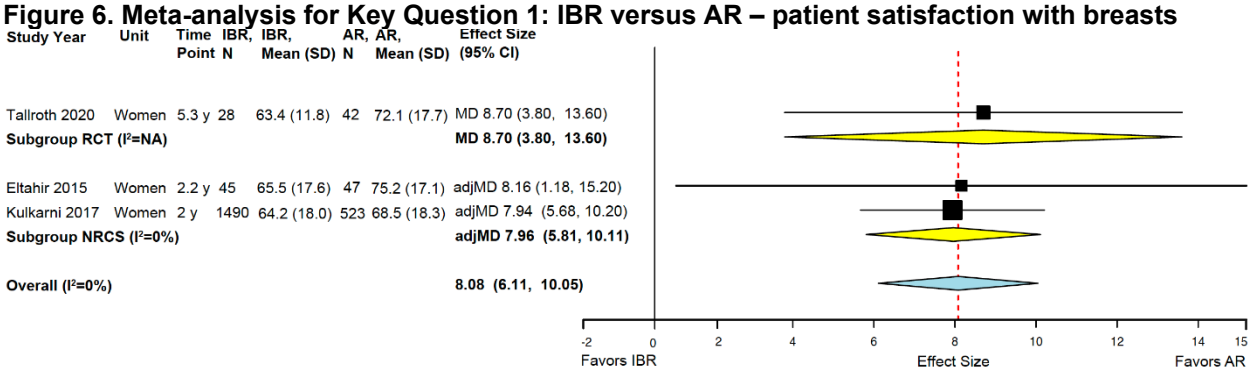
The one NRCS reporting sexual well-being data that were not included in the meta-analysis (Kouwenberg 2020) reported that, compared with patients who underwent IBR, patients who underwent AR experienced better sexual well-being beyond 6 months (P<0.05; adjusted effect size not reported). Kouwenberg 2020 also reported data on **sexual functioning** and **sexual enjoyment** using the EORTC QLQBR23 (0 to 100; higher is better; MCID 5[189]). Beyond 6 months of followup, compared with patients who underwent IBR, those who underwent AR experienced better sexual functioning (P<0.05) but not better sexual enjoyment (P=NS); adjusted effect sizes were not reported.

Satisfaction With Breasts

One RCT and six NRCS reported data on satisfaction with breasts or nipples.

The RCT (Tallroth 2020) and four NRCSs (Brito 2020, Eltahir 2015, Kouwenberg 2020, and Kulkarni 2017) reported on **satisfaction with breasts** using the BREAST-Q (0-100; higher is better; MCID 5[187]) (Figure 6 and Appendix Table E-1.1). Only two of the NRCSs (Eltahir 2015 and Kulkarni 2017) reported adjusted effect sizes, and therefore we combined their estimates and the RCT's estimate at average followup durations ranging from 2 to 5.3 years (Figure 6). Effect sizes ranged from 7.94 to 8.70 across these studies. The meta-analysis provided evidence that patients who underwent AR experienced clinically better satisfaction with breasts than patients who underwent IBR (adjMD 8.08, 95% CI 6.11 to 10.1; I^2=0%).

Figure 6. Meta-analysis for Key Question 1: IBR versus AR – patient satisfaction with breasts



Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), MD = mean difference, NA = not applicable, NRCS = nonrandomized comparative study, RCT = randomized controlled trial, SD = standard deviation, y = years.

Kulkarni 2017, which was included in the meta-analysis, reported additional data regarding satisfaction with breasts. At 2 years, the satisfaction advantage of AR over IBR existed even within the subgroups of women who had unilateral reconstruction (adjMD 9.85; P=0.001) or bilateral reconstruction (adjMD 5.13; P=0.001).

The two NRCSs reporting sexual satisfaction with breasts data that were not included in the meta-analysis (Brito 2020 and Kouwenberg 2020) also reported that, compared with patients who underwent IBR, patients who underwent AR experienced better satisfaction beyond 6 months (Kouwenberg 2020: P<0.05; adjusted effect size not reported) and at an unreported time-point (Brito 2020: P=0.004; adjusted effect size not reported).

Two NRCSs (Lei 2020 and Yueh 2009) reported categorical data regarding satisfaction with breasts (Appendix Table E-1.4). Lei 2020 reported that a comparable proportion of patients who underwent IBR or AR were satisfied (adjOR 0.85, 95% CI 0.36 to 1.63). However, Yueh 2009 reported that patients who underwent AR 2 were more likely to be satisfied than were patients who underwent IBR (adjOR 1.43, 95% 1.18 to 1.73). These findings were also observed when specifically comparing women who underwent AR with TRAM flaps versus women who underwent IBR (adjOR 3.49, 95% CI 1.91 to 6.40) and when comparing women who underwent AR with latissimus dorsi (LD) flaps versus women who underwent IBR (adjOR 1.99, 95% CI 1.09 to 3.65). However, the odds of being satisfied were comparable between the AR with deep inferior epigastric perforator (DIEP) flap and IBR groups.

The RCT (Tallroth 2020) and two NRCSs (Eltahir 2015 and Kouwenberg 2020) reported on **satisfaction with nipples** using the BREAST-Q questionnaire (0-100; higher is better; MCID 5[187]). The results were inconsistent. Two studies reported comparable satisfaction scores between IBR and AR groups: Tallroth 2020 at 5.3 years of followup (MD 2.3, 95% CI −5.5 to 10.1) and Eltahir 2015 at 2.2 years of followup (adjMD 1.70, 95% CI −14.2 to 17.6). However, Kouwenberg 2020 reported that patients who underwent AR had higher scores beyond 6 months of followup (P<0.05; adjusted effect size not reported).

Satisfaction With Surgical Outcome

One RCT (Tallroth 2020) and four NRCSs (Eltahir 2015, Kouwenberg 2020, Yueh 2009, and Lei 2020) reported on **satisfaction with the surgical outcome**. The results were inconsistent. Three of these studies reported continuous data (using the BREAST-Q; 0-100; higher is better; MCID 5) (Appendix Table E-1.1). Two studies reported comparable satisfaction scores between

IBR and AR groups: Tallroth at 5.3 years of followup (MD 2.9, 95% CI −3.1 to 8.9) and Eltahir 2015 at 2.2 years of followup (adjMD 4.9, 95% CI −3.1 to 12.9). However, Kouwenberg 2020 reported that patients who underwent AR had higher scores beyond 6 months of followup (P<0.05; adjusted effect size not reported).

Two NRCSs (Lei 2020 and Yueh 2009) reported categorical data on whether patients reported being satisfied with the surgical outcome (Appendix Table E-1.4). Lei 2020 reported comparable satisfaction in the IBR and AR groups (adjOR 0.69, 95% CI 0.45 to 1.67). On the other hand, Yueh 2009 reported that, compared with women who underwent IBR, there was greater likelihood of satisfaction in the overall AR group (adjOR 1.83, 95% CI 1.11 to 3.03) and in the AR with TRAM flap group (adjOR 2.05, 95% CI 1.13 to 3.72). However, the odds of being satisfied with the surgical outcome was comparable between the IBR and AR with DIEP flap group and between the IBR and AR with LD flap group.

Recurrence of Breast Cancer

Three NRCSs (Ha 2020, Kouwenberg 2020, and Wu 2021) reported inconsistent data for recurrence of breast cancer (Appendix Table E-1.3). Ha 2020 reported that at 4.8 years of followup, compared with women who underwent IBR, women who underwent AR experienced a greater risk of **recurrence of high histologic grade (Grade III) breast cancer** (adjOR 3.39, 95% CI 1.23 to 9.32). However, risks of **locoregional recurrence** were comparable (P=0.70; adjusted effect size not reported). The two other NRCSs (Kouwenberg 2020 and Wu 2021) also reported that local and distant recurrence risks were comparable between IBR and AR groups.

Note that recurrence of breast cancer was not a prioritized outcome for this review because its linkage to breast reconstruction surgery is not clear, and so does not appear in the Evidence Profiles.

Mortality

One NRCS (Jiang 2013) reported mortality data (Appendix Table E-1.5). At 8.9 years of followup, patients in the IBR and AR groups experienced comparable risks of **overall mortality** (adjOR 0.96, 95% CI 0.89 to 1.04) and **breast cancer-specific mortality** (adjOR 0.95, 95% CI 0.87 to 1.04).

Surgical Complications

Both RCTs, 35 of the 38 NRCSs, and all 69 single group studies reported on surgical complications for this KQ. For each outcome, we first summarize results from the comparative studies (i.e., RCTs and NRCSs; Appendix Tables E-1.5 to E-1.7 and Appendix Tables F-1.11 to F-1.26). Additional information on surgical complications from the single group studies is presented in Appendix Tables F-1.13 to F-1.26 and is summarized briefly here. Because this KQ is about the comparison between IBR and AR, conclusions (including SoE assessments) are based on results from the comparative studies only.

Unplanned Repeat Hospitalizations

Three NRCSs and four single group studies reported data for this outcome.

Two NRCSs (Merchant 2015 and Mioton 2013) reported that risks of **unplanned repeat hospitalizations** within the first month of followup were comparable between patients in the IBR and AR groups (Appendix Table E-1.5). Merchant 2015 reported an adjOR of 1.07 (95% CI 0.95 to 1.20) and Mioton 2013 reported that the comparison was not statistically significant (an

adjusted effect size was not reported). The third NRCS (Nasser 2018) reported that IBR and AR groups had comparable 1-month risks of **unplanned emergency department (ED) visits** (adjOR 1.11, 95% CI 0.91 to 1.25) and **unplanned ED visits with pain-related diagnoses** (adjOR 1.11, 95% CI 0.83 to 1.67).

Among the four single group studies, three assessed IBR and one AR (Appendix Table F-1.14). Among the three IBR studies, two studies reported 3-month risks of **unplanned repeat hospitalizations** of 18 and 16.5 percent, while the third study, without reporting the time point, reported a risk of 2.8 percent. In the AR study, the risk at 1 month was 6.7 percent.

Unplanned Repeat Surgeries for Revision

Three NRCSs and nine single group studies reported data for this outcome.

Findings in the three NRCSs (Fischer 2014, Zhang 2019, and Kulkarni 2017) were inconsistent (Appendix Table E-1.6). Two NRCSs (Fischer 2014 and Zhang 2019) reported that risks of **unplanned repeat surgeries for revision** were lower in the AR group than the IBR group, while Kulkarni 2017 reported the reverse. Without reporting adjusted effect sizes, Fischer 2014 reported lower risks in the AR group within the first 1 year (P=0.017) and at 2 years of followup (P=0.003). Zhang 2019 reported an adjOR of 0.72 (95% CI 0.50 to 1.06) at 4.9 years of followup. Kulkarni 2017, on the other hand, reported higher risks in most of the individual flap groups (DIEP, free TRAM, LD, and superficial inferior epigastric artery perforator [SIEA]) than in the IBR with tissue expanders group, with adjORs ranging from 1.83 to 2.66. The pedicled TRAM group, however, had a risk that was comparable to the IBR with tissue expanders group (adjOR 1.33, 95% CI 0.75 to 2.40).

Among the nine single group studies, three assessed IBR and six AR (Appendix Table F-1.14). Among the IBR studies, Park 2019 reported a 6-month risk of unplanned surgeries for revision of 8.7 percent, Coroneos 2019 reported a 3-year risk of 20.4 percent, and Rogoff 2020 reported a risk of 0.6 percent at an unreported time-point. The six AR studies reported that at various followup time-points between 5.6 months and 10 years, risks ranged from 1.0 to 19.1 percent.

Unplanned Repeat Surgeries for Complications

Three NRCSs and eight single group studies reported data for this outcome.

Findings in the three NRCSs (Hangge 2013, Mioton 2013, and Zhang 2011) were inconsistent (Appendix Table E-1.6). One NRCS (Hangge 2013) reported that, compared with the AR group, risks of **unplanned repeat surgeries for unspecified complications** were higher in the IBR direct-to-implant group (adjOR 2.03, 95% CI 1.03 to 3.98) and the IBR with tissue expanders group (adjOR 1.81, 95% CI 0.90 to 3.64). On the other hand, Mioton 2013 reported comparable risks of the above outcome between IBR and AR groups (adjOR 1.08, 95% CI 0.88 to 1.32) and Zhang 2011 reported comparable risks of **unplanned repeat surgeries for compromised implants or flaps** (adjOR 0.63, 95% CI 0.29 to 1.37).

Among the eight single group studies, three studies assessed IBR and five AR (Appendix Table F-1.15). Among the IBR studies, Sewart 2021 reported that, at 3 months of followup, the risk of **undergoing unplanned repeat surgeries for infections** was 16.8 percent; Hamdi 2011 reported that, at 2.6 years of followup, the risk of **undergoing AR after failure of IBR** was 7.8 percent; and Acosta 2011 reported that, at 9 years of followup, the risk of **undergoing wound revision** was 11.4 percent. The five AR studies reported risks of **reoperation for complications** at up to 3.1 years of followup ranging from 2.0 to 18.0 percent.

Pain

Five NRCSs and three single group studies reported inconsistent data regarding pain.

Three NRCSs (Kulkarni 2017, Shiraishi 2020, and Roth 2007) reported that, compared with IBR, AR, particularly when conducted using abdominal-based flaps (TRAM, SIEA, and DIEP), was generally associated with more chronic pain beyond 3 months after surgery (Appendix Table E-1.7). Kulkarni 2017 reported pain data using three different measurements: the sensory and affective components of the McGill Pain Questionnaire Short Form (MPQ-SF) (for each component: 0 to 10; higher is worse; MCIDs not available[190]) and a VAS (0 to 10; higher is worse; MCID 2 points[191]). At 1 week after surgery, compared with patients who underwent IBR, patients who underwent AR with SIEA flaps had higher MPQ-SF **sensory pain** scores (adjMD 2.41, 95% CI 0.38 to 4.44). At 3 months after surgery, compared with patients who underwent IBR with tissue expanders, patients who underwent AR with free TRAM flaps had higher scores (adjMD 2.48; P<0.001). At 1 week after surgery, MPQ-SF **affective pain** scores were comparable between various AR flap and IBR groups. However, at 2 years after surgery, compared with patients who underwent IBR with tissue expanders, scores were higher (i.e., worse) in patients who underwent AR with abdominally sourced flaps: DIEP (adjMD 0.33, 95% CI 0.07 to 0.59), free TRAM (adjMD 0.84; P<0.001), and SIEA (adjMD 1.24; P<0.0001). Using the VAS, however, Kulkarni 2017 reported comparable **pain** across study groups at 1 week after surgery whether analyzed as a continuous score (Appendix Table E-1.7) or as a dichotomous outcome of moderate to severe pain versus not (Appendix Table E-1.6). Shiraishi 2020 also reported data using the MPQ-SF. At 1 year of followup, patients who underwent AR (all with DIEP flaps) had higher mean MPQ-SF scores for overall (adjMD 1.08) as well as for the sensory (adjMD 0.80) and affective components (adjMD 0.28); no estimates of uncertainty or P values were reported (MCID also not available). Roth 2007 reported data using a different VAS (1 to 5; higher is better; MCID not available). At 2 years of followup, patients who underwent AR experienced lower (i.e., worse) **abdominal pain** scores (P<0.0001; adjusted effect size not reported). Scores for the other scores (i.e., **bodily pain, breast pain,** and **back pain**) were comparable between IBR and AR groups.

On the other hand, Eltahir 2015 reported comparable pain scores between IBR and AR groups (adjMD 2.40, 95% CI −5.37 to 10.2). This was based on the **pain** component of the SF-36 (scores 0 to 100; higher is better; MCID unavailable). Similarly, Kouwenberg 2020 reported comparable pain scores between IBR and AR groups (P=NS; adjusted effect size not reported). This was based on the **pain** component of the EORTC QLQC30 (scores 0 to 100; higher is worse; MCID unavailable).

Each of the three single group studies assessed IBR (Appendix Table F-1.16). Risks of **breast pain or tightness** were 5.1 percent at 1 year (1 study), 1.8 percent at 2 years (1 study), and 4.7 percent at an unreported time-point (1 study). Although a statistical test evaluating subgroup effects was not reported, obese and nonobese patients had comparable risks of breast pain at 1 year (5.8% and 4.8%) (1 study).

Analgesic Use

One NRCS (Shiraishi 2020) reported data using a score from 0 to 5 where 0 implies no analgesic use and 5 implies daily analgesic use (no MCID is available). At 1 year of followup, patients who underwent AR had higher mean analgesic use scores (adjMD 0.37), but no estimates of uncertainty or P values were reported.

Necrosis

Four NRCSs and 41 single group studies reported necrosis data.

Findings in the four NRCSs (Woo 2018, Naoum 2020a, Abedi 2016, and de Araujo 2016) were inconsistent (Appendix Table E-1.5). Locations of necrosis reported included the mastectomy flap and fat at followup time points ranging from 1.6 to 10 years. One NRCS (Woo 2018) reported that patients who underwent AR had a lower risk of **mastectomy flap necrosis** (adjOR 0.31, 95% CI 0.11 to 0.86), while two other NRCSs reported that IBR and AR groups had comparable risks (Naoum 2020a: adjOR 0.83, 95% CI 0.19 to 3.5 and Abedi 2016: adjOR 0.66, 95% CI 0.38 to 1.16). However, another NRCS (de Araujo 2016) reported a higher risk in the AR group, but the estimate was very imprecise (adjOR 17.9, 95% CI 0.52 to 610.5).

Naoum 2020a also reported that patients who underwent AR had a higher risk of **fat necrosis** at 4 to 10 years of followup, but the estimate was imprecise (adjOR 21.2, 95% CI 2.5 to 174.5).

Among the 41 single group studies, 16 studies assessed IBR and 25 AR (Appendix Table F-1.17). Among the 16 IBR studies, risk of **breast fat necrosis** was 5.0 percent in the first 12 months (1 study). Risk of **mastectomy flap necrosis** was 1.8 percent in the first month (1 study), between 0.1 and 8.5 percent between 1 month and 1 year (5 studies), between 1.6 and 3.1 percent after 1 year (2 studies), and between 2.0 and 12.3 percent at unreported time-points (4 studies). Risk of **necrosis at unspecified locations** was 1.5 percent in the first month (1 study), between 2.0 and 12.4 percent between 1 month and 1 year (3 studies), 9.7 percent after 1 year (1 study), and 3.2 percent at an unreported time-point (1 study). Although statistical tests evaluating subgroup effects were not reported, differences in risks of necrosis were reported among subgroups: immediate IBR had higher risk than delayed IBR (1 study); two-stage IBR had higher risk than single-stage IBR (2 studies), and patients who underwent radiation therapy before IBR had higher risk than who did not (2 studies). Obese patients had a higher risk of necrosis of the breast fat but not of the skin flap (1 study).

Among the 25 AR studies, risk of **breast fat necrosis** was between 10.0 and 11.2 percent in the first month (2 studies), between 1.3 and 11.1 percent between 1 month and 1 year (3 studies), between 0.3 and 13.0 percent after 1 year (5 studies), and between 0.9 percent and 19.4 percent at unreported time-points (10 studies). Risk of **mastectomy flap necrosis** was 0.4 percent in the first year (1 study), between 1.9 percent and 14.3 percent after 1 year (5 studies), and between 0.5 percent and 18.2 percent at unreported time-points (5 studies). Risk of **AR flap necrosis** was 5.5 percent in the first year (1 study), 2.5 percent at 2 years (1 study), and 5.5 percent at an unreported time-point (1 study). Risk of **umbilical necrosis** was 3.5 percent after 1 year (1 study) and 3.3 percent at an unreported time-point (1 study).

Although a statistical test evaluating subgroup effects was not reported, patients in the oldest age group (>70 years) had a higher risk of fat necrosis (26.3%) than younger categories of women (approximately 15% to 17%) (1 study).

Thromboembolic Events

Both RCTs, two NRCSs, and 26 single group studies reported thromboembolic event data.

One NRCS (Mioton 2013) reported that risks of **deep vein thrombosis (DVT)** in IBR and AR groups were comparable (adjOR 0.99, 95% CI 0.41 to 2.41), but patients who underwent AR had a statistically nonsignificant higher risk of **pulmonary embolism (PE)** (adjOR 1.84, 95% CI 0.71 to 4.77) (Appendix Table E-1.5). The other NRCS (Momeni 2018) reported that patients who underwent AR had a statistically significant higher risk of the **composite outcome of DVT or PE** (adjOR 2.27, 95% CI 1.79 to 2.86). Both RCTs (Brorson 2020a or Tallroth 2020)

provided unusable data for DVT, PE, arterial stop, and venous stasis because for each outcome one or both study groups (IBR and AR) experienced no events in the short (1-month) followup, so no effect sizes were calculable.

Among the 26 single group studies, one study assessed IBR and 25 AR (Appendix Table F-1.18). In the IBR study (Chen 2018a), risk of **DVT** was 0.04 percent and **PE** 0.09 percent (time points not reported).

Among the 25 AR studies, risk of **DVT** was 0.1 percent in the first month (1 study) and between 0.1 and 2.5 percent at unreported time-points (4 studies). Risk of **PE** was 0.2 percent in the first year (1 study), between 0.1 percent and 1.4 percent after 1 year (2 studies), and between 0.1 percent and 0.8 percent at unreported time-points (4 studies). Risk of the **composite outcome of DVT or PE** was 0.5 percent in the first month (1 study) and between 0 percent and 1.1 percent at unreported time-points (4 studies).

Risk of **venous congestion of the AR flap** was 1.2 percent in the first month (1 study), 4.4 percent between 1 month and 1 year (1 study), and 0.6 percent after 1 year (1 study). Risk of **venous thrombosis of the AR flap** was 2.7 percent between 1 month and 1 year (1 study). Risk of **venous thrombosis or occlusion of the AR flap** was between 0.5 percent and 5.6 percent in the first month (4 studies), 3.8 percent after 1 year (1 study), and between 1.2 percent and 3.9 percent at unreported time-points (3 studies). Risk of **insufficient venous drainage of the AR flap** was 0.8 percent after 1 year (1 study). Risk of **arterial thrombosis of the AR flap** was 1.6 percent between 1 month and 1 year (1 study). Risk of **arterial thrombosis or occlusion of the AR flap** was between 0.8 percent and 4.0 percent in the first month (4 studies), 0.5 percent after 1 year (1 study), and between 1.4 percent and 3.8 percent at unreported time-points (2 studies). Risk of **insufficient arterial supply of the AR flap** was 0.1 percent after 1 year (1 study). Risk of the **composite outcome of arterial or venous thrombosis or occlusion of the AR flap** was 0.1 percent in the first year (1 study) and between 0.8 percent and 3.5 percent at unreported time-points (2 studies). Although a statistical test evaluating subgroup effects was not reported, patients in the oldest age group (>70 years) had a higher risk of this composite outcome (5.3%) than younger categories of women (between 2.9% and 3.9% risk) (1 study).

Infections Not Explicitly Implant Related

Six NRCSs and 47 single group studies reported data on infections that were not explicitly implant-related.

Findings in the six NRCSs were inconsistent (Appendix Table E-1.6). One NRCS (Naoum 2020b) reported that patients who underwent AR had higher risks of **infections (location not specified)** than patients who underwent single-staged IBR (adjOR 3.2, 95% CI 0.6 to 16) and patients who underwent two-staged IBR (adjOR 8.1, 95% CI 1.7 to 39). Another NRCS (Mioton 2013) reported that, compared with patients who underwent IBR, patients who underwent AR had higher risks of **wound infections** (adjOR 1.40, 95% CI 1.01 to 1.96). Mioton 2013 also reported that patients who underwent AR had higher risks of **deep surgical site infections** (adjOR 1.81, 95% CI 1.12 to 2.94) but not **superficial surgical site infections** (adjOR 1.20, 95% CI 0.81 to 1.76). Two NRCSs reported imprecise comparisons of risks of **infections** between AR and IBR groups (de Araujo 2016: adjOR 0.86, 95% CI 0.18 to 4.11 and Naoum 2020a: adjOR 0.77, 95% CI 0.20 to 2.50). On the other hand, two NRCSs reported that AR may be associated with a lower risk of infections. Although Kulkarni 2017 reported comparable risks of **breast wound infections** between the AR flap types and IBR, patients in the DIEP flap group had a

lower risk than the IBR group (adjOR 0.44, 95% CI 0.25 to 0.78). Garvey 2012 reported a lower risk in the AR group than the IBR group (P<0.001), but an adjusted effect size was not reported.

Among the 47 single group studies, 25 studies assessed IBR and 22 AR (Appendix Table F-1.19). In the 25 IBR studies, risk of **infections** ranged from 1.7 to 3.0 percent in the first month (3 studies), from 2.1 to 25.7 percent between 1 month and 1 year (11 studies), from 1.7 to 10.8 percent after 1 year (7 studies), and from 0.3 to 24.7 percent at unreported time-points (7 studies).

In the 22 AR studies, risk of **breast infections** ranged from 2.3 to 10.6 percent in the first month (2 studies), from 0.4 to 6.9 percent between 1 month and 1 year (4 studies), from 1.1 to 10.3 percent after 1 year (5 studies), and from 0.4 to 7.8 percent at unreported time-points (8 studies). The risk of **donor site or flap infections** ranged from 0.5 to 7.4 percent between 1 month and 1 year (2 studies) and ranged from 1.0 to 1.9 percent at unreported time-points (3 studies). The risk of **major or systemic infections** was 3.8 percent after 1 year (1 study) and 0 percent (i.e., no major or systemic infections) at an unreported time-point (1 study).

Wound Dehiscence

Two NRCSs and 21 single group studies reported would dehiscence data.

One NRCS (Mioton 2013) reported that, compared with patients who underwent IBR, those who underwent AR had a near-significant higher risk of **wound dehiscence** at 1 month of followup (adjOR 1.79, 95% CI 0.83 to 3.84), but the other NRCS (Garvey 2012) reported that risks in IBR and AR groups were comparable at 1.5 years of followup (P=0.25; adjusted effect size not reported), (Appendix Table E-1.5).

Among the 21 single group studies, 10 studies assessed IBR and 11 assessed AR (Appendix Table F-1.20). Among the 10 IBR studies, risk of **breast wound dehiscence** was 1.9 percent in the first month (1 study), between 1.6 and 4.9 percent between 1 month and 1 year (4 studies), between 0.3 and 2.1 percent after 1 year (4 studies), and between 0.7 and 11.0 percent at unreported time-points (2 studies). Although a statistical test evaluating subgroup effects was not reported, compared with patients without prior radiation therapy, patients with prior radiation had comparable 1-year risk of wound dehiscence in one study (0.8% vs. 0.3%) but higher 3.4-year risk in another study (11.9% vs. 1.1%). In another study, obese and nonobese patients had comparable risks at 1 year of followup (3.6% vs. 2.8%). In yet another study, patients in single- and two-stage reconstruction had comparable risks at 3 months (2.5% vs. 4.2%).

Among the 11 AR studies, risk of **breast wound dehiscence** was 1.2 percent in the first month (1 study), between 0.3 and 3.9 percent between 1 month and 1 year (4 studies), 11.4 percent after 1 year (1 study), and between 0.1 and 1.0 percent at unreported time-points (6 studies). Risk of **donor site wound dehiscence** was 1.7 percent between 1 month and 1 year (1 study) and 1.4 percent at an unreported time-point (1 study). Although a statistical test evaluating subgroup effects was not reported, patients with and without prior radiation therapy had comparable 1-year risk of wound dehiscence in one study (0.8% vs. 0.3%) but higher 3.4-year risk in another study (11.9% vs. 1.1%).

Delayed Healing

Two NRCSs and 11 single group studies reported data for the outcome of delayed healing.

Both NRCSs (Fischer 2013 and Garvey 2012) reported higher risks of delayed healing among women who underwent AR than IBR (Appendix Table E-1.5). Fischer 2013 reported a higher risk of **delayed breast wound healing** in the AR group at 4 years of followup (adjOR

2.2, 95% CI 1.0 to 5.2) and Garvey 2012 reported a higher risk of **delayed healing at an unspecified location** in the AR group at 1.5 years of followup (P=0.01; adjusted effect size not reported).

Among the 11 single group studies, two assessed IBR and nine AR (Appendix Table F-1.21). In the two IBR studies, 1-year risk of a **nonhealing wound** was 4.8 percent (1 study) and 0.4 percent at an unreported time-point (1 study). Although statistical tests evaluating subgroup effects were not reported, risks were comparable between patients with or without prior radiation therapy (1 study), between patients undergoing immediate or delayed IBR (1 study), and between patients undergoing direct-to-implant or tissue expander-based IBR (1 study). In another study, obese patients had a higher risk than nonobese patients at 1 year of followup (7.6% vs. 3.7%).

Among the nine AR studies, the risk of **delayed breast wound healing** was between 1.5 and 7.6 percent between 1 month and 1 year (2 studies), 2.7 percent beyond 1 year (1 study), and 25.0 percent at an unreported time-point (1 study). The risk of **delayed donor site wound healing** was between 1.7 and 3.4 percent between 1 month and 1 year (2 studies), 0.5 percent beyond 1 year, and 11.5 percent at an unreported time-point (1 study). The other AR studies reported risks of **delayed healing at unspecified locations**. Risks were 9.2 percent at 1 month (1 study), 19.7 percent between 4.3 and 5.4 years (1 study), and between 1.2 and 18.7 percent at unreported time-points (2 studies).

Seroma

Two NRCSs and 33 single group studies reported seroma data.

Although they did not report adjusted effect sizes, both NRCSs (Fischer 2014 and Garvey 2012) reported higher risks of **breast seroma** among women who underwent IBR than AR. Fischer 2014 reported a higher risk of seroma (P=0.009), and Garvey 2012 reported a higher risk of the composite outcome of seroma or hematoma (P<0.001).

Among the 33 single group studies, 14 studies assessed IBR and 19 studies AR (Appendix Table F-1.22). Among the 14 IBR studies, **breast seroma** risks ranged from 1.6 to 4.6 percent in the first month (2 studies), from 1.1 to 12.6 percent between 1 month and 1 year (7 studies), from 0.3 to 5.6 percent after 1 year (3 studies), and from 0.2 to 4.5 percent at unreported time-points (3 studies). Four of the IBR studies also reported subgroup-specific data for seroma. Although statistical tests evaluating subgroup effects were not reported, comparable risks of seroma were reported among subgroups defined by history of prior radiation therapy (2 studies), use of immediate versus delayed IBR (1 study), and use of single- versus two-stage IBR (2 studies). However, in one study, obese patients had a higher risk of seroma than nonobese patients (11.4% vs. 4.7%).

Among the 19 AR studies, **breast seroma** risk was 3.1 percent in the first year (1 study), 3.9 percent beyond 1 year (1 study), and 2.7 percent at an unreported time-point (1 study). Risk of **donor site or flap seroma** was between 0.5 and 5.5 percent after the first year (2 studies) and between 0.4 and 4.1 percent at unreported time-points (3 studies). Although a statistical test evaluating subgroup effects was not reported, one study (Chang 2011) reported comparable risks of donor site seroma among patients aged <50 years, 50 to 59 years, 60 to 69 years, and >70 years. Risks of **seroma at unspecified locations** were 1.9 percent in the first month (1 study), between 1.6 and 2.9 percent between 1 month and 1 year (3 studies), between 0.3 and 4.6 percent after 1 year (4 studies), and between 0.6 and 2.1 percent at unreported time-points (5 studies).

Scarring

No NRCS reported on scarring.

Two single group studies (Cordeiro 2015a and Yoo 2014) reported scarring data (Appendix Table F-1.23). Cordeiro 2015a, which assessed IBR, reported that at 2 years of followup, 1.4 percent of patients experienced **hypertrophic or other scarring**. Yoo 2014, which assessed AR, reported that 2.6 percent of patients experienced **breast hypertrophic scarring** and 5.2 percent experienced **donor site hypertrophic scarring**. Yoo 2014 did not report time-points for either outcome.

Reconstructive Failure

Five NRCSs reported data for **reconstructive failure** (Appendix Table E-1.6).

Two NRCSs (Chetta 2017 and Mioton 2013) reported inconsistent data in the short-term (1 to 1.3 months of followup). Chetta 2017, without defining reconstructive failure, reported that, compared with women who underwent IBR, women who underwent AR had a considerably lower risk of reconstructive failure (adjOR 0.09, 95% CI 0.07 to 0.13). On the other hand, Mioton 2013, defining reconstructive failure as implant or flap failure, reported a higher risk among women who underwent AR than IBR (adjOR 1.69, 95% CI 1.08 to 2.62).

Three NRCSs (Fischer 2013, Garvey 2012, and Kulkarni 2017) reported considerably lower risks among women who underwent AR than IBR in the long-term (1.5 to 4 years of followup). Fischer 2013, defining reconstructive failure as unplanned nonaesthetic tissue expander or implant removal related to a complication in patients with IBR or flap loss in patients with AR, reported an adjOR of 0.19 (95% CI 0.04 to 0.80) at 4 years. Garvey 2012, without defining reconstructive failure, reported P<0.001 (adjusted effect size not reported) at 1.5 years. The findings of Kulkarni 2017 agreed with these two NRCSs, but Kulkarni 2017 reported data (without defining reconstructive failure) separately for women who underwent unilateral reconstructions (adjOR 0.12, 95% CI 0.04 to 0.36) and for women who underwent bilateral reconstructions (adjOR 0.14, 95% CI 0.05 to 0.45). We do not report a meta-analysis for reconstructive failure because of substantial heterogeneity across studies (I^2=98%).

Hematoma or Hemorrhage

One NRCS and 37 single group studies reported hematoma or hemorrhage data.

The NRCS (Fischer 2014) reported comparable risks of **breast hematoma** at 1.8 to 2.1 years between women who underwent IBR and AR (P=1.0; adjusted effect size not reported).

Among the 37 single group studies, 13 studies assessed IBR and 24 studies AR (Appendix Table F-1.25). Among the 13 IBR studies, **breast hematoma** risks ranged from 2.7 to 6.3 percent in the first month (2 studies), from 0 to 12.6 percent between 1 month and 1 year (6 studies), from 2.0 to 2.5 percent after 1 year (2 studies), and from 0.4 to 4.1 percent at unreported time-points (2 studies). One study reported that the risk of **breast hematoma or hemorrhage** was 2.1 percent at an unreported time-point. In two other studies, the risk of **needing blood transfusion** were 3.2 and 8.6 percent, but the time-points were not reported in either study.

Among the 24 AR studies, **breast (or unspecified location) hematoma** risks were between 1.6 and 4.7 percent in the first month (4 studies), between 1.3 and 3.2 percent between 1 month and 1 year (3 studies), between 1.3 and 5.8 percent after 1 year (4 studies), and between 0.9 and 6.4 percent at unreported time-points (8 studies). **Breast (or unspecified location) hematoma or hemorrhage** risks were between 3.1 and 3.5 percent at unreported time-points (2 studies). Risks of **breast (or unspecified location) hematoma necessitating transfusion or operation**

were 8.0 percent in the first month (1 study), 5.7 percent after 1 year (1 study), and between 0.9 and 8.0 percent at unreported time-points (2 studies). **Donor site or flap hematoma** risks were 0.8 percent between 1 month and 1 year (2 studies), 0.4 percent beyond 1 year (1 study), and 0.1 to 1.7 percent at unreported time-points (2 studies).

Composite or Unspecified Harms

One RCT, 13 NRCSs, and five single group studies reported on various composite or unspecified harms (Appendix Table F-1.26). There was considerable inconsistency across studies in how harms were defined, which precluded meta-analysis.

The RCT (Brorson 2020a) used the Clavien-Dindo classification system and reported that, at 1 month of followup, women who underwent IBR or AR experienced comparable risks of Grades I, II, IIIa, and IIIb complications. No patients experienced Grades IV or V complications.

Among the 13 NRCSs, patients who underwent AR generally experienced higher risks of composite or unspecified harms. Six NRCSs reported risks of **overall (or "any") complications**. Seven of these NRCSs (Chetta 2017, Kouwenberg 2020, Kulkarni 2017, Mak 2020, Palve 2020, Qin 2018, and Simon 2020), reported that, between 1 month and 3.7 years of followup, risks were higher among patients who underwent AR than those who underwent IBR (adjORs ranged from 1.36 to 8.28). Kulkarni 2017 reported separate comparisons between various AR flap types and IBR; risks of overall complications were higher for each flap group (DIEP, free TRAM, pedicled TRAM, LD, and SIEA) than the IBR group at both 1 and 2 years. On the other hand, two NRCSs (Laporta 2017 and Xu 2018) reported comparable risks of overall complications between IBR and AR groups.

Six NRCSs reported on risks of **major complications or complications requiring hospitalization**. Four of these NRCSs (Dauplat 2021, Fischer 2015, Kulkarni 2017, and Liu 2014) reported that, between 1 month and 1 year of followup, risks were higher among patients who underwent AR than those who underwent IBR (adjORs ranged from 1.36 to 5.36). Kulkarni 2017 reported that, compared with the IBR group, 1-year risks of major complications were higher for each flap group, except for the LD flap group, for which the risk was comparable to the IBR group (adjOR 0.98, 95% CI 0.47 to 2.00). Kulkarni 2017 reported a similar pattern of data for the outcome **re-operative complications** at 2 years of followup. However, the other two NRCSs (Mak 2020 and Fischer 2014) reported conflicting results. Mak 2020 reported that risks of **re-operative complications** were comparable in the IBR and AR groups at 1 month (P=0.99; adjusted effect size not reported), while Fischer 2014 reported that the risk of **complications requiring hospitalization** was near-significantly higher in the IBR group at 1.8-2.1 years (P=0.08; adjusted effect size not reported).

Among the five single group studies, one assessed IBR and four AR (Appendix Table F-1.26). In the IBR study (Salibian 2019), **major ischemic complications** occurred in 6.7 percent of patients at 3.3 years of followup. In the four AR studies, the risk of **overall complications** at 9 years of followup was 19.3 percent (1 study), the risk of **wound problems** at 9 to 10 months of followup was 12.6 percent (1 study), the risk of **breast seroma, hematoma, or wound infection** at 5 years of followup was 3.4 percent (1 study), and the risk of **deep vein thrombosis, pulmonary embolism, myocardial infarction and others** was 6.4 percent (1 study).

Heterogeneity of Treatment Effects (Subgroup Differences)

No NRCS formally analyzed possible heterogeneity of treatment effects, i.e., statistical tests for whether the comparative effect of AR versus IBR (e.g., the odds ratio [OR]) differs in one

subgroup of patients versus another. One NRCS (Kulkarni 2017) report data separately for the subgroups of women who underwent unilateral and bilateral reconstructions, but it is unclear whether relative outcomes differed between the subgroups. In Kulkarni 2017, the inferences regarding the relative effects of AR versus IBR on the clinical outcomes of psychosocial well-being, sexual well-being, and satisfaction with breasts as well as the surgical complication of reconstructive failure were similar between the unilateral and bilateral reconstruction subgroups.

Applicability

A majority of the studies were conducted in North America (55% of NRCSs and 64% of single group studies). From limited reported data, it appears that the large majority of women in the North American studies were White. However, because about 80 to 90 percent of women who undergo breast reconstruction in the U.S are White,[19] it is likely that the studies are applicable to the U.S. population, despite the implied large disparity.

Overall Summary for Key Question 1

Compared with IBR, AR is probably associated with clinically better patient satisfaction with breasts and sexual well-being but comparable general quality of life and psychosocial well-being (Moderate SoE, all outcomes). AR probably poses a greater risk of deep vein thrombosis or pulmonary embolism (Moderate SoE), but IBR probably poses a greater risk of reconstructive failure in the long term (1.5 to 4 years) (Moderate SoE) and may pose a greater risk of breast seroma (Low SoE).

Key Question 2: Timing of Implant-Based Reconstruction or Autologous Reconstruction in Relation to Chemotherapy and Radiation Therapy

Key Points

- We did not find any studies addressing timing of IBR or AR in relation to chemotherapy.
- Conducting IBR either before or after radiation therapy may result in comparable physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts (Low SoE for all). Because of sparse data, there is insufficient evidence for patient satisfaction with outcome regarding timing of IBR in relation to radiation therapy.
- Conducting IBR either before or after radiation therapy probably results in comparable risk of implant failure/loss or need for explant surgery (summary adjOR 0.87, 95% CI 0.62 to 1.24; 3 studies) (Moderate SoE).
- Because of sparse data, there is insufficient evidence regarding timing of IBR and risks of unplanned repeat surgeries for revision of reconstruction, pain, necrosis, or seroma.
- We did not find any studies addressing timing of AR in relation to radiation therapy.

Key Question 2a. Chemotherapy

None of the studies compared timing of chemotherapy relative to IBR or to AR.

Key Question 2b. Radiation Therapy

Five NRCSs, reported in 10 articles,[192-201] evaluated the timing of radiation therapy relative to IBR in a total of 2,834 patients. The studies are detailed in Appendix Tables C-3, D-2, and D-3. Appendix Tables C-1, D-2, D-3, and F-2.1 to F-2.15 include full results data for all NRCSs, irrespective of whether they reported adjusted effect sizes.

In Eriksson 2013, all patients received partial submuscular implants; other studies did not report the anatomic plane of implant placement. In Stein 2020, the mean size of the implants ranged from 406 to 444 cc; other studies did not report implant sizes. None of the studies reported additional information about the implants, such as surface (smooth versus textured) or shape (round versus tear drop). We rated four NRCSs to be at overall high risk of bias, mostly related to serious risk of confounding and the lack of blinding of participants, study personnel, and/or outcome assessors. We rated one NRCS (Yoon 2020) to be at overall moderate risk of bias.

The five studies included between 130 and 1,143 women each. The studies were conducted in the U.S. (n=2), U.S. and Canada (n=1), Canada (n=1), and Sweden (n=1). Average ages of patients were similar across studies, ranging from 45 to 55 years. Average BMIs were also similar across studies, ranging from 23.7 to 26.5 kg/m^2. In one of the North American studies (Yoon 2020) 94 percent of patients were White and 3 percent were Black; the other studies did not report on race. Studies followed women for between 2 and 3.6 years.

The study result summaries are in Figure 7 and Appendix Tables E-2.1 and E-2.2. Full results are in Appendix Tables F-2.1 to F-2.15.

Summary of Comparison of Timing of Chemotherapy and Radiation Therapy Relative to IBR or AR

Table 4 summarizes the evidence for the comparison of timing of chemotherapy and radiation therapy relative to IBR or AR. There is low SoE that physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts may be comparable whether IBR is conducted before or after radiation therapy There is moderate SoE that the risk of implant failure/loss or need for explant surgery may be comparable whether IBR is conducted before or after radiation therapy (adjOR 0.87, 95% CI 0.62 to 1.24). There is no evidence to support whether the effect of IBR timing differs based on patient, surgeon, implant, or other characteristics. There is insufficient (or no) comparative evidence regarding other outcomes related to timing of radiation therapy with IBR. There is no comparative evidence regarding timing of chemotherapy relative to IBR or AR or regarding timing of radiation therapy relative to AR.

Table 4. Evidence profile for Key Question 2: Timing of IBR and AR in relation to chemotherapy and radiation therapy

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
IBR before vs. after chemotherapy	Clinical outcomes	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IBR before vs. after radiation therapy	Clinical outcomes	Physical well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical outcomes	Psychosocial well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical outcomes	Sexual well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical outcomes	Satisfaction with breasts	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical outcomes	Satisfaction with outcome	1 (106)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat surgeries for revision	1 (368)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Pain	1 (317)	Moderate	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Necrosis	1 (876)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Implant failure/loss or need for explant	4 (2537)	High	Consistent	Precise	Direct	None	Moderate	Comparable in both groups: summary adjOR 0.87 (95% CI 0.62, 1.24); 3 studies
	Surgical complications	Seroma	1 (150)	Moderate	Unclear	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
AR before vs. after chemotherapy	Clinical outcomes	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR before vs. after radiation therapy	Clinical outcomes	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, OR = odds ratio, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Appendix Table G-2 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified

Clinical Outcomes

Two NRCSs (Cordeiro 2015 and Yoon 2020) compared clinical outcomes in women receiving IBR before versus or after radiation therapy (Appendix Table E-2.1).

Both NRCSs evaluated subscales of the BREAST-Q at a mean of 2 years (Yoon 2020) and 3.3 years (Cordeiro 2015) of followup. Each subscale score ranges from 0 to 100, with higher scores indicating better well-being or satisfaction. For patients receiving implants, the MCID for physical well-being has been estimated to be 3 points, psychosocial well-being 4 points, sexual well-being 5 points, and satisfaction with breasts 5 points.[187] We considered 5 points as the MCID for satisfaction with outcome. Yoon 2020 also reported data for physical function using PROMIS (scores 0 to 100; higher is worse; MCID 3 to 4.5 points[188]) and sexual function using the EORTC (scores 0 to 100; higher is worse; MCID 4 to 10 points[185]).

For **physical well-being**, Yoon 2020 reported comparable BREAST-Q scores before versus after radiation therapy (adjMD −0.64, 95% CI −7.19 to 5.90) and so did Cordeiro 2015 (mean 73.4 vs. 72.5; P=NS). Yoon 2020 also reported comparable PROMIS physical function scores (adjMD −0.04, 95% CI −2.40 to 2.32). For **psychosocial well-being**, Yoon 2020 reported comparable BREAST-Q scores before versus after radiation therapy (adjMD 0.48, 95% CI −7.72 to 8.68), and Cordeiro 2015 reported a difference that was statistically but not clinically significant (mean 72.3 vs. 71.1; P<0.01). For **sexual well-being**, Yoon 2020 reported comparable BREAST-Q scores before versus after radiation therapy (adjMD −1.00, 95% CI −8.41 to 6.40), and Cordeiro 2015 reported a difference that was statistically but not clinically significant (mean 54.0 vs. 55.4; P<0.01). Yoon 2020 also reported comparable EORTC sexual function scores (adjMD −1.40, 95% CI −8.58 to 5.77). For **satisfaction with breasts**, Yoon 2020 reported comparable BREAST-Q scores before versus after radiation therapy (adjMD −3.89, 95% CI −11.0 to 3.23) and so did Cordeiro 2015 (mean 56.2 vs. 57.2; P=NS). For **satisfaction with surgical outcome**, Cordeiro 2015 reported a difference in BREAST-Q scores that was statistically but not clinically significant (mean 68.4 vs. 70.2; P=0.02).

Surgical Complications

All five NRCSs reported on surgical complications comparing IBR before versus after radiation therapy (Figure 7 and Appendix Tables E-2.1 and E-2.2).

One NRCS (Yoon 2020) reported continuous data for **pain** using the pain interference component of PROMIS (scores 0 to 100; higher is worse; MCID 3 to 4.5 points[188]). At 2 years of followup, PROMIS scores were comparable before versus after radiation therapy (adjMD 2.86, 95% CI −1.05 to 6.77).

One NRCS (Eriksson 2013) reported that, at 3.6 years of followup, rates of **unplanned repeat surgeries for revision of reconstruction** were comparable between women who underwent IBR before radiation and those who underwent IBR after radiation (adjusted hazard ratio [adjHR] 0.94, 95% CI 0.63 to 1.40). Similarly, one NRCS (Hirsch 2014) reported that, at 3.1 years of followup, risks of **necrosis** were comparable between women who underwent IBR before radiation and after radiation (adjHR 0.96, 95% CI 0.68 to 1.35).

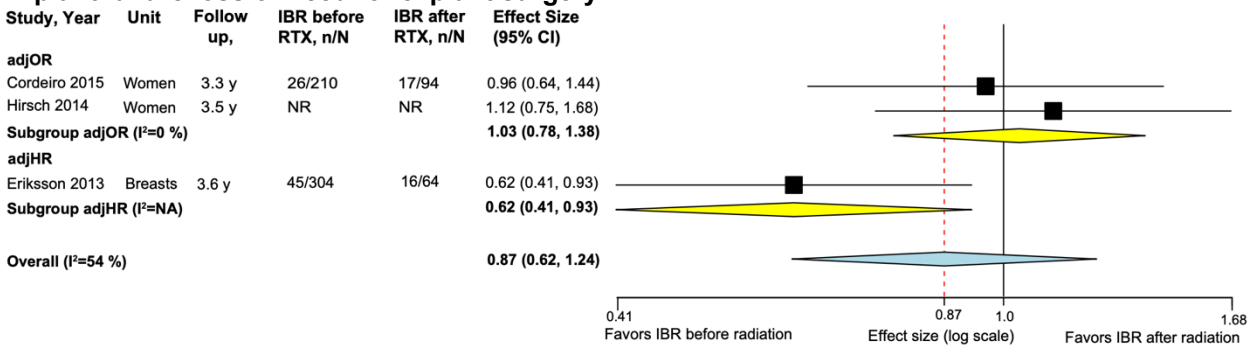
One NRCS (Yoon 2020) reported on **major** and **minor infections** at 2 years of followup after IBR. Major infections were defined as those requiring treatment with intravenous antibiotics with or without return to surgery, while minor infections were defined as those treated with oral antibiotics. Although adjusted effect sizes were not reported, the authors reported that there were no significant differences in risks of either major (P=0.40) or minor infections

(P=0.96) when comparing IBR before versus after radiation therapy. Yoon 2020 additionally reported that, at the same followup time-point (2 years), the incidence of three other surgical complications were also similar between the treatment groups: **wound dehiscence** (P=0.32), **seroma** (P=0.46), and **capsular contracture** (P=0.80).

Two NRCSs (Hirsch 2014 and Yoon 2020) reported that **hematoma** rates were similar between women receiving IBR before or after radiation therapy (Appendix Table E-2.1). Hirsch 2014 reported data at 3.1 years of followup (adjOR 0.56, 95% CI 0.22 to 1.45), while Yoon 2020 reported data at 2 years of followup (P=0.632).

Three NRCSs reported on **implant failure/loss or need for explant surgery** at average followup durations ranging from 2 to 3.5 years (Figure 7). Two studies reported adjORs, while one (Eriksson 2013) reported adjHRs. Because the events were rare (<2%) in both groups of the Eriksson 2013 study, we considered the adjHR to be a reliable estimate of the adjOR and therefore combined estimates from all four studies. Effect sizes ranged from 0.62 to 1.12 across studies. The meta-analysis did not provide evidence for a between-group difference for the outcome of implant failure/loss or need for explant surgery (adjOR 0.87, 95% CI 0.62 to 1.24; I^2 =54%).

Figure 7. Meta-analysis for Key Question 2b: Timing of IBR in relation to radiation therapy – implant failure/loss or need for explant surgery



Abbreviations: adj = adjusted, CI = confidence interval, HR = hazard ratio = IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), NR = not reported, OR = odds ratio, RTX = radiation therapy, y = years.

One NRCS reporting implant failure data that was not included in the meta-analysis due to the lack of a reported adjusted effect size (Yoon 2020) reported that implant failure was more common in patients who underwent IBR after radiation therapy (P=0.04).

Three NRCSs (Hirsch 2014, Stein 2020, and Yoon 2020) reported data for a heterogeneous group of **composite or unspecified harms**, each of which was comparable between groups of women receiving IBR before or after radiation therapy. These included any complication, major complications, major complications needing hospitalization or surgery, operative complications, nonoperative complications, and minor complications.

Heterogeneity of Treatment Effects (Subgroup Differences)

None of the studies reported subgroup results or other analyses of possible heterogeneity of treatment effects. The studies were too sparse to allow exploration of possible differences based on patient or other characteristics.

Applicability

Four of the five studies addressing this KQ were conducted in North America. All studies were published in the last 8 years. Generally, these studies, including the Swedish study (Eriksson 2013), contribute evidence that is directly applicable to the population of women receiving implants in the U.S. that has been shown to be between 80 and 90 percent White.[19]

Overall Summary for Key Question 2

Conducting IBR either before or after radiation therapy may result in comparable physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts (all Low SoE) and probably results in comparable risks of implant failure/loss or need for explant surgery (Moderate SoE). We found no evidence addressing timing of IBR or AR in relation to chemotherapy or timing of AR in relation to radiation therapy.

Key Question 3: Comparisons of Implant Materials for Implant-Based Reconstruction

Key Points

- Silicone and saline implants may result in clinically comparable assessments of patient satisfaction with breasts (Low SoE).
- Because of sparse data, there is insufficient evidence to make conclusions about other clinical outcomes or about surgical complications when comparing materials used for IBR (silicone, saline, or double lumen [i.e., silicone and saline]).

Five retrospective NRCSs, reported in five articles,[18, 192, 202-204] compared different implant materials in a total of 2,929 patients undergoing IBR. The studies are detailed in Appendix Tables C-4, D-2, and D-3. None of the studies reported additional information about the implants, such as surface (smooth versus textured), shape (round versus tear drop), size, or anatomic plane of placement. We rated all five NRCSs to be at overall high risk of bias, mostly related to serious risk of confounding and the lack of blinding of participants, study personnel, and/or outcome assessors. Not all the NRCSs reported adjusted effect sizes with confidence intervals; some reported adjusted P values without effect sizes.

All five NRCSs compared silicone and saline implants. One study (Le 2005) also included a third group of women with double lumen (i.e., silicone and saline) implants. The studies included between 143 and 1,143 women each and were conducted in the U.S. (n=3), Canada (n=1), or both (n=1). Among the studies reporting data, the women's mean ages ranged from 47 to 56 years and their mean BMIs ranged from 24.3 to 27.2 kg/m^2. Most studies did not report patient race. In Le 2005, the large majority (94%) were White; in Macadam 2010, a study conducted in Vancouver, Canada, the majority (66%) were Asian. Studies mostly followed women for about 3 to 5 years, with the exception of Le 2005, which included a median of 12.4 years of followup.

The study result summaries are in Appendix Tables E-3.1 and E-3.2. Full results are in Appendix Tables F-3.1 to F-3.9.

Summary of Comparison of Implant Materials

Table 5 summarizes the evidence comparing implant materials for IBR. The only conclusion we are able to make is that, in comparison with saline implants, silicone implants are associated with clinically comparable satisfaction with breasts. Due to sparse evidence, no conclusions regarding other clinical outcomes or regarding surgical complications are feasible for this comparison or for any comparison involving double lumen implants.

Table 5. Evidence profile for Key Question 3: Comparisons of implant materials for IBR

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Silicone vs. saline	Clinical outcomes	General quality of life	1 (139)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Physical well-being	1 (142)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Psychosocial well-being	1 (142)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Sexual well-being	1 (137)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Patient satisfaction with breasts	2 (624)	High	Consistent	Unclear	Direct	None	Low	Comparable in both groups
	Clinical outcomes	Patient satisfaction with outcome	1 (143)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Mortality	1 (NR)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Implant failure/loss or need for explant surgery	1 (288)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Capsular contracture	1 (345)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
Silicone vs. double lumen	Clinical outcomes	Mortality	1 (NR)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Saline vs. double lumen	Clinical outcomes	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, RoB = risk of bias, SoE = strength of evidence.

For continuous outcomes, clinical significance is based on published estimates of minimal clinically important differences (MCIDs), where available.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Appendix Table G-3 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified.

Clinical Outcomes

Three NRCSs (Macadam 2010, McCarthy 2010, and Le 2005) assessed clinical outcomes in women receiving either silicone or saline implants (Appendix Tables E-3.1 and E-3.2).

One NRCS (Macadam 2010) reported on **general quality of life** using the EORTC QLQ-C30 (0 to 100; higher is better; MCID 5 to 10 points[205]) (Appendix Table E-3.1). Patients with silicone implants had higher mean global health status scores than those with saline implants. The difference was marginally clinically important, favoring silicone, but was not statistically significant (79.9 vs. 74.9; P=0.13).

Macadam 2010 also evaluated five subscales of the BREAST-Q at a mean of 3.6 years (range 2.6 to 4.5). Each subscale score ranges from 0 to 100, with higher scores indicating better well-being or satisfaction. For patients receiving implants, the MCID for physical well-being has been estimated to be 3 points, psychosocial well-being 4 points, sexual well-being 5 points, and satisfaction with breasts 5 points.[187] We considered 5 points as the MCID for satisfaction with outcome. **Physical well-being** (per the physical function score) was similar between women receiving silicone and saline implants (mean 76.2 vs. 73.4; P=0.29). **Psychosocial well-being** was both clinically and statistically significantly better among women receiving silicone implants (77.6 vs. 70.8; P=0.03). **Sexual well-being** was clinically but not statistically significantly better among women receiving silicone implants (54.4 vs. 47.6; P=0.06). **Satisfaction with outcome** (defined as overall satisfaction) was also clinically but not statistically significantly better among women receiving silicone implants (75.4 vs. 69.5; P=0.08).

Satisfaction with breasts on the BREAST-Q was evaluated by two NRCSs (Macadam 2010 and McCarthy 2010) at similar time-points (ranging from 2.4 to 4.5 years). McCarthy 2010 reported that patients in the silicone group scored higher by 4.1 points (95% CI 1.31 to 6.89), but this difference was not clinically significant. Macadam 2010 reported that patients with silicone implants had statistically significantly higher scores (P=0.008), but no effect size was reported.

One NRCS (Le 2005) reported **mortality** data at a median of 12.4 years comparing groups of patients who underwent IBR with silicone, saline, or double lumen implants (Appendix Table E-3.2). **Breast cancer mortality** was similar in the silicone and saline groups (adjHR 1.01, 95% CI 0.44 to 2.34). Near-significantly higher breast cancer mortality was reported in the double lumen implant group than in the silicone group (adjHR 1.49, 95% CI 0.83 to 2.70). Similar results were observed for **non-breast cancer mortality**, although the estimates were highly imprecise.

Surgical Complications

Two NRCSs (Cordeiro 2015a and Antony 2014) reported surgical complications (Appendix Table E-3.2).

Cordeiro 2015a reported that, at 3.3 years of followup, **implant failure/loss** occurred less frequently among patients with silicone implants than patients with saline implants, but this was not statistically significant (adjOR 0.61, 95% CI 0.36 to 1.07).

Antony 2014 reported that, at 3 to 5 years of followup, patients who received silicone or saline implants experienced **capsular contractures** (of Baker Classification Grades 3 or 4) at rates that were not statistically significantly different. No further data were reported.

Heterogeneity of Treatment Effects (Subgroup Differences)

No studies reported subgroup results or other analyses of heterogeneity of treatment effects. The studies were too sparse to explore differences based on patient or other characteristics.

Applicability

All five studies addressing this KQ were conducted in North America. All studies were published in the last 10 years, except for Le 2005, which was published 16 years ago. In one U.S. study (Le 2005), the large majority of women were White, while in another study in Vancouver, Canada (Macadam 2010), a substantial proportion of women (66%) were Asian. Notwithstanding the one Canadian study, these studies generally contribute evidence that is directly applicable to the population of women receiving implants in the U.S. who have been shown to be between 80 and 90 percent White.[19]

Overall Summary for Key Question 3

Silicone and saline implants may result in clinically comparable patient satisfaction with breasts (Low SoE). There is insufficient evidence regarding double lumen implants.

Key Question 4: Comparisons of Anatomic Planes of Implant Placement for Implant-Based Reconstruction

Key Points

- Whether the implant is placed in prepectoral or total submuscular planes may not impact the risk of infections that are not explicitly implant-related (Low SoE). Because of sparse data, there is insufficient evidence addressing clinical outcomes for this comparison of planes.
- Because of sparse data, there is insufficient evidence addressing clinical outcomes and surgical complications for comparisons of prepectoral versus partial submuscular planes.
- There is no evidence for partial versus total submuscular planes of implant placement.

One RCT (Lee 2021b[206]) and seven NRCSs (Avila 2020, Cattelani 2018, Gabriel 2020, Kim 2020, Kraenzlin 2021, Nealon 2020a, and Ozgur 2020)[207-214] compared prepectoral, partial submuscular, and total submuscular planes of implant placement in a total of 1,555 patients undergoing IBR. Cattelani 2018 and Kim 2021b, conducted in Italy and South Korea, respectively, used textured implants, while Nealon 2020a, conducted in the U.S., used smooth implants; the other five studies did not report on the surface of the implants. In seven of the eight studies, reconstruction was immediate (i.e., implanted during the mastectomy) and single-staged (i.e., without use of tissue expanders).

We rated the RCT to be at overall moderate risk of bias, mostly related to lack of blinding of participants and study personnel and unclear risk of selective outcome reporting. We rated six of the seven NRCSs to be at overall high risk of bias and one at overall moderate risk of bias. Ratings were mostly related to critical or serious risk of confounding and the lack of blinding of participants, study personnel, and/or outcome assessors. The women's mean ages in the eight studies ranged from 43 to 53 years and mean BMIs 24.9 and 27.4 kg/m^2. None of the studies reported information on patient race. Participant followup ranged from 6 months to 6.1 years.

The studies are detailed in Appendix Tables C-5, D-2, D-3, E-4.1, and E-4.2. Full results data are in Appendix Tables F-4.1 to F-4.13.

Summary of Comparisons of Anatomic Planes of Implant Placement

Table 6 summarizes the evidence for the comparison of anatomic planes of implant placement for IBR. Due to sparse evidence, the only conclusion that is feasible regarding any comparison of anatomic planes is that prepectoral and total submuscular placement of implants may be associated with comparable risks of infections that are not explicitly implant-related. No conclusions regarding clinical outcomes are feasible.

Table 6. Evidence profile for Key Question 4: Comparisons of anatomic planes of implant placement for IBR

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions
Prepectoral vs. total submuscular	Clinical outcomes	Physical well-being	1 (84)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Psychosocial well-being	1 (84)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Satisfaction with breasts	1 (84)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat surgeries for revision	1 (405)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Pain	2 (230)	High	Inconsistent	Precise	Direct	N/A	Insufficient	None (Inconsistent results)
	Surgical complications	Analgesic use	1 (146)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Necrosis	1 (256)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Implant failure/loss or need for explant surgery	1 (256)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Infections (not explicitly implant-related)	2 (542)	High	Direct	Precise	Direct	N/A	Low	Comparable risk
	Surgical complications	Capsular contracture	1 (256)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Seroma	1 (256)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions
Prepectoral vs. partial submuscular	Clinical outcomes	Physical well-being	1 (34)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical outcomes	Psychosocial well-being	1 (34)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Pain	1 (167)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Capsular contracture	1 (34)	Moderate	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Seroma	1 (34)	Moderate	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
Partial vs. total submuscular	Clinical outcomes	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: IBR = implant-based reconstruction, N/A = not applicable, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Appendix Table G-4 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified.

Clinical Outcomes

The RCT (Lee 2021b) and one NRCS (Cattelani 2018) assessed patient-reported clinical outcomes (Appendix Table E-4.1).

Both studies reported on **physical well-being**. The RCT (Lee 2021b) used the physical component summary of the SF-36 (scores 0 to 100; higher is better; MCID not available) and reported comparable scores between patients who underwent IBR with prepectoral and partial submuscular implants (P=0.689). The NRCS (Cattelani 2018) used two different measurements: the Constant Murley score and the Disabilities of the Arm, Shoulder, and Hand (DASH) score. The Constant Murley score was designed to measure changes (or differences) in physical function in patients who have undergone shoulder surgery. The score ranges from 0 to 100, with higher scores indicating better function. The MCID has been estimated to be 10 points.[215] Compared with patients who underwent IBR with total submuscular placement, patients who underwent prepectoral placement had both clinically and statistically significantly higher mean Constant Murley scores at 1 day (71.6 vs. 60.4; P<0.001) as well as at 7 days after surgery (65.7 vs. 52.4; P<0.001). The DASH was designed to measure the ability of patients with upper extremity musculoskeletal disorders to perform certain upper extremity activities. The score ranges from 0 to 100, with higher scores indicating less ability. The MCID has been estimated to be 10 to 15 points.[216] Cattelani 2018 reported that at 1 year of followup, patients with prepectoral placement had both clinically and statistically significantly lower (i.e., better) mean DASH scores than patients with total submuscular placement (9.9 vs. 29.2; P<0.001).

Both studies reported on **psychosocial well-being**. The RCT (Lee 2021b) used the mental component summary of the SF-36 (scores 0 to 100; higher is better; MCID not available) and reported comparable scores between patients who underwent IBR with prepectoral and partial submuscular implants at 6 months (P=0.904). Lee 2021b also reported on anxiety and depression using the Hospital Anxiety and Depression Scale (scores 0 to 21 for each; higher is worse; MCID not available). At 6 months of followup, patients who underwent IBR with prepectoral and partial submuscular implants had comparable levels of anxiety (P=0.959) and depression (P=0.924). The NRCS (Cattelani 2018) reported that patients who underwent prepectoral placement experienced better psychosocial well-being (measured by number of days until return to usual work). Patients with prepectoral placement returned to their usual work sooner than did patients who underwent total submuscular placement (mean 34.6 vs. 57.3 days; P<0.001).

Cattelani 2018 reported on patient **satisfaction with breasts** using the BREAST-Q (0 to 100, higher is better, MCID 5 points[187]). At 1 year of followup, patients with prepectoral placement had both clinically and statistically significantly greater satisfaction with breasts than patients with total submuscular placement (92.2 vs. 76.1; P<0.001).

Surgical Complications

All eight studies reported on surgical complications.

One NRCS (Cattelani 2018) reported data on **unplanned repeat surgeries for revision of reconstruction** (Appendix Table E-4.2). Patients who underwent prepectoral or total submuscular placements of implants had comparable risks (P=NS; adjusted effect size not reported).

Three NRCSs reported inconsistent data on **pain**. Two NRCS used the VAS (0 to 10; higher is worse; MCID 2 points[191]). Avila 2020 reported that patients who underwent IBR with prepectoral and total submuscular placement had clinically comparable albeit statistically

significantly different pain levels (3.94 vs. 5.25; P<0.001). Kim 2020 reported that patients who underwent prepectoral and partial submuscular placement had comparable pain levels at 1 day (adjMD −0.08; P=0.33) at 7 days after surgery (adjMD −0.12; P=0.12). Cattelani 2018 reported pain data using the Brief Pain Inventory-Short Form (BPI-SF) (Appendix Table E-4.1). The score ranges from 0 to 100, with higher scores indicating greater pain. The MCID has been estimated to be 2 points.[217] Compared with patients who underwent IBR with total submuscular placement, patients with prepectoral placement had both clinically and statistically significantly lower pain at 1 day (17.6 vs. 44.1; P<0.001) as well as at 7 days after surgery (8.2 vs. 22.0; P<0.001).

One NRCS (Avila 2020) reported on **analgesic use** expressed in terms of oral morphine equivalents. Patients who underwent IBR with total submuscular placement had higher levels of analgesic use at 1 month (63.0 vs. 17.4; P=0.03).

One NRCS (Nealon 2020a) reported that risks of **necrosis** (of the skin) at 1.7 to 2.4 years were comparable between women who underwent prepectoral or total submuscular implants (adjOR 1.01, 95% CI 0.74 to 5.95).

Two NRCSs (Nealon 2020a and Kraenzlin 2021) reported that risks of **infections that were not explicitly implant related** were comparable between groups of women who underwent prepectoral or total submuscular implants. Nealon 2020a reported an imprecise adjOR of 0.31 (95% CI <0.01 to 8.65) at 1.7 to 2.4 years and Kraenzlin 2021 reported a P value of 0.21 (adjusted effect size not reported) at an unreported time-point.

One NRCS (Nealon 2020a) reported that risks of **needing explant surgery** by 1.7 to 2 years were comparable between women who underwent prepectoral or total submuscular implants, although the estimate was highly imprecise (adjOR 1.01, 95% CI 0.07 to 14.1).

Two studies reported on **capsular contracture**. No events occurred in the partial submuscular in the RCT by 6 months (Lee 2021b), so an effect size was not calculable. One NRCS (Nealon 2020a) reported that patients who underwent IBR with prepectoral and total submuscular implants had comparable risks at 1.7 to 2.4 years, but the estimate was imprecise (adjOR 0.30, 95% CI 0.03 to 1.55).

Two studies reported on **seroma** although the estimates were highly imprecise. The RCT (Lee 2021b) reported that patients who underwent IBR with prepectoral and partial submuscular implants had comparable risks at 6 months (OR 1.06, 95% CI 0.15 to 7.34). One NRCS (Nealon 2020a) reported that patients who underwent IBR with prepectoral and total submuscular implants had comparable risks at 1.7 to 2.4 years (adjOR 1.49, 95% CI 0.37 to 6.11).

One NRCS (Nealon 2020a) reported that risks of **hematoma** at 1.7 to 2.4 years were comparable between women who underwent prepectoral or total submuscular implants, although the estimate was highly imprecise (adjOR 5.18, 95% CI 0.39 to 7.05).

Three NRCSs reported a variety of **composite/unspecified harms**. Avila 2020 reported that patients with prepectoral and total submuscular implants had comparable risks of a composite of necrosis, infection, wound dehiscence, hematoma, and seroma at 1 month (P=NS; adjusted effect size not reported). Gabriel 2020 reported that at 2 years, compared with patients with prepectoral implants, patients with partial submuscular implants had a higher risk of any complication (adjOR 3.04, 95% CI 1.34 to 7.61). Ozgur 2020 reported that at 5.3 to 6.1 years, compared with patients with partial submuscular implants, patients with total submuscular implants had a higher risk of a composite of capsular contracture, inframammary fold problems, bottoming out, rippling, mechanical shift, and animation deformity (adjOR 3.28, 95% CI 1.39 to 7.76).

Heterogeneity of Treatment Effects (Subgroup Differences)

None of the eight studies reported subgroup results or other analyses of possible heterogeneity of treatment effects. The studies were too sparse to allow exploration of possible differences based on patient or other characteristics.

Applicability

None of the eight studies addressing this KQ reported information about patient race. The Italian study (Cattelani 2018) and one of the South Korean studies (Kim 2021b) used textured implants, which are not commonly used in the U.S.

Overall Summary for Key Question 4

Whether the implant is placed in the prepectoral or total submuscular plane may not be associated with risk of infections that are not explicitly implant-related (Low SoE). There is insufficient evidence addressing the comparisons between prepectoral and partial submuscular and between partial and total submuscular planes.

Key Question 5: Use of Human Acellular Dermal Matrices for Implant-Based Reconstruction

Key Points

- In patients undergoing IBR, because of inconsistent results, the evidence is insufficient regarding whether human ADM use impacts the patient-reported outcomes of physical well-being, psychosocial well-being, or satisfaction with breasts. Because of sparse data, there is insufficient evidence regarding whether human ADM use improves sexual well-being.
- Patients undergoing IBR with human ADMs probably are at greater risk than those not receiving human ADMs of implant failure/loss or need for explant surgery (summary adjOR 1.28, 95% CI 0.97 to 1.70; 6 studies) (Moderate SoE) and may be at greater risk of infections not explicitly implant- or ADM-related (summary adjOR 1.56, 95% CI 0.96 to 2.53; 7 studies) (Low SoE). Compared with nonuse, use of human ADMs probably does not impact the risks of unplanned repeat surgeries for revision (Moderate SoE) and seroma (summary adjOR 1.52, 95% CI 0.62 to 3.71; 4 studies) (Moderate SoE). Compared with nonuse, use of human ADMs may not impact the risk of necrosis (summary adjOR 0.89, 95% CI 0.63 to 1.25; 4 studies) (Low SoE).
- Because of inconsistent results, there is insufficient evidence regarding whether use of human ADMs impacts pain or risks of wound dehiscence, implant malposition, or capsular contracture.
- Because of sparse data, there is insufficient evidence regarding whether human ADM use is associated with risks of mortality, unplanned repeat surgeries for complications, analgesic use, implant rupture, thromboembolic events, or delayed healing.

Twenty-two studies, including two RCTs reported in two articles[218, 219] and 20 NRCSs reported in 29 articles[65, 66, 194, 196-198, 200, 209, 218-238] evaluated the comparison of use versus nonuse of human ADMs in a total of 43,334 patients undergoing IBR. The studies are detailed in Figures 8 to 12 and Appendix Tables C-6, D-1 to D-3, and E-5.1 to E-5.4.

Most studies did not report any additional information about the implants, such as surface (smooth versus textured), shape (round versus tear drop), size, or anatomic plane of placement. Among the two RCTs, we rated Wendel 2013 to be at high risk of bias because of the lack of blinding of participants and study personnel and because of incomplete outcome data and selective outcome reporting. We rated McCarthy 2012 to be at moderate risk of bias because of the lack of blinding of participants and study personnel and because of selective outcome reporting. Among the 20 NRCSs, we rated 15 to be at high risk of bias, four at moderate risk, and one at low risk. High risk of bias ratings were mostly related to critical or serious risk of confounding and the lack of blinding of study personnel and/or outcome assessors. Not all the NRCSs reported complete results data: some reported adjusted P values without effect sizes or effect sizes without CIs or P values.

The 22 studies included between 36 and 18,977 women and were conducted mostly in North America (16 in the U.S., 2 in Canada, 1 in both). Two studies were conducted in South Korea and one in Italy. Among the studies reporting data, the women's mean ages ranged from 47 to 51 years and their mean BMIs ranged from 22.3 to 27.0 kg/m^2. Only the NRCS by Ibrahim 2013

reported on patient race. The majority of women (79%) were White, 6.4 percent were Black, and 2.8 percent were Asian. Studies mostly followed women for about 2 to 5 years.

The study result summaries are in Figures 4 to 9 and Appendix Tables E-5.1 to E-5.4. Full results are in Appendix Tables F-5.1 to F-5.21.

Summary of Comparison of Use Versus Nonuse of Human ADMs

There is moderate SoE that, when compared with ADM nonuse during IBR, ADM use is associated with comparable risks of seroma and unplanned repeat surgeries for revision of reconstruction, but increased risk of implant failure/loss or need for explant surgery (Table 7). There is low SoE that ADM use may not impact the clinical outcomes of physical well-being, psychosocial well-being, and patient satisfaction with breasts, and the surgical complications of pain and capsular contracture. There is also low SoE of comparable risks between ADM use and nonuse groups in necrosis and seroma, but of increased risk of infections that are not explicitly related to implants or ADMs.

Table 7. Evidence profile for Key Question 5: Use versus nonuse of human ADMs during IBR

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Clinical outcomes	Physical well-being	3 (1604)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Psychosocial well-being	2 (1535)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Sexual well-being	1 (1451)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Patient satisfaction with breasts	2 (1535)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Mortality	1 (36)	High	N/A	N/A	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Unplanned repeat surgeries for revision	3 (20808)	High	Consistent	Precise	Direct	None	Moderate	Comparable in both groups
	Unplanned repeat surgeries for complications	1 (128)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Pain	2 (153)	Moderate	Inconsistent	Unclear	Direct	None	Insufficient	None (Inconsistent results)
	Analgesic use	1 (68)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Necrosis	7 (2101)	High	Consistent	Precise	Direct	None	Low	Comparable in both groups: summary adjOR 0.89 (95% CI 0.63, 1.25); 4 studies
	Implant rupture	1 (1451)	Moderate	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Implant malposition	2 (1654)	Moderate	Inconsistent	Unclear	Direct	None	Insufficient	None (Inconsistent results)
	Implant failure/loss or need for explant surgery	10 (38983)	Moderate	Consistent	Precise	Direct	None	Moderate	Higher risk with ADM: summary adjOR 1.28 (95% CI 0.97, 1.70); 6 studies
	Capsular contracture	4 (3485)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Thromboembolic events	1 (18997)	Moderate	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Infections (not explicitly implant- or ADM-related)	13 (25228)	Moderate	Inconsistent	Precise	Direct	None	Low	Higher risk with ADM: summary adjOR 1.56 (95% CI 0.96, 2.53); 7 studies
	Wound dehiscence	4 (21798)	Moderate	Inconsistent	Unclear	Direct	None	Insufficient	None (Inconsistent results)
	Delayed healing	1 (398)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Seroma	6 (3575)	Moderate	Consistent	Precise	Direct	None	Moderate	Comparable in both groups: summary adjOR 1.52 (95% CI 0.62, 3.71); 4 studies

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, OR = odds ratio, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. The color does not add unique information.

Appendix Table G-5 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified.

Clinical Outcomes

One RCT (McCarthy 2017) and two NRCSs (Cattelani 2018 and Ganesh Kumar 2021) reported on clinical outcomes comparing women who underwent IBR with or without the use of ADMs (Appendix Tables E-5.1 and E-5.2).

All three studies reported on **physical well-being**. The RCT (McCarthy 2017) used the BREAST-Q **chest and upper body** scores (0-100; higher is better; MCID 3[187]) (Appendix Table E-5.1). Scores were comparable whether or not ADM was used during IBR, when measured during the expansion phase of the tissue expander (net mean difference [NMD] 0.60, 95% CI −4.87 to 6.07), or after expansion (NMD 0.50, 95% CI −5.93 to 6.93). One NRCS (Ganesh Kumar 2021) used the **overall physical well-being** score of the BREAST-Q (0-100; higher is better; MCID 3[187]) and similarly reported that scores were comparable whether or not ADM was used (adjMD −0.82, 95% CI −3.01 to 1.37). The other NRCS (Cattelani 2018) reported on physical well-being using two different measurements: the Constant Murley score, which measures **shoulder** function (0 to 100; higher is better; MCID 10) and the DASH score, which measures function of the **arm, shoulder, and hand** (0 to 100; higher is worse; MCID 10 to 15[216]). Compared with patients who underwent IBR with ADM, patients without ADM had both clinically and statistically significantly higher mean Constant Murley scores at 1 day (71.6 vs. 60.4; P<0.001) and 7 days after surgery (65.7 vs. 52.4; P<0.001). At 1 year of followup, patients who underwent IBR with ADMs had both clinically and statistically significantly lower (i.e., better) mean DASH scores than patients who underwent IBR without ADMs (9.9 vs. 29.2; P<0.001).

Two NRCSs (Ganesh Kumar 2021 and Cattelani 2018) reported on **psychosocial well-being**. Ganesh Kumar 2021 used the BREAST-Q: psychosocial well-being scores (0 to 100; higher is better; MCID 4[187]) at 2 years of followup. Psychosocial well-being scores were comparable whether or not ADMs were used (adjMD −0.26, 95% CI −2.97 to 2.45). Cattelani 2018 reported that patients who underwent IBR with ADMs returned to their usual work sooner than did patients without ADMs (mean 34.6 vs. 57.3 days; P<0.001).

Ganesh Kumar 2021 also reported on **sexual well-being** using the BREAST-Q: sexual well-being scores (0 to 100; higher is better; MCID 5[187]) at 2 years of followup. Sexual well-being scores were comparable whether or not ADMs were used during IBR (adjMD −2.28, 95% CI −5.63 to 1.06).

Both NRCSs (Cattelani 2018 and Ganesh Kumar 2021) reported on **patient satisfaction with breasts** using the BREAST-Q: satisfaction with breast scores (0 to 100; higher is better; MCID 5[187]). Cattelani 2018, using data at 1 year of followup, reported that patients who had received ADMs were more satisfied with their breasts (P<0.001), although an adjusted effect size was not reported. Ganesh Kumar 2021, however, reported that, at 2 years of followup, satisfaction scores were comparable whether or not ADMs were used (adjMD −1.95, 95% CI −4.96 to 1.06).

Mortality

One RCT (Wendel 2013) reported on 1-month **mortality**, but no deaths occurred (Appendix Table E-5.2).

Surgical Complications

All 22 studies (2 RCTs and 20 NRCSs) reported on surgical complications comparing women who underwent IBR with or without use of ADMs (Figures 5 to 9 and Appendix Tables E-5.2 to E-5.4).

Unplanned Repeat Surgeries

Three NRCSs (Ibrahim 2013, Nealon 2020b, and Sobti 2018) reported on **unplanned repeat surgeries for revision of reconstruction** (Appendix Table E-5.2). Ibrahim 2013 reported that, at 6 months of followup, risks were comparable whether or not ADMs were used (P=0.14). An adjusted effect size was not reported. At approximately 5 years of followup, no significant between-group differences in risks of unplanned surgeries were reported by both Nealon 2020b (adjOR 0.86, 95% CI 0.69 to 1.08) and Sobti 2018 (adjOR 1.10, 95% CI 0.63 to 1.92).

One NRCS (Peled 2012) reported on **unplanned repeat surgeries for complications**, specifically wound-healing or infectious complications. At 2.6 to 3.3 years of followup, patients receiving ADMs underwent fewer unplanned surgeries for complications (P<0.05). However, an adjusted effect size was not reported.

Pain and Analgesic Use

One RCT (McCarthy 2012) and one NRCS (Cattelani 2018) reported on the outcome of **pain** (Appendix Table E-5.3). McCarthy 2012 reported data using a VAS at 24 hours, during the expansion phase, and upon completion of the expansion phase. The VAS score used ranges from 0 to 100, with higher scores indicating greater pain. The MCID has been estimated to be 5 points.[239] McCarthy 2012 reported that patients randomized to receive ADMs experienced clinically significant greater increases in pain in the first 24 hours (NMD 6.2, 95% CI −4.9 to 17.3) and during the expansion phase (NMD 6.8, 95% CI 1.1 to 12.5); although, the earlier time point was not statistically significant. After the expansion phase, changes in pain were comparable between ADM use and nonuse groups (NMD −4.6, 95% CI −9.8 to 0.6).

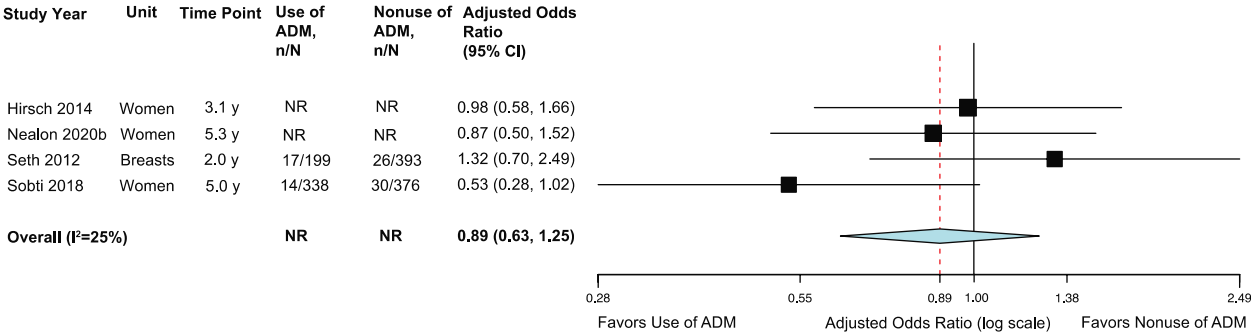
Cattelani 2018 reported on pain using the BPI-SF (0 to 100; higher implies greater pain; MCID has been estimated to be 2 points[217]). Compared with patients who did not receive ADMs (with total submuscular implant placement), patients who received ADMs (with prepectoral implant placement) experienced both clinically and statistically significantly lower pain at 1 day (17.6 vs. 44.1; P<0.001) and 7 days after surgery (8.2 vs. 22.0; P<0.001).

One RCT (McCarthy 2012) reported on **analgesic use** within the first 24 hours after surgery. McCarthy 2012 reported that analgesic use overall in the first 24 hours was statistically similar whether or not ADMs were used during IBR (MD −134 mg, 95% CI −440 to 172).

Necrosis

Seven NRCSs reported data on **necrosis** (Appendix Table F-5.10). Among them, four NRCSs (Hirsch 2014, Nealon 2020b, Seth 2012, and Sobti 2018) reported adjusted effect sizes and thus were included in a meta-analysis (Figure 8). Effect sizes ranged from 0.53 to 1.32. The meta-analysis suggested comparable risks of necrosis comparing patients who received or did not receive ADMs during their IBR (adjOR 0.83, 95% CI 0.63 to 1.25; I^2=25%).

Figure 8. Meta-analysis for Key Question 5: Use versus nonuse of human ADMs during IBR – necrosis



Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), NR = not reported, OR = odds ratio.

Among the three studies reporting necrosis data that were not included in the meta-analysis, Craig 2019 reported an adjusted effect size for only the subgroup of patients who did not receive postoperative radiation therapy; it was therefore excluded from the meta-analysis. In that subgroup, patients who received ADMs had a higher risk of necrosis at 7 months of followup (adjOR 4.99, 95% CI 3.28 to 8.03). Qureshi 2016 was not included in the meta-analysis because only an adjOR (3.1) with no CI was reported. Ganesh Kumar 2021 reported that, at 2 years of followup, risks of necrosis were comparable whether or not ADMs were used (P=0.28; adjusted effect size not reported).

Thus, among the three NRCSs not included in the meta-analysis, two studies (Craig 2019 and Qureshi 2016) suggested that ADM use may be associated with increased risk of necrosis, while one study (Ganesh Kumar 2021) was in agreement with the meta-analysis findings of comparable risk of necrosis.

Thromboembolic Events

One NRCS (Ibrahim 2013) reported on thromboembolic events (Appendix Table E-5.2). No differences were found between IBR with or without ADMs in terms of risks of **deep vein thrombosis** (P=0.47) or **pulmonary embolism** (P=0.11). No adjusted effect sizes were reported.

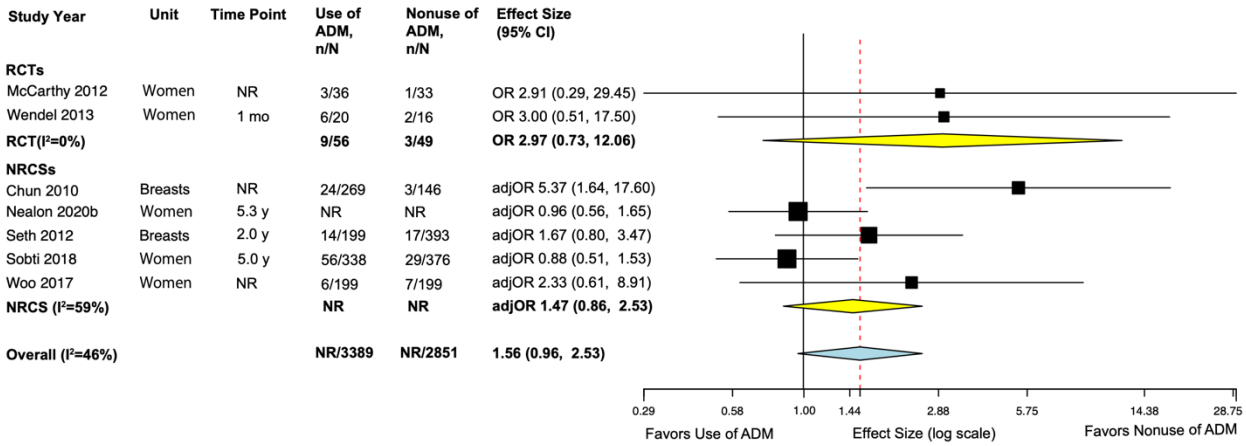
Infections Not Explicitly Related to Implants or ADMs

Thirteen studies (2 RCTs and 11 NRCSs) reported data on **infections that were not explicitly related to implants or ADMs** (Appendix Table F-5.15). Various types and extents of infections were described, and we summarize them separately below.

Any or Undefined Infections

Nine studies (both RCTs and seven NRCSs) reported on **any or undefined infections**. Seven studies, comprising both RCTs (McCarthy 2012 and Wendel 2013) and five NRCSs (Chun 2010, Nealon 2020b, Seth 2012, Sobti 2018, and Woo 2017), reported effect sizes that adequately accounted for confounders and were thus included in a meta-analysis (Figure 9). Effect sizes ranged from 0.88 to 5.37. The meta-analysis suggested a near-significant increased risk of infections in patients who received ADMs during their IBR (adjOR 1.56, 95% CI 0.96 to 2.53; I^2=46%). The findings in the RCTs were not significantly different from the NRCSs (P=0.44 from a meta-regression, and as suggested by the lack of heterogeneity across studies).

Figure 9. Meta-analysis for Key Question 5: Use versus nonuse of human ADMs during IBR – Any or undefined infections



Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, RCT = randomized controlled trial, y = years.

The two NRCSs that were not included in the meta-analysis reported inconsistent findings. Brooke 2012 reported comparable risks of infections whether or not ADMs were used (P=0.09; no adjusted effect size was reported), while Craig 2019 reported an adjusted effect size for only the subgroup of patients who did not receive postoperative radiation therapy (adjOR 2.68, 95% CI 1.54 to 5.06).

Thus, among the two NRCSs not included in the meta-analysis, one NRCS (Brooke 2012) suggested that ADM use or nonuse may be associated with comparable risks of infections, while subgroup data from another NRCS (Craig 2019) were in agreement with the meta-analysis findings of increased risk with ADM use.

Defined Infections

Five NRCSs (Liu 2011, Ganesh Kumar 2021, Ibrahim 2013, Chun 2010, and Peled 2012) reported data for defined infections. Their findings were inconsistent.

Three NRCSs (Liu 2011, Ganesh Kumar 2021, and Ibrahim 2013) reported on **wound infections**. Liu 2011 reported that ADM use was associated with greater risk of major or minor wound infections (adjOR 3.25, 95% CI 0.80 to 13.1). Ganesh Kumar 2021 reported that ADM use and nonuse groups had comparable overall risks of wound infections (P=0.138) and infections requiring intravenous antibiotics or reoperation (P=0.045), but ADM use was associated with greater risks of wound infections requiring oral antibiotics (adjOR 1.49, 95% CI 0.90 to 2.44). Ibrahim 2013 reported that ADM use was associated with greater risk of superficial surgical site infection (P=0.021) but not deep incisional surgical site infection (P=0.366). Ibrahim 2013 also reported that ADM use and nonuse groups experienced comparable risks of **organ space infection** (P=0.290) and **sepsis** (P=0.516).

Chun 2010 reported that ADM use was associated with a greater risk of **major infection requiring admission for intravenous antibiotics and/or surgery** (P=0.0016). However, Peled 2012 reported that ADM use was associated with a lower risk of **localized or systemic infections that were treated with oral antibiotics or admission for intravenous antibiotics** (P<0.05). Neither Chun 2010 nor Peled 2012 reported adjusted effect sizes.

Wound Dehiscence and Delayed Healing

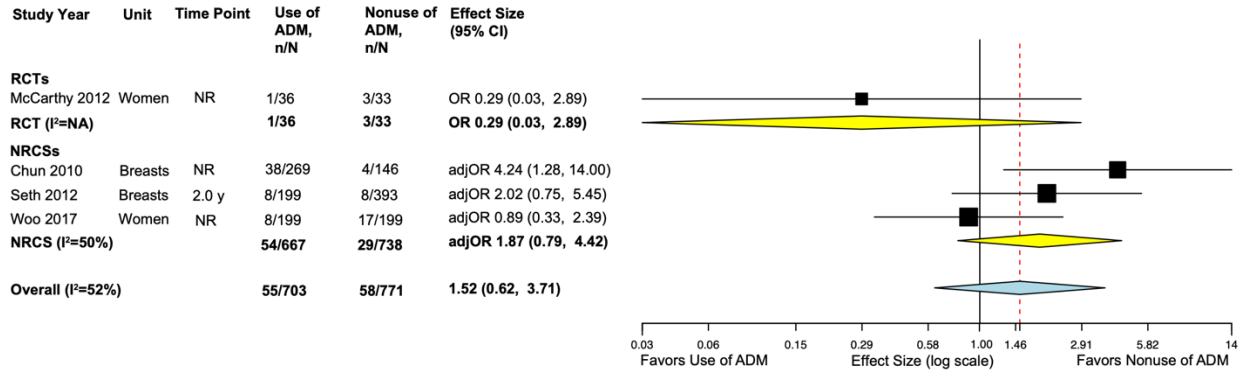
Four NRCSs (Ganesh Kumar 2021, Qureshi 2016, Ibrahim 2013, and Craig 2019) reported on **wound dehiscence**, but their findings were inconsistent (Appendix Table E-5.2). Ganesh Kumar 2021 reported that risk of wound dehiscence was higher among patients receiving ADMs (P=0.009) but did not report an adjusted effect size. Ibrahim 2013 reported that risks of wound dehiscence were comparable in the two groups (P=0.26) but did not report an adjusted effect size or CIs. However, Qureshi 2016 reported that the risk of wound dehiscence was lower among patients receiving ADMs (adjOR 0.4; P<0.05). Craig 2019 reported adjusted data only for the subgroup of patients who did not receive postoperative radiation therapy; ADM use was associated with higher risk of wound dehiscence at 7 months of followup (adjOR 2.46, 95% CI 1.23 to 4.93).

One NRCS (Woo 2017) reported on **delayed healing**, defined as a composite outcome of delayed wound healing or skin flap necrosis. Comparable risks were observed in women receiving or not receiving ADMs during IBR (adjOR 1.41, 95% CI 0.67 to 2.96).

Seroma

Six studies (one RCT and five NRCSs) reported data on **seroma** (Appendix Table F-5.14). Among them, four studies, comprising one RCT (McCarthy 2012) and three NRCSs (Chun 2010, Seth 2012, and Woo 2017), reported effect sizes that adequately accounted for confounders and were thus included in a meta-analysis (Figure 10). Effect sizes ranged from 0.29 to 4.24 across all studies. The meta-analysis suggests that seroma risks in patients who received or did not receive ADMs during their IBR were comparable (adjOR 1.52, 95% CI 0.62 to 3.71; I^2=52%). The single RCT (McCarthy 2012) provided a highly imprecise estimate, but it was not significantly different from the NRCSs' estimates (P=0.30 from a metaregression).

Figure 10. Meta-analysis for Key Question 5: Use versus nonuse of human ADMs during IBR – seroma



Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), NR = not reported, OR = odds ratio.

The two NRCSs that were not included in the meta-analysis (Craig 2019 and Ganesh Kumar 2021) reported inconsistent findings. Craig 2019, excluded because it reported an adjusted effect size for only the subgroup of patients who did not receive postoperative radiation therapy, reported that patients who received ADMs had a higher risk of seroma at 7 months of followup (adjOR 3.19, 95% CI 1.84 to 5.52). However, Ganesh Kumar 2021, excluded because of the lack

of a reported adjusted effect size, reported that risks of seroma at 2 years of followup in ADM use and nonuse groups were comparable (P=0.72).

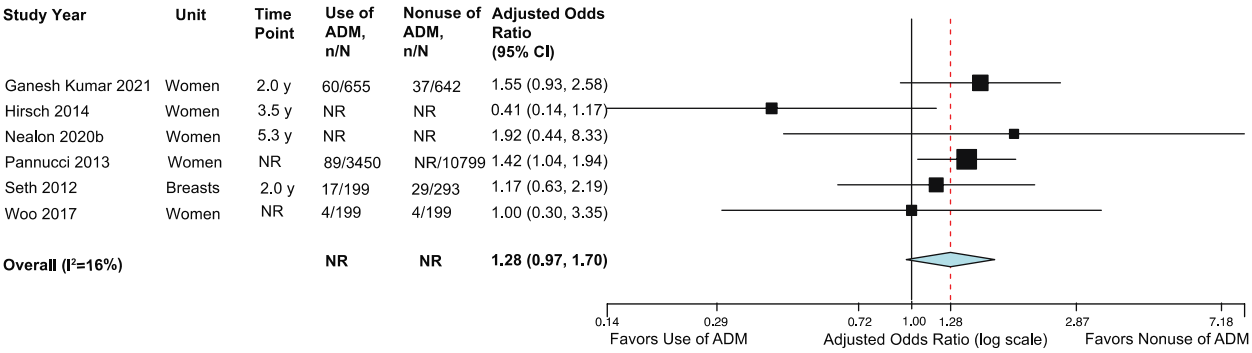
Implant Rupture, Malposition, and Extrusion

One NRCS (Ganesh Kumar 2021) reported that risks of **implant rupture** (defined as implant rupture, leakage, or deflation) were comparable in ADM use and nonuse groups (P=0.665) (Appendix Table E-5.2). An adjusted effect size was not reported. Two NRCSs (Ganesh Kumar 2021 and Vardanian 2011) reported on **implant malposition**, but the data were conflicting. Ganesh Kumar 2021, without reporting an adjusted effect size, reported that risks of implant malposition were comparable between ADM use and nonuse groups (P=0.83), but Vardanian 2011 reported that ADM use was associated with a lower risk of implant malposition (adjOR 0.23, 95% CI 0.06 to 0.78). One NRCS (Seth 2012) reported a highly imprecise estimate comparing risks of **implant extrusion** between ADM use and nonuse groups.

Implant Failure/Loss or Need for Explant Surgery

Ten NRCSs reported data on **implant failure/loss or need for explant surgery** (Appendix Table F-5.16). Among them, six NRCSs (Ganesh Kumar 2021, Hirsch 2014, Nealon 2020b, Pannucci 2013, Seth 2012, and Woo 2017) reported effect sizes that adequately accounted for confounders and were thus included in a meta-analysis (Figure 11). AdjORs ranged from 0.41 to 1.92 across these studies. The meta-analysis suggested a near-significant increased risk in patients who received ADMs during their IBR (adjOR 1.28, 95% CI 0.97 to 1.70; I^2=16%).

Figure 11. Meta-analysis for Key Question 5: Use versus nonuse of human ADMs during IBR – implant failure/loss or need for explant surgery



Abbreviations: ADM = acellular dermal matrix, mo = months, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), NR = not reported.

The four NRCSs that were not included in the meta-analysis (Craig 2019, Ibrahim 2013, Qureshi 2016, and Peled 2012) reported inconsistent findings. Craig 2019, excluded because it reported an adjusted effect size for only the subgroup of patients who did not receive postoperative radiation therapy, reported that patients who received ADMs had a higher risk of implant failure/loss at 7 months of followup (adjOR 1.90, 95% CI 1.03 to 3.51). The other three NRCSs were excluded because they did not report an adjusted effect size. Ibrahim 2013 reported that risks of implant failure were comparable whether or not ADMs were used (P=0.9). However, Qureshi 2016 reported an adjOR for explant surgery of 0.2 (without CIs or a P value) and Peled 2012 reported that ADM use was associated with a lower risk of implant failure/loss (P<0.05).

Capsular Contracture and Harms to the Inframammary Fold

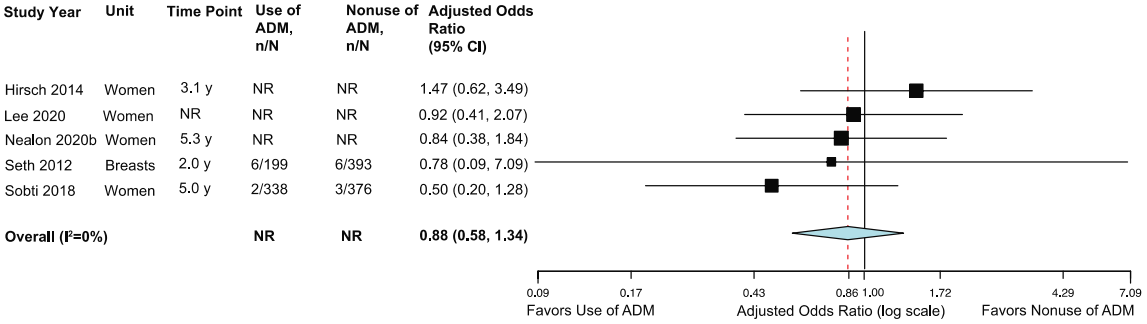
Four NRCSs (Ganesh Kumar 2021, Nealon 2020b, Sobti 2018, and Vardanian 2011) reported on risk of **capsular contracture**, but their findings were inconsistent (Appendix Table E-5.2). We do not report a meta-analysis for this outcome due to substantial statistical heterogeneity (i.e., marked between-study variability in results, as suggested by an I^2 of 85%). Three of these NRCSs reported that rates of capsular contracture were comparable, irrespective of ADM use. These included one NRCS at 2 years of followup (Ganesh Kumar 2021) and two at approximately 5 years of followup (Nealon 2020b and Sobti 2018). Vardanian 2011, however, reported that ADM use was associated with a lower risk of capsular contracture at 2.4 years of followup (adjOR 0.18, 95% CI 0.08 to 0.43).

One NRCS (Vardanian 2011) reported on **harms to the inframammary fold**, defined as issues related to the integrity of the fold but not bottoming out or shifting of the fold. ADM use was associated with a lower risk of this outcome (adjOR 0.49, 95% CI 0.23 to 1.01).

Hematoma

Six NRCSs reported data on **hematoma** (Appendix Table F-5.19). Five of these NRCSs (Hirsch 2014, Lee 2020, Nealon 2020b, Seth 2012, and Sobti 2018) reported effect sizes that adequately accounted for confounders and were thus included in a meta-analysis (Figure 12). AdjORs ranged from 0.50 to 1.47 across these studies. The meta-analysis suggested that risks of hematoma were comparable whether or not ADMs were used during IBR (adjOR 0.88, 95% CI 0.58 to 1.34; I^2=0%).

Figure 12. Meta-analysis for Key Question 5: Use versus nonuse of human ADMs during IBR – hematoma



Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, I^2 = measure of statistical heterogeneity (% of total variability that is due to between-study variability), OR = odds ratio.

Ganesh Kumar 2021, excluded from the meta-analysis because of the lack of a reported adjusted effect size, also reported that risks of hematoma were comparable whether or not ADMs were used (P=0.12).

Composite or Unspecified Harms

One RCT (Wendel 2013) and eight NRCSs (Brooke, 2012, Ganesh Kumar 2021, Hirsch 2014, Liu 2011, Safran 2020, Stein 2020, Weichman 2012, and Woo 2017) reported on various composite or unspecified harms (Appendix Table E-5.4). We did not conduct a meta-analysis of these studies because of great variability in how these outcomes were defined.

The RCT (Wendel 2013) reported that no **serious adverse events** occurred in either the ADM use or nonuse groups. Among the NRCSs, Liu 2011 reported a higher risk of **surgical complications** among patients who received ADMs than those who did not (adjOR 1.76, 95% CI

1.03 to 3.01) and Ganesh Kumar 2021 reported a higher risk of **major complications** among patients who received ADMs than those who did not (adjOR 1.43, 95% CI 1.00 to 2.05). The other six NRCSs reported comparable risks in ADM and non-ADM groups for major complications and various other composite or unspecified harms, such as **any complication**, **minor complications**, and **operative complications except explant surgery**.

Heterogeneity of Treatment Effects (Subgroup Differences)

No study evaluated whether the relative effect of ADM use varied in different subgroups of patients who underwent IBR. Craig 2019 reported wound dehiscence data among the subgroup of women who had not received postoperative radiation therapy but did not compare these results with those who had. Across studies, the studies were too sparse to allow exploration of possible differences based on patient or other characteristics.

Applicability

Only one eligible study, which was conducted in the U.S., reported on race, with the large majority of women being White. However, most studies (20 of 22) were conducted in North America. Generally, the studies addressing this KQ contribute evidence that is directly applicable to the population of women receiving implants in the U.S. who have been shown to be between 80 and 90 percent White.[19] All 22 studies addressing this KQ were published in the last 10 years.

Overall Summary for Key Question 5

The evidence is inconsistent regarding whether human ADM use during IBR impacts physical well-being, psychosocial well-being, or satisfaction with breasts. However, ADM use probably increases the risk of implant failure/loss or need for explant surgery (Moderate SoE) and may increase the risk of infections not explicitly implant-related (Low SoE). Whether or not ADM is used probably is associated with comparable risks of seroma and unplanned repeat surgeries for revision (Moderate SoE for both) and possibly necrosis (Low SoE).

Key Question 6. Comparisons of Flap Types for Autologous Reconstruction

Key Points

- TRAM versus DIEP flaps
  - AR with TRAM and DIEP flaps may result in comparable levels of patient satisfaction with breasts (Low SoE).
  - Although risks of necrosis may be comparable (Low SoE), AR with TRAM flaps probably poses a greater risk of harms to the area of flap harvest (abdominal bulge/hernia and need for abdominal hernia repair surgery) (Moderate SoE).
  - Because of sparse data, there is insufficient evidence to make conclusions about other clinical outcomes (physical, psychosocial, or social well-being, patient satisfaction with breasts, and duration of initial hospitalization) or about surgical complications (infections and wound dehiscence).
- Other comparisons of flaps
  - Because of sparse data, there is insufficient evidence regarding various clinical outcomes or surgical complications.

We found 13 studies (reported in 15 articles[43, 45, 51, 96, 240-250]) that conducted randomized or adjusted analyses for the comparison of different flap types among women undergoing AR. An additional six studies (reported in 15 articles[41, 42, 47, 50, 63, 78, 80, 83, 84, 87, 90, 91, 251-253]) did not report any adjusted effect sizes or P values and are thus not discussed further in this section. Appendix Tables C-7, D-1, D-2, and D-3 describe all 19 studies, irrespective of whether they reported adjusted effect sizes. They reported data for six different flap types: TRAM, DIEP, LD, SIEA, lateral thoracodorsal (LTD), and thoracodorsal artery perforator (TAP).

The 13 studies included three RCTs and 10 NRCSs. Among the three RCTs, we rated Brandberg 2000 and Brorson 2020b to be at high risk of bias because of the lack of blinding of participants, study personnel, and outcome assessors and because of incomplete outcome data and selective outcome reporting. We rated Rindom 2019 to be at moderate risk of bias because of the lack of blinding of participants, study personnel, and outcome assessors. Among the 10 NRCSs, we rated eight to be at high risk of bias and two at moderate risk. High risk of bias ratings for NRCSs were mostly related to critical or serious risk of confounding and the lack of blinding of participants, study personnel, and/or outcome assessors. Not all NRCSs reported adjusted effect sizes with confidence intervals; some reported adjusted P values without effect sizes or effect sizes without confidence intervals or P values.

The 13 studies included between 50 and 15,836 women and were conducted mostly in North America (four in the U.S., three in Canada, and one in both). The remaining five studies were conducted in Sweden (n=2) and Denmark, France, and the U.K. (n=1 each). Among the studies reporting data, the women's mean ages ranged from 49 to 52 years and their mean BMIs ranged from 25.9 to 28.6 kg/m2. Two studies, both from the U.S., reported on patient race; the majority (80% and 70%) of patients were White. Studies followed women for about up to 2 to 3 years. The study result summaries are in Appendix Tables E-6.1 to E-6.6. Full results are in Appendix Tables F-6.1 to F-6.25.

Summary of Comparisons of Flap Types for Autologous Reconstruction

Table 8 summarizes the evidence for the comparisons of various flap types for AR. Women who undergo AR with TRAM and DIEP flaps may experience similar levels of satisfaction with their breasts. However, when compared with women with DIEP flaps, women with TRAM flaps may be at greater risks of abdominal bulge/hernia and of needing abdominal hernia repair surgery but not at greater risk of necrosis.

While six different flaps have been compared, the evidence for comparisons of specific pairs of flaps is sparse. The evidence identified for this KQ was too sparse to allow pairwise meta-analysis, let alone network meta-analysis. It is unclear whether any specific flap type is clearly associated with better patient-reported (clinical) outcomes than the others.

Table 8. Evidence profile for Key Question 6: Comparisons of flap types for AR

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
TRAM vs. DIEP	Clinical outcomes	Physical well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Psychosocial well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Sexual well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Patient satisfaction with breasts	2 (NR)	Moderate	Consistent	Precise	Direct	Low	Comparable in both groups
	Clinical outcomes	Patient satisfaction with outcome	1 (260)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Duration of initial hospitalization	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Necrosis	2 (959)	High	Consistent	Unclear	Direct	Low	Comparable in both groups
	Surgical complications	Harms to area of flap harvest	4 (9253)	High	Consistent	Precise	Direct	Moderate	TRAM had increased risk of abdominal bulge/hernia and abdominal hernia repair surgery
	Surgical complications	Infections	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Wound dehiscence	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
DIEP vs. LD	Clinical outcomes	Patient satisfaction with breasts	1 (229)	HIgh	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Patient satisfaction with outcome	1 (229)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Thromboembolic events	1 (56)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
SIEA vs. DIEP	Clinical outcomes	Physical well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Psychosocial well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Sexual well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Patient satisfaction with breasts	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Harms to area of flap harvest	1 (417)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
TAP vs. LD	Clinical outcomes	Physical well-being	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Duration of initial hospitalization	1 (40)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)

	Surgical complications	Pain	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Necrosis	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Infections	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Seroma	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
TRAM vs. LD	Clinical outcomes	Patient satisfaction with breasts	1 (49)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Patient satisfaction with outcome	1 (255)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Mortality	1 (59)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat surgeries for revision	1 (3296)	High	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
TRAM vs. LTD	Clinical outcomes	Patient satisfaction with breasts	1 (38)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Mortality	1 (45)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
LD vs. LTD	Clinical outcomes	Patient satisfaction with breasts	1 (35)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical outcomes	Mortality	1 (46)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal, OR = odds ratio, N/A = not applicable, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SoE = strength of evidence, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Appendix Table G-6 provides the complete version of this evidence profile, including displaying all outcomes for which no evidence was identified.

Clinical Outcomes

Two RCTs (Brandberg 2000 and Rindom 2019) and three NRCSs (Erdmann-Sager 2018, Yueh 2009, and Zoghbi 2017) reported on clinical outcomes (Appendix Tables E-6.1 to E-6.5).

Physical Well-Being

One RCT (Rindom 2019) and one NRCS (Erdmann-Sager 2018) reported on physical well-being (Appendix Table E-6.1).

Rindom 2019, which randomized women undergoing AR to receive either the LD or TAP flap, reported overall and subscale data for the Constant Murley Score evaluating **physical function of the shoulder** at 1 year of followup. The overall score ranges from 0 to 100, with subscale scores ranging from 0 to 15 (pain), 0 to 20 (activity in daily life), 0 to 40 (range of motion), and 0 to 25 (strength). Higher scores indicate better physical function of the shoulder. The MCID for the overall Constant Murley Score has been estimated to be 10 points.[215] To our knowledge, MCIDs have not been estimated for the subscale scores. Rindom 2019 reported that, overall and across the subscales, women with TAP and LD flaps had clinically similar scores (Appendix Table E-6.1). However, women who received TAP flaps had statistically significantly higher scores overall and for the pain and activity in daily life subscales, but not for the range of motion and strength subscales.

Erdmann-Sager 2018 reported on physical well-being at 1 and 2 years of followup for patients undergoing AR with DIEP, free TRAM, pedicled TRAM, or SIEA flaps. Data were reported for the BREAST-Q physical function: abdomen- and chest/upper body-specific score (0 to 100; higher is better; MCID 3 for patients undergoing AR[187]). At 1 year of followup, patients undergoing AR with DIEP flaps reported clinically better **abdominal physical function** than patients undergoing AR with TRAM flaps, whether free (adjMD 4.16, 95% CI 0.02 to 8.33) or pedicled (adjMD 4.01, 95% CI 0.45 to 8.48). Similar results were observed at 2 years of followup. At 1 year, patients undergoing AR with SIEA flaps experienced abdominal physical function that was clinically better than patients who received DIEP flaps (adjMD 4.72, 95% CI −0.07 to 9.52). However, at 2 years, abdominal physical function scores were similar between SIEA and DIEP flap groups (adjMD 0.58, 95% CI −4.79 to 5.95).

Erdmann-Sager 2018 reported that, at 1 year of followup, patients undergoing AR with DIEP flaps experienced clinically similar **chest and upper body physical function** as patients undergoing AR with TRAM flaps, whether free or pedicled. However, patients undergoing AR with SIEA flaps experienced clinically better chest and upper body physical function than patients who received DIEP flaps (adjMD 3.42, 95% CI −0.22 to 7.05). At 2 years of followup, though, chest and upper body physical function scores were comparable between SIEA and DIEP groups and between DIEP and both TRAM groups.

Erdmann-Sager 2018 also reported data for the **physical functioning and pain interference** components of the PROMIS instrument. Both component scores range from 0 to 100, with higher scores indicating poorer outcomes. For both, the MCID has been estimated to be 4 to 6 points.[188] At both 1 and 2 years of followup, Erdmann-Sager 2018 reported that physical functioning as well as pain interference were clinically comparable between SIEA and DIEP groups and between DIEP and both TRAM groups.

Psychosocial and Sexual Well-Being

One NRCS (Erdmann-Sager 2018) reported on **psychosocial well-being** using the BREAST-Q (0 to 100; higher is better; MCID 4 for patients undergoing AR[187]) (Appendix Table E-6.2). At both 1 and 2 years of followup, psychosocial well-being was clinically comparable between patients undergoing AR with DIEP flaps, free TRAM flaps, and pedicled TRAM flaps, and between patients undergoing AR with DIEP and SIEA flaps.

Erdmann-Sager 2018 also reported on **sexual well-being** using the BREAST-Q (0 to 100; higher is better; MCID 5 for patients undergoing AR[187]) (Appendix Table E-6.2). At both 1 and 2 years of followup, sexual well-being was clinically comparable between patients undergoing AR with DIEP flaps, free TRAM flaps, and pedicled TRAM flaps, and between patients undergoing AR with DIEP and SIEA flaps.

Patient Satisfaction With Breasts

One RCT (Brandberg 2000) and two NRCSs (Erdmann-Sager 2018 and Yueh 2009) reported on **patient satisfaction with breasts** (Appendix Tables E-6.3 and E-6.4). Brandberg 2000 randomized women undergoing AR to receive either TRAM, LD, or LTD flaps (Appendix Table E-6.3). The authors constructed their own questionnaire that included six satisfaction-related items: cosmetic, shape, size, scars on the breast, donor site scars, and similarity with contralateral breast. Each item was measured on a scale of 1 to 6 and reported separately (without a total score), with higher scores representing greater satisfaction. To our knowledge, an MCID has not been estimated for this questionnaire. At 1 year of followup, scores for each of the six items were reported to be similar between the TRAM, LD, and LTD groups. All between-flap differences for each item were within 1 point.

One NRCS (Erdmann-Sager 2018) reported on patient satisfaction with breasts at 1 and 2 years of followup for patients undergoing AR with DIEP, free TRAM, pedicled TRAM, or SIEA flaps. Data were reported using the BREAST-Q satisfaction with breasts (0 to 100; higher is better; MCID 5 for patients undergoing AR[187]). At both 1 and 2 years of followup, satisfaction levels with breasts were clinically similar between patients undergoing AR with DIEP flaps, free TRAM flaps, and pedicled TRAM flaps, and between patients undergoing AR with DIEP and SIEA flaps.

The other NRCS (Yueh 2009), which evaluated patients who underwent AR with DIEP, TRAM, or LD flaps, reported data on whether or not patients were satisfied with their breasts (Appendix Table E-6.4). The proportions of patients reporting satisfaction were comparable between patients with DIEP and TRAM flaps (adjOR 0.67, 95% CI 0.37 to 1.23), between patients with LD and TRAM flaps (adjOR 0.78, 95% CI 0.54, 1.14), and between patients with DIEP and LD flaps (adjOR 0.90, 95% CI 0.60, 1.34).

Patient Satisfaction With Surgical Outcome

One NRCS (Yueh 2009) reported that proportions of patients who reported **satisfaction with their surgical outcome** (defined as general satisfaction with surgery) were comparable between patients who underwent AR with DIEP, TRAM, and LD flaps (Appendix Table E-6.4).

Recurrence of Breast Cancer

One RCT (Brandberg 2000) reported low risks of **breast cancer recurrence** at 1 year of followup across flap types in patients who underwent AR with TRAM, LD, or LTD flaps (Appendix Table E-6.4). Data for between-flap comparisons were highly imprecise.

Duration of Initial Hospitalization

One RCT (Rindom 2019) and one NRCS (Zoghbi 2017) reported data for **duration of initial hospitalization** (Appendix Tables E-6.3 and E-6.4). Rindom 2019 reported that patients randomized to AR with LD or TAP flaps had similar durations of initial hospitalization (adjMD 0.9 days, 95% CI −1.4 to 3.2) (Appendix Table E-6.3). Zoghbi 2017, which was a large NRCS (15,836 women), reported that women with TRAM flaps had statistically significant longer hospital stays than women with DIEP flaps (P<0.001; an adjusted effect size was not reported). Zoghbi 2017 also reported that women with TRAM flaps had higher odds of having an **increased length of stay** (adjOR 1.59, 95% CI 1.45 to 1.72) (Appendix Table E-6.4).

Mortality

One RCT (Brandberg 2000) reported low rates of **mortality** at 1 year of followup across flap types in patients who underwent AR with TRAM, LD, or LTD flaps (Appendix Table E-6.5). Data for between-flap comparisons were highly imprecise.

Surgical Complications

Both RCTs (Brandberg 2000 and Rindom 2019) and eight NRCSs (Abedi 2016, Erdmann-Sager 2018, Knox 2016, Kroll 2000, Massenburg 2015, Mennie 2015, Zhong 2014, and Zoghbi 2017) reported on surgical complications of various flap types.

Unplanned Repeat Surgeries for Revision of Reconstruction

One NRCS (Massenburg 2015) reported on **unplanned repeat surgeries for revision of reconstruction** in women who underwent AR with pedicled TRAM or LD flaps (Appendix Table E-6.4). Compared with women who underwent AR with LD flaps, risks of unplanned repeat surgery at 1 month of followup were higher in women who underwent AR with pedicled TRAM flaps (adjOR 1.71, 95% CI 1.25 to 2.33).

Pain and Necrosis

One RCT (Rindom 2019) reported that patients randomized to undergo AR with TAP flaps were considerably less likely than patients randomized to undergo AR with LD flaps to experience **shoulder-related pain** at 1 year of followup (OR 0.05, 95% CI 0.005, 0.51) (Appendix Table E-6.5).

One RCT (Rindom 2019) and two NRCSs (Abedi 2016 and Kroll 2000) reported on the outcome of **necrosis** (Appendix Table E-6.5). Rindom 2019 randomized patients to undergo AR with LD or TAP flaps (both flaps required the use of implants). Data were reported for **major necrosis** (defined as necrosis necessitating removal of the implant) and **minor necrosis** (defined as epidermolysis or small necrosis of the most distal part of the flap) at 1 year of followup. For both outcomes, data for between-flap comparisons were highly imprecise. Abedi 2016 reported that risks of **mastectomy flap necrosis** at 1.6 to 1.9 years of followup were comparable between patients who underwent AR with DIEP and TRAM flaps (P=0.610; adjusted effect size not reported). Kroll 2000 reported, however, that the risk of **fat necrosis** at 3 months of followup was higher among patients undergoing AR with DIEP flaps than TRAM flaps (adjOR 2.10, 95% CI 0.87, 5.10), but this was not statistically significant.

Harms to Area of Flap Harvest

Four NRCSs (Erdmann-Sager 2018, Knox 2016, Mennie 2015, and Zhong 2014) reported on harms to the area of flap harvest (Appendix Table E-6.5). Erdmann-Sager 2018 reported that, at 2 years of followup, compared with patients who underwent AR with DIEP flaps, patients who underwent AR with free TRAM flaps had a lower risk of **donor site complications** (adjOR 0.52, 95% CI 0.27 to 1.02), while women who underwent AR with SIEA flaps had a higher risk (adjOR 2.73, 95% CI 1.51 to 4.96). Patients who underwent AR with DIEP or pedicled TRAM flaps had comparable risks.

The other three NRCSs (Knox 2016, Mennie 2015, and Zhong 2014) reported that AR with TRAM flaps were associated with greater risks of harms to the area of flap harvest than was AR with DIEP flaps. Higher risks of **abdominal bulge/hernia** were reported for AR with TRAM flaps by Knox 2016 (adjOR 5.2, 95% CI 1.3 to 20.9) and by Zhong 2014 (adjOR 2.73, 95% CI 1.01 to 7.07). Mennie 2015 reported higher risks of needing **hernia repair surgery** in both the free TRAM flap group (adjOR 1.81, 95% CI 1.24 to 2.64) and the pedicled TRAM flap group (adjOR 2.89, 95% CI 1.91 to 4.37) when compared with the DIEP flap group.

Thromboembolic Events, Infections, Wound Dehiscence, Seroma, and Hematoma

One RCT (Brorson 2020b) reported on the outcome of **thromboembolic events** in patients who underwent AR with DIEP and LD flaps. (Appendix Table E-6.5). Neither group experienced any **DVT** or **PE** events at 1 month of followup.

One RCT (Rindom 2019) and one NRCS (Zoghbi 2017) reported on the outcome of **infections** (Appendix Table E-6.5). Rindom 2019 reported low risks (one case of infection each) in the LD and TAP groups. Data for between-flap comparisons were highly imprecise. Zoghbi 2017 reported that **wound infections** were more common in women who underwent AR with TRAM than DIEP flaps (adjOR 1.67, 95% CI 1.23 to 2.27).

One NRCS (Zoghbi 2017) reported that the risk of **wound dehiscence** was higher among patients undergoing AR with TRAM than DIEP flaps (adjOR 4.3; CIs not reported; $P<0.001$) (Appendix Table E-6.5).

One RCT (Rindom 2019) reported on the outcome of **seroma** in patients randomized to AR with either LD or TAP flaps (Appendix Table E-6.5). Only one case of seroma occurred in the LD group and none in the TAP group. Data for the between-flap comparison were highly imprecise.

One RCT (Rindom 2019) reported on the outcome of **hematoma** at 1 year of followup in patients randomized to AR with either LD or TAP flaps (Appendix Table E-6.5). Only one case of hematoma occurred in the TAP group and none in the LD group. Data for the between-flap comparison were highly imprecise.

Flap Failure/Loss

Two NRCSs (Kroll 2000 and Massenburg 2015) reported on flap failure or loss (Appendix Table E-6.5). Kroll 2000 reported a considerably higher risk of **partial flap loss** at 3 months of followup among patients undergoing AR with DIEP than TRAM flaps (adjOR 6.74, 95% CI 1.83 to 24.7). Without specifying whether **flap failure/loss** was defined as partial or total, Massenburg 2015 reported that, compared with patients who underwent AR with LD flaps, higher risks of flap failure/loss were observed at 1 month of followup in patients who underwent AR with pedicled TRAM flaps (adjOR 2.28, 95% CI 1.38 to 3.77).

Composite or Unspecified Harms

Two RCTs (Brorson 2020b and Rindom 2019) and four NRCSs (Dauplat 2021, Erdmann-Sager 2018, Massenburg 2015, and Zhong 2014) reported on various composite or unspecified harms (Appendix Table E-6.6). There was considerable inconsistency across studies in how harms were defined.

Brorson 2020b reported on **complications** using the Clavien-Dindo Grading system in patients randomized to undergo AR with either DIEP or LD flaps. Risks of complications were similar between groups at 1 month of followup, except that patients who underwent AR with LD flaps had a lower incidence of Grade IIIb complications (OR 0.22, 95% CI 0.05 to 0.87; P=0.031)

Rindom 2019 reported on both **major and minor complications** at 1 year of followup in patients randomized to undergo AR with either LD or TAP flaps. For both outcomes, data for the between-flap comparisons were highly imprecise.

Dauplat 2021 reported on **major breast complications requiring surgical intervention or readmission** at 1 year of followup. Patients who underwent AR with LD without implant had a higher risk than patients who underwent AR with TRAM (adjOR 1.69, 95% CI 1.19 to 2.41) or AR with LD without implant (adjOR 4.85, 95% CI 1.67 to 14.1).

Zhong 2014 reported on **major breast complications**, defined as the composite of total or partial flap loss, fat necrosis, and breast hematoma (time-point not reported). Patients who underwent AR with DIEP or LD flaps experienced similar risks for this composite outcome.

Erdmann-Sager 2018 reported that, at 2 years of followup, compared with patients who underwent AR with DIEP flaps, patients who underwent AR with free TRAM flaps had a lower risk of **any complication** (adjOR 0.51, 95% CI 0.25 to 1.02). Women who underwent AR with pedicled TRAM flaps or SIEA flaps had risks that were comparable with women who underwent AR with DIEP flaps.

Massenburg 2015 reported that, compared with patients who underwent AR with LD flaps, higher risks of **any complication** were observed at 1 month of followup in patients who underwent AR with pedicled TRAM flaps (adjOR 1.92, 95% CI 1.45 to 2.55). Similarly, higher risks of the **composite outcome of superficial or deep surgical site infection, organ space infection, or wound disruption/dehiscence** were also observed at 1 month of followup in patients who underwent AR with free TRAM flaps (adjOR 1.46, 95% CI 1.00 to 2.12) or pedicled TRAM flaps (adjOR 1.80, 95% CI 1.29 to 2.51).

Heterogeneity of Treatment Effects (Subgroup Differences)

None of the studies reported subgroup results or other analyses of possible heterogeneity of treatment effects. The studies were too sparse to allow exploration of possible differences based on patient or other characteristics.

Applicability

Although only 2 (of 13) studies addressing this KQ reported information about patient race, more than half of the studies (8 of 13) were conducted in North America. Generally, these studies contribute evidence that is directly applicable to the population of women undergoing AR in the U.S. However, in addition to the paucity of the evidence for the flap types addressed, we did not find any studies of other flap types that are used in the U.S. These include the profunda artery perforator (PAP), superior gluteal artery perforator (SGAP), transverse musculocutaneous

gracilis (TMG), and transverse upper gracilis (TUG) flaps. Eleven of the 13 studies were published in the last 12 years. Two studies (Brandberg 2000 and Kroll 2000) were published 20 years ago with data from mostly the 1990s, and so their applicability to today's clinical practice should be interpreted with caution.

Overall Summary for Key Question 6

AR with either TRAM or DIEP flaps may result in comparable patient satisfaction with breasts (Low SoE), but TRAM flaps probably increase the risk of harms to the area of flap harvest (Moderate SoE). AR with either DIEP or LD flaps may result in comparable patient satisfaction with breasts (Low SoE), but there is insufficient evidence regarding thromboembolic events and no evidence regarding other surgical complications.

Discussion

Findings in Relation to the Decisional Dilemmas

Despite a large overall body of evidence (160 studies), the evidence was sparse for most specific questions of interest in this systematic review (SR). Notably, we found only eight randomized controlled trials (RCTs). Table 9 summarizes the identified evidence addressing the six Key Questions (KQs).

Although the largest number of studies addressed the overall choice between **implant-based reconstruction (IBR)** and **autologous reconstruction (AR)**, the evidence does not clearly establish which is more likely to be preferred. AR is probably associated with better sexual well-being and satisfaction with breasts, but the evidence suggests that it is associated with comparable general quality of life and psychosocial well-being. In terms of surgical complications, AR probably poses a greater risk of deep vein thrombosis or pulmonary embolism, but IBR may pose a greater risk of breast seroma. Risks of other adverse events are largely comparable, or the evidence is insufficient and/or inconsistent across studies, precluding conclusions. Although the findings were inconsistent in the short term (1 to 1.3 months), compared with AR, IBR probably poses greater risk of reconstructive failure in the long term (1.5 to 4 years).

Among women who decide to undergo IBR, we found little evidence to address the best **timing of the IBR** in relation to the two main categories of nonsurgical treatments for cancer: chemotherapy and radiation therapy. We found no evidence regarding whether the IBR should be conducted before or after chemotherapy. We found that timing of IBR in relation to radiation therapy may not affect the patient-reported clinical outcomes of physical well-being, psychosocial well-being, sexual well-being, and satisfaction with breasts. The evidence, though, suggests that the risks of implant failure or loss is probably comparable whether the IBR is conducted before or after radiation therapy. The evidence was insufficient to make conclusions about other harms, such as pain, necrosis, and seroma.

For women choosing between **silicone** and **saline implants**, the evidence suggests that the two types of implant materials may be associated with clinically comparable levels of patient satisfaction with breasts. The evidence was insufficient to make conclusions about surgical complications, such as implant failure or loss and capsular contracture. There was also insufficient evidence comparing double lumen implants and other implant types. Studies eligible for this SR did not address the risk of new neoplasms, in particular implant-associated anaplastic large cell lymphoma (BIA-ALCL).

Evidence was largely insufficient regarding the choice of **anatomic plane of implant placement** for IBR. Prepectoral and total submuscular placements may be associated with comparable risks of infections that are not explicitly implant-related. Evidence for the comparisons involving partial submuscular placement was insufficient. The eligible studies provided insufficient or no evidence regarding two of the principal concerns when determining which plane to use, animation deformity and pain.

Studies examining **use versus nonuse of human acellular dermal matrices (ADMs)** during IBR report inconsistent results addressing the clinical outcomes of physical well-being, psychosocial well-being, and satisfaction with breasts. However, ADM use probably increases the risk of implant failure or loss and may increase the risk of infections that are not explicitly implant- or ADM-related. Some surgical complications, such as necrosis and seroma may be comparable whether or not ADMs are used, although results for others, such as pain and capsular

contracture, are inconsistent. The inconsistent (and thus insufficient) evidence regarding whether ADM use impacts capsular contracture risk is a surprising finding because this risk has traditionally been thought to be lower when ADMs are used.[28]

Among women who decide to undergo AR, we found no evidence to address the best **timing of the AR** before or after chemotherapy or radiation therapy. Finally, regarding choice of **flap type** to use for AR, we found evidence for six different flap types, but conclusions could only be made for the comparison between deep inferior epigastric perforator (DIEP) and transverse rectus abdominis myocutaneous (TRAM) flaps. The only patient-reported clinical outcome for which a conclusion is feasible is patient satisfaction with breasts, which was comparable. The only surgical complications for which conclusions were feasible are risks of necrosis and of harms to the area of flap harvest. Necrosis risks were comparable between DIEP and TRAM flaps, but TRAM flaps had a higher risk of harms to the area of flap harvest (abdominal bulge/ hernia and needing abdominal hernia repair surgery).

Table 9. Full summary of evidence identified in this systematic review

Outcome Categories	Outcomes	KQ 1: IBR Versus AR	KQ 2b:* IBR Before Versus After Radiation	KQ 3: IBR Materials: Silicone Versus Saline	KQ 4: Prepectoral Versus Total Submuscular Placement for IBR	KQ 5: ADM Use Versus Nonuse During IBR	KQ 6: AR Flap Types
Clinical outcomes	General quality of life	~~ Comparable	nd	? No conclusion	nd	nd	nd
	Physical well-being	↑↓ No conclusion	~ Comparable	? No conclusion	? No conclusion	↑↓ No conclusion	? No conclusion
	Psychosocial well-being	~~ Comparable	~ Comparable	? No conclusion	? No conclusion	↑↓ No conclusion	? No conclusion
	Sexual well-being	▲▲ AR clinically better	~ Comparable	? No conclusion	nd	? No conclusion	? No conclusion
	Patient satisfaction with breasts	▲▲ AR clinically better	~ Comparable	~ Comparable	? No conclusion	↑↓ No conclusion	~ Comparable for TRAM vs. DIEP
	Patient satisfaction with outcome	↑↓ No conclusion	? No conclusion	? No conclusion	nd	nd	? No conclusion
	Planned surgeries for reconstruction	N/P	N/P	nd	nd	nd	nd
	Recurrence of breast cancer	N/P	N/P	N/P	N/P	N/P	N/P
	Duration of initial hospitalization	.	.	.	.	.	? No conclusion
	Mortality	? No conclusion	nd	? No conclusion: silicone vs. saline ? No conclusion: silicone vs. double lumen	nd	? No conclusion	? No conclusion
Surgical complications	Unplanned repeat hospitalization	~~ Comparable	nd	nd	nd	nd	nd
	Duration of unplanned repeat hospitalization	nd	nd	nd	nd	nd	nd
	Unplanned repeat surgery for revision	↑↓ No conclusion	? No conclusion	nd	? No conclusion	~~ Comparable	? No conclusion
	Unplanned repeat surgery for complications	↑↓ No conclusion	nd	nd	nd	? No conclusion	nd
	Pain	↑↓ No conclusion	? No conclusion	nd	↑↓ No conclusion	↑↓ No conclusion	? No conclusion
	Analgesic use	? No conclusion	nd	nd	? No conclusion	? No conclusion	nd
	Necrosis	? No conclusion	? No conclusion	nd	? No conclusion	~ Comparable	~ Comparable for TRAM vs. DIEP
	Harms to area of flap harvest	.	.	.	.	.	◆◆ Abdominal bulge/ hernia, hernia repair surgery with TRAM than DIEP
	Animation deformity	nd	nd	nd	nd	nd	.
	Implant-related infections	.	nd	nd	nd	nd	.

	Implant rupture	.	nd	nd	nd	? No conclusion	.
	Implant deflation	.	nd	nd	nd	nd	.
	Implant malposition	.	nd	nd	nd	? No conclusion	.
	Implant failure/loss or need for explant	.	~~ Comparable	? No conclusion	? No conclusion	◆◆ with ADM	.
	Capsular contracture	.	N/P	? No conclusion	? No conclusion	↑↓ No conclusion	.
	New neoplasms	.	N/A	nd	nd	nd	.
	Complications that delay other cancer treatments	nd	nd	nd	nd	nd	nd
	Thromboembolic events	◆◆ Deep vein thrombosis or pulmonary embolism with AR	nd	nd	nd	? No conclusion	? No conclusion
	Infections not explicitly implant-related	↑↓ No conclusion	N/P	.	~ Comparable for prepectoral vs. total submuscular	◆ with ADM use	? No conclusion
	Wound dehiscence	N/P	N/P	N/P	N/P	↑↓ No conclusion	? No conclusion
	Delayed healing	N/P	N/P	N/P	N/P	? No conclusion	nd
	Seroma	◆ Breast seroma with IBR	? No conclusion	nd	? No conclusion	~~ Comparable	nd
	Chronic conditions	N/P	N/P	nd	nd	N/P	.
	Touch sensitivity	N/P	N/P	N/P	N/P	N/P	N/P
	Scarring	N/P	N/P	N/P	N/P	N/P	N/P
	Red breast syndrome	.	.	N/P	N/P	N/P	.
	Flap failure/loss	.	. (for AR)	.	.	.	N/P
	Reconstructive failure	◆◆ with IBR in the long term (1.5 to 4 years)	.	.	.	.	.

Abbreviations: ADM = acellular dermal matrix, AR = autologous reconstruction, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, KQ = Key Question, LD = latissimus dorsi, N/P = not prioritized (for strength of evidence assessment), nd = no data (no evidence identified), TRAM = transverse rectus abdominis myocutaneous.

* No evidence addressed timing of IBR or AR in relation to chemotherapy (KQ 2a) or timing of AR in relation to radiation therapy (KQ 2b).
▲ = Low SoE of better clinical outcomes, ▲▲ = Moderate SoE of better clinical outcomes, ▲▲▲ = High SoE of better clinical outcomes (no instances in this table)
◆ = Low SoE of increased complications, ◆◆ = Moderate SoE of increased complications, ◆◆◆ = High SoE of increased complications (no instances in this table)
~ = Low SoE of comparable outcomes, ~~ = Moderate SoE of comparable outcomes, ~~~ = High SoE of comparable outcomes (no instances in this table)
? = Insufficient strength of evidence due to sparse evidence, ↑↓ = Insufficient strength of evidence due to inconsistent or conflicting results, . = not applicable (i.e., outcome not applicable to KQ)

Color legend: Insufficient strength of evidence (gray), Low strength of evidence (pink), Moderate strength of evidence (purple), High strength of evidence (tan) (no instances in this table). The colors do not provide unique information compared with the text and symbols.

Strengths and Limitations

Strengths and Limitations of the Evidence Base

The main strength of the evidence base is its applicability to the decisionmaking context in the U.S. The evidence is relevant to various decisional dilemmas underpinning surgical options for women undergoing breast reconstruction after mastectomy for breast cancer (see section *Applicability*).

However, despite numerous being published studies on the topic of breast reconstruction after mastectomy, the evidence is still sparse for many topics. A sizeable proportion of the studies included in this SR (69/160; 43%) were single group studies. Although these single group studies provided estimates of risks of various surgical complications in women who underwent either IBR or AR, their noncomparative nature precluded their use in informing conclusions regarding choices *between* surgical options posed by the six KQs. Among the 91 comparative studies in this SR, there were only eight RCTs, each of which was small, with sample sizes ranging from 36 to 150 patients. We identified RCTs only on the choice of IBR versus AR (KQ 1), anatomic planes of implant placement for IBR (KQ 4), ADM use during IBR (KQ 5), and the choice of flap types for AR (KQ 6). Few studies of any design addressed timing of reconstruction (KQ 2; 5 nonrandomized comparative studies [NRCSs]), implant materials for IBR (KQ 3; five NRCSs), or anatomic planes of implant placement for IBR (KQ 4; one RCT and seven NRCSs). All five NRCSs that addressed timing of reconstruction (KQ 2) addressed timing of IBR in relation to radiation therapy; none addressed timing of IBR in relation to chemotherapy or timing of AR in relation to chemotherapy or radiation therapy.

Two limitations are specific to the NRCSs identified. First, NRCSs commonly did not report adjusted between-group effect sizes for all outcomes of clinical interest. Without access to the individual patient data, we were unable to calculate adjusted effect sizes. Given the personal decision making involved regarding choice of breast reconstruction surgery, use of implanted materials, and timing in relation to cancer therapy (both by the patient and the surgeons), it is very likely that the women in each treatment group within a study would be fundamentally dissimilar on one or more important confounders. Thus, we determined *a priori* that unadjusted effect sizes would likely be highly biased and of limited value. We also decided *a priori* on a list of confounders that would be necessary for studies to have adjusted for in order for us to include their results. Second, some NRCSs reported adjusted effect sizes without confidence intervals or P values or they reported P values without adjusted effect sizes. These forms of inadequate reporting limited our ability to make conclusions because we could comment only on directionality (i.e., only adjusted effect sizes) or statistical significance (i.e., only P values). Both of these limitations to the NRCSs compromised our ability to make conclusions for some outcomes.

Across study designs, data were often reported within subgroups based on factors such as age, obesity status, unilateral versus bilateral reconstruction, and (for IBR) number of stages. However, none of the studies reported statistical analyses that evaluated either differences between subgroups or, preferable, evidence of heterogeneity of treatment effects (different relative effects in different subgroups of patients). Thus, although in this report we commented wherever results for a certain outcome appeared to be different in one subgroup versus another, we refrained from concluding that there was (or was not) heterogeneity of treatment effects.

The evidence base identified in this SR is also limited by the lack of very long term followup. The longest followup time-point at which studies reported data was 10 years. Breast

reconstruction is intended to last for decades, and so the very long-term benefit and harm outcomes of the various reconstruction options is largely unknown. Another limitation is that most studies reporting data for the patient satisfaction outcomes did not report information regarding who collected the data. Thus, there is the potential for social desirability bias if patients did not accurately report satisfaction data. However, most studies reporting data for this patient-reported outcome used the BREAST-Q, a validated and standard instrument.

We assessed most of the comparative studies (RCTs and NRCSs) to be at overall moderate or high risk of bias, primarily because participants, care providers, and/or outcome assessors were not blinded and because of incomplete outcome data. While blinding of participants (i.e., patients) and care providers (i.e., surgeons) will almost always be impossible in studies addressing the surgical KQs in this SR, lack of blinding can still lead to bias. Moreover, although for subjective patient-reported outcomes, such as sexual well-being, it may be impossible to blind the outcome assessors (i.e., patients), it is possible to blind the outcome assessors (e.g., nurses) for objective outcomes, such as most harms. The NRCSs were also often considered to be at serious or critical risk of confounding. Furthermore, the participant eligibility criteria, interventions, and outcomes were often inadequately described.

Strengths and Limitations of the Systematic Review Process

We followed contemporary standards for SRs, including multiple stakeholder engagement in KQ development and refinement and careful adherence to recommended methods for literature searching, screening, data extraction, risk of bias assessment, qualitative synthesis, quantitative synthesis, and SoE assessment. We were very inclusive in our eligibility criteria for studies, especially in terms of study designs, including RCTs, NRCSs, and (large) single group studies of reconstruction surgeries for women who had undergone or were undergoing mastectomy for breast cancer.

Despite our comprehensive search for studies and our inclusion of a total of 160 studies, all conclusions made in this SR are either based on low or moderate strength of evidence. For all interventions examined, our conclusions were predominantly about surgical complications rather than patient-reported clinical outcomes. Perhaps our most definitive conclusions were for the overall comparison of IBR versus AR (KQ 1). Regarding IBR, we were able to make only a few conclusions about timing in relation to radiation therapy (KQ 2b), about implant materials (KQ 3), about anatomic planes of implant placement (KQ 4), and about use of ADMs (KQ 5), but no conclusions about timing in relation to chemotherapy (KQ 2a; lack of evidence). Regarding AR, we were able to make only a few conclusions about comparisons between different flap types (KQ 6), but no conclusions about timing in relation to chemotherapy (KQ 2a) or radiation therapy (KQ 2b).

During protocol development, we prioritized outcomes in consultation with panels of key informants and technical experts and in keeping with a published core outcome set for breast reconstruction surgery.[36] However, many of the prioritized outcomes were either not reported in any included study or were reported in an insufficient number of studies to merit conclusions. Unreported or rarely reported clinical outcomes included general quality of life and number of planned surgeries for reconstruction. Unreported or rarely reported surgical complications included duration of unplanned repeat hospitalizations, analgesic use, animation deformity, and complications that delay other cancer-related treatments.

Applicability

Most studies in this SR were conducted in North America (U.S. or Canada), Europe, or high- or middle-income East Asian countries (South Korea and China, respectively). Among the North American studies, the racial makeup of study participants largely mirrored the population of women who undergo breast reconstruction in the U.S., who have been shown to be overwhelmingly White.[19] Average ages of patients ranged from the early to late 50s and their average body mass indices (BMIs) ranged from 22 to 29 kg/m^2. Large proportions of patients in most studies had undergone mastectomy for therapeutic purposes, with few undergoing prophylactic mastectomies (for high risk such as due to BRCA1 or BRCA2 gene mutations). As such, the conclusions in this SR apply generally to mostly White, middle-aged, nonobese women in high-income countries who are being treated for breast cancer. It is unclear to what extent the findings of this SR are broadly applicable beyond these populations.

The applicability of the findings may also be limited to the specific interventions that have been studied. Specifically, the evidence reflects the implant materials that are in use in the U.S. (silicone and saline implants), and we restricted our review to human ADMs, which are commonly used in the U.S. In terms of anatomic planes, the sparse evidence we identified addresses prepectoral and total submuscular implants, but we found insufficient evidence for partial submuscular implants, the other anatomic plane commonly used in the U.S. The evidence identified addressing flap types for AR considered some but not all the commonly used flap types in the U.S.

Implications for Clinical Practice

The findings in this SR summarize what is known about the comparative effectiveness and harms of various treatment options for patients who have undergone or are undergoing mastectomy and have made the decision to undergo breast reconstruction.

Briefly, our analysis of all surgical choices examined as KQs in this SR finds no clear winners. The strongest evidentiary basis is for the KQ addressing the broad choice of IBR versus AR. When making this choice, clinicians and patients should note that although some patient-reported outcomes may be better with AR than IBR (e.g., sexual well-being), this is not true for other patient-reported outcomes (e.g., physical well-being). In terms of harms, some serious harms, such as pulmonary embolism, are probably more likely with AR, but other harms, such as breast seroma, may be more likely with IBR. The choice of IBR versus AR also needs to consider that IBR typically involves multiple surgeries and that implants may require monitoring and replacement, but AR usually involves a single surgery (revision surgeries may at times be needed), and the reconstruction is intended to be lifelong. However, AR surgery is usually more extensive (involving both breast and donor site incisions) and, in the case of abdominal donor sites, may lead to greater chronic abdominal pain than IBR. Moreover, based on such factors as body habitus and history of previous surgery, some women may not be candidates for AR.

For women who choose to undergo IBR, issues of timing of reconstruction relative to other cancer therapies (chemotherapy and radiation therapy), type of implant materials, anatomic plane of implant placement, and use of ADMs need consideration. Unfortunately, the evidence supporting these choices is weaker. There is no evidence to inform the issue of timing of IBR in relation to chemotherapy; this lack of evidence may be related to the preference of practitioners to base decisions regarding timing of chemotherapy on the severity of the underlying cancer – for patients with more aggressive cancers, chemotherapy is usually administered before surgery.

There is only limited evidence suggesting that conducting IBR before or after radiation therapy may not affect physical well-being, psychosocial well-being, sexual well-being, and patient satisfaction with breasts, and probably does not affect the risk of implant failure or loss. The evidence is also weak for whether silicone or saline should be used as implant materials and whether the implant should be placed in the prepectoral, total submuscular, or partial submuscular planes. Implant placement in prepectoral or total submuscular planes may result in comparable risk of infections that are not explicitly implant-related. Regarding ADMs, there is insufficient evidence whether their use impact patient-reported clinical outcomes. However, ADM use may be associated with some surgical complications, such as infections that are not explicitly implant-related and implant failure, but not others, such as necrosis and seroma. It is worth noting that ADM use may be used more frequently when the implant is placed in prepectoral or partial submuscular planes. Although studies of ADM use did not frequently report the anatomic plane of implant placement, this factor is a possible confounder of the observed treatment effect of ADM use. Nevertheless, our findings that ADM use may be associated with a higher incidence of infections and implant failure are consistent with a recent U.S. Food and Drug Administration Safety Communication regarding ADM use during IBR.[254]

If the decision is made to undergo AR, the choices of timing of reconstruction relative to other cancer therapies (chemotherapy and radiation therapy) and of which flap types should be used need consideration. Unfortunately, there is no evidence to inform the choice of timing of AR in relation to either chemotherapy or radiation therapy. As in the case of IBR, for patients with more aggressive cancers, practitioners may more often choose to administer chemotherapy before AR. We hypothesize a possible reason why the issue of timing of AR in relation to radiation therapy has not been researched. Practitioners may generally prefer to deliver the radiation therapy before AR to avoid radiating tissue from another location in the body, which in some cases involves very delicate microvascular anastomoses by the plastic surgeon. In terms of flap types, DIEP flaps may be associated with comparable satisfaction with breasts as TRAM flaps. However, compared with DIEP flaps, TRAM flaps may be associated with a greater risk of harms to the area of flap harvest, such as abdominal bulge/hernia and needing abdominal hernia repair surgery. Decisions regarding flap types should consider the location of the source tissue, patient body habitus, and availability of plastic surgeons with advanced training in microvascular techniques (for free flaps, such as DIEP and free TRAM flaps).

Given the relatively weak evidence addressing some breast reconstruction-related key decisions that need to be made in clinical practice and the highly patient preference-sensitive nature of the decisions,[255, 256] we encourage clinicians to inform patients about the limitations of existing research. The patient's values and preferences and the clinician's expertise and experience are highly important.

Various clinical decision support tools have been developed to facilitate the decision making process.[256-259] These tools range from those that provide standard information about breast reconstruction options and their risks[256, 257, 259] to tools that provide personalized risk assessments tailored to individual patients.[260] The *BREASTChoice* tool is one example of a personalized tool. It was developed by incorporating the perspectives of breast cancer patients who had undergone mastectomy, plastic surgeons performing reconstructions, and nurses caring for patients who undergo reconstructions.[260] Although we are not aware of (and did not systematically search for) SRs comparing clinical decision support tools for breast reconstruction, one tool, *BREASTChoice,* has been compared with usual care in an RCT of patients undergoing breast reconstruction after mastectomy in the U.S.[258] Use of the tool was associated with patients

having better knowledge about reconstruction options and their risks, but there were no differences in decision process quality, patient quality of life, or patient decisions made.[258]

Clinicians should also consider and emphasize to patients that much of the research that has been done addressing breast reconstruction has focused largely on patients whose mastectomy was performed for therapeutic (and not prophylactic) purposes. In addition, patients in existing studies have been mostly White, middle-aged, and nonobese women living in high-income countries. For patients in clinical practice who do not belong to these categories, clinicians and patients will need to consider the appropriateness of extrapolating information about benefits and harms of breast reconstruction options from the evidence to the decision making context.

Implications for Research

Research is needed to address various questions related to breast reconstruction, particularly the timing of IBR and AR in relation to chemotherapy and radiation therapy, implant materials (for IBR), anatomic planes of implant placement (for IBR), and choice of flaps (for AR). Because of the absence of studies that predominantly enrolled women undergoing mastectomy for prophylactic purposes, researchers should also design studies that, either entirely or in part, enroll these patients. The recent decade has witnessed a steady and sizeable increase in the number of prophylactic mastectomies.[261-265] The risk-benefit assessments for reconstruction choices among these women may be different than for women who undergo therapeutic mastectomies. Perceived (subjective) benefits and harms may also differ. When enrolled as part of a larger study, subgroup-specific data for patients undergoing mastectomy for prophylactic purposes, should be reported. In addition, studies should also enroll more diverse groups of women, such as by age group, race, ethnicity, and socioeconomic status.

It is important that when possible future studies conduct randomization (to avoid selection bias). We recognize that studies may not always be possible; in that context, studies should report between-group estimates of treatment effect that adequately account for important confounders, such as age, BMI, and stage of breast cancer. Ideally, propensity score analyses (or similar rigorous techniques) should be used to adequately adjust for potential confounders. A propensity score analysis, for example, estimates the likelihood that each patient had one or the other intervention (conditional on her measured characteristics) and controls for this likelihood. These analyses generally require relatively large numbers of patients for whom there are granular data about risk factors for outcomes. In terms of performance and detection biases, while blinding of participants and care providers will rarely be feasible (if at all), studies should blind the assessors of outcomes that are not patient reported. In addition, there is a need for long-term followup of large, prospective studies to assess long term risks of surgical complications.

Future studies should also evaluate important outcomes that were not adequately reported in the identified evidence, such as quality of life, number of planned surgeries for reconstruction, incidence and duration of unplanned repeat hospitalizations and surgeries, analgesic use, animation deformity, and complications that may delay other cancer-related treatments.

Conclusions

Although we found a large body of evidence, we were able to make only a few specific conclusions in this SR, all of which were based on low or moderate strength of evidence. Future research, ideally comprising large RCTs and/or well-designed and well-analyzed long-term observational studies, is needed to compare timing of reconstruction relative to chemotherapy

and radiation therapy, different implant materials, different anatomic planes of implant placement, and use of ADMs in patients undergoing reconstruction.

References

1. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on November 2018 submission data (1999-2016). 2019. www.cdc.gov/cancer/dataviz. Accessed on December 28, 2019.
2. American Cancer Society. Breast Cancer Facts & Figures 2019-2020. . 2019. https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/breast-cancer-facts-and-figures-2019-2020.pdf. Accessed on December 28, 2019.
3. Recht A, Comen EA, Fine RE, et al. Postmastectomy Radiotherapy: An American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Focused Guideline Update. Pract Radiat Oncol. 2016 Nov-Dec;6(6):e219-e34. doi: 10.1016/j.prro.2016.08.009. PMID: 27659727.
4. Jonczyk MM, Jean J, Graham R, et al. Surgical trends in breast cancer: a rise in novel operative treatment options over a 12 year analysis. Breast Cancer Res Treat. 2019 Jan;173(2):267-74. doi: 10.1007/s10549-018-5018-1. PMID: 30361873.
5. Baker JL, Dizon DS, Wenziger CM, et al. "Going Flat" After Mastectomy: Patient-Reported Outcomes by Online Survey. Ann Surg Oncol. 2021 May;28(5):2493-505. doi: 10.1245/s10434-020-09448-9. PMID: 33393025.
6. Wakeley ME, Bare CF, Pine R, et al. A social media survey of women who do not pursue reconstruction after mastectomy for breast cancer: Characterizing the "Going Flat" movement. Breast J. 2020 Jul;26(7):1455-7. doi: 10.1111/tbj.13781. PMID: 32067326.
7. American Society of Plastic Surgeons. 2019 Plastic Surgery Statistics Report. 2019. https://www.plasticsurgery.org/documents/News/Statistics/2019/plastic-surgery-statistics-full-report-2019.pdf. Accessed on February 13, 2021.
8. Employee Benefits Security Administration. Your Rights After a Mastectomy.; 2018. https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/your-rights-after-a-mastectomy.pdf. Accessed on December 28, 2019.
9. Haffty BG, Harrold E, Khan AJ, et al. Outcome of conservatively managed early-onset breast cancer by BRCA1/2 status. Lancet. 2002 Apr 27;359(9316):1471-7. doi: 10.1016/s0140-6736(02)08434-9. PMID: 11988246.
10. Shahedi K, Emanuelsson M, Wiklund F, et al. High risk of contralateral breast carcinoma in women with hereditary/familial non-BRCA1/BRCA2 breast carcinoma. Cancer. 2006 Mar 15;106(6):1237-42. doi: 10.1002/cncr.21753. PMID: 16475207.
11. van den Broek AJ, van 't Veer LJ, Hooning MJ, et al. Impact of Age at Primary Breast Cancer on Contralateral Breast Cancer Risk in BRCA1/2 Mutation Carriers. J Clin Oncol. 2016 Feb 10;34(5):409-18. doi: 10.1200/jco.2015.62.3942. PMID: 26700119.
12. Al-Ghazal SK, Sully L, Fallowfield L, et al. The psychological impact of immediate rather than delayed breast reconstruction. Eur J Surg Oncol. 2000 Feb;26(1):17-9. doi: 10.1053/ejso.1999.0733. PMID: 10718173.
13. Hershenhouse KS, Bick K, Shauly O, et al. "Systematic review and meta-analysis of immediate versus delayed autologous breast reconstruction in the setting of post-mastectomy adjuvant radiation therapy". J Plast Reconstr Aesthet Surg. 2020 Dec 5. doi: 10.1016/j.bjps.2020.11.027. PMID: 33423976.
14. Motwani SB, Strom EA, Schechter NR, et al. The impact of immediate breast reconstruction on the technical delivery of postmastectomy radiotherapy. Int J Radiat Oncol Biol Phys. 2006 Sep 1;66(1):76-82. doi: 10.1016/j.ijrobp.2006.03.040. PMID: 16765534.

15. Schechter NR, Strom EA, Perkins GH, et al. Immediate breast reconstruction can impact postmastectomy irradiation. Am J Clin Oncol. 2005 Oct;28(5):485-94. doi: 10.1097/01.coc.0000170582.38634.b6. PMID: 16199989.

16. Middleton MS, McNamara MP, Jr. Breast implant classification with MR imaging correlation: (CME available on RSNA link). Radiographics. 2000 May;20(3):E1. doi: 10.1148/radiographics.20.3.g00mae11. PMID: 10835136.

17. U.S. Food and Drug Administration Center for Devices and Radiological Health. FDA Update on the Safety of Silicone Gel-Filled Breast Implants. 2011. https://www.fda.gov/media/80685/download. Accessed on April 9, 2020.

18. McCarthy CM, Klassen AF, Cano SJ, et al. Patient satisfaction with postmastectomy breast reconstruction: a comparison of saline and silicone implants. Cancer. 2010 Dec 15;116(24):5584-91. doi: 10.1002/cncr.25552. PMID: 21136577.

19. Balk EM, Earley A, Avendano EA, et al. Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: A Systematic Review. Ann Intern Med. 2016 Feb 2;164(3):164-75. doi: 10.7326/m15-1169. PMID: 26550776.

20. U.S. Food and Drug Administration. The FDA Requests Allergan Voluntarily Recall Natrelle BIOCELL Textured Breast Implants and Tissue Expanders from the Market to Protect Patients: FDA Safety Communication.; 2019. https://www.fda.gov/medical-devices/safety-communications/fda-requests-allergan-voluntarily-recall-natrelle-biocell-textured-breast-implants-and-tissue. Accessed on April 9, 2020.

21. U.S. Food and Drug Administration. Breast Implants - Certain Labeling Recommendations to Improve Patient Communication. Guidance for Industry and Food and Drug Administration Staff. 2020. https://www.fda.gov/media/131885/download. Accessed on February 13, 2021.

22. Hanna KR, DeGeorge BR, Jr., Mericli AF, et al. Comparison study of two types of expander-based breast reconstruction: acellular dermal matrix-assisted versus total submuscular placement. Ann Plast Surg. 2013 Jan;70(1):10-5. doi: 10.1097/SAP.0b013e31822f6765. PMID: 21862915.

23. Cordeiro PG, Jazayeri L. Two-Stage Implant-Based Breast Reconstruction: An Evolution of the Conceptual and Technical Approach over a Two-Decade Period. Plast Reconstr Surg. 2016 Jul;138(1):1-11. doi: 10.1097/prs.0000000000002243. PMID: 27348635.

24. Walia GS, Aston J, Bello R, et al. Prepectoral Versus Subpectoral Tissue Expander Placement: A Clinical and Quality of Life Outcomes Study. Plast Reconstr Surg Glob Open. 2018 Apr;6(4):e1731. doi: 10.1097/gox.0000000000001731. PMID: 29876176.

25. Wainwright DJ. Use of an acellular allograft dermal matrix (AlloDerm) in the management of full-thickness burns. Burns. 1995 Jun;21(4):243-8. doi: 10.1016/0305-4179(95)93866-i. PMID: 7662122.

26. Dikmans RE, Negenborn VL, Bouman MB, et al. Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial. Lancet Oncol. 2017 Feb;18(2):251-8. doi: 10.1016/s1470-2045(16)30668-4. PMID: 28012977.

27. Negenborn VL, Young-Afat DA, Dikmans REG, et al. Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial. Lancet Oncol. 2018 Sep;19(9):1205-14. doi: 10.1016/s1470-2045(18)30378-4. PMID: 30104147.

28. Salzberg CA, Ashikari AY, Berry C, et al. Acellular Dermal Matrix-Assisted Direct-to-Implant Breast Reconstruction and Capsular Contracture: A 13-Year Experience. Plast Reconstr Surg. 2016 Aug;138(2):329-37. doi: 10.1097/prs.0000000000002331. PMID: 27064232.

29. Smith JM, Broyles JM, Guo Y, et al. Human acellular dermis increases surgical site infection and overall complication profile when compared with submuscular breast reconstruction: An updated meta-analysis incorporating new products(). J Plast Reconstr Aesthet Surg. 2018 Nov;71(11):1547-56. doi: 10.1016/j.bjps.2018.06.012. PMID: 30093286.

30. Feng J, Pardoe CI, Mota AM, et al. Two-Stage Latissimus Dorsi Flap with Implant for Unilateral Breast Reconstruction: Getting the Size Right. Arch Plast Surg. 2016 Mar;43(2):197-203. doi: 10.5999/aps.2016.43.2.197. PMID: 27018318.

31. Berkman ND, Lohr KN, Ansari M, et al. AHRQ Methods for Effective Health Care: Grading the Strength of a Body of Evidence When Assessing Health Care Interventions for the Effective Health Care Program of the Agency for Healthcare Research and Quality: An Update. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008.

32. Higgins JP, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Bmj. 2011 Oct 18;343:d5928. doi: 10.1136/bmj.d5928. PMID: 22008217.

33. Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. Bmj. 2016 Oct 12;355:i4919. doi: 10.1136/bmj.i4919. PMID: 27733354.

34. National Heart, Lung, and Blood Institute. Study Quality Assessment Tools.; 2019. https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools. Accessed on January 23, 2020.

35. Berkman ND, Lohr KN, Ansari MT, et al. Grading the strength of a body of evidence when assessing health care interventions: an EPC update. J Clin Epidemiol. 2015 Nov;68(11):1312-24. doi: 10.1016/j.jclinepi.2014.11.023. PMID: 25721570.

36. Potter S, Holcombe C, Ward JA, et al. Development of a core outcome set for research and audit studies in reconstructive breast surgery. Br J Surg. 2015 Oct;102(11):1360-71. doi: 10.1002/bjs.9883. PMID: 26179938.

37. Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. Trials. 2012 Aug 6;13:132. doi: 10.1186/1745-6215-13-132. PMID: 22867278.

38. Guyatt GH, Oxman AD, Kunz R, et al. Going from evidence to recommendations. Bmj. 2008 May 10;336(7652):1049-51. doi: 10.1136/bmj.39493.646875.AE. PMID: 18467413.

39. Gerrity M, Fiordalisi C, Pillay J, et al. AHRQ Methods for Effective Health Care. Roadmap for Narratively Describing Effects of Interventions in Systematic Reviews. Rockville (MD): Agency for Healthcare Research and Quality (US); 2020.

40. Murad MH, Fiordalisi C, Pillay J, et al. Making Narrative Statements to Describe Treatment Effects. J Gen Intern Med. 2020 Oct 27. doi: 10.1007/s11606-020-06330-y. PMID: 33111244.

41. Carramaschi F, Bricout N, Servant JM, et al. [Breast reconstruction after mastectomy. Critical analysis of 240 cases]. AMB Rev Assoc Med Bras. 1989 Jan-Feb;35(1):15-9. PMID: 2602589.

42. Garbay JR, Rietjens M, Petit JY. [Esthetic results of breast reconstruction after amputation for cancer. 323 cases]. J Gynecol Obstet Biol Reprod (Paris). 1992;21(4):405-12. PMID: 1624727.

43. Brorson F, Thorarinsson A, Kölby L, et al. Early complications in delayed breast reconstruction: A prospective, randomized study comparing different reconstructive methods in radiated and non-radiated patients. Eur J Surg Oncol. 2020 Dec;46(12):2208-17. doi: 10.1016/j.ejso.2020.07.010. PMID: 32807615.

44. Tallroth L, Velander P, Klasson S. A short-term comparison of expander prosthesis and DIEP flap in breast reconstructions: A prospective randomized study. J Plast Reconstr Aesthet Surg. 2020 Nov 12. doi: 10.1016/j.bjps.2020.10.104. PMID: 33436336.

45. Abedi N, Ho AL, Knox A, et al. Predictors of Mastectomy Flap Necrosis in Patients Undergoing Immediate Breast Reconstruction: A Review of 718 Patients. Ann Plast Surg. 2016 Jun;76(6):629-34. doi: 10.1097/sap.0000000000000262. PMID: 25003437.

46. Atisha D, Alderman AK, Lowery JC, et al. Prospective analysis of long-term psychosocial outcomes in breast reconstruction: two-year postoperative results from the Michigan Breast Reconstruction Outcomes Study. Ann Surg. 2008 Jun;247(6):1019-28. doi: 10.1097/SLA.0b013e3181728a5c. PMID: 18520230.

47. Bennett KG, Qi J, Kim HM, et al. Comparison of 2-Year Complication Rates Among Common Techniques for Postmastectomy Breast Reconstruction. JAMA Surg. 2018 Oct 1;153(10):901-8. doi: 10.1001/jamasurg.2018.1687. PMID: 29926077.

48. Brito IM, Fernandes A, Andresen C, et al. Patient satisfaction with breast reconstruction: how much do timing and surgical technique matter? Eur J Plast Surg. 2020;43:809-18.

49. Chetta MD, Aliu O, Zhong L, et al. Reconstruction of the Irradiated Breast: A National Claims-Based Assessment of Postoperative Morbidity. Plast Reconstr Surg. 2017 Apr;139(4):783-92. doi: 10.1097/prs.0000000000003168. PMID: 28002254.

50. Cohen WA, Ballard TN, Hamill JB, et al. Understanding and Optimizing the Patient Experience in Breast Reconstruction. Ann Plast Surg. 2016 Aug;77(2):237-41. doi: 10.1097/sap.0000000000000550. PMID: 26101986.

51. Dauplat J, Thivat E, Rouanet P, et al. Risk Factors Associated With Complications After Unilateral Immediate Breast Reconstruction: A French Prospective Multicenter Study. In Vivo. 2021 Mar-Apr;35(2):937-45. doi: 10.21873/invivo.12334. PMID: 33622886.

52. de Araujo TB, Jue Xu M, Susarla SM, et al. Impact of Prior Unilateral Chest Wall Radiotherapy on Outcomes in Bilateral Breast Reconstruction. Plast Reconstr Surg. 2016 Oct;138(4):575e-80e. doi: 10.1097/prs.0000000000002532. PMID: 27673527.

53. Eltahir Y, Werners LL, Dreise MM, et al. Which breast is the best? Successful autologous or alloplastic breast reconstruction: patient-reported quality-of-life outcomes. Plast Reconstr Surg. 2015 Jan;135(1):43-50. doi: 10.1097/prs.0000000000000804. PMID: 25539295.

54. Fischer JP, Fox JP, Nelson JA, et al. A Longitudinal Assessment of Outcomes and Healthcare Resource Utilization After Immediate Breast Reconstruction-Comparing Implant- and Autologous-based Breast Reconstruction. Ann Surg. 2015 Oct;262(4):692-9. doi: 10.1097/sla.0000000000001457. PMID: 26366550.

55. Fischer JP, Nelson JA, Cleveland E, et al. Breast reconstruction modality outcome study: a comparison of expander/implants and free flaps in select patients. Plast Reconstr Surg. 2013 May;131(5):928-34. doi: 10.1097/PRS.0b013e3182865977. PMID: 23629074.

56. Fischer JP, Wes AM, Nelson JA, et al. Propensity-matched, longitudinal outcomes analysis of complications and cost: comparing abdominal free flaps and implant-based breast reconstruction. J Am Coll Surg. 2014 Aug;219(2):303-12. doi: 10.1016/j.jamcollsurg.2014.02.028. PMID: 24916480.

57. Garvey PB, Villa MT, Rozanski AT, et al. The advantages of free abdominal-based flaps over implants for breast reconstruction in obese patients. Plast Reconstr Surg. 2012 Nov;130(5):991-1000. doi: 10.1097/PRS.0b013e318267efc5. PMID: 23096600.

58. Ha JH, Hong KY, Lee HB, et al. Oncologic outcomes after immediate breast reconstruction following mastectomy: comparison of implant and flap using propensity score matching. BMC Cancer. 2020 Jan 30;20(1):78. doi: 10.1186/s12885-020-6568-2. PMID: 32000718.

59. Hangge PT, Jogerst K, Mohsen A, et al. Making an informed choice: Which breast reconstruction type has the lowest complication rate? Am J Surg. 2019 Dec;218(6):1040-5. doi: 10.1016/j.amjsurg.2019.09.033. PMID: 31606126.

60. Jiang YZ, Liu YR, Yu KD, et al. Immediate postmastectomy breast reconstruction showed limited advantage in patient survival after stratifying by family income. PLoS One. 2013;8(12):e82807. doi: 10.1371/journal.pone.0082807. PMID: 24349366.

61. Kouwenberg CAE, de Ligt KM, Kranenburg LW, et al. Long-Term Health-Related Quality of Life after Four Common Surgical Treatment Options for Breast Cancer and the Effect of Complications: A Retrospective Patient-Reported Survey among 1871 Patients. Plast Reconstr Surg. 2020 Jul;146(1):1-13. doi: 10.1097/prs.0000000000006887. PMID: 32590633.

62. Kouwenberg CAE, Kranenburg LW, Visser MS, et al. "The validity of the EQ-5D-5L in measuring quality of life benefits of breast reconstruction". J Plast Reconstr Aesthet Surg. 2019 Jan;72(1):52-61. doi: 10.1016/j.bjps.2018.08.023. PMID: 30270015.

63. Kulkarni AR, Pusic AL, Hamill JB, et al. Factors Associated with Acute Postoperative Pain Following Breast Reconstruction. JPRAS Open. 2017 Mar;11:1-13. doi: 10.1016/j.jpra.2016.08.005. PMID: 28713853.

64. Laporta R, Sorotos M, Longo B, et al. Breast Reconstruction in Elderly Patients: Risk Factors, Clinical Outcomes, and Aesthetic Results. J Reconstr Microsurg. 2017 May;33(4):257-67. doi: 10.1055/s-0036-1597822. PMID: 28061518.

65. Lee KT, Bang SI, Pyon JK, et al. Method of breast reconstruction and the development of lymphoedema. Br J Surg. 2017 Feb;104(3):230-7. doi: 10.1002/bjs.10397. PMID: 27861758.

66. Lee KT, Pyon JK, Bang SI, et al. Does the reconstruction method influence development of mastectomy flap complications in nipple-sparing mastectomy? J Plast Reconstr Aesthet Surg. 2013 Nov;66(11):1543-50. doi: 10.1016/j.bjps.2013.06.032. PMID: 23834909.

67. Lei C, Xu L, Xu F, et al. Patient satisfaction in one-stage immediate breast reconstruction after mastectomy: A multi-center comparative patient evaluation of prosthesis, LDMF, and TRAM techniques. Medicine (Baltimore). 2020 May 29;99(22):e19991. doi: 10.1097/md.0000000000019991. PMID: 32481367.

68. Liu C, Momeni A, Zhuang Y, et al. Outcome analysis of expander/implant versus microsurgical abdominal flap breast reconstruction: a critical study of 254 cases. Ann Surg Oncol. 2014 Jun;21(6):2074-82. doi: 10.1245/s10434-014-3521-0. PMID: 24558063.

69. Mak JC, Kwong A. Complications in Post-mastectomy Immediate Breast Reconstruction: A Ten-year Analysis of Outcomes. Clin Breast Cancer. 2020 Oct;20(5):402-7. doi: 10.1016/j.clbc.2019.12.002. PMID: 32665188.

70. McCarthy CM, Mehrara BJ, Long T, et al. Chest and upper body morbidity following immediate postmastectomy breast reconstruction. Ann Surg Oncol. 2014 Jan;21(1):107-12. doi: 10.1245/s10434-013-3231-z. PMID: 24201740.

71. Merchant SJ, Goldstein L, Kruper LL. Patterns and Trends in Immediate Postmastectomy Reconstruction in California: Complications and Unscheduled Readmissions. Plast Reconstr Surg. 2015 Jul;136(1):10e-9e. doi: 10.1097/prs.0000000000001326. PMID: 26111325.

72. Mioton LM, Smetona JT, Hanwright PJ, et al. Comparing thirty-day outcomes in prosthetic and autologous breast reconstruction: a multivariate analysis of 13,082 patients? J Plast Reconstr Aesthet Surg. 2013 Jul;66(7):917-25. doi: 10.1016/j.bjps.2013.03.009. PMID: 23562485.

73. Mlodinow AS, Ver Halen JP, Lim S, et al. Predictors of readmission after breast reconstruction: a multi-institutional analysis of 5012 patients. Ann Plast Surg. 2013 Oct;71(4):335-41. doi: 10.1097/SAP.0b013e3182a0df25. PMID: 24025652.

74. Momeni A, Fox JP. Venous Thromboembolism After Surgical Treatment of Breast Cancer. Ann Plast Surg. 2018 Feb;80(2):188-92. doi: 10.1097/sap.0000000000001249. PMID: 29095189.

75. Naoum GE, Oladeru OT, Niemierko A, et al. Optimal breast reconstruction type for patients treated with neoadjuvant chemotherapy, mastectomy followed by radiation therapy. Breast Cancer Res Treat. 2020 Aug;183(1):127-36. doi: 10.1007/s10549-020-05747-7. PMID: 32607638.

76. Naoum GE, Salama L, Niemierko A, et al. Single Stage Direct-to-Implant Breast Reconstruction Has Lower Complication Rates Than Tissue Expander and Implant and Comparable Rates to Autologous Reconstruction in Patients Receiving Postmastectomy Radiation. Int J Radiat Oncol Biol Phys. 2020 Mar 1;106(3):514-24. doi: 10.1016/j.ijrobp.2019.11.008. PMID: 31756414.

77. Nasser JS, Huetteman HE, Chung TT, et al. Unplanned Emergency Department Visits within 30 Days of Mastectomy and Breast Reconstruction. Plast Reconstr Surg. 2018 Dec;142(6):1411-20. doi: 10.1097/prs.0000000000004970. PMID: 30204678.

78. Nelson JA, Voineskos SH, Qi J, et al. Elective Revisions after Breast Reconstruction: Results from the Mastectomy Reconstruction Outcomes Consortium. Plast Reconstr Surg. 2019 Dec;144(6):1280-90. doi: 10.1097/prs.0000000000006225. PMID: 31764633.

79. Palve JS, Luukkaala TH, Kääriäinen MT. Predictive risk factors of complications in different breast reconstruction methods. Breast Cancer Res Treat. 2020 Jul;182(2):345-54. doi: 10.1007/s10549-020-05705-3. PMID: 32468337.

80. Pusic AL, Matros E, Fine N, et al. Patient-Reported Outcomes 1 Year After Immediate Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium Study. J Clin Oncol. 2017 Aug 1;35(22):2499-506. doi: 10.1200/jco.2016.69.9561. PMID: 28346808.

81. Qin Q, Tan Q, Lian B, et al. Postoperative outcomes of breast reconstruction after mastectomy: A retrospective study. Medicine (Baltimore). 2018 Feb;97(5):e9766. doi: 10.1097/md.0000000000009766. PMID: 29384865.

82. Roth RS, Lowery JC, Davis J, et al. Persistent pain following postmastectomy breast reconstruction: long-term effects of type and timing of surgery. Ann Plast Surg. 2007 Apr;58(4):371-6. doi: 10.1097/01.sap.0000239810.38137.84. PMID: 17413877.

83. Roth RS, Qi J, Hamill JB, et al. Is chronic postsurgical pain surgery-induced? A study of persistent postoperative pain following breast reconstruction. Breast. 2018 Feb;37:119-25. doi: 10.1016/j.breast.2017.11.001. PMID: 29145033.

84. Santosa KB, Qi J, Kim HM, et al. Long-term Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. JAMA Surg. 2018 Oct 1;153(10):891-9. doi: 10.1001/jamasurg.2018.1677. PMID: 29926096.

85. Shiraishi M, Sowa Y, Fujikawa K, et al. Factors associated with chronic pain following breast reconstruction in Japanese women. J Plast Surg Hand Surg. 2020 Oct;54(5):317-22. doi: 10.1080/2000656x.2020.1780246. PMID: 32589082.

86. Simon P, Barrou J, Cohen M, et al. Types of Mastectomies and Immediate Reconstructions for Ipsilateral Breast Local Recurrences. Front Oncol. 2020;10:567298. doi: 10.3389/fonc.2020.567298. PMID: 33363007.

87. Taylor EM, Wilkins EG, Pusic AL, et al. Impact of Unilateral versus Bilateral Breast Reconstruction on Procedure Choices and Outcomes. Plast Reconstr Surg. 2019 Jun;143(6):1159e-68e. doi: 10.1097/prs.0000000000005602. PMID: 31136472.

88. Tong WM, Baumann DP, Villa MT, et al. Obese Women Experience Fewer Complications after Oncoplastic Breast Repair following Partial Mastectomy Than after Immediate Total Breast Reconstruction. Plast Reconstr Surg. 2016 Mar;137(3):777-91. doi: 10.1097/01.prs.0000479939.69211.19. PMID: 26910658.

89. Weichman KE, Clavin NW, Miller HC, et al. Does the use of biopatch devices at drain sites reduce perioperative infectious complications in patients undergoing immediate tissue expander breast reconstruction? Plast Reconstr Surg. 2015 Jan;135(1):9e-17e. doi: 10.1097/prs.0000000000000810. PMID: 25539357.

90. Weichman KE, Hamill JB, Kim HM, et al. Understanding the recovery phase of breast reconstructions: Patient-reported outcomes correlated to the type and timing of reconstruction. J Plast Reconstr Aesthet Surg. 2015 Oct;68(10):1370-8. doi: 10.1016/j.bjps.2015.05.039. PMID: 26165633.

91. Wilkins EG, Hamill JB, Kim HM, et al. Complications in Postmastectomy Breast Reconstruction: One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study. Ann Surg. 2018 Jan;267(1):164-70. doi: 10.1097/sla.0000000000002033. PMID: 27906762.

92. Woo KJ, Lee KT, Mun GH, et al. Effect of breast reconstruction modality on the development of postmastectomy shoulder morbidity. J Plast Reconstr Aesthet Surg. 2018 Dec;71(12):1761-7. doi: 10.1016/j.bjps.2018.07.033. PMID: 30360958.

93. Wu ZY, Han HH, Kim HJ, et al. A propensity score-matched comparison of recurrence outcomes after immediate implant vs autologous flap reconstruction in patients receiving neoadjuvant chemotherapy for breast cancer. Breast Cancer Res Treat. 2021 Mar 19. doi: 10.1007/s10549-021-06114-w. PMID: 33740204.

94. Xu F, Sun H, Zhang C, et al. Comparison of surgical complication between immediate implant and autologous breast reconstruction after mastectomy: A multicenter study of 426 cases. J Surg Oncol. 2018 Nov;118(6):953-8. doi: 10.1002/jso.25238. PMID: 30261115.

95. Yueh JH, Slavin SA, Adesiyun T, et al. Patient satisfaction in postmastectomy breast reconstruction: a comparative evaluation of DIEP, TRAM, latissimus flap, and implant techniques. Plast Reconstr Surg. 2010 Jun;125(6):1585-95. doi: 10.1097/PRS.0b013e3181cb6351. PMID: 20517080.

96. Yueh JH, Slavin SA, Bar-Meir ED, et al. Impact of regional referral centers for microsurgical breast reconstruction: the New England perforator flap program experience. J Am Coll Surg. 2009 Feb;208(2):246-54. doi: 10.1016/j.jamcollsurg.2008.10.033. PMID: 19228537.

97. Zhang L, Jin K, Wang X, et al. The Impact of Radiotherapy on Reoperation Rates in Patients Undergoing Mastectomy and Breast Reconstruction. Ann Surg Oncol. 2019 Apr;26(4):961-8. doi: 10.1245/s10434-018-07135-4. PMID: 30675702.

98. Acosta R, Smit JM, Audolfsson T, et al. A clinical review of 9 years of free perforator flap breast reconstructions: an analysis of 675 flaps and the influence of new techniques on clinical practice. J Reconstr Microsurg. 2011 Feb;27(2):91-8. doi: 10.1055/s-0030-1267835. PMID: 21046538.

99. Albornoz CR, Cordeiro PG, Hishon L, et al. A nationwide analysis of the relationship between hospital volume and outcome for autologous breast reconstruction. Plast Reconstr Surg. 2013 Aug;132(2):192e-200e. doi: 10.1097/PRS.0b013e31829586c1. PMID: 23897346.

100. Andree C, Munder BI, Seidenstuecker K, et al. Skin-sparing mastectomy and immediate reconstruction with DIEP flap after breast-conserving therapy. Med Sci Monit. 2012 Dec;18(12):Cr716-20. doi: 10.12659/msm.883598. PMID: 23197233.

101. Banuelos J, Taslakian EN, Nguyen MT, et al. The American College of Surgeons National Quality Improvement Program Incompletely Captures Implant-Based Breast Reconstruction Complications. Ann Plast Surg. 2020 Mar;84(3):271-5. doi: 10.1097/sap.0000000000002051. PMID: 31663932.

102. Beugels J, Bod L, van Kuijk SMJ, et al. Complications following immediate compared to delayed deep inferior epigastric artery perforator flap breast reconstructions. Breast Cancer Res Treat. 2018 Jun;169(2):349-57. doi: 10.1007/s10549-018-4695-0. PMID: 29399731.

103. Beugels J, Kool M, Hoekstra LT, et al. Quality of Life of Patients After Immediate or Delayed Autologous Breast Reconstruction: A Multicenter Study. Ann Plast Surg. 2018 Nov;81(5):523-7. doi: 10.1097/sap.0000000000001618. PMID: 30247195.

104. Brooks S, Djohan R, Tendulkar R, et al. Risk factors for complications of radiation therapy on tissue expander breast reconstructions. Breast J. 2012 Jan-Feb;18(1):28-34. doi: 10.1111/j.1524-4741.2011.01182.x. PMID: 22098451.

105. Chang DW, Wang B, Robb GL, et al. Effect of obesity on flap and donor-site complications in free transverse rectus abdominis myocutaneous flap breast reconstruction. Plast Reconstr Surg. 2000 Apr;105(5):1640-8. doi: 10.1097/00006534-200004050-00007. PMID: 10809092.

106. Chang EI, Chang EI, Soto-Miranda MA, et al. Demystifying the use of internal mammary vessels as recipient vessels in free flap breast reconstruction. Plast Reconstr Surg. 2013 Oct;132(4):763-8. doi: 10.1097/PRS.0b013e31829fe321. PMID: 24076668.

107. Chang EI, Chang EI, Soto-Miranda MA, et al. Comprehensive Evaluation of Risk Factors and Management of Impending Flap Loss in 2138 Breast Free Flaps. Ann Plast Surg. 2016 Jan;77(1):67-71. doi: 10.1097/sap.0000000000000263. PMID: 25003429.

108. Chang EI, Chang EI, Soto-Miranda MA, et al. Comprehensive analysis of donor-site morbidity in abdominally based free flap breast reconstruction. Plast Reconstr Surg. 2013 Dec;132(6):1383-91. doi: 10.1097/PRS.0b013e3182a805a3. PMID: 24005365.

109. Chang EI, Vaca L, DaLio AL, et al. Assessment of advanced age as a risk factor in microvascular breast reconstruction. Ann Plast Surg. 2011 Sep;67(3):255-9. doi: 10.1097/SAP.0b013e3181f9b20c. PMID: 21407063.

110. Chen AD, Chi D, Wu WW, et al. The Influence of Connective Tissue Disease in Breast Reconstruction: A National Database Analysis. Ann Plast Surg. 2018 Apr;80(4 Suppl 4):S182-s8. doi: 10.1097/sap.0000000000001387. PMID: 29596085.

111. Chen CF, Lin SF, Hung CF, et al. Risk of infection is associated more with drain duration than daily drainage volume in prosthesis-based breast reconstruction: A cohort study. Medicine (Baltimore). 2016 Dec;95(49):e5605. doi: 10.1097/md.0000000000005605. PMID: 27930584.

112. Chen Y, Chen J, Chen J, et al. [Current trends of breast reconstruction after mastectomy for breast cancer patients in China: a survey report]. Zhonghua Zhong Liu Za Zhi. 2014 Nov;36(11):851-7. PMID: 25620484.

113. Cleveland EC, Fischer JP, Nelson JA, et al. Optimizing the fascial closure: an analysis of 1261 abdominally based free flap reconstructions. Ann Plast Surg. 2013 Sep;71(3):255-60. doi: 10.1097/SAP.0b013e318286380e. PMID: 23945529.

114. Collier W, Scheefer Van Boerum M, Kim J, et al. Are 30-Day Outcomes Enough? Late Infectious Readmissions following Prosthetic-Based Breast Reconstruction. Plast Reconstr Surg. 2019 Sep;144(3):360e-8e. doi: 10.1097/prs.0000000000005903. PMID: 31461001.

115. Cordeiro PG, Albornoz CR, McCormick B, et al. The impact of postmastectomy radiotherapy on two-stage implant breast reconstruction: an analysis of long-term surgical outcomes, aesthetic results, and satisfaction over 13 years. Plast Reconstr Surg. 2014 Oct;134(4):588-95. doi: 10.1097/prs.0000000000000523. PMID: 25357021.

116. Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part I. A prospective analysis of early complications. Plast Reconstr Surg. 2006 Sep 15;118(4):825-31. doi: 10.1097/01.prs.0000232362.82402.e8. PMID: 16980842.

117. Cordeiro PG, McGuire P, Murphy DK. Natrelle 410 Extra-Full Projection Silicone Breast Implants: 2-Year Results from Two Prospective Studies. Plast Reconstr Surg. 2015 Oct;136(4):638-46. doi: 10.1097/prs.0000000000001636. PMID: 26090764.

118. Cordeiro PG, Snell L, Heerdt A, et al. Immediate tissue expander/implast breast reconstruction after salvage mastectomy for cancer recurrence following lumpectomy/irradiation. Plast Reconstr Surg. 2012 Feb;129(2):341-50. doi: 10.1097/PRS.0b013e318205f203. PMID: 22286416.

119. Coroneos CJ, Selber JC, Offodile AC, 2nd, et al. US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients. Ann Surg. 2019 Jan;269(1):30-6. doi: 10.1097/sla.0000000000002990. PMID: 30222598.

120. Daly LT, Doval AF, Lin SJ, et al. Role of CTA in Women with Abdominal Scars Undergoing DIEP Breast Reconstruction: Review of 1,187 Flaps. J Reconstr Microsurg. 2020 May;36(4):294-300. doi: 10.1055/s-0039-1701040. PMID: 31994156.

121. Enajat M, Rozen WM, Whitaker IS, et al. A single center comparison of one versus two venous anastomoses in 564 consecutive DIEP flaps: investigating the effect on venous congestion and flap survival. Microsurgery. 2010;30(3):185-91. doi: 10.1002/micr.20712. PMID: 19790180.

122. Fitzgerald O'Connor E, Rozen WM, Chowdhry M, et al. The microvascular anastomotic coupler for venous anastomoses in free flap breast reconstruction improves outcomes. Gland Surg. 2016 Apr;5(2):88-92. doi: 10.3978/j.issn.2227-684X.2015.05.14. PMID: 27047776.

123. Gfrerer L, Mattos D, Mastroianni M, et al. Assessment of patient factors, surgeons, and surgeon teams in immediate implant-based breast reconstruction outcomes. Plast Reconstr Surg. 2015 Feb;135(2):245e-52e. doi: 10.1097/prs.0000000000000912. PMID: 25626807.

124. Gill PS, Hunt JP, Guerra AB, et al. A 10-year retrospective review of 758 DIEP flaps for breast reconstruction. Plast Reconstr Surg. 2004 Apr 1;113(4):1153-60. doi: 10.1097/01.prs.0000110328.47206.50. PMID: 15083015.

125. Goodwin SJ, McCarthy CM, Pusic AL, et al. Complications in smokers after postmastectomy tissue expander/implant breast reconstruction. Ann Plast Surg. 2005 Jul;55(1):16-9; discussion 9-20. doi: 10.1097/01.sap.0000168282.81348.b3. PMID: 15985785.

126. Haddock NT, Cho MJ, Teotia SS. Comparative Analysis of Single versus Stacked Free Flap Breast Reconstruction: A Single-Center Experience. Plast Reconstr Surg. 2019 Sep;144(3):369e-77e. doi: 10.1097/prs.0000000000005906. PMID: 31461004.

127. Haddock NT, Culver AJ, Teotia SS. Abdominal weakness, bulge, or hernia after DIEP flaps: An algorithm of management, prevention, and surgical repair with classification. J Plast Reconstr Aesthet Surg. 2020 Dec 26. doi: 10.1016/j.bjps.2020.12.044. PMID: 33487570.

128. Hamdi M, Andrades P, Thiessen F, et al. Is a second free flap still an option in a failed free flap breast reconstruction? Plast Reconstr Surg. 2010 Aug;126(2):375-84. doi: 10.1097/PRS.0b013e3181de22f3. PMID: 20679823.

129. Hamdi M, Casaer B, Andrades P, et al. Salvage (tertiary) breast reconstruction after implant failure. J Plast Reconstr Aesthet Surg. 2011 Mar;64(3):353-9. doi: 10.1016/j.bjps.2010.05.019. PMID: 20576480.

130. Hansen N, Espino S, Blough JT, et al. Evaluating Mastectomy Skin Flap Necrosis in the Extended Breast Reconstruction Risk Assessment Score for 1-Year Prediction of Prosthetic Reconstruction Outcomes. J Am Coll Surg. 2018 Jul;227(1):96-104. doi: 10.1016/j.jamcollsurg.2018.05.003. PMID: 29778821.

131. Hembd AS, Yan J, Zhu H, et al. Intraoperative Assessment of DIEP Flap Breast Reconstruction Using Indocyanine Green Angiography: Reduction of Fat Necrosis, Resection Volumes, and Postoperative Surveillance. Plast Reconstr Surg. 2020 Jul;146(1):1e-10e. doi: 10.1097/prs.0000000000006888. PMID: 32590635.

132. Heo JW, Park SO, Jin US. Donor-site morbidities in 615 patients after breast reconstruction using a free muscle-sparing type I transverse rectus abdominis myocutaneous flap: a single surgeon experience. J Plast Surg Hand Surg. 2018 Dec;52(6):325-32. doi: 10.1080/2000656x.2018.1493389. PMID: 30039735.

133. Hunsicker LM, Ashikari AY, Berry C, et al. Short-Term Complications Associated With Acellular Dermal Matrix-Assisted Direct-to-Implant Breast Reconstruction. Ann Plast Surg. 2017 Jan;78(1):35-40. doi: 10.1097/sap.0000000000000742. PMID: 26849284.

134. Huo J, Smith BD, Giordano SH, et al. A comparison of patient-centered economic and clinical outcomes of post-mastectomy breast reconstruction between obese and non-obese patients. Breast. 2016 Dec;30:118-24. doi: 10.1016/j.breast.2016.09.004. PMID: 27697676.

135. Jo T, Hur J, Min K, et al. Immediate breast reconstruction after salvage mastectomy: Case control outcome comparisons of DIEP flap and DTI reconstruction. J Plast Reconstr Aesthet Surg. 2020 Dec 9. doi: 10.1016/j.bjps.2020.11.034. PMID: 33386262.

136. Kanuri A, Liu AS, Guo L. Whom should we SPY? A cost analysis of laser-assisted indocyanine green angiography in prevention of mastectomy skin flap necrosis during prosthesis-based breast reconstruction. Plast Reconstr Surg. 2014 Apr;133(4):448e-54e. doi: 10.1097/prs.0000000000000025. PMID: 24675199.

137. Kato H, Nakagami G, Iwahira Y, et al. Risk factors and risk scoring tool for infection during tissue expansion in tissue expander and implant breast reconstruction. Breast J. 2013 Nov-Dec;19(6):618-26. doi: 10.1111/tbj.12175. PMID: 24011080.

138. Kim EK, Eom JS, Ahn SH, et al. Evolution of the pedicled TRAM flap: a prospective study of 500 consecutive cases by a single surgeon in Asian patients. Ann Plast Surg. 2009 Oct;63(4):378-82. doi: 10.1097/SAP.0b013e3181951708. PMID: 19745709.

139. Kim EK, Eom JS, Ahn SH, et al. The efficacy of prophylactic low-molecular-weight heparin to prevent pulmonary thromboembolism in immediate breast reconstruction using the TRAM flap. Plast Reconstr Surg. 2009 Jan;123(1):9-12. doi: 10.1097/PRS.0b013e3181904be7. PMID: 19116509.

140. Kim HJ, Park EH, Lim WS, et al. Nipple areola skin-sparing mastectomy with immediate transverse rectus abdominis musculocutaneous flap reconstruction is an oncologically safe procedure: a single center study. Ann Surg. 2010 Mar;251(3):493-8. doi: 10.1097/SLA.0b013e3181c5dc4e. PMID: 20134317.

141. Langer S, Munder B, Seidenstuecker K, et al. Development of a surgical algorithm and optimized management of complications - based on a review of 706 abdominal free flaps for breast reconstruction. Med Sci Monit. 2010 Nov;16(11):Cr518-22. PMID: 20980954.

142. Lantieri L, Hivelin M, Benjoar MD, et al. [Setting of a breast autologous microsurgical reconstructive surgery evolution in 20 years and review of 1138 cases]. Ann Chir Plast Esthet. 2015 Dec;60(6):484-9. doi: 10.1016/j.anplas.2015.06.009. PMID: 26238173.

143. Law TY, Moeller E, Hubbard ZS, et al. Preoperative Hypoglycemia and Hyperglycemia Are Related to Postoperative Infection Rates in Implant-Based Breast Reconstruction. J Surg Res. 2018 Dec;232:437-41. doi: 10.1016/j.jss.2018.06.068. PMID: 30463754.

144. Lee KT, Bae J, Jeon BJ, et al. Adjuvant Chemotherapy in Two-Stage Tissue Expander/Implant Breast Reconstruction: Does it Affect Final Outcomes? Ann Surg Oncol. 2021 Apr;28(4):2191-8. doi: 10.1245/s10434-020-09177-z. PMID: 32974692.

145. Lee KT, Kim S, Jeon BJ, et al. Association of the Implant Surface Texture Used in Reconstruction With Breast Cancer Recurrence. JAMA Surg. 2020 Dec 1;155(12):1132-40. doi: 10.1001/jamasurg.2020.4124. PMID: 33026424.

146. Liao EC, Taghinia AH, Nguyen LP, et al. Incidence of hematoma complication with heparin venous thrombosis prophylaxis after TRAM flap breast reconstruction. Plast Reconstr Surg. 2008 Apr;121(4):1101-7. doi: 10.1097/01.prs.0000302454.43201.83. PMID: 18349626.

147. Lovecchio F, Jordan SW, Lim S, et al. Risk Factors for Complications Differ Between Stages of Tissue-Expander Breast Reconstruction. Ann Plast Surg. 2015 Sep;75(3):275-80. doi: 10.1097/sap.0000000000000109. PMID: 24691330.

148. Masoomi H, Blumenauer BJ, Blakkolb CL, et al. Predictors of blood transfusion in autologous breast reconstruction surgery: A retrospective study using the nationwide inpatient sample database. J Plast Reconstr Aesthet Surg. 2019 Oct;72(10):1616-22. doi: 10.1016/j.bjps.2019.06.012. PMID: 31331721.

149. Masoomi H, Paydar KZ, Wirth GA, et al. Predictive risk factors of venous thromboembolism in autologous breast reconstruction surgery. Ann Plast Surg. 2014 Jan;72(1):30-3. doi: 10.1097/sap.0000000000000003. PMID: 24317244.

150. McCarthy CM, Mehrara BJ, Riedel E, et al. Predicting complications following expander/implant breast reconstruction: an outcomes analysis based on preoperative clinical risk. Plast Reconstr Surg. 2008 Jun;121(6):1886-92. doi: 10.1097/PRS.0b013e31817151c4. PMID: 18520873.

151. Mehrara BJ, Santoro TD, Arcilla E, et al. Complications after microvascular breast reconstruction: experience with 1195 flaps. Plast Reconstr Surg. 2006 Oct;118(5):1100-9; discussion 10-1. doi: 10.1097/01.prs.0000236898.87398.d6. PMID: 17016173.

152. Mirzabeigi MN, Nelson JA, Fischer JP, et al. Tamoxifen (selective estrogen-receptor modulators) and aromatase inhibitors as potential perioperative thrombotic risk factors in free flap breast reconstruction. Plast Reconstr Surg. 2015 Apr;135(4):670e-9e. doi: 10.1097/prs.0000000000001127. PMID: 25811579.

153. Munder B, Andree C, Witzel C, et al. The DIEP Flap as Well-established Method of Choice for Autologous Breast Reconstruction with a Low Complication Rate - Retrospective Single-centre 10-Year Experience. Geburtshilfe Frauenheilkd. 2020 Jun;80(6):628-38. doi: 10.1055/a-1116-2102. PMID: 32565553.

154. Nelson JA, Fischer JP, Grover R, et al. The impact of anemia on microsurgical breast reconstruction complications and outcomes. Microsurgery. 2014 May;34(4):261-70. doi: 10.1002/micr.22202. PMID: 24436188.

155. Nelson JA, Stransky CA, Fischer JP, et al. Reexamining free flap breast reconstruction in the community and university setting: is there a difference? Ann Plast Surg. 2014 Dec;73 Suppl 2:S171-4. doi: 10.1097/sap.0000000000000204. PMID: 25046665.

156. O'Neill AC, Barandun M, Cha J, et al. Restrictive use of perioperative blood transfusion does not increase complication rates in microvascular breast reconstruction. J Plast Reconstr Aesthet Surg. 2016 Aug;69(8):1092-6. doi: 10.1016/j.bjps.2016.04.021. PMID: 27236504.

157. O'Neill AC, Sebastiampillai S, Zhong T, et al. Increasing body mass index increases complications but not failure rates in microvascular breast reconstruction: A retrospective cohort study. J Plast Reconstr Aesthet Surg. 2019 Sep;72(9):1518-24. doi: 10.1016/j.bjps.2019.05.013. PMID: 31196805.

158. Parikh RP, Brown GM, Sharma K, et al. Immediate Implant-Based Breast Reconstruction with Acellular Dermal Matrix: A Comparison of Sterile and Aseptic AlloDerm in 2039 Consecutive Cases. Plast Reconstr Surg. 2018 Dec;142(6):1401-9. doi: 10.1097/prs.0000000000004968. PMID: 30204676.

159. Park JW, Lee KT, Jeon BJ, et al. Effects of Antihypertensive Drugs on Outcomes of Breast Reconstruction. Ann Surg Oncol. 2019 Jun;26(6):1712-9. doi: 10.1245/s10434-019-07293-z. PMID: 30863940.

160. Phan R, Rozen WM, Chowdhry M, et al. Risk factors and timing of postoperative hematomas following microvascular breast reconstruction: A prospective cohort study. Microsurgery. 2020 Feb;40(2):99-103. doi: 10.1002/micr.30473. PMID: 31124177.

161. Polanco TO, Shamsunder MG, Hicks MEV, et al. Goal-directed fluid therapy in autologous breast reconstruction results in less fluid and more vasopressor administration without outcome compromise. J Plast Reconstr Aesthet Surg. 2021 Feb 4. doi: 10.1016/j.bjps.2021.01.017. PMID: 33745850.

162. Potter S, Conroy EJ, Cutress RI, et al. Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study. Lancet Oncol. 2019 Feb;20(2):254-66. doi: 10.1016/s1470-2045(18)30781-2. PMID: 30639093.

163. Prantl L, Moellhoff N, von Fritschen U, et al. Immediate versus secondary DIEP flap breast reconstruction: a multicenter outcome study. Arch Gynecol Obstet. 2020 Dec;302(6):1451-9. doi: 10.1007/s00404-020-05779-w. PMID: 32895743.

164. Ricci JA, Kamali P, Becherer BE, et al. Umbilical necrosis rates after abdominal-based microsurgical breast reconstruction. J Surg Res. 2017 Jul;215:257-63. doi: 10.1016/j.jss.2017.04.010. PMID: 28688657.

165. Rogoff H, Marquez JE, Ghosh K, et al. Clinical Outcomes After Hematoma Development: A Study of 627 Tissue Expander Breast Reconstructions. Ann Plast Surg. 2020 Jul;85(S1 Suppl 1):S63-s7. doi: 10.1097/sap.0000000000002343. PMID: 32243320.

166. Roy M, Sebastiampillai S, Zhong T, et al. Synergistic Interaction Increases Complication Rates following Microvascular Breast Reconstruction. Plast Reconstr Surg. 2019 Jul;144(1):1e-8e. doi: 10.1097/prs.0000000000005695. PMID: 31246793.

167. Rubio GA, McGee CS, Thaller SR. Autologous breast reconstruction surgery outcomes in patients with autoimmune connective tissue disease. J Plast Reconstr Aesthet Surg. 2019 May;72(5):848-62. doi: 10.1016/j.bjps.2018.12.038. PMID: 30665841.

168. Salibian AA, Frey JD, Bekisz JM, et al. Ischemic Complications after Nipple-sparing Mastectomy: Predictors of Reconstructive Failure in Implant-based Reconstruction and Implications for Decision-making. Plast Reconstr Surg Glob Open. 2019 May;7(5):e2280. doi: 10.1097/gox.0000000000002280. PMID: 31333984.

169. Seidenstuecker K, van Waes C, Munder BI, et al. DIEAP flap for safe definitive autologous breast reconstruction. Breast. 2016 Apr;26:59-66. doi: 10.1016/j.breast.2015.12.005. PMID: 27017243.

170. Selber JC, Bergey M, Sonnad SS, et al. Free flap breast reconstruction in advanced age: is it safe? Plast Reconstr Surg. 2009 Oct;124(4):1015-22. doi: 10.1097/PRS.0b013e3181b453fd. PMID: 19935283.

171. Seth AK, Silver HR, Hirsch EM, et al. Comparison of Delayed and Immediate Tissue Expander Breast Reconstruction in the Setting of Postmastectomy Radiation Therapy. Ann Plast Surg. 2015 Nov;75(5):503-7. doi: 10.1097/sap.0000000000000191. PMID: 25180955.

172. Sewart E, Turner NL, Conroy EJ, et al. Patient-reported outcomes of immediate implant-based breast reconstruction with and without biological or synthetic mesh. BJS Open. 2021 Jan 8;5(1). doi: 10.1093/bjsopen/zraa063. PMID: 33609398.

173. Shaikh IA, Thomas H, Vidyadharan R, et al. Post mastectomy immediate breast reconstruction 13 years experience in a single centre. Indian J Surg Oncol. 2010 Sep;1(3):250-5. doi: 10.1007/s13193-011-0051-0. PMID: 22693373.

174. Shammas RL, Ren Y, Thomas SM, et al. The Association of Overall Annual Hospital Volume and Perioperative Outcomes following Free Flap Breast Reconstruction. Plast Reconstr Surg. 2021 Feb 1;147(2):196e-206e. doi: 10.1097/prs.0000000000007549. PMID: 33565821.

175. Singh D, Slavin BR, Holton T. Comparing Surgical Site Occurrences in 1 versus 2-stage Breast Reconstruction via Federated EMR Network. Plast Reconstr Surg Glob Open. 2021 Jan;9(1):e3385. doi: 10.1097/gox.0000000000003385. PMID: 33564597.

176. Singh N, Reaven NL, Funk SE. Immediate 1-stage vs. tissue expander postmastectomy implant breast reconstructions: a retrospective real-world comparison over 18 months. J Plast Reconstr Aesthet Surg. 2012 Jul;65(7):917-23. doi: 10.1016/j.bjps.2011.12.040. PMID: 22342636.

177. Song D, Slater K, Papsdorf M, et al. Autologous Breast Reconstruction in Women Older Than 65 Years Versus Women Younger Than 65 Years: A Multi-Center Analysis. Ann Plast Surg. 2016 Feb;76(2):155-63. doi: 10.1097/sap.0000000000000527. PMID: 26637165.

178. Tran BNN, Ruan QZ, Cohen JB, et al. Does Hormone Therapy Use Increase Perioperative Complications in Abdominally Based Microsurgical Breast Reconstruction? Plast Reconstr Surg. 2018 Jun;141(6):805e-13e. doi: 10.1097/prs.0000000000004359. PMID: 29794694.

179. Vargas CR, Koolen PG, Ho OA, et al. Preoperative CT-angiography in autologous breast reconstruction. Microsurgery. 2016 Nov;36(8):623-7. doi: 10.1002/micr.30065. PMID: 27159778.

180. Warren DK, Nickel KB, Hostler CJ, et al. Surgeon choice in the use of postdischarge antibiotics for prophylaxis following mastectomy with and without breast reconstruction. Infect Control Hosp Epidemiol. 2021 Apr;42(4):467-70. doi: 10.1017/ice.2020.462. PMID: 33040748.

181. Watterson PA, Bostwick J, 3rd, Hester TR, Jr., et al. TRAM flap anatomy correlated with a 10-year clinical experience with 556 patients. Plast Reconstr Surg. 1995 Jun;95(7):1185-94. doi: 10.1097/00006534-199506000-00007. PMID: 7761505.

182. Williams JK, Bostwick J, 3rd, Bried JT, et al. TRAM flap breast reconstruction after radiation treatment. Ann Surg. 1995 Jun;221(6):756-64; discussion 64-6. doi: 10.1097/00000658-199506000-00014. PMID: 7794079.

183. Yoo H, Kim BH, Kim HH, et al. Local recurrence of breast cancer in reconstructed breasts using TRAM flap after skin-sparing mastectomy: clinical and imaging features. Eur Radiol. 2014 Sep;24(9):2220-6. doi: 10.1007/s00330-014-3214-x. PMID: 24852813.

184. Pickard AS, Neary MP, Cella D. Estimation of minimally important differences in EQ-5D utility and VAS scores in cancer. Health Qual Life Outcomes. 2007 Dec 21;5:70. doi: 10.1186/1477-7525-5-70. PMID: 18154669.

185. Musoro JZ, Coens C, Fiteni F, et al. Minimally Important Differences for Interpreting EORTC QLQ-C30 Scores in Patients With Advanced Breast Cancer. JNCI Cancer Spectr. 2019 Sep;3(3):pkz037. doi: 10.1093/jncics/pkz037. PMID: 32328553.

186. Eton DT, Cella D, Yost KJ, et al. A combination of distribution- and anchor-based approaches determined minimally important differences (MIDs) for four endpoints in a breast cancer scale. J Clin Epidemiol. 2004 Sep;57(9):898-910. doi: 10.1016/j.jclinepi.2004.01.012. PMID: 15504633.

187. Voineskos SH, Klassen AF, Cano SJ, et al. Giving Meaning to Differences in BREAST-Q Scores: Minimal Important Difference for Breast Reconstruction Patients. Plast Reconstr Surg. 2020 Jan;145(1):11e-20e. doi: 10.1097/prs.0000000000006317. PMID: 31577663.

188. Yost KJ, Eton DT, Garcia SF, et al. Minimally important differences were estimated for six Patient-Reported Outcomes Measurement Information System-Cancer scales in advanced-stage cancer patients. J Clin Epidemiol. 2011 May;64(5):507-16. doi: 10.1016/j.jclinepi.2010.11.018. PMID: 21447427.

189. Hamidou Z, Dabakuyo-Yonli TS, Guillemin F, et al. Impact of response shift on time to deterioration in quality of life scores in breast cancer patients. PLoS One. 2014;9(5):e96848. doi: 10.1371/journal.pone.0096848. PMID: 24828426.

190. Harrington S, Gilchrist L, Sander A. Breast Cancer EDGE Task Force Outcomes: Clinical Measures of Pain. Rehabil Oncol. 2014;32(1):13-21. PMID: 25346950.

191. Farrar JT, Young JP, Jr., LaMoreaux L, et al. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain. 2001 Nov;94(2):149-58. doi: 10.1016/s0304-3959(01)00349-9. PMID: 11690728.

192. Cordeiro PG, Albornoz CR, McCormick B, et al. What Is the Optimum Timing of Postmastectomy Radiotherapy in Two-Stage Prosthetic Reconstruction: Radiation to the Tissue Expander or Permanent Implant? Plast Reconstr Surg. 2015 Jun;135(6):1509-17. doi: 10.1097/prs.0000000000001278. PMID: 25742523.

193. Eriksson M, Anveden L, Celebioglu F, et al. Radiotherapy in implant-based immediate breast reconstruction: risk factors, surgical outcomes, and patient-reported outcome measures in a large Swedish multicenter cohort. Breast Cancer Res Treat. 2013 Dec;142(3):591-601. doi: 10.1007/s10549-013-2770-0. PMID: 24258257.

194. Hirsch EM, Seth AK, Kim JY, et al. Analysis of risk factors for complications in expander/implant breast reconstruction by stage of reconstruction. Plast Reconstr Surg. 2014 Nov;134(5):692e-9e. doi: 10.1097/prs.0000000000000607. PMID: 25347643.

195. Santosa KB, Chen X, Qi J, et al. Postmastectomy Radiation Therapy and Two-Stage Implant-Based Breast Reconstruction: Is There a Better Time to Irradiate? Plast Reconstr Surg. 2016 Oct;138(4):761-9. doi: 10.1097/prs.0000000000002534. PMID: 27673513.

196. Seth AK, Hirsch EM, Fine NA, et al. Additive risk of tumescent technique in patients undergoing mastectomy with immediate reconstruction. Ann Surg Oncol. 2011 Oct;18(11):3041-6. doi: 10.1245/s10434-011-1913-y. PMID: 21947584.

197. Seth AK, Hirsch EM, Kim JY, et al. Two surgeons, one patient: the impact of surgeon-surgeon familiarity on patient outcomes following mastectomy with immediate reconstruction. Breast. 2013 Oct;22(5):914-8. doi: 10.1016/j.breast.2013.04.013. PMID: 23673077.

198. Seth AK, Hirsch EM, Kim JY, et al. Hematoma after mastectomy with immediate reconstruction: an analysis of risk factors in 883 patients. Ann Plast Surg. 2013 Jul;71(1):20-3. doi: 10.1097/SAP.0b013e318243355f. PMID: 22791066.

199. Seth AK, Hirsch EM, Kim JY, et al. Long-term outcomes following fat grafting in prosthetic breast reconstruction: a comparative analysis. Plast Reconstr Surg. 2012 Nov;130(5):984-90. doi: 10.1097/PRS.0b013e318267d34d. PMID: 22777039.

200. Stein MJ, Chung A, Arnaout A, et al. Complication rates of acellular dermal matrix in immediate breast reconstruction with radiation: A single-institution retrospective comparison study. J Plast Reconstr Aesthet Surg. 2020 Dec;73(12):2156-63. doi: 10.1016/j.bjps.2020.05.065. PMID: 32561384.

201. Yoon AP, Qi J, Kim HM, et al. Patient-Reported Outcomes after Irradiation of Tissue Expander versus Permanent Implant in Breast Reconstruction: A Multicenter Prospective Study. Plast Reconstr Surg. 2020 May;145(5):917e-26e. doi: 10.1097/prs.0000000000006724. PMID: 32332528.

202. Antony AK, McCarthy C, Disa JJ, et al. Bilateral implant breast reconstruction: outcomes, predictors, and matched cohort analysis in 730 2-stage breast reconstructions over 10 years. Ann Plast Surg. 2014;72(6):625-30. doi: 10.1097/SAP.0b013e31826af03e. PMID: 24135689.

203. Le GM, O'Malley CD, Glaser SL, et al. Breast implants following mastectomy in women with early-stage breast cancer: prevalence and impact on survival. Breast Cancer Res. 2005;7(2):R184-93. doi: 10.1186/bcr974. PMID: 15743498.

204. Macadam SA, Ho AL, Cook EF, Jr., et al. Patient satisfaction and health-related quality of life following breast reconstruction: patient-reported outcomes among saline and silicone implant recipients. Plast Reconstr Surg. 2010 Mar;125(3):761-71. doi: 10.1097/PRS.0b013e3181cb5cf8. PMID: 20009795.

205. Osoba D, Rodrigues G, Myles J, et al. Interpreting the significance of changes in health-related quality-of-life scores. J Clin Oncol. 1998 Jan;16(1):139-44. doi: 10.1200/jco.1998.16.1.139. PMID: 9440735.

206. Lee JS, Park E, Lee JH, et al. A prospective comparison study of early functional outcomes after implant-based breast reconstruction: subpectoral versus prepectoral technique. Ann Palliat Med. 2021 Mar;10(3):2520-9. doi: 10.21037/apm-20-1550. PMID: 33691448.

207. Avila A, Bartholomew AJ, Sosin M, et al. Acute Postoperative Complications in Prepectoral versus Subpectoral Reconstruction following Nipple-Sparing Mastectomy. Plast Reconstr Surg. 2020 Dec;146(6):715e-20e. doi: 10.1097/prs.0000000000007326. PMID: 33234947.

208. Bozzuto LM, Bartholomew AJ, Tung S, et al. Decreased postoperative pain and opioid use following prepectoral versus subpectoral breast reconstruction after mastectomy: A retrospective cohort study: Pain after pre- versus subpectoral reconstruction. J Plast Reconstr Aesthet Surg. 2020 Dec 13. doi: 10.1016/j.bjps.2020.12.009. PMID: 33451949.

209. Cattelani L, Polotto S, Arcuri MF, et al. One-Step Prepectoral Breast Reconstruction With Dermal Matrix-Covered Implant Compared to Submuscular Implantation: Functional and Cost Evaluation. Clin Breast Cancer. 2018 Aug;18(4):e703-e11. doi: 10.1016/j.clbc.2017.11.015. PMID: 29275104.

210. Gabriel A, Sigalove S, Storm-Dickerson TL, et al. Dual-Plane versus Prepectoral Breast Reconstruction in High-Body Mass Index Patients. Plast Reconstr Surg. 2020 Jun;145(6):1357-65. doi: 10.1097/prs.0000000000006840. PMID: 32195862.

211. Kim JH, Hong SE. A Comparative Analysis between Subpectoral versus Prepectoral Single Stage Direct-to-Implant Breast Reconstruction. Medicina (Kaunas). 2020 Oct 13;56(10). doi: 10.3390/medicina56100537. PMID: 33066236.

212. Kraenzlin F, Darrach H, Khavanin N, et al. Tissue Expander-Based Breast Reconstruction in the Prepectoral Versus Subpectoral Plane: An Analysis of Short-Term Outcomes. Ann Plast Surg. 2021 Jan;86(1):19-23. doi: 10.1097/sap.0000000000002415. PMID: 32568752.

213. Nealon KP, Weitzman RE, Sobti N, et al. Prepectoral Direct-to-Implant Breast Reconstruction: Safety Outcome Endpoints and Delineation of Risk Factors. Plast Reconstr Surg. 2020 Feb 5. doi: 10.1097/prs.0000000000006721. PMID: 32032345.

214. Ozgur I, Kurul S, Bademler S, et al. Comparison of subpectoral versus dual-plane implant based immediate breast reconstruction after nipple-areola sparing mastectomy. Ann Chir Plast Esthet. 2020 Nov 19. doi: 10.1016/j.anplas.2020.10.002. PMID: 33223365.

215. Kukkonen J, Kauko T, Vahlberg T, et al. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg. 2013 Dec;22(12):1650-5. doi: 10.1016/j.jse.2013.05.002. PMID: 23850308.

216. Franchignoni F, Vercelli S, Giordano A, et al. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). J Orthop Sports Phys Ther. 2014 Jan;44(1):30-9. doi: 10.2519/jospt.2014.4893. PMID: 24175606.

217. Mathias SD, Crosby RD, Qian Y, et al. Estimating minimally important differences for the worst pain rating of the Brief Pain Inventory-Short Form. J Support Oncol. 2011 Mar-Apr;9(2):72-8. doi: 10.1016/j.suponc.2010.12.004. PMID: 21542414.

218. McCarthy CM, Lee CN, Halvorson EG, et al. The use of acellular dermal matrices in two-stage expander/implant reconstruction: a multicenter, blinded, randomized controlled trial. Plast Reconstr Surg. 2012 Nov;130(5 Suppl 2):57s-66s. doi: 10.1097/PRS.0b013e31825f05b4. PMID: 23096987.

219. Wendel J. Use of Dermal Matrix in Breast Reconstruction. ClinicalTrials.gov; 2013.

220. Brooke S, Mesa J, Uluer M, et al. Complications in tissue expander breast reconstruction: a comparison of AlloDerm, DermaMatrix, and FlexHD acellular inferior pole dermal slings. Ann Plast Surg. 2012 Oct;69(4):347-9. doi: 10.1097/SAP.0b013e31824b3d97. PMID: 22868313.

221. Chun YS, Verma K, Rosen H, et al. Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications. Plast Reconstr Surg. 2010 Feb;125(2):429-36. doi: 10.1097/PRS.0b013e3181c82d90. PMID: 20124828.

222. Clarke-Pearson EM, Lin AM, Hertl C, et al. Revisions in Implant-Based Breast Reconstruction: How Does Direct-to-Implant Measure Up? Plast Reconstr Surg. 2016 Jun;137(6):1690-9. doi: 10.1097/prs.0000000000002173. PMID: 27219225.

223. Craig ES, Clemens MW, Koshy JC, et al. Outcomes of Acellular Dermal Matrix for Immediate Tissue Expander Reconstruction with Radiotherapy: A Retrospective Cohort Study. Aesthet Surg J. 2019 Feb 15;39(3):279-88. doi: 10.1093/asj/sjy127. PMID: 29800083.

224. Ganesh Kumar N, Berlin NL, Kim HM, et al. Development of an evidence-based approach to the use of acellular dermal matrix in immediate expander-implant-based breast reconstruction. J Plast Reconstr Aesthet Surg. 2021 Jan;74(1):30-40. doi: 10.1016/j.bjps.2020.10.005. PMID: 33172826.

225. Ibrahim AM, Shuster M, Koolen PG, et al. Analysis of the National Surgical Quality Improvement Program database in 19,100 patients undergoing implant-based breast reconstruction: complication rates with acellular dermal matrix. Plast Reconstr Surg. 2013 Nov;132(5):1057-66. doi: 10.1097/PRS.0b013e3182a3beec. PMID: 24165587.

226. Lee KT, Lee H, Jeon BJ, et al. Impact of overweight/obesity on the development of hematoma following tissue expander-based breast reconstruction. J Plast Reconstr Aesthet Surg. 2020;74(2):307-15.

227. Liu AS, Kao HK, Reish RG, et al. Postoperative complications in prosthesis-based breast reconstruction using acellular dermal matrix. Plast Reconstr Surg. 2011 May;127(5):1755-62. doi: 10.1097/PRS.0b013e31820cf233. PMID: 21228744.

228. Nealon KP, Sobti N, Gadd M, et al. Assessing the additional surgical risk of contralateral prophylactic mastectomy and immediate breast implant reconstruction. Breast Cancer Res Treat. 2020 Jan;179(2):255-65. doi: 10.1007/s10549-019-05460-0. PMID: 31605310.

229. Pannucci CJ, Antony AK, Wilkins EG. The impact of acellular dermal matrix on tissue expander/implant loss in breast reconstruction: an analysis of the tracking outcomes and operations in plastic surgery database. Plast Reconstr Surg. 2013 Jul;132(1):1-10. doi: 10.1097/PRS.0b013e318290f917. PMID: 23508050.

230. Peled AW, Foster RD, Garwood ER, et al. The effects of acellular dermal matrix in expander-implant breast reconstruction after total skin-sparing mastectomy: results of a prospective practice improvement study. Plast Reconstr Surg. 2012 Jun;129(6):901e-8e. doi: 10.1097/PRS.0b013e31824ec447. PMID: 22634688.

231. Qureshi AA, Broderick KP, Belz J, et al. Uneventful versus Successful Reconstruction and Outcome Pathways in Implant-Based Breast Reconstruction with Acellular Dermal Matrices. Plast Reconstr Surg. 2016 Aug;138(2):173e-83e. doi: 10.1097/prs.0000000000002402. PMID: 27465177.

232. Safran T, Al-Halabi B, Viezel-Mathieu A, et al. Direct-to-Implant, Prepectoral Breast Reconstruction: A Single-Surgeon Experience with 201 Consecutive Patients. Plast Reconstr Surg. 2020 Apr;145(4):686e-96e. doi: 10.1097/prs.0000000000006654. PMID: 32221195.

233. Seth AK, Hirsch EM, Fine NA, et al. Utility of acellular dermis-assisted breast reconstruction in the setting of radiation: a comparative analysis. Plast Reconstr Surg. 2012 Oct;130(4):750-8. doi: 10.1097/PRS.0b013e318262f009. PMID: 23018687.

234. Sobti N, Ji E, Brown RL, et al. Evaluation of Acellular Dermal Matrix Efficacy in Prosthesis-Based Breast Reconstruction. Plast Reconstr Surg. 2018 Mar;141(3):541-9. doi: 10.1097/prs.0000000000004109. PMID: 29481386.

235. Sorkin M, Qi J, Kim HM, et al. Acellular Dermal Matrix in Immediate Expander/Implant Breast Reconstruction: A Multicenter Assessment of Risks and Benefits. Plast Reconstr Surg. 2017 Dec;140(6):1091-100. doi: 10.1097/prs.0000000000003842. PMID: 28806288.

236. Vardanian AJ, Clayton JL, Roostaeian J, et al. Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. Plast Reconstr Surg. 2011 Nov;128(5):403e-10e. doi: 10.1097/PRS.0b013e31822b6637. PMID: 22030500.

237. Weichman KE, Wilson SC, Weinstein AL, et al. The use of acellular dermal matrix in immediate two-stage tissue expander breast reconstruction. Plast Reconstr Surg. 2012 May;129(5):1049-58. doi: 10.1097/PRS.0b013e31824a2acb. PMID: 22544088.

238. Woo KJ, Park JW, Mun GH, et al. Does the Use of Acellular Dermal Matrix Increase Postoperative Complications of the First-Stage Reconstruction of Immediate Expander-Implant Breast Reconstruction: A Matched Cohort Study. Ann Plast Surg. 2017 Oct;79(4):341-5. doi: 10.1097/sap.0000000000001067. PMID: 28509694.

239. Flaherty SA. Pain measurement tools for clinical practice and research. Aana j. 1996 Apr;64(2):133-40. PMID: 9095685.

240. Brandberg Y, Malm M, Blomqvist L. A prospective and randomized study, "SVEA," comparing effects of three methods for delayed breast reconstruction on quality of life, patient-defined problem areas of life, and cosmetic result. Plast Reconstr Surg. 2000 Jan;105(1):66-74; discussion 5-6. doi: 10.1097/00006534-200001000-00011. PMID: 10626972.

241. Brandberg Y, Malm M, Rutqvist LE, et al. A prospective randomised study (named SVEA) of three methods of delayed breast reconstruction. Study design, patients' preoperative problems and expectations. Scand J Plast Reconstr Surg Hand Surg. 1999 Jun;33(2):209-16. doi: 10.1080/02844319950159479. PMID: 10450579.

242. Erdmann-Sager J, Wilkins EG, Pusic AL, et al. Complications and Patient-Reported Outcomes after Abdominally Based Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium Study. Plast Reconstr Surg. 2018 Feb;141(2):271-81. doi: 10.1097/prs.0000000000004016. PMID: 29019862.

243. Gart MS, Smetona JT, Hanwright PJ, et al. Autologous options for postmastectomy breast reconstruction: a comparison of outcomes based on the American College of Surgeons National Surgical Quality Improvement Program. J Am Coll Surg. 2013 Feb;216(2):229-38. doi: 10.1016/j.jamcollsurg.2012.11.003. PMID: 23211118.

244. Knox AD, Ho AL, Leung L, et al. Comparison of Outcomes following Autologous Breast Reconstruction Using the DIEP and Pedicled TRAM Flaps: A 12-Year Clinical Retrospective Study and Literature Review. Plast Reconstr Surg. 2016 Jul;138(1):16-28. doi: 10.1097/prs.0000000000001747. PMID: 26267400.

245. Kroll SS. Fat necrosis in free transverse rectus abdominis myocutaneous and deep inferior epigastric perforator flaps. Plast Reconstr Surg. 2000 Sep;106(3):576-83. doi: 10.1097/00006534-200009030-00008. PMID: 10987463.

246. Massenburg BB, Sanati-Mehrizy P, Ingargiola MJ, et al. Flap Failure and Wound Complications in Autologous Breast Reconstruction: A National Perspective. Aesthetic Plast Surg. 2015 Dec;39(6):902-9. doi: 10.1007/s00266-015-0575-8. PMID: 26487657.

247. Mennie JC, Mohanna PN, O'Donoghue JM, et al. Donor-Site Hernia Repair in Abdominal Flap Breast Reconstruction: A Population-Based Cohort Study of 7929 Patients. Plast Reconstr Surg. 2015 Jul;136(1):1-9. doi: 10.1097/prs.0000000000001398. PMID: 25839173.

248. Rindom MB, Gunnarsson GL, Lautrup MD, et al. Shoulder-related donor site morbidity after delayed breast reconstruction with pedicled flaps from the back: An open label randomized controlled clinical trial. J Plast Reconstr Aesthet Surg. 2019 Dec;72(12):1942-9. doi: 10.1016/j.bjps.2019.07.027. PMID: 31515191.

249. Zhong T, Novak CB, Bagher S, et al. Using propensity score analysis to compare major complications between DIEP and free muscle-sparing TRAM flap breast reconstructions. Plast Reconstr Surg. 2014 Apr;133(4):774-82. doi: 10.1097/prs.0000000000000024. PMID: 24675183.

250. Zoghbi Y, Gerth DJ, Tashiro J, et al. Deep Inferior Epigastric Perforator Versus Free Transverse Rectus Abdominis Myocutaneous Flap: Complications and Resource Utilization. Ann Plast Surg. 2017 May;78(5):516-20. doi: 10.1097/sap.0000000000000936. PMID: 28052051.

251. Baumann DP, Lin HY, Chevray PM. Perforator number predicts fat necrosis in a prospective analysis of breast reconstruction with free TRAM, DIEP, and SIEA flaps. Plast Reconstr Surg. 2010 May;125(5):1335-41. doi: 10.1097/PRS.0b013e3181d4fb4a. PMID: 20440154.

252. Israeli R, Funk S, Reaven NL. Comparative analysis of 18-month outcomes and costs of breast reconstruction flap procedures. Plast Reconstr Surg. 2014 Mar;133(3):471-9. doi: 10.1097/prs.0000000000000064. PMID: 24572840.

253. Macadam SA, Zhong T, Weichman K, et al. Quality of Life and Patient-Reported Outcomes in Breast Cancer Survivors: A Multicenter Comparison of Four Abdominally Based Autologous Reconstruction Methods. Plast Reconstr Surg. 2016 Mar;137(3):758-71. doi: 10.1097/01.prs.0000479932.11170.8f. PMID: 26910656.

254. U.S. Food and Drug Administration. Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication.; 2021. https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication. Accessed on May 18, 2021.

255. Keirns CC, Goold SD. Patient-centered care and preference-sensitive decision making. Jama. 2009 Oct 28;302(16):1805-6. doi: 10.1001/jama.2009.1550. PMID: 19861674.

256. Lee CN, Ubel PA, Deal AM, et al. How Informed Is the Decision About Breast Reconstruction After Mastectomy?: A Prospective, Cross-sectional Study. Ann Surg. 2016 Dec;264(6):1103-9. doi: 10.1097/sla.0000000000001561. PMID: 26727092.

257. Lee CN, Belkora J, Chang Y, et al. Are patients making high-quality decisions about breast reconstruction after mastectomy? [outcomes article]. Plast Reconstr Surg. 2011 Jan;127(1):18-26. doi: 10.1097/PRS.0b013e3181f958de. PMID: 21200195.

258. Politi MC, Lee CN, Philpott-Streiff SE, et al. A Randomized Controlled Trial Evaluating the BREASTChoice Tool for Personalized Decision Support About Breast Reconstruction After Mastectomy. Ann Surg. 2020 Feb;271(2):230-7. doi: 10.1097/sla.0000000000003444. PMID: 31305282.

259. Sun CS, Reece GP, Crosby MA, et al. Plastic Surgeon Expertise in Predicting Breast Reconstruction Outcomes for Patient Decision Analysis. Plast Reconstr Surg Glob Open. 2013 Nov 1;1(6):e78. doi: 10.1097/gox.0000000000000010. PMID: 24910814.

260. Hasak JM, Myckatyn TM, Grabinski VF, et al. Stakeholders' Perspectives on Postmastectomy Breast Reconstruction: Recognizing Ways to Improve Shared Decision Making. Plast Reconstr Surg Glob Open. 2017 Nov;5(11):e1569. doi: 10.1097/gox.0000000000001569. PMID: 29263969.

261. Alaofi RK, Nassif MO, Al-Hajeili MR. Prophylactic mastectomy for the prevention of breast cancer: Review of the literature. Avicenna J Med. 2018 Jul-Sep;8(3):67-77. doi: 10.4103/ajm.AJM_21_18. PMID: 30090744.

262. Euhus DM, Diaz J. Breast cancer prevention. Breast J. 2015 Jan-Feb;21(1):76-81. doi: 10.1111/tbj.12352. PMID: 25413630.

263. Morrow M, Mehrara B. Prophylactic mastectomy and the timing of breast reconstruction. Br J Surg. 2009 Jan;96(1):1-2. doi: 10.1002/bjs.6463. PMID: 19109821.

264. Tuttle TM, Habermann EB, Grund EH, et al. Increasing use of contralateral prophylactic mastectomy for breast cancer patients: a trend toward more aggressive surgical treatment. J Clin Oncol. 2007 Nov 20;25(33):5203-9. doi: 10.1200/jco.2007.12.3141. PMID: 17954711.

265. Wong SM, Freedman RA, Sagara Y, et al. Growing Use of Contralateral Prophylactic Mastectomy Despite no Improvement in Long-term Survival for Invasive Breast Cancer. Ann Surg. 2017 Mar;265(3):581-9. doi: 10.1097/sla.0000000000001698. PMID: 28169929.

Appendix Contents

Tables

Figures

Appendix A. Methods

Details of Study Selection

Search Strategy (Details)

We searched for studies for all Key Questions in MEDLINE (via PubMed), Embase, The Cochrane Central Register of Clinical Trials, and CINAHL. Duplicate citations were removed prior to screening. We did not employ any date or language restrictions to the search but included filters to remove nonhuman studies and articles that are not primary studies. We included MeSH or Emtree terms, along with free-text words, related to breast, cancer, mastectomy, implants/implantation, and autologous reconstruction. The searches were independently peer reviewed. The exact search terms used for identifying studies in each database are listed below. To identify additional eligible studies, we also reviewed the reference lists of relevant existing systematic reviews (SRs).

We also ran a search of the ClinicalTrials.gov registry for ongoing studies, unpublished study protocols, and unpublished study results.

Medline (via **PubMed**)
Last run on March 23, 2021
Search 1

(“Mastectomy”[Mesh] OR Mastectomy[Title/Abstract] OR Mammectomies[Title/Abstract] OR Mastectomies[Title/Abstract] OR Mammectomy[Title/Abstract])

AND

(“Mammaplasty”[MeSH Terms] OR “Breast implants”[MeSH Terms] OR "Breast Implantation"[Mesh] OR mammaplasty OR mammoplasty OR Mammaplasties OR Mammoplasties OR ((breast* OR mammar*) AND (implant OR implants OR Reconstruction* OR prosthe* OR “Prostheses and Implants”[MeSH Terms] OR “Transplantation, Autologous”[Mesh]) OR “Autografts"[Mesh] OR Autotransplantation OR Autotransplantations OR Autografting OR Autograftings OR Autologous OR Autograft OR Autotransplants OR Autotransplant OR “Silicones”[Mesh] OR “Saline Solution”[Mesh] OR "Prosthesis Design"[Mesh] OR Silicone OR silicones OR saline OR “gummy bear” OR nanomaterials OR ((“Acellular Dermis”[Mesh] OR “Tissue Expansion Devices”[Mesh] OR acellular OR dermal OR peritoneal) AND (matrices OR matrix)) OR “Surgical Flaps”[Mesh] OR “Adipose Tissue/transplantation”[Mesh] OR “Tissue Transplantation”[Mesh] OR ((flap OR flaps) AND (surgical OR surgery))))

Search 2 to get AE studies not captured by search 1. Searches 1 and 2 were subsequently to identify unique records.

(“Mammaplasty”[MeSH Terms] OR “Breast implants”[MeSH Terms] OR "Breast Implantation"[Mesh] OR mammaplasty OR mammoplasty OR Mammaplasties OR

Mammoplasties OR ((breast* OR mammar*) AND (implant OR implants OR Reconstruction* OR prosthe* OR “Prostheses and Implants”[MeSH Terms])))

AND

(“Transplantation, Autologous”[Mesh] OR “Autografts"[Mesh] OR Autotransplantation OR Autotransplantations OR Autografting OR Autografting OR Autologous OR Autograft OR Autotransplants OR Autotransplant OR “Silicones”[Mesh] OR “Saline Solution”[Mesh] OR "Prosthesis Design"[Mesh] OR Silicone OR silicones OR saline OR “gummy bear” OR nanomaterials OR ((“Acellular Dermis”[Mesh] OR “Tissue Expansion Devices”[Mesh] OR acellular OR dermal OR peritoneal) AND (matrices OR matrix)) OR “Surgical Flaps”[Mesh] OR “Adipose Tissue/transplantation”[Mesh] OR “Tissue Transplantation”[Mesh] OR ((flap OR flaps) AND (surgical OR surgery)))

AND

(safe* or adverse* or undesirable or harm or harms or injurious or risk or risks or reaction* or complication* or poison* OR side effect* or safety or unsafe OR ((adverse or undesirable or harm or harms or toxic or injurious or serious or fatal) AND (effect* or reaction* or event* or outcome* or incident*)) OR death or deaths or fatal or fatality or fatalities OR Rupture)

NOT

(“address”[pt] or “autobiography”[pt] or “bibliography”[pt] or “biography”[pt] or “case reports”[pt] or “comment”[pt] or “congress”[pt] or “dictionary”[pt] or “directory”[pt] or “festschrift”[pt] or “government publication”[pt] or “historical article”[pt] or “interview”[pt] or “lecture”[pt] or “legal case”[pt] or “legislation”[pt] or “news”[pt] or “newspaper article”[pt] or “patient education handout”[pt] or “periodical index”[pt] or "comment on" or ("Animals"[Mesh] NOT "Humans"[Mesh]))

EMBASE
Last run on March 23, 2021

#19	#3 AND #16 AND ([article]/lim OR [article in press]/lim)
#17	#3 AND #16
#16	#4 OR #15
#15	#5 OR #7 OR #13 OR #14
#14	flap OR flaps
#13	dermal AND matrix
#7	'autograft'
#6	#4 AND #5
#5	mammaplasty OR mammoplasty OR mammaplasties OR mammoplasties
#4	'breast reconstruction'
#3	#1 OR #2
#2	mammectomies OR mastectomies OR mammectomy
#1	'mastectomy'/de

Cochrane CENTRAL
Last run on March 23, 2021

#1 MeSH descriptor: [Mastectomy] explode all trees
#2 Mastectomy OR Mammectomies OR Mastectomies OR Mammectomy
#3 #1 OR #2
#4 MeSH descriptor: [Mammaplasty] explode all trees
#5 MeSH descriptor: [Breast Implants] explode all trees
#6 MeSH descriptor: [Breast Implantation] explode all trees
#7 mammaplasty OR mammoplasty OR Mammaplasties OR Mammoplasties
#8 #4 OR #5 OR #6 OR #7
#9 breast* OR mammar*
#10 MeSH descriptor: [Prostheses and Implants] explode all trees
#11 MeSH descriptor: [Transplantation, Autologous] explode all trees
#12 implant OR implants OR Reconstruction* OR prosthe*
#13 #10 OR #11 OR #12
#14 #9 AND #13
#15 #8 OR #14
#16 MeSH descriptor: [Autografts] explode all trees
#17 MeSH descriptor: [Silicones] explode all trees
#18 MeSH descriptor: [Saline Solution] explode all trees
#19 MeSH descriptor: [Prosthesis Design] explode all trees
#20 Silicone OR silicones OR saline OR "gummy bear" OR nanomaterials OR Autotransplantation OR Autotransplantations OR Autografting OR Autograftings OR Autologous OR Autograft OR Autotransplants OR Autotransplant
#21 #15 OR #16 OR #17 OR #18 OR #19 OR #20
#22 MeSH descriptor: [Acellular Dermis] explode all trees
#23 MeSH descriptor: [Tissue Expansion Devices] explode all trees
#24 acellular OR dermal OR peritoneal
#25 #22 OR #23 OR #24
#26 matrices OR matrix
#27 #25 AND #26
#28 #27 OR #21
#29 MeSH descriptor: [Surgical Flaps] explode all trees
#30 MeSH descriptor: [Tissue Transplantation] explode all trees
#31 ((flap OR flaps) AND (surgical OR surgery))
#32 #28 OR #29 OR #30 OR #31
#33 #32 AND #3

CINAHL
Last run on March 23, 2021

(Mastectomy OR Mammectomies OR Mastectomies OR Mammectomy)

AND

(mammaplasty OR mammoplasty OR Mammaplasties OR Mammoplasties OR ((breast* OR mammar*) AND (implant OR implants OR Reconstruction* OR prosthe*)) OR Silicone OR silicones OR saline OR "gummy bear" OR nanomaterials OR Autotransplantation OR

Autotransplantations OR Autografting OR Autograftings OR Autologous OR Autograft OR Autotransplants OR Autotransplant OR ((acellular OR dermal OR peritoneal) AND (matrices OR matrix)) OR ((flap OR flaps) AND (surgical OR surgery)))

We also asked all members of the Technical Expert Panel (TEP) and the American Society for Plastic Surgeons (ASPS) to review our list of included studies and suggest any additional studies that might be relevant, which we checked against our list of citations and, where applicable, added to our list. Non-English language articles were screened by readers of the relevant languages or after translation via Google Translate (https://translate.google.com/), where possible. Additional articles suggested to us in any language from any source, during peer and public review, will be screened applying identical eligibility criteria.

Inclusion and Exclusion Criteria (Details)

Key Question 1 (IBR Versus AR)

Population

- Adult (≥18 years old) women who are undergoing (or have undergone) mastectomy for any type of breast cancer (or carcinoma in situ) and have decided to undergo breast reconstruction
- Either therapeutic or prophylactic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions

- IBR
  - Either single- or multi-stage
  - Any type of implant material, either smooth or textured, silicone or saline
  - Any anatomic plane of implant placement
  - With or without use of human ADM
  - With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
  - With or without symmetry procedure (e.g., mastopexy) in the contralateral breast

Comparators

- AR using any flap (either free flap or pedicled), for example:
  - Deep inferior epigastric perforator (DIEP)
  - Latissimus dorsi (LD)
  - Transverse rectus abdominis myocutaneous (TRAM)
  - Superficial inferior epigastric artery perforator (SIEA)
  - Gluteal artery perforator (GAP)
  - Transverse musculocutaneous gracilis (TMG)
  - Transverse upper gracilis (TUG)

    - Profundal artery perforator (PAP)
- Combination of IBR and AR
- Exclude: Non-autologous flap transplants (i.e., cadaveric or xenotransplant)
- Exclude: Exclusive lipofilling/autologous fat reconstruction

Outcomes (* denotes important outcomes that were used when developing Strength of Evidence tables)

- Clinical outcomes
    - General quality of life*
    - Physical well-being (e.g., pain, discomfort)*
    - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
    - Sexual well-being*
    - Patient satisfaction with breast*
    - Patient satisfaction with outcome (e.g., satisfaction with care)*
    - Planned surgeries for reconstruction
    - Recurrence of breast cancer
    - Mortality*
- Surgical complications
    - Unplanned repeat hospitalization*
    - Duration of unplanned repeat hospitalization*
    - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
    - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
    - Pain, including chronic pain*
    - Analgesic (e.g., opioid) use*
    - Necrosis, such as of the nipple or of the flap*
    - Animation deformity*
    - Complications that lead to delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
    - Thromboembolic events*
    - Infections not explicitly implant-related*
    - Wound dehiscence
    - Delayed healing
    - Seroma*
    - Chronic conditions (e.g., rheumatologic diseases)
    - Touch sensitivity
    - Scarring
    - Reconstructive failure/loss

Potential Effect Modifiers

- Age
- Stage of breast cancer
- First occurrence versus recurrent breast cancer
- Immediate versus delayed reconstruction
- Single-stage (direct to reconstruction) versus multi-stage (with tissue expander) reconstruction

- Unilateral versus bilateral reconstruction
- Radiation therapy versus no radiation therapy
- Chemotherapy versus no chemotherapy

Timing
- Any

Setting
- Any, including single- and multicenter

Design
- Randomized controlled trials (RCTs), N≥10 per group
- Nonrandomized comparative studies (NRCSs), N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- Exclude: case reports and series of individually reported case reports

Key Question 2 (Optimal Time for IBR or AR)

Population(s)
- Adult (≥18 years old) women who are undergoing IBR or AR after a mastectomy for breast cancer (or carcinoma in situ) that requires either chemotherapy or radiation therapy
- Therapeutic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for solely prophylactic purposes (i.e., without diagnosed breast cancer)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions
- IBR or AR before chemotherapy
- IBR (whether tissue expander or implant itself) or AR before radiation therapy
  - Either single- or multistage
  - With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
  - With or without symmetry procedure (e.g., mastopexy) in the contralateral breast
  - With or without use of human ADM
  - For IBR – Any type of implant material, either smooth or textured
  - For IBR – Any anatomic plane of implant placement
  - For AR – Any flap type

Comparators
- IBR or AR after chemotherapy (when used for the current treatment of breast cancer)

- IBR (whether tissue expander or implant itself) or AR after radiation therapy (when used for the current treatment of breast cancer)

Outcomes (* denotes important outcomes that were used when developing Strength of Evidence tables)

- Clinical outcomes
  - General quality of life*
  - Physical well-being (e.g., pain, discomfort)*
  - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
  - Sexual well-being*
  - Patient satisfaction with breast*
  - Patient satisfaction with outcome (e.g., satisfaction with care)*
  - Planned surgeries for reconstruction
  - Recurrence of breast cancer
  - Mortality*
- Surgical complications
  - Unplanned repeat hospitalization*
  - Duration of unplanned repeat hospitalization*
  - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
  - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
  - Pain, including chronic pain*
  - Analgesic (e.g., opioid) use*
  - Necrosis, such as of the nipple or of the flap*
  - Animation deformity*
  - Implant-related infections (for IBR)*
  - Implant rupture, including asymptomatic rupture (for IBR)*
  - Implant deflation (for IBR)*
  - Implant malposition (for IBR)*
  - Implant failure/loss or need for explant surgery (for IBR)*
  - Capsular contracture (for IBR)
  - Complications that cause delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
  - Thromboembolic events*
  - Infections
  - Wound dehiscence
  - Delayed healing
  - Seroma*
  - Chronic conditions (e.g., rheumatologic diseases)
  - Touch sensitivity
  - Scarring
  - Flap failure/loss (for AR)

Potential Effect Modifiers

- Age
- Stage of breast cancer
- First occurrence versus recurrent breast cancer

- Type of chemotherapy (for KQ 2a) or radiation therapy (for KQ 2b)
- Immediate versus delayed reconstruction
- Single-stage (direct to reconstruction) versus multi-stage (with tissue expander) reconstruction
- Unilateral versus bilateral reconstruction

Timing
- Any

Setting
- Any, including single- and multicenter

Design
- RCTs, N≥10 per group
- NRCSs, N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- Exclude: case reports and series of individually reported case reports

Key Question 3 (Type of Implant Material)

Population(s)
- Adult (≥18 years old) women who are undergoing (or have undergone) mastectomy for any type of breast cancer (or carcinoma in situ) and have decided to undergo IBR
- Either therapeutic or prophylactic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions
- IBR using one type of implant material
  - Saline
  - Silicone
  - Other materials
  - Either smooth or textured
  - Either single- or multistage
  - Any anatomic plane of implant placement
  - With or without use of human ADM
  - With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
  - With or without symmetry procedure (e.g., mastopexy) in the contralateral breast

Comparators

- IBR using another type of implant material

Outcomes (* denotes important outcomes [i.e., unilateral or bilateral] that were used when developing Strength of Evidence tables)

- Clinical outcomes
  - General quality of life*
  - Physical well-being (e.g., pain, discomfort)*
  - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
  - Sexual well-being*
  - Patient satisfaction with breast*
  - Patient satisfaction with outcome (e.g., satisfaction with care)*
  - Planned surgeries for reconstruction*
  - Recurrence of breast cancer
  - Mortality*
- Surgical complications
  - Unplanned repeat hospitalization*
  - Duration of unplanned repeat hospitalization*
  - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
  - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
  - Pain, including chronic pain*
  - Analgesic (e.g., opioid) use*
  - Necrosis, such as of the nipple*
  - Animation deformity*
  - Implant-related infections*
  - Implant rupture, including asymptomatic rupture*
  - Implant deflation*
  - Implant malposition*
  - Implant failure/loss or need for explant surgery*
  - Capsular contracture*
  - New neoplasms (e.g., BIA-ALCL)*
  - Complications that cause delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
  - Thromboembolic events*
  - Wound dehiscence
  - Delayed healing
  - Seroma*
  - Chronic conditions (e.g., rheumatologic diseases)*
  - Touch sensitivity
  - Scarring
  - Red breast syndrome

Potential Effect Modifiers

- Age
- Stage of breast cancer
- First occurrence versus recurrent breast cancer

- Immediate versus delayed reconstruction
- Single-stage (direct to reconstruction) versus multistage (with tissue expander) reconstruction
- Unilateral versus bilateral reconstruction
- Surface of implant (smooth versus textured)
- Shape of implant (round versus anatomic/teardrop)
- Size of implant (volume)

Timing
- Any

Setting
- Any, including single- and multicenter

Design
- RCTs, N≥10 per group
- NRCSs, N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- Exclude: case reports and series of individually reported case reports

Key Question 4 (Anatomic Plane of Implant Placement)

Population(s)
- Adult (≥18 years old) women who are undergoing (or have undergone) mastectomy for any type of breast cancer (or carcinoma in situ) and have decided to undergo IBR
- Either therapeutic or prophylactic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions
- IBR with implant placement in one anatomic plane
  - Prepectoral placement
  - Partial submuscular placement
  - Total submuscular placement

  - Either single- or multi-stage
  - Any type of implant material, either smooth or textured
  - With or without use of human ADM
  - With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
  - With or without symmetry procedure (e.g., mastopexy) in the contralateral breast

Comparators

- IBR with implant placement in a different anatomic plane

Outcomes (* denotes important outcomes that were used when developing Strength of Evidence tables)

- Clinical outcomes
  - General quality of life*
  - Physical well-being (e.g., pain, discomfort)*
  - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
  - Sexual well-being*
  - Patient satisfaction with breast*
  - Patient satisfaction with outcome (e.g., satisfaction with care)*
  - Planned surgeries for reconstruction*
  - Recurrence of breast cancer
  - Mortality*
- Surgical complications
  - Unplanned repeat hospitalization*
  - Duration of unplanned repeat hospitalization*
  - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
  - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
  - Pain, including chronic pain*
  - Analgesic (e.g., opioid) use*
  - Necrosis, such as of the nipple*
  - Animation deformity*
  - Implant-related infections*
  - Implant rupture, including asymptomatic rupture*
  - Implant deflation*
  - Implant malposition*
  - Implant failure/loss or need for explant surgery*
  - Capsular contracture*
  - New neoplasms (e.g., BIA-ALCL)*
  - Complications that cause delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
  - Thromboembolic events*
  - Infections not explicitly implant-related*
  - Wound dehiscence
  - Delayed healing
  - Seroma*
  - Chronic conditions (e.g., rheumatologic diseases)*
  - Touch sensitivity
  - Scarring
  - Red breast syndrome

Potential Effect Modifiers

- Age
- Stage of breast cancer

- First occurrence versus recurrent breast cancer
- Immediate versus delayed reconstruction
- Single-stage (direct to reconstruction) versus multistage (with tissue expander) reconstruction
- Unilateral versus bilateral reconstruction
- Surface of implant (smooth versus textured)
- Shape of implant (round versus anatomic/teardrop)
- Size of implant (volume)

Timing
- Any

Setting
- Any, including single- and multicenter

Design
- RCTs, N≥10 per group
- NRCSs, N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- Exclude: case reports and series of individually reported case reports

Key Question 5 (Use of Human ADM)

Population(s)
- Adult (≥18 years old) women who are undergoing (or have undergone mastectomy) for any type of breast cancer (or carcinoma in situ) and have decided to undergo IBR
- Either therapeutic or prophylactic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions
- IBR with use of human ADM
  - Either single- or multistage
  - Any anatomic plane of implant placement
  - Any type of implant material, either smooth or textured
  - With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
  - With or without symmetry procedure (e.g., mastopexy) in the contralateral breast

Comparators
- IBR without use of human or nonhuman ADM

Outcomes (* denotes important outcomes that were used when developing Strength of Evidence tables)

- Clinical outcomes
  - General quality of life*
  - Physical well-being (e.g., pain, discomfort)*
  - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
  - Sexual well-being*
  - Patient satisfaction with breast*
  - Patient satisfaction with outcome (e.g., satisfaction with care)*
  - Planned surgeries for reconstruction*
  - Recurrence of breast cancer
  - Mortality*
- Surgical complications
  - Unplanned repeat hospitalization*
  - Duration of unplanned repeat hospitalization*
  - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
  - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
  - Pain, including chronic pain*
  - Analgesic (e.g., opioid) use*
  - Necrosis, such as of the nipple*
  - Animation deformity*
  - Implant-related infections*
  - Implant rupture, including asymptomatic rupture*
  - Implant deflation*
  - Implant malposition*
  - Implant failure/loss or need for explant surgery*
  - Capsular contracture*
  - New neoplasms (e.g., BIA-ALCL)*
  - Complications that cause delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
  - Thromboembolic events*
  - Infections*
  - Wound dehiscence*
  - Delayed healing*
  - Seroma*
  - Chronic conditions (e.g., rheumatologic diseases)
  - Touch sensitivity
  - Scarring
  - Red breast syndrome

Potential Effect Modifiers

- Age
- Stage of breast cancer
- First occurrence versus recurrent breast cancer
- Immediate versus delayed reconstruction

- Single-stage (direct to reconstruction) versus multi-stage (with tissue expander) reconstruction
- Unilateral versus bilateral reconstruction
- Anatomic plane of implant placement (prepectoral versus partial submuscular versus total submusclar)
- Surface of implant (smooth versus textured)
- Shape of implant (round versus anatomic/teardrop)
- Size of implant (volume)
- Brand of human ADM (e.g., Alloderm®, FlexHD®, BellaDerm®, AlloMax®, Cortiva®, DermACELL®)

Timing
- Any

Setting
- Any, including single- and multicenter

Design
- RCTs, N≥10 per group
- NRCSs, N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective
- Exclude: case reports and series of individually reported case reports

Key Question 6 (Different Flap Types for AR)

Population(s)
- Adult (≥18 years old) women who are undergoing (or have undergone mastectomy) for any type of breast cancer (or carcinoma in situ) and have decided to undergo AR
- Either therapeutic or prophylactic mastectomy
- Exclude: Studies where ≥10% of women underwent breast reconstruction (combined across reasons):
  - for solely cosmetic purposes (i.e., augmentation)
  - for revision reconstruction (i.e., after a previous reconstruction for breast cancer)

Interventions
- AR using one flap (either free flap or pedicled), for example:
  - Deep inferior epigastric perforator (DIEP)
  - Latissimus dorsi (LD)
  - Transverse rectus abdominis myocutaneous (TRAM)
  - Superficial inferior epigastric artery perforator (SIEA)
  - Gluteal artery perforator (GAP)
  - Transverse musculocutaneous gracilis (TMG)
  - Transverse upper gracilis (TUG)

- Profunda artery perforator (PAP)
- Superior gluteal artery perforator (SGAP)

- With or without mastectomy and reconstruction of the contralateral breast (i.e., unilateral or bilateral)
- With or without symmetry procedure (e.g., mastopexy) in the contralateral breast
- Exclude: Non-autologous flap transplants (i.e., cadaveric or xenotransplant)
- Exclude: Exclusive lipofilling/autologous fat reconstruction

Comparators

- AR using a different flap (either free flap or pedicled)
- Combination of IBR and AR
- Exclude: Non-autologous flap transplants (i.e., cadaveric or xenotransplant)
- Exclude: Exclusive lipofilling/autologous fat reconstruction

Outcomes (* denotes important outcomes that were used when developing Strength of Evidence tables)

- Clinical outcomes
  - General quality of life*
  - Physical well-being (e.g., pain, discomfort)*
  - Psychosocial well-being (e.g., self-esteem, emotionality, normality)*
  - Sexual well-being*
  - Patient satisfaction with breast*
  - Patient satisfaction with outcome (e.g., satisfaction with care)*
  - Planned surgeries for reconstruction*
  - Recurrence of breast cancer
  - Duration of initial hospitalization*
  - Mortality*
- Surgical complications
  - Unplanned repeat hospitalization*
  - Duration of unplanned repeat hospitalization*
  - Unplanned repeat surgeries – for revision of reconstruction (e.g., for asymmetry)*
  - Unplanned repeat surgeries – for complications (e.g., for infection, bleeding)*
  - Pain, including chronic pain*
  - Analgesic (e.g., opioid) use*
  - Necrosis, such as of the nipple or of the flap*
  - Harms to area of flap harvest (e.g., hernia, bulge formation)*
  - Complications that lead to delays in other cancer-related treatments (e.g., chemotherapy, radiation therapy)*
  - Thromboembolic events*
  - Infections*
  - Wound dehiscence*
  - Delayed healing*
  - Seroma*
  - Touch sensitivity
  - Scarring

- Flap failure/loss

Potential Effect Modifiers

- Age
- Stage of breast cancer
- First occurrence versus recurrent breast cancer
- Immediate versus delayed reconstruction
- Single-stage (direct to reconstruction) versus multi-stage (with tissue expander) reconstruction
- Unilateral versus bilateral reconstruction

Timing

- Any

Setting

- Any, including single- and multicenter

Design

- RCTs, N≥10 per group
- NRCSs, N≥30 per group, provided adjusted analyses
- Case-control studies, N≥100 per group
- Single group studies, N≥500
- Studies may be prospective or retrospective

Exclude: case reports and series of individually reported case reports

Screening Process

Citations from all searches were deduplicated and then entered into abstrackr software (http://abstrackr.cebm.brown.edu/) to enable title and abstract screening. The team conducted three rounds of pilot screening. During each pilot round, we all screened the same 100 abstracts and discuss conflicts, with the goal of training the team in the nuances of the eligibility criteria and refining them as needed. After the pilot rounds, we screened all remaining abstracts in duplicate. The abstrackr software has machine learning capabilities that predict the likelihood of relevance of each citation. Daily, the list of unscreened abstracts was sorted so that the most potentially relevant articles were presented first. This process made screening more efficient and enabled us to capture the large majority of relevant articles relatively early in the abstract screening process.

Based on empirical research on abstrackr (that is soon to be submitted for publication), we switched to single screening of remaining abstracts once *both* of the following criteria were fulfilled: (1) all remaining unscreened abstracts had a prediction value less than 0.40 (on a scale of 0 to 1), and (2) no eligible citations were identified in a consecutive sample of 400 abstracts (this threshold for number of abstracts was chosen because it comfortably exceeds 370 abstracts, which is the threshold above which the upper 97.5% confidence interval bound for a proportion of irrelevant abstracts [i.e., 0/370] is less than 1%). The empirical research suggests that at this threshold, all remaining abstracts would have been rejected.

Potentially relevant citations were retrieved in full text. These articles were rescreened in duplicate.

Data Extraction and Data Management (Details)

We extracted data from eligible primary studies into the Systematic Review Data Repository-Plus (https://srdrplus.ahrq.gov). For each study, one researcher extracted and entered data, which were confirmed by a second, independent researcher. Each individual study that was reported in multiple articles was extracted as a single record. In the instance where two studies were reported within a single article, each study was extracted separately.

For each study, we extracted article-identifying information, study design features, funding source, population characteristics and sample sizes, intervention and comparator names and descriptions, and relevant clinical outcomes and surgical complication outcomes and their definitions.

Assessing Applicability

For each KQ (or specific subquestion), we assessed the applicability of the included studies primarily based on the studies' eligibility criteria and their included participants, specifically related to such factors as age, type of breast cancer, and first occurrence versus recurrent breast cancer. These were qualitatively compared with typical distributions of these factors among patients undergoing breast reconstruction in the U.S.

Addressing the Contextual Questions

Based on data and input garnered during our systematic review of the KQs, we answered the Contextual Questions in a narrative format. We did not systematically extract or review eligible studies, create summary tables, or assess the strength of evidence for the Contextual Questions.

Peer Review and Public Commentary

Experts in plastic surgery, breast surgical oncology, medical oncology, radiation oncology, national policy, clinical practice guidelines, and individuals representing stakeholder and user communities are being invited to provide external peer review of this SR. AHRQ and an Associate Editor from a fellow Evidence-based Practice Center were invited to provide comments. The draft report was posted on the AHRQ Website to elicit public comment for a period of 4 weeks. We addressed all reviewer and public comments, revising the text as appropriate. A disposition of comments table of peer and public comments is posted on the EHC Website.

Abbreviations

ADM	acellular dermal matrix
AHRQ	Agency for Healthcare Research and Quality
AR	autologous reconstruction
ASPS	American Society of Plastic Surgeons
BIA-ALCL	breast implant-associated anaplastic large cell lymphoma
BMI	body mass index
BPI-SF	Brief Pain Inventory-Short Form
CI	confidence interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COI	conflicts of interest

DASH	Disabilities of the Arm, Should, and Hand
DIEP	deep inferior epigastric perforator
DVT	deep vein thrombosis
EHC	Effective Health Care Program
EORTC QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30
EPC	Evidence-based Practice Center
FACT-B	Functional Assessment of Cancer Therapy
FDA	Food and Drug Administration
GAP	gluteal artery perforator
HR	hazard ratio
IBR	implant-based reconstruction
KI	Key Informant
KQ	Key Question
LD	latissimus dorsi
LTD	lateral thoracodorsal
MCID	minimal clinically important difference
MD	mean difference
MeSH	medical subject heading
MPQ-SF	McGill Pain Questionnaire Short Form
NHLBI	National Heart, Lung, and Blood Institute
NLM	National Library of Medicine
NMD	net mean difference
NRCS	nonrandomized comparative study
OR	odds ratio
PAP	profundal artery perforator
PE	pulmonary embolism
PMID	PubMed identifier
PMRT	postmastectomy radiation therapy
PROMIS	Patient-Reported Outcomes Measurement Information System
RCT	randomized controlled trial
RoB	risk of bias
ROBINS-I	Risk of Bias in Nonrandomized Studies of Interventions
RR	relative risk
SD	standard deviation
SE	standard error
SF-36	Short Form-36
SGAP	superior gluteal artery perforator
SIEA	superficial inferior epigastric artery perforator
SoE	strength of evidence
SR	systematic review
SRDR+	Systematic Review Data Repository Plus
TAP	thoracodorsal artery perforator
TEP	Technical Expert Panel
TMG	transverse musculocutaneous gracilis
TOO	Task Order Officer

TRAM	transverse rectus abdominis myocutaneous
TUG	transverse upper gracilis
U.K.	United Kingdom
U.S.	United States
VAS	Visual Analog Scale

Appendix B. List of Excluded Studies

The 1,050 excluded articles, along with reasons for exclusion, are summarized in Appendix Table B-1. The most common reasons for exclusion were that the articles did not address any Key Question (n=313 articles), described nonrandomized comparative studies without adequate adjustment (n=234 articles), or described Single group studies with fewer than 500 participants (n=187 articles).

Table B-1. Excluded primary studies with reasons for exclusion

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1	31772899	Abdelrahman	Oncoplastic Volume Replacement for Breast Cancer: Latissimus Dorsi Flap versus Thoracodorsal Artery Perforator Flap	*Plast Reconstr Surg Glob Open*	Not mastectomy for breast cancer
2	25133469	Abt	Neoadjuvant chemotherapy and short-term morbidity in patients undergoing mastectomy with and without breast reconstruction	*JAMA Surg*	Does not address KQ1-KQ6
3	32162180	Adachi	Effects of neoadjuvant chemotherapy on operative adverse events and chemotherapy and radiotherapy in patients undergoing immediate breast reconstruction	*Breast Cancer*	Does not address KQ1-KQ6
4	20584583	Adesiyun	Impact of sequencing of postmastectomy radiotherapy and breast reconstruction on timing and rate of complications and patient satisfaction	*Int J Radiat Oncol Biol Phys*	NRCS not adjusted
5	22156884	Adetayo	A Meta-analysis of Outcomes Using Acellular Dermal Matrix in Breast and Abdominal Wall Reconstructions: Event Rates and Risk Factors Predictive of Complications	*Ann Plast Surg*	Narrative review/ Commentary
6	22487264	Agarwal	A population-based study of breast cancer-specific survival following mastectomy and immediate or early-delayed breast reconstruction	*Breast J*	Single group >500, but no complications data
7	20604794	Agarwal	Survival in breast cancer patients undergoing immediate breast reconstruction	*Breast J*	Does not address KQ1-KQ6
8	24119787	Agrawal	Surgical and oncological outcome after skin-sparing mastectomy and immediate breast reconstruction	*Clin Breast Cancer*	Single group N enrolled <500
9	107920554	Agrawal	Surgical and oncological outcome after skin-sparing mastectomy and immediate breast reconstruction	*Clinical Breast Cancer*	Single group N enrolled <500
10	28582783	Akita	Contribution of Simultaneous Breast Reconstruction by Deep Inferior Epigastric Artery Perforator Flap to the Efficacy of Vascularized Lymph Node Transfer in Patients with Breast Cancer-Related Lymphedema	*J Reconstr Microsurg*	NRCS <30 per arm
11	31810892	Akyurek	Two-stage prosthetic breast reconstruction with latissimus flap: Prepectoral versus subpectoral approach	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
12	26208580	Al-Hilli	Reoperation for Complications after Lumpectomy and Mastectomy for Breast Cancer from the 2012 National Surgical Quality Improvement Program (ACS-NSQIP)	*Ann Surg Oncol*	Does not address KQ1-KQ6
13	CN-01984885	Alamouti	Multidisciplinary management of risk-reducing mastectomy and immediate reconstruction: treatment algorithm and patient satisfaction	*European journal of plastic surgery*	NRCS <30 per arm
14	31645075	Alba	Postoperative Upper Extremity Function in Implant and Autologous Breast Reconstruction	*J Reconstr Microsurg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
15	23271515	Albornoz	A paradigm shift in U.S. Breast reconstruction: increasing implant rates	*Plast Reconstr Surg*	Not breast reconstruction
16	25158715	Albornoz	Diminishing relative contraindications for immediate breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
17	25159019	Albornoz	Diminishing relative contraindications for immediate breast reconstruction: a multicenter study	*J Am Coll Surg*	Does not address KQ1-KQ6
18	17189107	Alderman	Does patient satisfaction with breast reconstruction change over time? Two-year results of the Michigan Breast Reconstruction Outcomes Study	*J Am Coll Surg*	Single group N enrolled <500
19	16772906	Alderman	A two-year prospective analysis of trunk function in TRAM breast reconstructions	*Plastic and Reconstructive Surgery*	No outcome of interest
20	12045548	Alderman	Complications in postmastectomy breast reconstruction: two-year results of the Michigan Breast Reconstruction Outcome Study	*Plast Reconstr Surg*	NRCS not adjusted
21	33526361	Aliotta	A controlled cost and outcomes analysis of acellular dermal matrix and implant-based reconstruction	J Plast Reconstr Aesthet Surg	NRCS not adjusted
22	32201323	Allan	The effect of operative time on complication profile and length of hospital stay in autologous and implant-based breast reconstruction patients: An analysis of the 2007-2012 ACS-NSQIP database	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
23	30545644	Allue Cabanuz	Influence of radiotherapy on immediate breast reconstruction after skin-sparing mastectomy. Before or after: Does it matter?	*Cir Esp*	NRCS not adjusted
24	19121986	Alonso-Burgos	Preoperative planning of DIEP and SGAP flaps: preliminary experience with magnetic resonance angiography using 3-tesla equipment and blood-pool contrast medium	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
25	30899456	Alshammari	Patient-reported outcomes after breast reconstructive surgery: A prospective cross-sectional study	*Ann Med Surg (Lond)*	NRCS <30 per arm
26	104823788	Anavekar	Achieving autologous breast reconstruction for breast cancer patients in the setting of post-mastectomy radiotherapy	*Journal of Cancer Survivorship*	Narrative review/ Commentary
27	32190584	Anbiyaiee	Breast Reconstruction after Mastectomy in Women with Breast Cancer: A Systematic and Meta-Analysis Review	*World J Plast Surg*	Does not address KQ1-KQ6
28	15234042	Anderson	Low complication rates are achievable after postmastectomy breast reconstruction and radiation therapy	*Int J Radiat Oncol Biol Phys*	NRCS not adjusted
29	15234042	Anderson	Low complication rates are achievable after postmastectomy breast reconstruction and radiation therapy	*International Journal of Radiation Oncology Biology Physics*	NRCS not adjusted
30	23770544	Andree	A single center prospective study of bilateral breast reconstruction with free abdominal flaps: A critical analyses of 144 patients	*Medical Science Monitor*	>=10% revision reconstruction only
31	23197233	Andree	Skin-sparing mastectomy and immediate reconstruction with DIEP flap after breast-conserving therapy	*Medical Science Monitor*	Duplicate of another publication

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
32	31526955	Angarita	Does timing of alloplastic breast reconstruction in older women impact immediate postoperative complications? An analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database	*Breast*	Does not address KQ1-KQ6
33	31154580	Angarita	Is immediate breast reconstruction safe in women over 70? An analysis of the National Surgical Quality Improvement Program (NSQIP) database	*Breast Cancer Res Treat*	Copublication of included study with no new data
34	32449079	Angarita	Does oncoplastic surgery increase immediate (30-day) postoperative complications? An analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database	Breast Cancer Res Treat	Does not address KQ1-KQ6
35	29660924	Anker	Vasopressor support vs. liberal fluid administration in deep inferior epigastric perforator (DIEP) free flap breast reconstruction - a randomized controlled trial	*Clin Hemorheol Microcirc*	Does not address KQ1-KQ6
36	31468214	Anker	Assessment of DIEP Flap Perfusion with Intraoperative Indocyanine Green Fluorescence Imaging in Vasopressor-Dominated Hemodynamic Support Versus Liberal Fluid Administration: A Randomized Controlled Trial With Breast Cancer Patients	*Ann Surg Oncol*	Single group N enrolled <500
37	31738381	Anna Loch-Wilkinson	Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia: A Longitudinal Study of Implant and Other Related Risk Factors	*Aesthet Surg J*	Single group N enrolled <500
38	28628501	Arikawa	Comparison of Donor Site Drainage Duration and Seroma Rate Between Latissimus Dorsi Musculocutaneous Flaps and Thoracodorsal Artery Perforator Flaps	*Ann Plast Surg*	NRCS not adjusted
39	27229369	Armstrong	Determinants of increased acute postoperative pain after autologous breast reconstruction within an enhanced recovery after surgery protocol: A prospective cohort study	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
40	23582505	Arya	Post-operative assessment of perfusion of Deep Inferior Epigastric Perforator (DIEP) free flaps via Pulsatility Index (PI) using a portable colour Doppler sonogram device	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
41	32803638	Asaad	The impact of co-surgeons on complication rates and healthcare cost in patients undergoing microsurgical breast reconstruction: analysis of 8680 patients	Breast Cancer Research and Treatment	Does not address KQ1-KQ6
42	24756811	Ashfaq	Impact of breast reconstruction on the decision to undergo contralateral prophylactic mastectomy	*Ann Surg Oncol*	Single group >500, but no complications data
43	23706394	Ashraf	Patient involvement in the decision-making process improves satisfaction and quality of life in postmastectomy breast reconstruction	*Journal of Surgical Research*	Does not address KQ1-KQ6
44	19593108	Atisha	A systematic review of abdominal wall function following abdominal flaps for postmastectomy breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
45	18520874	Atisha	The impact of obesity on patient satisfaction with breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
46	25465378	Atisha	A national snapshot of satisfaction with breast cancer procedures	*Ann Surg Oncol*	Does not address KQ1-KQ6
47	30589826	Atisha	A National Snapshot of Patient-Reported Outcomes Comparing Types of Abdominal Flaps for Breast Reconstruction	*Plast Reconstr Surg*	Single group >500, but no complications data

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
48	8197555	August	Breast reconstruction in older women	*Surgery*	Unable to retrieve article
49	30892486	Augustinho	Patient satisfaction with breast reconstruction using musculocutaneous flap from latissimus dorsi versus from rectus abdominis: A cross-sectional study	*Sao Paulo Medical Journal*	Duplicate of another publication
50	None	Augustinho	Patient satisfaction with breast reconstructionusing musculocutaneous flap from latissimus dorsiversus from rectus abdominis: a cross-sectional study	*Sao Paulo Med J*	NRCS not adjusted
51	26132336	Avraham	Postoperative Expansion is not a Primary Cause of Infection in Immediate Breast Reconstruction with Tissue Expanders	*Breast J*	Does not address KQ1-KQ6
52	32718111	Azizi	Does surgical procedure type impact postoperative pain and recovery in deep inferior epigastric artery perforator flap breast reconstruction?	Arch Plast Surg	Single group N enrolled <500
53	28522026	Babin	[Breast reconstruction in elderly patients: Studies of the practices at institut Bergonie during 2005-2015]	*Bull Cancer*	Single group N enrolled <500
54	25396188	Baek	A retrospective analysis of ruptured breast implants	*Arch Plast Surg*	NRCS <30 per arm
55	16525258	Bajaj	Comparison of donor-site complications and functional outcomes in free muscle-sparing TRAM flap and free DIEP flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
56	29697602	Baker	A Prospective Comparison of Short-Term Outcomes of Subpectoral and Prepectoral Strattice-Based Immediate Breast Reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
57	33051937	Baker	The impact of axillary node surgery on outcomes following immediate breast reconstruction	Breast J	NRCS not adjusted
58	27219260	Baldelli	Implant-Based Breast Reconstruction Using a Polyester Mesh (Surgimesh-PET): A Retrospective Single-Center Study	*Plast Reconstr Surg*	Does not address KQ1-KQ6
59	26550776	Balk	Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: A Systematic Review	*Ann Intern Med*	Not mastectomy for breast cancer
60	28458959	Baltodano	Preoperative Radiotherapy Is Not Associated with Increased Post-mastectomy Short-term Morbidity: Analysis of 77,902 Patients	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
61	32842096	Baltodano	Early Discontinuation of Breast Free Flap Monitoring: A Strategy Driven by National Data	Plast Reconstr Surg	Does not address KQ1-KQ6
62	24091489	Bank	Economic analysis and review of the literature on implant-based breast reconstruction with and without the use of the acellular dermal matrix	*Aesthetic Plast Surg*	NRCS <30 per arm
63	31513083	Banuelos	Microbiology of Implant-Based Breast Reconstruction Infections: A Systematic Review	*Ann Plast Surg*	Does not address KQ1-KQ6
64	31663932	Banuelos	The American College of Surgeons National Quality Improvement Program Incompletely Captures Implant-Based Breast Reconstruction Complications	Annals of plastic surgery	Duplicate of another publication
65	21336948	Barry	Radiotherapy and breast reconstruction: a meta-analysis	*Breast Cancer Res Treat*	Narrative review/ Commentary
66	29452438	Bartlett	Algorithmic Approach for Intraoperative Salvage of Venous Congestion in DIEP Flaps	*J Reconstr Microsurg*	Single group N enrolled <500
67	26218386	Basta	A Propensity-Matched Analysis of the Influence of Breast Reconstruction on Subsequent Development of Lymphedema	*Plast Reconstr Surg*	No outcome of interest
68	26595013	Basta	A Systematic Review and Head-to-Head Meta-Analysis of Outcomes following Direct-to-Implant versus Conventional Two-Stage Implant Reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
69	31650347	Batenburg	Patient-reported cosmetic satisfaction and the long-term association with quality of life in irradiated breast cancer patients	*Breast Cancer Res Treat*	Single group N enrolled <500
70	28743179	Becherer	Prevalence of psychiatric comorbidities among women undergoing free tissue autologous breast reconstruction	*J Surg Oncol*	Does not address KQ1-KQ6
71	18843123	Beier	Breast reconstruction after breast-cancer surgery...N Engl J Med. 2008 Oct 9;359(15):1590-601	*New England Journal of Medicine*	Narrative review/ Commentary
72	None	Beier	Human Acellular Dermal Matrix (Epiflex®) in Immediate Implant-Based Breast Reconstruction after Skin- A nd Nipple-Sparing Mastectomy and Treatment of Capsular Fibrosis: Results of a Multicenter, Prospective, Observational NOGGO-AWOGyn Study	Breast Care	Single group N enrolled <500
73	10783510	Benadiba	[Survivorship of breast implants used in breast reconstruction. 949 implants]	*Ann Chir Plast Esthet*	Unable to retrieve article
74	None	Bence	Assessing the needs of Hungarian breast cancer patients for modern oncoplastic breast surgical treatment: Questionnaire study of 500 patients	Orvosi Hetilap	Unable to retrieve article
75	30003763	Benderli Cihan	The role of radiotherapy following mastectomy and reconstruction	*J buon*	Narrative review/ Commentary
76	24737845	Benditte-Klepetko	Analysis of patient satisfaction and donor-site morbidity after different types of breast reconstruction	*Scand J Surg*	NRCS <30 per arm
77	18090813	Bengtson	Style 410 highly cohesive silicone breast implant core study results at 3 years	*Plast Reconstr Surg*	NRCS not adjusted
78	28658472	Bennett	Association of Fat Grafting With Patient-Reported Outcomes in Postmastectomy Breast Reconstruction	*JAMA Surg*	Does not address KQ1-KQ6
79	29506826	Berlin	Nonresponse bias in survey research: lessons from a prospective study of breast reconstruction	*J Surg Res*	Does not address KQ1-KQ6
80	28215963	Berlin	Racial and ethnic variations in one-year clinical and patient-reported outcomes following breast reconstruction	*Am J Surg*	Does not address KQ1-KQ6
81	29489482	Berlin	Hospital Variations in Clinical Complications and Patient-reported Outcomes at 2 Years After Immediate Breast Reconstruction	*Ann Surg*	Does not address KQ1-KQ6
82	20853034	Berry	Complication rates of radiation on tissue expander and autologous tissue breast reconstruction	*Ann Surg Oncol*	No outcome of interest
83	28918997	Berthet	Tolerance of latissimus dorsi in immediate breast reconstruction without implant to radiotherapy	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
84	28831365	Bettinger	Comparative Study of Prepectoral and Subpectoral Expander-Based Breast Reconstruction and Clavien IIIb Score Outcomes	*Plast Reconstr Surg Glob Open*	Single group N enrolled <500
85	29399731	Beugels	Complications following immediate compared to delayed deep inferior epigastric artery perforator flap breast reconstructions	*Breast Cancer Research and Treatment*	Duplicate of another publication
86	30247195	Beugels	Quality of Life of Patients After Immediate or Delayed Autologous Breast Reconstruction: A Multicenter Study	*Annals of plastic surgery*	Duplicate of another publication
87	31030303	Beugels	The influence of neoadjuvant chemotherapy on complications of immediate DIEP flap breast reconstructions	*Breast Cancer Res Treat*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
88	27449746	Beugels	Reply to the Letter to the Editor by Wade et al. 'The importance of the Unit of Analysis'. Commentary on: Beugels J et al. Complications in unilateral versus bilateral deep inferior epigastric artery perforator flap breast reconstructions: A multicentre study	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
89	19634163	Bezuhly	Immediate postmastectomy reconstruction is associated with improved breast cancer-specific survival: Evidence and new challenges from the surveillance, epidemiology, and end results database	*Cancer*	Duplicate of another publication
90	19634163	Bezuhly	Immediate postmastectomy reconstruction is associated with improved breast cancer-specific survival: evidence and new challenges from the Surveillance, Epidemiology, and End Results database	*Cancer*	Does not address KQ1-KQ6
91	28198770	Billig	Should Immediate Autologous Breast Reconstruction Be Considered in Women Who Require Postmastectomy Radiation Therapy? A Prospective Analysis of Outcomes	*Plast Reconstr Surg*	Single group N enrolled <500
92	28724133	Billig	A Nationwide Analysis of Cost Variation for Autologous Free Flap Breast Reconstruction	*JAMA Surg*	Single group >500, but no complications data
93	27286854	Billner	Poly Implant Prothese and Rofil Substandard Breast Implant Explantations from a Large German Single Centre from 2011 to 2014: A Comparative Study	*Aesthetic Plast Surg*	Single group N enrolled <500
94	28676319	Billon	Impact of adjuvant anti-estrogen therapies (tamoxifen and aromatase inhibitors) on perioperative outcomes of breast reconstruction	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
95	None	Bjelic-Radisic	Short-term outcome and complications rate after immediate breast reconstruction with implants and acellular dermis	European Journal of Cancer	Single group N enrolled <500
96	28185324	Blackburn	The musculoskeletal consequences of breast reconstruction using the latissimus dorsi muscle for women following mastectomy for breast cancer: A critical review	*Eur J Cancer Care (Engl)*	Does not address KQ1-KQ6
97	32557451	Blankensteijn	Racial Disparities in Outcomes of Reconstructive Breast Surgery: An Analysis of 51,362 Patients from the ACS-NSQIP	J Reconstr Microsurg	NRCS not adjusted
98	9583482	Blomqvist	The inflammatory reaction in elective flap surgery	*Plast Reconstr Surg*	NRCS <30 per arm
99	9245865	Blondeel	The donor site morbidity of free DIEP flaps and free TRAM flaps for breast reconstruction	*Br J Plast Surg*	NRCS not adjusted
100	10343589	Blondeel	Sensory nerve repair in perforator flaps for autologous breast reconstruction: sensational or senseless?	*Br J Plast Surg*	NRCS not adjusted
101	25382588	Bodin	Venous coupler use for free-flap breast reconstructions: specific analyses of TMG and DIEP flaps	*Microsurgery*	NRCS <30 per arm
102	32434696	Boehm	Increasing abdominal wall thickness predicts complications in abdominally based breast reconstruction: A review of 106 consecutive patients	J Plast Reconstr Aesthet Surg	Single group N enrolled <500
103	10826338	Boikov	[Reconstructive surgery after mastectomy--the anatomical prerequisites]	*Akush Ginekol (Sofiia)*	Unable to retrieve article
104	22395320	Bonomi	Current indications for and comparative analysis of three different types of latissimus dorsi flaps	*Aesthet Surg J*	Single group N enrolled <500
105	28766231	Boughey	Contralateral Prophylactic Mastectomy with Immediate Breast Reconstruction Increases Healthcare Utilization and Cost	*Ann Surg Oncol*	No outcome of interest

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
106	19483561	Boyd	Comparison of superior gluteal artery musculocutaneous and superior gluteal artery perforator flaps for microvascular breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
107	31083604	Brandon	New Evaluation Procedure for Multi-Dimensional Mechanical Strains and Tangent Moduli of Breast Implants: IDEAL IMPLANT((R)) Structured Breast Implant Compared to Silicone Gel Implants	*Bioengineering (Basel)*	Not breast reconstruction
108	32699924	Braun	Do Nipple Necrosis Rates Differ in Prepectoral Versus Submuscular Implant-Based Reconstruction After Nipple-Sparing Mastectomy?	Ann Surg Oncol	NRCS not adjusted
109	28513834	Browne	The association between complications and quality of life after mastectomy and breast reconstruction for breast cancer	*Cancer*	Does not address KQ1-KQ6
110	28958570	Browne	Measuring the patient perspective on latissimus dorsi donor site outcomes following breast reconstruction	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
111	125841979	Browne	The association between complications and quality of life after mastectomy and breast reconstruction for breast cancer	*Cancer (0008543X)*	Duplicate of another publication
112	28701264	Buckley	Impact of rural-urban status on survival after mastectomy without reconstruction versus mastectomy with reconstruction	*Am J Surg*	Does not address KQ1-KQ6
113	28634720	Bucknor	The financial impact and drivers of hospital charges in contralateral prophylactic mastectomy and reconstruction: a Nationwide Inpatient Sample hospital analysis	*Breast Cancer Res Treat*	Single group >500, but no complications data
114	23542856	Buseman	Comparison of sterile versus nonsterile acellular dermal matrices for breast reconstruction	*Ann Plast Surg*	NRCS <30 per arm
115	25576165	Butler	African-American women have equivalent outcomes following autologous free flap breast reconstruction despite greater preoperative risk factors	*Am J Surg*	Copublication of included study with no new data
116	26545345	Butler	Racial and age disparities persist in immediate breast reconstruction: an updated analysis of 48,564 patients from the 2005 to 2011 American College of Surgeons National Surgery Quality Improvement Program data sets	*Am J Surg*	Does not address KQ1-KQ6
117	25626808	Butz	Advanced age is a predictor of 30-day complications after autologous but not implant-based postmastectomy breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
118	16490892	Byung	Changing patterns in the clinical characteristics of Korean patients with breast cancer during the last 15 years	*Archives of Surgery*	Single group N enrolled <500
119	27047784	Cabalag	Alloplastic adjuncts in breast reconstruction	*Gland Surg*	Does not address KQ1-KQ6
120	31079136	Cai	Autologous Breast Reconstruction with Transverse Rectus Abdominis Musculocutaneous (TRAM) or Deep Inferior Epigastric Perforator (DIEP) Flaps: An Analysis of the 100 Most Cited Articles	*Med Sci Monit*	Narrative review/ Commentary
121	32149849	Cai	National Trends in Hospitalization Charges for Autologous Free Flap Breast Reconstruction	*Ann Plast Surg*	Single group >500, but no complications data
122	29595713	Calobrace	Introduction to 'Sientra Shaped and Round Cohesive Gel Implants: Long-Term Safety Outcomes'	*Plast Reconstr Surg*	Narrative review/ Commentary
123	25158767	Caplin	Indications for the use of MemoryShape breast implants in aesthetic and reconstructive breast surgery: long-term clinical outcomes of shaped versus round silicone breast implants	*Plast Reconstr Surg*	Not breast reconstruction

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
124	33308993	Caputo	Quality of Life and Early Functional Evaluation in Direct-to-Implant Breast Reconstruction After Mastectomy: A Comparative Study Between Prepectoral Versus Dual-Plane Reconstruction	Clin Breast Cancer	NRCS not adjusted
125	11293510	Carlson	Results of immediate breast reconstruction after skin-sparing mastectomy	*Ann Plast Surg*	NRCS not adjusted
126	18434833	Carlson	Effects of radiation therapy on pedicled transverse rectus abdominis myocutaneous flap breast reconstruction	*Ann Plast Surg*	NRCS <30 per arm
127	12620903	Carlson	Local recurrence after skin-sparing mastectomy: Tumor biology or surgical conservatism?	*Annals of Surgical Oncology*	Single group >500, but no complications data
128	14998566	Carlson	The use of skin sparing mastectomy in the treatment of breast cancer: The Emory experience	*Surg Oncol*	Not breast reconstruction
129	30656095	Carminati	Immediate Implant-based Breast Reconstruction with Acellular Dermal Matrix Compared with Tissue-expander Breast Reconstruction: Rate of Infection	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
130	27406093	Carter	Operative and Oncologic Outcomes in 9861 Patients with Operable Breast Cancer: Single-Institution Analysis of Breast Conservation with Oncoplastic Reconstruction	*Ann Surg Oncol*	Does not address KQ1-KQ6
131	27600636	Casella	Current trends and outcomes of breast reconstruction following nipple-sparing mastectomy: results from a national multicentric registry with 1006 cases over a 6-year period	Breast Cancer	Single group >500, but no complications data
132	25339795	Casella	TiLoop® Bra mesh used for immediate breast reconstruction: comparison of retropectoral and subcutaneous implant placement in a prospective single-institution series	*European journal of plastic surgery*	NRCS <30 per arm
133	25339795	Casella	TiLoop® Bra mesh used for immediate breast reconstruction: comparison of retropectoral and subcutaneous implant placement in a prospective single-institution series	*European Journal of Plastic Surgery*	Duplicate of another publication
134	22941163	Casey	Etiology of breast masses after autologous breast reconstruction	*Ann Surg Oncol*	Single group N enrolled <500
135	29316048	Cassidy	Does response to neo-adjuvant chemotherapy impact breast reconstruction?	*Breast J*	Does not address KQ1-KQ6
136	30507481	Catanuto	Quality of life after breast reconstruction-the BRIOS study	*Lancet Oncology*	Duplicate of another publication
137	29275104	Cattelani	One-Step Prepectoral Breast Reconstruction With Dermal Matrix-Covered Implant Compared to Submuscular Implantation: Functional and Cost Evaluation	*Clin Breast Cancer*	Duplicate of another publication
138	8579262	Cederna	Postmastectomy reconstruction: comparative analysis of the psychosocial, functional, and cosmetic effects of transverse rectus abdominis musculocutaneous flap versus breast implant reconstruction	*Ann Plast Surg*	NRCS <30 per arm
139	31356269	Cerullo	Is Bigger Better?: The Effect of Hospital Consolidation on Index Hospitalization Costs and Outcomes Among Privately Insured Recipients of Immediate Breast Reconstruction	*Ann Surg*	Single group >500, but no complications data
140	24316992	Cha	Patient-reported outcomes following breast reconstruction surgery in a public hospital: use of the Breast-Q questionnaire	*N Z Med J*	NRCS not adjusted
141	32309084	Chan	No-drain Technique in Abdominal Closure for Breast Reconstruction: Lower Complication Rate, Shorter Hospitalization Stay	Plast Reconstr Surg Glob Open	NRCS <30 per arm

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
142	18626350	Chang	Effects of an autologous flap combined with an implant for breast reconstruction: an evaluation of 1000 consecutive reconstructions of previously irradiated breasts	*Plast Reconstr Surg*	NRCS not adjusted
143	20048582	Chang	Breast reconstruction and lymphedema	*Plast Reconstr Surg*	NRCS not adjusted
144	10845289	Chang	Effect of smoking on complications in patients undergoing free TRAM flap breast reconstruction	*Plast Reconstr Surg*	Copublication of included study with no new data
145	10845289	Chang	Effect of smoking on complications in patients undergoing free TRAM flap breast reconstruction	*Plastic and Reconstructive Surgery*	Duplicate of another publication
146	10809092	Chang	Effect of obesity on flap and donor-site complications in free transverse rectus abdominis myocutaneous flap breast reconstruction	*Plastic and Reconstructive Surgery*	Duplicate of another publication
147	25626809	Chang	Challenging a traditional paradigm: 12-year experience with autologous free flap breast reconstruction for inflammatory breast cancer	*Plast Reconstr Surg*	Single group N enrolled <500
148	23123613	Chang	Simultaneous contralateral reduction mammoplasty or mastopexy during unilateral free flap breast reconstruction	*Ann Plast Surg*	Single group N enrolled <500
149	27866726	Chang	Trends in mastectomy and reconstruction for breast cancer; a twelve year experience from a tertiary care center	*Am J Surg*	Single group N enrolled <500
150	132784872	Chang	Influence of Hypofractionated Radiation Therapy Following Mastectomy on Complication in Breast Cancer Patients Undergoing Two-Stage Prosthetic Breast Reconstruction	*International Journal of Radiation Oncology, Biology, Physics*	Single group N enrolled <500
151	15096930	Chang	Reconstruction of complex oncologic chest wall defects: a 10-year experience	*Ann Plast Surg*	Single group N enrolled <500
152	26289806	Chao	Processes of Care in Breast Reconstruction and the Long-Term Impact of a Comprehensive Breast Center	*Ann Surg Oncol*	Does not address KQ1-KQ6
153	CN-01421299	Charton	Time to health-related quality of life score deterioration at 1-year follow-up after immediate latissimus dorsi breast reconstructions: a prospective study in breast cancer	*Quality of life research*	Single group N enrolled <500
154	25719690	Chatterjee	The use of mesh versus primary fascial closure of the abdominal donor site when using a transverse rectus abdominis myocutaneous flap for breast reconstruction: a cost-utility analysis	*Plast Reconstr Surg*	Does not address KQ1-KQ6
155	28833196	Chattha	Comparison of risk factors and complications in patients by stratified mastectomy weight: An institutional review of 1041 consecutive cases	*J Surg Oncol*	Does not address KQ1-KQ6
156	32102003	Chattha	Revisiting the Relationship Between Hospital Case Volume and Outcomes in Abdominally Based Free Flap Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
157	12243831	Chawla	Radiotherapy and breast reconstruction: complications and cosmesis with TRAM versus tissue expander/implant	*Int J Radiat Oncol Biol Phys*	NRCS <30 per arm

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
158	20548236	Chen	Effects of vasopressor administration on the outcomes of microsurgical breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
159	18040176	Chen	Immediate postoperative complications in DIEP versus free/muscle-sparing TRAM flaps	*Plast Reconstr Surg*	NRCS not adjusted
160	30497928	Chen	Immediate Breast Reconstruction in De Novo Metastatic Breast Cancer: An Analysis of 563 Cases Based on the SEER Database	*Clin Breast Cancer*	Does not address KQ1-KQ6
161	29442215	Chen	Meta-analysis for psychological impact of breast reconstruction in patients with breast cancer	*Breast Cancer*	Does not address KQ1-KQ6
162	16128096	Chen	[The clinic analysis of complications of varied breast implant]	*Zhonghua Zheng Xing Wai Ke Za Zhi*	NRCS not adjusted
163	31417055	Chen	A short follow-up of prosthesis-based breast reconstruction using TiLOOP((R)) Bra surgical mesh	*Niger J Clin Pract*	Single group N enrolled <500
164	16772907	Cheng	Comparisons of resource costs and success rates between immediate and delayed breast reconstruction using DIEP or SIEA flaps under a well-controlled clinical trial	*Plast Reconstr Surg*	NRCS <30 per arm
165	32895461	Cheng	A retrospective study to compare the clinical effects of individualized anatomic single- and double-bundle anterior cruciate ligament reconstruction surgery	Sci Rep	Not breast reconstruction
166	32901309	Cheng	Comparisons Between Normal Body Mass Index and Overweight Patients Who Underwent Unilateral Microsurgical Breast Reconstructions	Ann Surg Oncol	Single group N enrolled <500
167	15457015	Chevray	Breast reconstruction with superficial inferior epigastric artery flaps: a prospective comparison with TRAM and DIEP flaps	*Plast Reconstr Surg*	NRCS <30 per arm
168	32670569	Chirappapha	Comparisons of complications between extended latissimus dorsi flap and latissimus dorsi flap in total breast reconstruction: A prospective cohort study	Ann Med Surg (Lond)	NRCS <30 per arm
169	31801159	Cho	Clinical Decision Making Using CTA in Conjoined, Bipedicled DIEP and SIEA for Unilateral Breast Reconstruction	*J Reconstr Microsurg*	Single group N enrolled <500
170	27465178	Choi	Breast in a Day': Examining Single-Stage Immediate, Permanent Implant Reconstruction in Nipple-Sparing Mastectomy	*Plast Reconstr Surg*	Single group N enrolled <500
171	1410349	Chu	Radiation therapy of cancer in prosthetically augmented or reconstructed breasts	*Radiology*	NRCS <30 per arm
172	20555301	Chun	Comparison of morbidity, functional outcome, and satisfaction following bilateral TRAM versus bilateral DIEP flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
173	30791946	Chung	The effect of post mastectomy radiation therapy on breast reconstruction with and without acellular dermal matrix: a systematic review and meta-analysis protocol	*Syst Rev*	Protocol/methods with no results
174	25910179	Chung	Surgical Site Infections after Free Flap Breast Reconstruction: An Analysis of 2,899 Patients from the ACS-NSQIP Datasets	*J Reconstr Microsurg*	Does not address KQ1-KQ6
175	23096982	Clemens	Acellular dermal matrix in irradiated tissue expander/implant-based breast reconstruction: evidence-based review	*Plast Reconstr Surg*	Systematic review
176	26161307	Clemens	Current perspectives on radiation therapy in autologous and prosthetic breast reconstruction	*Gland Surg*	Narrative review/ Commentary
177	12890459	Cocquyt	Better cosmetic results and comparable quality of life after skin-sparing mastectomy and immediate autologous breast reconstruction compared to breast conservative treatment	*Br J Plast Surg*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
178	12890459	Cocquyt	Better cosmetic results and comparable quality of life after skin-sparing mastectomy and immediate autologous breast reconstruction compared to breast conservative treatment	*British Journal of Plastic Surgery*	Single group N enrolled <500
179	26505698	Cohen	Breast Implant-Associated Infections: The Role of the National Surgical Quality Improvement Program and the Local Microbiome	*Plast Reconstr Surg*	>=10% augmentation reconstruction only
180	28336245	Cohen	Does the Timing of Chemotherapy Affect Post-Mastectomy Breast Reconstruction Complications?	*Clin Breast Cancer*	Single group N enrolled <500
181	28841600	Cohen	Determining the Oncologic Safety of Autologous Fat Grafting as a Reconstructive Modality: An Institutional Review of Breast Cancer Recurrence Rates and Surgical Outcomes	*Plast Reconstr Surg*	NRCS not adjusted
182	26534828	Cohen	Is Unilateral Implant or Autologous Breast Reconstruction Better in Obtaining Breast Symmetry?	*Breast J*	NRCS not adjusted
183	21460651	Colakoglu	Impact of complications on patient satisfaction in breast reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
184	24581765	Collier	The effect of timing of postmastectomy radiation on implant-based breast reconstruction: a retrospective comparison of complication outcomes	*Am J Surg*	NRCS not adjusted
185	21825969	Collis	Acellular dermal matrix slings in tissue expander breast reconstruction: are there substantial benefits?	*Ann Plast Surg*	NRCS not adjusted
186	10873353	Contant	Morbidity of immediate breast reconstruction (IBR) after mastectomy by a subpectorally placed silicone prosthesis: the adverse effect of radiotherapy	*Eur J Surg Oncol*	NRCS <30 per arm
187	106511232	Contant	Satisfaction and prosthesis related complaints in women with immediate breast reconstruction following prophylactic and oncological mastectomy	*Psychology, Health and Medicine*	Duplicate of another publication
188	106511232	Contant	Satisfaction and prosthesis related complaints in women with immediate breast reconstruction following prophylactic and oncological mastectomy	*Psychology, Health & Medicine*	Single group N enrolled <500
189	27879581	Cooney	Matching Procedures at the Time of Immediate Breast Reconstruction: An American College of Surgeons National Surgical Quality Improvement Program Study of 24,191 Patients	*Plast Reconstr Surg*	Does not address KQ1-KQ6
190	28410984	Corban	A systematic review of complications associated with direct implants vs. tissue expanders following Wise pattern skin-sparing mastectomy	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
191	27890331	Cordeiro	The safety of same-day breast reconstructive surgery: An analysis of short-term outcomes	*Am J Surg*	Does not address KQ1-KQ6
192	32008941	Cordeiro	Risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in a cohort of 3546 women prospectively followed long term after reconstruction with textured breast implants	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
193	25919262	Coroneos	SIEA versus DIEP Arterial Complications: A Cohort Study	*Plast Reconstr Surg*	NRCS not adjusted
194	23806951	Costa	Incidence of surgical-site infection is not affected by method of immediate breast reconstruction	*Plast Reconstr Surg*	Copublication of included study with no new data

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
195	21460649	Craft	Patient satisfaction in unilateral and bilateral breast reconstruction [outcomes article]	*Plast Reconstr Surg*	Copublication of included study with no new data
196	22437263	Craig	Venous thromboembolism risk factors in breast cancer patients undergoing deep inferior epigastric perforator flap reconstruction	*Microsurgery*	Narrative review/ Commentary
197	8060066	Crespo	Postmastectomy complications in breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
198	22544109	Crosby	Immediate breast reconstruction and lymphedema incidence	*Plast Reconstr Surg*	No outcome of interest
199	31738641	Cuccolo	Does age or frailty have more predictive effect on outcomes following pedicled flap reconstruction? An analysis of 44,986 cases(dagger)	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
200	19437068	Cunningham	Safety and effectiveness of Mentor's MemoryGel implants at 6 years	*Aesthetic Plast Surg*	Single group N enrolled <500
201	None	Cuomo	Optimization of Prepectoral Breast Reconstruction	*Breast Care*	NRCS <30 per arm
202	21717397	Curtis	Immediate microsurgical breast reconstruction and simultaneous sentinel lymph node dissection: issues with node positivity and recipient vessel selection	*J Reconstr Microsurg*	Does not address KQ1-KQ6
203	21735435	D'Souza	Immediate versus delayed reconstruction following surgery for breast cancer	*Cochrane Database Syst Rev*	Does not address KQ1-KQ6
204	23642795	Damen	Improving outcomes in microsurgical breast reconstruction: lessons learnt from 406 consecutive DIEP/TRAM flaps performed by a single surgeon	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
205	21317054	Damen	Medium-term cost analysis of breast reconstructions in a single Dutch centre: a comparison of implants, implants preceded by tissue expansion, LD transpositions and DIEP flaps	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
206	None	Darrach	Pectoral placement of tissue expanders affects inpatient opioid use	Breast Journal	NRCS not adjusted
207	28401542	Dauplat	Quality of life after mastectomy with or without immediate breast reconstruction	*Br J Surg*	Single group >500, but no complications data
208	8901297	Dauplat	Mastectomy with immediate reconstruction for invasive breast cancer. Comments on indications and techniques. A series of 112 cases	*Journal de Gynecologie Obstetrique et Biologie de la Reproduction*	Unable to retrieve article
209	8901297	Dauplat	[Mastectomy with immediate reconstruction for invasive breast cancer. Comments on indications and technique. A series of 112 cases]	*J Gynecol Obstet Biol Reprod (Paris)*	Unable to retrieve article
210	27855106	Dave	The iBRA-2 (immediate breast reconstruction and adjuvant therapy audit) study: protocol for a prospective national multicentre cohort study to evaluate the impact of immediate breast reconstruction on the delivery of adjuvant therapy	*BMJ Open*	Protocol/methods with no results
211	32990360	Dave	Risk factors for complications and implant loss after prepectoral implant-based immediate breast reconstruction: medium-term outcomes in a prospective cohort	Br J Surg	Single group N enrolled <500
212	23547540	Davila	Immediate two-stage tissue expander breast reconstruction compared with one-stage permanent implant breast reconstruction: a multi-institutional comparison of short-term complications	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
213	23547540	Davila	Immediate two-stage tissue expander breast reconstruction compared with one-stage permanent implant breast reconstruction: A multi-institutional comparison of short-term complications	*Journal of Plastic Surgery and Hand Surgery*	Duplicate of another publication
214	23362476	Davila	Human acellular dermis versus submuscular tissue expander breast reconstruction: A multivariate analysis of short-term complications	*Archives of Plastic Surgery*	Duplicate of another publication
215	29064925	Dayan	Lower Extremity Free Flaps for Breast Reconstruction	*Plast Reconstr Surg*	Narrative review/ Commentary
216	21587037	de Blacam	Cost analysis of implant-based breast reconstruction with acellular dermal matrix	*Ann Plast Surg*	Does not address KQ1-KQ6
217	22179850	de la Pena-Salcedo	Back to the future: a 15-year experience with polyurethane foam-covered breast implants using the partial-subfascial technique	*Aesthetic Plast Surg*	Single group N enrolled <500
218	25539293	De Lorenzi	Poly implant prothese asymmetrical anatomical breast implants: a product recall study	*Plast Reconstr Surg*	Does not address KQ1-KQ6
219	28121852	De Vita	Outcome Evaluation after 2023 Nipple-Sparing Mastectomies: Our Experience	*Plast Reconstr Surg*	Single group N enrolled <500
220	22739071	Decker	Impact of neoadjuvant chemotherapy on wound complications after breast surgery	*Surgery*	Does not address KQ1-KQ6
221	25096386	Degnim	Randomized trial of drain antisepsis after mastectomy and immediate prosthetic breast reconstruction	*Ann Surg Oncol*	Single group N enrolled <500
222	31042802	DelMauro	Reducing Length of Stay after Microsurgical Breast Reconstruction with a Standardized Postoperative Protocol	*J Reconstr Microsurg*	Single group N enrolled <500
223	31764630	DeLong	Systematic Review of the Impact of Acellular Dermal Matrix on Aesthetics and Patient Satisfaction in Tissue Expander-to-Implant Breast Reconstructions	*Plast Reconstr Surg*	Narrative review/ Commentary
224	28346311	DeLong	Latissimus Dorsi Flap Breast Reconstruction-A Nationwide Inpatient Sample Review	*Ann Plast Surg*	Single group >500, but no complications data
225	29372268	Demiri	Outcomes of Fat-Augmented Latissimus Dorsi (FALD) Flap Versus Implant-Based Latissimus Dorsi Flap for Delayed Post-radiation Breast Reconstruction	*Aesthetic Plast Surg*	Single group N enrolled <500
226	32892331	Demiri	Fat-Augmented Latissimus Dorsi versus Deep Inferior Epigastric Perforator Flap: Comparative Study in Delayed Autologous Breast Reconstruction	J Reconstr Microsurg	NRCS not adjusted
227	25480591	Deng	Two modified surgical procedures for treating early stage breast cancer in China	*J Huazhong Univ Sci Technolog Med Sci*	Single group N enrolled <500
228	29481390	Devulapalli	The Effect of Radiation on Quality of Life throughout the Breast Reconstruction Process: A Prospective, Longitudinal Pilot Study of 200 Patients with Long-Term Follow-Up	*Plast Reconstr Surg*	Does not address KQ1-KQ6
229	31235319	Dewael	Immediate versus delayed autologous breast reconstruction: A retrospective matched cohort study of irradiated patients	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
230	CN-01139314	Dikmans	Two-stage implant-based breast reconstruction is safer than immediate one-stage implant-based breast reconstruction augmented with an a cellular dermal matrix: a multicentre randomized controlled trial	*European journal of cancer*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
231	CN-01340949	Dikmans	Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial	*The lancet. Oncology*	Duplicate of another publication
232	28012977	Dikmans	Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial	*Lancet Oncol*	Duplicate of another publication
233	28012977	Dikmans	Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial	*The Lancet Oncology*	Does not address KQ1-KQ6
234	121069020	Dikmans	Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial	*Lancet Oncology*	Duplicate of another publication
235	10541166	Disa	The premature removal of tissue expanders in breast reconstruction	*Plast Reconstr Surg*	No outcome of interest
236	10597680	Disa	Efficacy of conventional monitoring techniques in free tissue transfer: an 11-year experience in 750 consecutive cases	*Plast Reconstr Surg*	Does not address KQ1-KQ6
237	31531928	Doherty	Trends in immediate breast reconstruction and radiation after mastectomy: A population study	*Breast J*	No outcome of interest
238	26942453	Dolen	Impact of Neoadjuvant and Adjuvant Chemotherapy on Immediate Tissue Expander Breast Reconstruction	*Ann Surg Oncol*	No outcome of interest
239	24409778	Dong	[The impact of acellular dermal matrix on complications of breast reconstruction using tissue expander/implant: a meta-analysis]	*Zhonghua Zheng Xing Wai Ke Za Zhi*	Does not address KQ1-KQ6
240	21963981	Donker	Surgical complications of skin sparing mastectomy and immediate prosthetic reconstruction after neoadjuvant chemotherapy for invasive breast cancer	*European Journal of Surgical Oncology*	Single group N enrolled <500
241	26505700	Doren	Comparison of Allergan, Mentor, and Sientra Contoured Cohesive Gel Breast Implants: A Single Surgeon's 10-Year Experience	*Plast Reconstr Surg*	Single group N enrolled <500
242	29267860	Dorfman	The Effect of Implant Type on Nipple Position Geometry and Aesthetics Following Tissue Expander Reconstruction After Nipple Sparing Mastectomy	*Aesthet Surg J*	NRCS not adjusted
243	30059382	Doval	Deep Inferior Epigastric Artery Perforator Flap Breast Reconstruction in Women With Previous Abdominal Incisions: A Comparison of Complication Rates	*Ann Plast Surg*	Single group N enrolled <500
244	31056434	Drinane	Depression is associated with worse outcomes among women undergoing breast reconstruction following mastectomy	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
245	8041820	Duffy	Health risks of failed silicone gel breast implants: a 30-year clinical experience	*Plast Reconstr Surg*	Single group N enrolled <500
246	110864376	Duraes	Aesthetics and patient-reported outcomes following microsurgical breast reconstruction after nipple-sparing mastectomy	*Journal of the American College of Surgeons*	Single group N enrolled <500
247	23025955	Durkan	Postmastectomy radiation of latissimus dorsi myocutaneous flap reconstruction is well tolerated in women with breast cancer	*Am Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
248	30595378	Durry	[Patients' satisfaction after immediate breast reconstruction: Comparison between five surgical techniques]	*Ann Chir Plast Esthet*	NRCS not adjusted
249	30611562	Durry	[Postoperative course after immediate breast reconstruction: Comparison between five surgical techniques]	*Ann Chir Plast Esthet*	NRCS not adjusted
250	11505709	Duskova	Breast reconstruction as an integral part of breast carcinoma therapy (a self-present final report of a research project IGA MZ CR)	*Acta Chirurgiae Plasticae*	Unable to retrieve article
251	11505709	Duskova	Breast reconstruction as an integral part of breast carcinoma therapy (a self-present final report of a research project IGA MZ CR)	*Acta Chir Plast*	Single group N enrolled <500
252	29040345	Duteille	Eight-Year Safety Data for Round and Anatomical Silicone Gel Breast Implants	*Aesthet Surg J*	>=10% augmentation reconstruction only
253	25289331	Duteille	Five-year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants	*Plast Reconstr Surg Glob Open*	NRCS <30 per arm
254	26887685	Duxbury	Systematic review of the effectiveness of polyurethane-coated compared with textured silicone implants in breast surgery	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
255	32041661	Dyrberg	Direct-to-Implant Extracellular Matrix Hammock-based Breast Reconstruction; Prepectoral or Subpectoral'	*Trials*	Duplicate of another publication
256	32041661	Dyrberg	Direct-to-Implant Extracellular Matrix Hammock-based Breast Reconstruction; Prepectoral or Subpectoral?	*Trials*	Protocol/methods with no results
257	32041661	Dyrberg	Direct-to-Implant Extracellular Matrix Hammock-based Breast Reconstruction; Prepectoral or Subpectoral'	*Trials*	Protocol/methods with no results
258	32041661	Dyrberg	Direct-to-Implant Extracellular Matrix Hammock-based Breast Reconstruction; Prepectoral or Subpectoral?	Trials	Protocol/methods with no results
259	32855081	Early	Breast Cancer and Secondary Cancer Recurrences After Autologous Tissue Reconstruction	Clinical Breast Cancer	Single group N enrolled <500
260	22841854	Egeberg	Comparing the donor-site morbidity using DIEP, SIEA or MS-TRAM flaps for breast reconstructive surgery: a meta-analysis	*J Plast Reconstr Aesthet Surg*	Narrative review/ Commentary
261	29487671	El-Haddad	A 10-Year Prospective Study of Implant-Based Breast Augmentation and Reconstruction	*Eplasty*	Single group N enrolled <500
262	28416138	El-Sabawi	Patient-centered outcomes of breast reconstruction in the setting of post-mastectomy radiotherapy: A comprehensive review of the literature	*J Plast Reconstr Aesthet Surg*	Systematic review
263	26345465	El-Sabawi	Breast reconstruction and adjuvant therapy: A systematic review of surgical outcomes	*J Surg Oncol*	Systematic review
264	32420440	Eltahir	Satisfaction with cosmetic outcomes of breast reconstruction: Investigations into the correlation between the patients' Breast-Q outcome and the judgment of panels	JPRAS Open	NRCS not adjusted
265	24022602	Enajat	Effect of acetylsalicylic acid on microvascular thrombosis in autologous breast reconstruction	*J Reconstr Microsurg*	Single group N enrolled <500
266	23924650	Endara	Breast reconstruction following nipple-sparing mastectomy: a systematic review of the literature with pooled analysis	*Plast Reconstr Surg*	Does not address KQ1-KQ6
267	33268290	Erlichman	Comparing outcomes of post-mastectomy breast reconstruction between United States and Western Europe	J Plast Reconstr Aesthet Surg	Systematic review

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
268	8273633	Fajardo	Mammographic surveillance of breast cancer patients: should the mastectomy site be imaged?	*AJR Am J Roentgenol*	Single group N enrolled <500
269	18952229	Fancher	A woman's influence to choose mastectomy as treatment for breast cancer	*J Surg Res*	Single group N enrolled <500
270	28489683	Fang	Intraoperative Use of Vasopressors Does Not Increase the Risk of Free Flap Compromise and Failure in Cancer Patients	*Ann Surg*	Does not address KQ1-KQ6
271	10654733	Feng	Analysis of risk factors associated with rupture of silicone gel breast implants	*Plast Reconstr Surg*	Not breast reconstruction
272	18390839	Fernandez-Delgado	Satisfaction with and psychological impact of immediate and deferred breast reconstruction	*Ann Oncol*	Single group N enrolled <500
273	19228514	Fernandez-Frias	Immediate reconstruction after mastectomy for breast cancer: which factors affect its course and final outcome?	*J Am Coll Surg*	Narrative review/ Commentary
274	25536206	Fischer	A Systematic Meta-analysis of Prosthetic-Based Breast Reconstruction in Irradiated Fields With or Without Autologous Muscle Flap Coverage	*Ann Plast Surg*	Does not address KQ1-KQ6
275	24076667	Fischer	Breast reconstruction in the morbidly obese patient: assessment of 30-day complications using the 2005 to 2010 National Surgical Quality Improvement Program data sets	*Plast Reconstr Surg*	Does not address KQ1-KQ6
276	23865900	Fischer	Complications and morbidity following breast reconstruction--a review of 16,063 cases from the 2005-2010 NSQIP datasets	*J Plast Surg Hand Surg*	Copublication of included study with no new data
277	23891077	Fischer	Impact of obesity on outcomes in breast reconstruction: analysis of 15,937 patients from the ACS-NSQIP datasets	*J Am Coll Surg*	NRCS not adjusted
278	23845908	Fischer	Peri-operative risk factors associated with early tissue expander (TE) loss following immediate breast reconstruction (IBR): a review of 9305 patients from the 2005-2010 ACS-NSQIP datasets	*J Plast Reconstr Aesthet Surg*	No outcome of interest
279	23629107	Fischer	Free tissue transfer in the obese patient: an outcome and cost analysis in 1258 consecutive abdominally based reconstructions	*Plast Reconstr Surg*	NRCS not adjusted
280	23357982	Fischer	Comprehensive outcome and cost analysis of free tissue transfer for breast reconstruction: an experience with 1303 flaps	*Plast Reconstr Surg*	Does not address KQ1-KQ6
281	24328902	Fischer	A 30-day risk assessment of mastectomy alone compared to immediate breast reconstruction (IBR)	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
282	24443774	Fischer	Effect of BMI on modality-specific outcomes in immediate breast reconstruction (IBR)--a propensity-matched analysis using the 2005-2011 ACS-NSQIP datasets	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
283	25175274	Fischer	Mastectomy with or without immediate implant reconstruction has similar 30-day perioperative outcomes	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
284	24074811	Fischer	Risk analysis and stratification of surgical morbidity after immediate breast reconstruction	*J Am Coll Surg*	Does not address KQ1-KQ6
285	24572870	Fischer	Venous thromboembolism risk in mastectomy and immediate breast reconstruction: analysis of the 2005 to 2011 American College of Surgeons National Surgical Quality Improvement Program data sets	*Plast Reconstr Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
286	23973103	Fischer	Risk analysis of early implant loss after immediate breast reconstruction: a review of 14,585 patients	*J Am Coll Surg*	Copublication of included study with no new data
287	27047777	Fitzgerald O'Connor	Preoperative computed tomography angiography for planning DIEP flap breast reconstruction reduces operative time and overall complications	*Gland Surg*	NRCS not adjusted
288	23407253	Fitzpatrick	Cost and outcome analysis of breast reconstruction paradigm shift	*Ann Plast Surg*	Does not address KQ1-KQ6
289	23975313	Fitzsullivan	Incidence and consequence of close margins in patients with ductal carcinoma-in situ treated with mastectomy: is further therapy warranted?	*Ann Surg Oncol*	Does not address KQ1-KQ6
290	31342397	Flanagan	A Comparison of Patient-Reported Outcomes After Breast-Conserving Surgery and Mastectomy with Implant Breast Reconstruction	*Ann Surg Oncol*	Single group >500, but no complications data
291	110864110	Flanagan	Adverse outcomes and quality of life associated with immediate breast reconstruction after mastectomy in Washington state, 2011-2013	*Journal of the American College of Surgeons*	No outcome of interest
292	24374398	Forsberg	Aesthetic outcomes of acellular dermal matrix in tissue expander/implant-based breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
293	21681129	Fosnot	Closer to an understanding of fate: the role of vascular complications in free flap breast reconstruction	*Plastic and reconstructive surgery*	No outcome of interest
294	21681129	Fosnot	Closer to an understanding of fate: the role of vascular complications in free flap breast reconstruction	*Plast Reconstr Surg*	Duplicate of another publication
295	12052757	Foster	Skin-sparing mastectomy and immediate breast reconstruction: a prospective cohort study for the treatment of advanced stages of breast carcinoma	*Ann Surg Oncol*	Single group N enrolled <500
296	26545214	Fracol	Bilateral Free Flap Breast Reconstruction After Unilateral Radiation: Comparing Intraoperative Vascular Complications and Postoperative Outcomes in Radiated Versus Nonradiated Breasts	*Ann Plast Surg*	Single group N enrolled <500
297	33133885	Fracol	Lateral and Inferior Implant Malposition in Prosthetic Breast Reconstruction: Incidence and Risk Factors	Plast Reconstr Surg Glob Open	Single group >500, but no harms data
298	29651851	Fracon	PATIENT SATISFACTION AFTER BREAST RECONSTRUCTION: IMPLANTS VS. AUTOLOGOUS TISSUES	*Acta chirurgiae plasticae*	NRCS not adjusted
299	29651851	Fracon	PATIENT SATISFACTION AFTER BREAST RECONSTRUCTION: IMPLANTS VS. AUTOLOGOUS TISSUES	*Acta Chir Plast*	NRCS not adjusted
300	32875463	Franceschini	Compliance with Specific Recommendations and Tasks Reduces Nipple Necrosis Rates in Prepectoral Implant-Based Reconstruction After Nipple-Sparing Mastectomy	Ann Surg Oncol	Narrative review/Commentary
301	33671712	Franceschini	Immediate Prosthetic Breast Reconstruction after Nipple-Sparing Mastectomy: Traditional Subpectoral Technique versus Direct-to-Implant Prepectoral Reconstruction without Acellular Dermal Matrix	J Pers Med	NRCS not adjusted
302	7761508	Franchelli	Psychological evaluation of patients undergoing breast reconstruction using two different methods: autologous tissues versus prostheses	*Plast Reconstr Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
303	7761508	Franchelli	Psychological evaluation of patients undergoing breast reconstruction using two different methods: Autologous tissues versus prostheses	*Plastic and Reconstructive Surgery*	NRCS not adjusted
304	9678622	Franchelli	Can the cost affect the choice of various methods of postmastectomy breast reconstruction?	*Tumori*	Single group N enrolled <500
305	7478060	Franchelli	[Psychological assessment of patients who have ++undergone breast reconstruction using 2 different technics: autologous tissue versus prosthesis]	*Minerva Chir*	NRCS not adjusted
306	7761508	Franchelli	Psychological evaluation of patients undergoing breast reconstruction using two different methods: Autologous tissues versus prostheses	*Plast Reconstr Surg*	NRCS not adjusted
307	29660396	Franchelli	Analysis of clinical management of infected breast implants and of factors associated to successful breast pocket salvage in infections occurring after breast reconstruction	*International Journal of Infectious Diseases*	Single group N enrolled <500
308	104164872	Fraser	Lumbar herniation following extended autologous latissimus dorsi breast reconstruction	*BMC Surgery*	Case report or series of case reports
309	28066037	Fraser	THE EPIDEMIOLOGY AND OUTCOMES OF BREAST CANCER SURGERY	*Trans Am Clin Climatol Assoc*	NRCS not adjusted
310	31663939	Freniere	Outcomes Following Breast Reconstruction in Patients With Prior Mantle Radiation for Treatment of Hodgkin's Lymphoma	*Ann Plast Surg*	NRCS <30 per arm
311	26495218	Frey	Breast Reconstruction Using Contour Fenestrated AlloDerm: Does Improvement in Design Translate to Improved Outcomes?	*Plast Reconstr Surg Glob Open*	NRCS not adjusted
312	28538548	Frey	Comparison of Outcomes with Tissue Expander, Immediate Implant, and Autologous Breast Reconstruction in Greater Than 1000 Nipple-Sparing Mastectomies	*Plast Reconstr Surg*	NRCS not adjusted
313	29794639	Frey	Comparing Therapeutic versus Prophylactic Nipple-Sparing Mastectomy: Does Indication Inform Oncologic and Reconstructive Outcomes?	*Plast Reconstr Surg*	NRCS not adjusted
314	25059787	Freyvogel	Screening mammography following autologous breast reconstruction: an unnecessary effort	*Ann Surg Oncol*	Does not address KQ1-KQ6
315	25059787	Freyvogel	Screening Mammography Following Autologous Breast Reconstruction: An Unnecessary Effort	*Annals of Surgical Oncology*	Single group >500, but no complications data
316	9229085	Friis	Connective tissue disease and other rheumatic conditions following breast implants in Denmark	*Ann Plast Surg*	Single group >500, but no complications data
317	11000074	Futter	A retrospective comparison of abdominal muscle strength following breast reconstruction with a free TRAM or DIEP flap	*Br J Plast Surg*	NRCS <30 per arm
318	28279888	Fuzesi	Validation of the electronic version of the BREAST-Q in the army of women study	*Breast*	Single group >500, but no complications data
319	31788914	Gabrick	Breast reconstruction patterns and outcomes in academic and community practices within a single institution	*Breast J*	Does not address KQ1-KQ6
320	8190133	Gabriel	Risk of connective-tissue diseases and other disorders after breast implantation	*N Engl J Med*	Single group N enrolled <500
321	9041097	Gabriel	Complications leading to surgery after breast implantation	*New England Journal of Medicine*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
322	23211118	Gart	Autologous options for postmastectomy breast reconstruction: A comparison of outcomes based on the american college of surgeons national surgical quality improvement program	*Journal of the American College of Surgeons*	Duplicate of another publication
323	16651940	Garvey	DIEP and pedicled TRAM flaps: a comparison of outcomes	*Plast Reconstr Surg*	NRCS not adjusted
324	24469158	Garvey	Muscle-sparing TRAM flap does not protect breast reconstruction from postmastectomy radiation damage compared with the DIEP flap	*Plast Reconstr Surg*	Does not address KQ1-KQ6
325	21617453	Garvey	Abdominal donor-site outcomes for medial versus lateral deep inferior epigastric artery branch perforator harvest	*Plast Reconstr Surg*	Does not address KQ1-KQ6
326	25626783	Gassman	Comparison of postoperative pain control in autologous abdominal free flap versus implant-based breast reconstructions	*Plast Reconstr Surg*	NRCS not adjusted
327	26761517	Gdalevitch	Reply to: Comments on Effects of Nitroglycerin Ointment on Mastectomy Flap Necrosis in Immediate Breast Reconstruction: A Randomized Controlled Trial	*Plast Reconstr Surg*	Not breast reconstruction
328	24867734	Gdalevitch	Direct-to-implant single-stage immediate breast reconstruction with acellular dermal matrix: predictors of failure	*Plast Reconstr Surg*	Not mastectomy for breast cancer
329	9588052	Germain	[Breast reconstruction using free rectus abdominis myocutaneous flap]	*Chirurgie*	Unable to retrieve article
330	9588052	Germain	Breast reconstruction for cancer with free transverse rectus abdominis myocutaneous flap	*Chirurgie - Memoires de l'Academie de Chirurgie*	NRCS <30 per arm
331	20502959	Giacalone	New concept for immediate breast reconstruction for invasive cancers: feasibility, oncological safety and esthetic outcome of post-neoadjuvant therapy immediate breast reconstruction versus delayed breast reconstruction: a prospective pilot study	*Breast Cancer Res Treat*	NRCS not adjusted
332	122477529	Gibreel	Mastectomy and Immediate Breast Reconstruction for Cancer in the Elderly: A National Cancer Data Base Study	*Journal of the American College of Surgeons*	Does not address KQ1-KQ6
333	105522143	Gill	Quality of life, abdominal muscle strength and endurance of women following breast reconstruction	*Journal of Women's Health Physical Therapy*	Single group N enrolled <500
334	22327891	Glasberg	AlloDerm and Strattice in breast reconstruction: a comparison and techniques for optimizing outcomes	*Plast Reconstr Surg*	Does not address KQ1-KQ6
335	27743083	Golpanian	Free Versus Pedicled TRAM Flaps: Cost Utilization and Complications	*Aesthetic Plast Surg*	Does not address KQ1-KQ6
336	29146071	Gomez-Escolar Larranaga	Comparison among the levels of patients' satisfaction according to the surgical technique used in breast reconstruction after mastectomy	*Cir Esp*	NRCS not adjusted
337	23983109	Gopie	Impact of delayed implant and DIEP flap breast reconstruction on body image and sexual satisfaction: a prospective follow-up study	*Psychooncology*	NRCS <30 per arm
338	22033976	Gopie	The short-term psychological impact of complications after breast reconstruction	*Psychooncology*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
339	21514911	Gopie	Information-seeking behaviour and coping style of women opting for either implant or DIEP-flap breast reconstruction	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
340	25910024	Grinsell	The Deep Inferior Epigastric Perforator Learning Curve in the Current Era	*Ann Plast Surg*	NRCS not adjusted
341	33062963	Groth	A Picture of Breast Reconstruction in a Public Oncology Hospital in Latin America: A Ten-Year Experience	Eur J Breast Health	Does not address KQ1-KQ6
342	2523544	Grotting	Conventional TRAM flap versus free microsurgical TRAM flap for immediate breast reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
343	7232564	Gruber	Breast reconstruction following mastectomy: A comparison of submuscular and subcutaneous techniques	*Plastic and Reconstructive Surgery*	NRCS not adjusted
344	7232564	Gruber	Breast reconstruction following mastectomy: a comparison of submuscular and subcutaneous techniques	*Plast Reconstr Surg*	NRCS not adjusted
345	24792480	Gryskiewicz	Transaxillary Nonendoscopic Subpectoral Augmentation Mammaplasty: A 10-Year Experience With Gel vs Saline in 2000 Patients-With Long-Term Patient Satisfaction Measured by the BREAST-Q	*Aesthet Surg J*	>=10% augmentation reconstruction only
346	26947961	Gschwantler-Kaulich	Mesh versus acellular dermal matrix in immediate implant-based breast reconstruction - A prospective randomized trial	*Eur J Surg Oncol*	Does not address KQ1-KQ6
347	16932175	Gusenoff	Free tissue transfer: comparison of outcomes between university hospitals and community hospitals	*Plast Reconstr Surg*	Does not address KQ1-KQ6
348	141474299	Ha	Oncologic outcomes after immediate breast reconstruction following mastectomy: comparison of implant and flap using propensity score matching	*BMC Cancer*	Duplicate of another publication
349	30616906	Hadad	Sub-muscular plane for augmentation mammoplasty patients increases silicone gel implant rupture rate	*J Plast Reconstr Aesthet Surg*	>=10% augmentation reconstruction only
350	29068920	Haddock	Five Steps to Internal Mammary Vessel Preparation in Less than 15 Minutes	*Plast Reconstr Surg*	Single group N enrolled <500
351	32440397	Haddock	Consecutive 265 Profunda Artery Perforator Flaps: Refinements, Satisfaction, and Functional Outcomes	Plast Reconstr Surg Glob Open	Single group N enrolled <500
352	32221196	Hagarty	Decreased Length of Postoperative Drain Use, Parenteral Opioids, Length of Stay, and Complication Rates in Patients Receiving Meshed versus Unmeshed Acellular Dermal Matrix in 194 Submuscular Tissue Expander-Based Breast Reconstructions: A Single-Surgeon Cohort Study	*Plast Reconstr Surg*	Does not address KQ1-KQ6
353	21200201	Hall-Findlay	Breast implant complication review: double capsules and late seromas	*Plast Reconstr Surg*	Not breast reconstruction
354	29320921	Hallberg	Benefits and risks with acellular dermal matrix (ADM) and mesh support in immediate breast reconstruction: a systematic review and meta-analysis	*J Plast Surg Hand Surg*	Systematic review
355	31144025	Hamann	Quality of life in breast cancer patients and surgical results of immediate tissue expander/implant-based breast reconstruction after mastectomy	*Arch Gynecol Obstet*	NRCS <30 per arm
356	33480982	Hamdi	The 'Hug Flap': Surgical Technique to Enhance the Aesthetic Breast Projection in Autologous Breast Reconstruction	Aesthet Surg J	Single group N enrolled <500
357	32988607	Hammond	Capsular contracture in the modern era: A multidisciplinary look at the incidence and risk factors after mastectomy and implant-based breast reconstruction	Am J Surg	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
358	19338905	Handel	Long-term safety and efficacy of polyurethane foam-covered breast implants	*Aesthet Surg J*	Single group N enrolled <500
359	1871226	Handel	Comparative experience with smooth and polyurethane breast implants using the Kaplan-Meier method of survival analysis	*Plast Reconstr Surg*	Single group N enrolled <500
360	31606126	Hangge	Making an informed choice: Which breast reconstruction type has the lowest complication rate?	*American Journal of Surgery*	Duplicate of another publication
361	21862915	Hanna	Comparison study of two types of expander-based breast reconstruction: acellular dermal matrix-assisted versus total submuscular placement	*Ann Plast Surg*	NRCS not adjusted
362	130221949	Hansen	Evaluating Mastectomy Skin Flap Necrosis in the Extended Breast Reconstruction Risk Assessment Score for 1-Year Prediction of Prosthetic Reconstruction Outcomes	*Journal of the American College of Surgeons*	Duplicate of another publication
363	27757331	Hanson	Fewer Revisions in Abdominal-based Free Flaps than Latissimus Dorsi Breast Reconstruction after Radiation	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
364	33051871	Hansson	First-year complications after immediate breast reconstruction with a biological and a synthetic mesh in the same patient: A randomized controlled study	J Surg Oncol	Does not address KQ1-KQ6
365	23769660	Hanwright	The differential effect of BMI on prosthetic versus autogenous breast reconstruction: a multivariate analysis of 12,986 patients	*Breast*	Does not address KQ1-KQ6
366	27505449	Hart	The Impact of Diabetes Mellitus on Wound Healing in Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
367	32405724	Hartmann	A Novel Method of Outcome Assessment in Breast Reconstruction Surgery: Comparison of Autologous and Alloplastic Techniques Using Three-Dimensional Surface Imaging	Aesthetic Plast Surg	NRCS <30 per arm
368	30217311	Hauck	Secondary breast reconstruction after mastectomy using the DIEP flap	*Surg Oncol*	Single group N enrolled <500
369	19546667	Haykal	One hundred forty-one consecutive attempts at autologous tissue single-stage breast cancer reconstruction	*Ann Plast Surg*	Single group N enrolled <500
370	27798424	He	Considering the Optimal Timing of Breast Reconstruction With Abdominal Flaps With Adjuvant Irradiation in 370 Consecutive Pedicled Transverse Rectus Abdominis Myocutaneous Flap and Free Deep Inferior Epigastric Perforator Flap Performed in a Chinese Oncology Center: Is There a Significant Difference Between Immediate and Delayed?	*Ann Plast Surg*	NRCS not adjusted
371	31386193	Heeg	Nationwide population-based study of the impact of immediate breast reconstruction after mastectomy on the timing of adjuvant chemotherapy	*British Journal of Surgery*	No outcome of interest
372	33241589	Heidekrueger	Comparison of venous couplers versus hand-sewn technique in 4577 cases of DIEP-flap breast reconstructions - A multicenter study	Microsurgery	Copublication of included study with no new data
373	33461890	Heidekrueger	Impact of body mass index on free DIEP flap breast reconstruction: A multicenter cohort study	J Plast Reconstr Aesthet Surg	Copublication of included study with no new data

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
374	29464161	Heidemann	Complications following Nipple-Sparing Mastectomy and Immediate Acellular Dermal Matrix Implant-based Breast Reconstruction-A Systematic Review and Meta-analysis	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
375	16365235	Henriksen	Reconstructive breast implantation after mastectomy for breast cancer: clinical outcomes in a nationwide prospective cohort study	*Arch Surg*	Single group N enrolled <500
376	31913883	Henton	Microsurgical Training Opportunities at the Queen Victoria Hospital: A Retrospective Review of 848 Free Flaps for Breast Reconstruction	*Ann Plast Surg*	Single group >500, but no complications data
377	33625028	Hermiz	Use of a 5-Item Modified Frailty Index for Risk Stratification in Patients Undergoing Breast Reconstruction	Ann Plast Surg	NRCS not adjusted
378	22531395	Hill	Infectious complications associated with the use of acellular dermal matrix in implant-based bilateral breast reconstruction	*Ann Plast Surg*	NRCS <30 per arm
379	30100676	Hillberg	Is single-stage implant-based breast reconstruction (SSBR) with an acellular matrix safe?: Strattice or Meso Biomatrix(R) in SSBR	*Eur J Plast Surg*	NRCS <30 per arm
380	22286418	Hirsch	Outcomes of tissue expander/implant breast reconstruction in the setting of prereconstruction radiation	*Plast Reconstr Surg*	Single group N enrolled <500
381	21918963	Ho	Long-term outcomes in breast cancer patients undergoing immediate 2-stage expander/implant reconstruction and postmastectomy radiation	*Cancer*	Does not address KQ1-KQ6
382	22421476	Ho	A systematic review and meta-analysis of complications associated with acellular dermal matrix-assisted breast reconstruction	*Ann Plast Surg*	Systematic review
383	31350217	Hoejvig	Delayed two-stage breast reconstruction: The impact of radiotherapy	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
384	7622124	Hoflehner	[Mammography of the reconstructed breast--a comparison of different methods of reconstruction]	*Handchir Mikrochir Plast Chir*	NRCS <30 per arm
385	30930124	Holmes	Salvage of the failed implant-based breast reconstruction using the Deep Inferior Epigastric Perforator Flap: A single centre experience with tertiary breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
386	18580143	Holmich	Delayed breast reconstruction with implants after invasive breast cancer does not impair prognosis	*Ann Plast Surg*	Single group >500, but no complications data
387	31075801	Holoyda	Immediate Bilateral Breast Reconstruction Using Abdominally Based Flaps: An Analysis of the Nationwide Inpatient Sample Database	*J Reconstr Microsurg*	NRCS not adjusted
388	30694847	Homsy	Regional Anesthetic Blocks in Plastic Surgery Using Portable Ultrasound: A Simplified Approach	*Ann Plast Surg*	Single group N enrolled <500
389	22084645	Hoppe	Complications following expander/implant breast reconstruction utilizing acellular dermal matrix: a systematic review and meta-analysis	*Eplasty*	Narrative review/ Commentary
390	112727680	Hsueh-Hsing	Predictors for Reconstruction and Mood Disorder Associated With Reconstruction in Patients With Breast Cancer and Mastectomy: A Retrospective Cohort Study	*Medicine*	Duplicate of another publication
391	21264833	Hu	Impact of neoadjuvant chemotherapy on breast reconstruction	*Cancer*	Does not address KQ1-KQ6
392	104650234	Hu	Impact of neoadjuvant chemotherapy on breast reconstruction	*Cancer (0008543X)*	Duplicate of another publication

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
393	32167044	Huang	Factors Associated with Reconstruction in Patients Undergoing Mastectomy	*Am Surg*	Does not address KQ1-KQ6
394	27198885	Huang	Routine sampling of internal mammary lymph nodes during microsurgical breast reconstruction-Experience based on 524 microsurgical breast reconstructions	*Journal of Surgical Oncology*	Does not address KQ1-KQ6
395	27294034	Huang	Current status of breast reconstruction in China: an experience of 951 breast reconstructions from a single institute	*Gland Surg*	Single group N enrolled <500
396	12800900	Hultman	Skin-sparing mastectomy flap complications after breast reconstruction: review of incidence, management, and outcome	*Ann Plast Surg*	NRCS <30 per arm
397	12800900	Hultman	Skin-sparing mastectomy flap complications after breast reconstruction: Review of incidence, management, and outcome	*Annals of Plastic Surgery*	NRCS <30 per arm
398	26796375	Hunsinger	Long-Term Follow-Up of Quality of Life following DIEP Flap Breast Reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
399	26808742	Hunter	Superior Gluteal Artery Perforator Flap: The Beauty of the Buttock	*Ann Plast Surg*	NRCS <30 per arm
400	27178333	Huo	Post-mastectomy breast reconstruction and its subsequent complications: a comparison between obese and non-obese women with breast cancer	*Breast Cancer Research and Treatment*	Does not address KQ1-KQ6
401	27178333	Huo	Post-mastectomy breast reconstruction and its subsequent complications: a comparison between obese and non-obese women with breast cancer	*Breast Cancer Res Treat*	Does not address KQ1-KQ6
402	25894022	Ibrahim	Does acellular dermal matrix really improve aesthetic outcome in tissue expander/implant-based breast reconstruction?	*Aesthetic Plast Surg*	NRCS <30 per arm
403	27988412	Ilonzo	Breast reconstruction after mastectomy: A ten-year analysis of trends and immediate postoperative outcomes	*Breast*	Does not address KQ1-KQ6
404	28032163	Imahiyerobo	Transition from Round to Shaped Implants in Immediate Breast Reconstruction: Our Preferred Approach and Clinical Outcomes	*Aesthetic Plast Surg*	NRCS not adjusted
405	31119358	Isaksson	Bilateral Risk-Reducing Mastectomies with Implant-Based Reconstructions Followed Long Term: A Consecutive Series of 185 Patients	*World J Surg*	Does not address KQ1-KQ6
406	27475116	Islam	The largest and neglected giant phyllodes tumor of the breast – A case report and literature review	*International Journal of Surgery Case Reports*	Case report or series of case reports
407	23710783	Israeli Ben-Noon	The effect of acellular dermal matrix on drain secretions after immediate prosthetic breast reconstruction	*J Plast Surg Hand Surg*	NRCS <30 per arm
408	CN-01848602	Isrctn	The iBRA (implant breast reconstruction evaluation) study	*http://www.who.int/trialsearch/Trial2.aspx?TrialID=ISRCTN37664281*	Protocol/methods with no results
409	CN-01832640	Isrctn	QUEST Trial B - Quality of life following mastectomy and breast reconstruction	*http://www.who.int/trialsearch/Trial2.aspx?TrialID=ISRCTN92581226*	NRCS <30 per arm
410	CN-01843414	Isrctn	A trial evaluating outcomes of immediate implant-based breast reconstruction using an acellular dermal matrix (ADM) (POBRAD trial)	*http://www.who.int/trialsearch/Trial2.as*	Protocol/methods with no results

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
				px?TrialID=ISRCTN67956295	
411	CN-01821781	Isrctn	QUEST Trial A - Quality of life following mastectomy and breast reconstruction	*http://www.who.int/trialsearch/Trial2.aspx?TrialID=ISRCTN38846532*	Protocol/methods with no results
412	30589768	Ivey	Total Muscle Coverage versus AlloDerm Human Dermal Matrix for Implant-Based Breast Reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
413	26380109	Iwahira	Nummular Eczema of Breast: A Potential Dermatologic Complication after Mastectomy and Subsequent Breast Reconstruction	*Plast Surg Int*	Single group N enrolled <500
414	30014454	Jabo	Impact of Breast Reconstruction on Time to Definitive Surgical Treatment, Adjuvant Therapy, and Breast Cancer Outcomes	*Ann Surg Oncol*	Does not address KQ1-KQ6
415	124774782	Jacobson	Risk Factors for Implant-Based Reconstruction Failure after Mastectomy with or without Radiation in Patients Treated for Breast Cancer	*International Journal of Radiation Oncology, Biology, Physics*	NRCS not adjusted
416	25876011	Jagsi	Complications After Mastectomy and Immediate Breast Reconstruction for Breast Cancer: A Claims-Based Analysis	*Ann Surg*	Copublication of included study with no new data
417	28954300	Jagsi	Impact of radiotherapy on complications and patient-reported satisfaction with breast reconstruction: findings from the prospective multicenter MROC study	*Cancer research. Conference: 39th annual CTRC-AACR san antonio breast cancer symposium. United states*	Does not address KQ1-KQ6
418	28954300	Jagsi	Impact of Radiotherapy on Complications and Patient-Reported Outcomes After Breast Reconstruction	*J Natl Cancer Inst*	Duplicate of another publication
419	21617454	Jandali	Breast reconstruction with free tissue transfer from the abdomen in the morbidly obese	*Plast Reconstr Surg*	Single group N enrolled <500
420	20195107	Jandali	1000 consecutive venous anastomoses using the microvascular anastomotic coupler in breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
421	10717013	Janowsky	Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases	*N Engl J Med*	Systematic review
422	2333815	Jarrett	Aesthetic refinements in prophylactic mastectomy with immediate reconstruction	*Aesthetic Plast Surg*	Duplicate of another publication
423	2333815	Jarrett	Aesthetic refinements in prophylatic mastectomy with immediate reconstruction	*Aesthetic Plastic Surgery*	Does not address KQ1-KQ6
424	16482786	Javaid	Radiation effects on the cosmetic outcomes of immediate and delayed autologous breast reconstruction: an argument about timing	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
425	32596186	Jayaraman	The Impact of Combined Risk-Reducing Gynecological Surgeries on Outcomes in DIEP Flap and Tissue-Expander Breast Reconstruction	Plast Surg (Oakv)	NRCS <30 per arm
426	31418290	Jeevan	Reconstructive utilisation and outcomes following mastectomy surgery in women with breast cancer treated in England	*Ann R Coll Surg Engl*	No outcome of interest
427	28445349	Jeevan	Surgical Determinants of Patient-Reported Outcomes following Postmastectomy Reconstruction in Women with Breast Cancer	*Plast Reconstr Surg*	Does not address KQ1-KQ6
428	26075654	Jeevan	Socioeconomic deprivation and inpatient complication rates following mastectomy and breast reconstruction surgery	*Br J Surg*	Does not address KQ1-KQ6
429	24908545	Jeevan	Findings of a national comparative audit of mastectomy and breast reconstruction surgery in England	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
430	24908545	Jeevan	Findings of a national comparative audit of mastectomy and breast reconstruction surgery in England	*Journal of Plastic, Reconstructive and Aesthetic Surgery*	Duplicate of another publication
431	21174155	Jensen	Nipple-sparing mastectomy in 99 patients with a mean follow-up of 5 years	*Ann Surg Oncol*	NRCS not adjusted
432	29227815	Jeong	Meta-analysis of flap perfusion and donor site complications for breast reconstruction using pedicled versus free TRAM and DIEP flaps	*Breast*	Does not address KQ1-KQ6
433	30665838	Jepsen	Complications, patient-reported outcomes, and aesthetic results in immediate breast reconstruction with a dermal sling: A systematic review and meta-analysis	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
434	18472362	Jhaveri	Clinical outcomes of postmastectomy radiation therapy after immediate breast reconstruction	*Int J Radiat Oncol Biol Phys*	NRCS not adjusted
435	26313786	Jia-jian	Current Status of Breast Reconstruction in Southern China: A 15 Year, Single Institutional Experience of 20,551 Breast Cancer Patients	*Medicine (Baltimore)*	Does not address KQ1-KQ6
436	27159061	Jimenez-Puente	[Breast Reconstruction Post-Mastectomy in the Public Health System of Andalusia, Spain]	*Rev Esp Salud Publica*	NRCS not adjusted
437	21388901	JoAnna Nguyen	Use of human acellular dermal matrix in implant- based breast reconstruction: evaluating the evidence	*J Plast Reconstr Aesthet Surg*	Narrative review/ Commentary
438	25954837	Johnson	Advanced Age Does Not Worsen Recovery or Long-Term Morbidity After Postmastectomy Breast Reconstruction	*Ann Plast Surg*	NRCS not adjusted
439	23266307	Johnson	Cost minimisation analysis of using acellular dermal matrix (Strattice) for breast reconstruction compared with standard techniques	*Eur J Surg Oncol*	NRCS <30 per arm
440	30795637	Jonczyk	Trending Towards Safer Breast Cancer Surgeries? Examining Acute Complication Rates from A 13-Year NSQIP Analysis	*Cancers (Basel)*	Copublication of included study with no new data
441	27018665	Jordan	Seroma in Prosthetic Breast Reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
442	CN-01881181	Jprn	The study of assessing the safety of NEOVEIL sheet in immediate two-stage tissue expander/implant breast reconstruction	*http://www.who.int/trialsearch/Trial2.aspx?TrialID=JPRN-UMIN000018644*	Protocol/methods with no results
443	28543692	Jubbal	The impact of resident involvement in breast reconstruction surgery outcomes by modality: An analysis of 4,500 cases	*Microsurgery*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
444	28085525	Juhl	Unilateral breast reconstruction after mastectomy – patient satisfaction, aesthetic outcome and quality of life	*Acta Oncol*	NRCS not adjusted
445	121307353	Juhl	Unilateral breast reconstruction after mastectomy – patient satisfaction, aesthetic outcome and quality of life	*Acta Oncologica*	NRCS not adjusted
446	32007227	Julien	[Comparing outcomes of Immediate Breast reconstruction with and without use of radiotherapy]	Ann Chir Plast Esthet	NRCS not adjusted
447	33482758	Jung	Does chemotherapy or radiotherapy affect the postoperative complication in breast cancer patients who underwent immediate breast reconstruction with tissue expander?	BMC Cancer	Does not address KQ1-KQ6
448	26382872	Kadle	A 35-Year Evolution of Free Flap-Based Breast Reconstruction at a Large Urban Academic Center	*J Reconstr Microsurg*	Single group >500, but no complications data
449	20459373	Kalaaji	Quality of life after breast reconstruction: comparison of three methods	*Scand J Plast Reconstr Surg Hand Surg*	NRCS not adjusted
450	28409847	Kamali	Trends in immediate breast reconstruction and early complication rates among older women: A big data analysis	*J Surg Oncol*	NRCS not adjusted
451	26986990	Kamali	Analyzing Regional Differences over a 15-Year Trend of One-Stage versus Two-Stage Breast Reconstruction in 941,191 Postmastectomy Patients	*Plast Reconstr Surg*	Does not address KQ1-KQ6
452	28338587	Kamali	Medial Row Perforators Are Associated with Higher Rates of Fat Necrosis in Bilateral DIEP Flap Breast Reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
453	28079533	Kamali	National and Regional Differences in 32,248 Postmastectomy Autologous Breast Reconstruction Using the Updated National Inpatient Survey	*Ann Plast Surg*	Does not address KQ1-KQ6
454	29464148	Kamali	Immediate Breast Reconstruction among Patients with Medicare and Private Insurance: A Matched Cohort Analysis	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
455	31764628	Kamel	Patient-Reported Satisfaction and Quality of Life in Obese Patients: A Comparison between Microsurgical and Prosthetic Implant Recipients	*Plast Reconstr Surg*	Single group N enrolled <500
456	30716775	Kamel	Patient-Reported Satisfaction and Quality of Life in Postmastectomy Radiated Patients: A Comparison between Delayed and Delayed Immediate Autologous Breast Reconstruction in a Predominantly Minority Patient Population	*J Reconstr Microsurg*	Single group N enrolled <500
457	10724253	Kaplan	Cost-based comparison between perforator flaps and TRAM flaps for breast reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
458	33462766	Karadsheh	Early postoperative outcomes in implant, pedicled, and free flap reconstruction for breast cancer: an analysis of 23,834 patients from the ACS-NSQIP datasets	Breast Cancer Res Treat	Does not address KQ1-KQ6
459	32892332	Karamanos	Impact of Blood Transfusion in Free Flap Breast Reconstruction Using Propensity Score Matching	J Reconstr Microsurg	Single group N enrolled <500
460	12601605	Kassmann	[Myosonographic evaluation of rectus abdominis muscle function after DIEP flap breast reconstruction]	*Handchir Mikrochir Plast Chir*	Single group N enrolled <500
461	31800564	Kaviani	A Study on Breast Reconstruction in a Developing Country: A Comprehensive Evaluation of the Techniques and Oncologic Outcomes	*Ann Plast Surg*	NRCS not adjusted
462	26526860	Kearney	Timing of radiation and outcomes in implant-based breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
463	24473643	Kelley	A systematic review of morbidity associated with autologous breast reconstruction before and after exposure to radiotherapy: are current practices ideal?	*Ann Surg Oncol*	Systematic review
464	21987043	Kelley	Tamoxifen increases the risk of microvascular flap complications in patients undergoing microvascular breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
465	30794884	Kellou	[Limitations of breast reconstruction using exclusive lipofilling: A retrospective study over 10 years]	*Gynecol Obstet Fertil Senol*	Does not address KQ1-KQ6
466	24388599	Kelly	Lateralising paraumbilical medial row perforators: dangers and pitfalls in DIEP FLAP planning: a systematic review of 1116 DIEP flaps	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
467	9283576	Kern	Carcinogenic potential of silicone breast implants: a Connecticut statewide study	*Plast Reconstr Surg*	Not mastectomy for breast cancer
468	32207573	Khajuria	Immediate and delayed autologous abdominal microvascular flap breast reconstruction in patients receiving adjuvant, neoadjuvant or no radiotherapy: a meta-analysis of clinical and quality-of-life outcomes	*BJS Open*	Narrative review/ Commentary
469	31772906	Khajuria	A Meta-analysis of Clinical, Patient-Reported Outcomes and Cost of DIEP versus Implant-based Breast Reconstruction	*Plast Reconstr Surg Glob Open*	Systematic review
470	29166926	Khajuria	Protocol for a systematic review and meta-analysis on the clinical outcomes and cost of deep inferior epigastric perforator (DIEP) flap versus implants for breast reconstruction	*Syst Rev*	Narrative review/ Commentary
471	21451371	Khansa	Postmastectomy breast reconstruction after previous lumpectomy and radiation therapy: analysis of complications and satisfaction	*Ann Plast Surg*	Does not address KQ1-KQ6
472	24123194	Khansa	Timing of prophylactic hysterectomy-oophorectomy, mastectomy, and microsurgical breast reconstruction in BRCA1 and BRCA2 carriers	*Microsurgery*	Does not address KQ1-KQ6
473	28445350	Khavanin	Shaped versus Round Implants in Breast Reconstruction: A Multi-Institutional Comparison of Surgical and Patient-Reported Outcomes	*Plast Reconstr Surg*	Copublication of included study with no new data
474	24121881	Khavanin	Tumescent technique does not increase the risk of complication following mastectomy with immediate reconstruction	*Ann Surg Oncol*	Single group N enrolled <500
475	24121881	Khavanin	Tumescent technique does not increase the risk of complication following mastectomy with immediate reconstruction	*Annals of Surgical Oncology*	Does not address KQ1-KQ6
476	24454465	Khavanin	Synergistic interactions with a high intraoperative expander fill volume increase the risk for mastectomy flap necrosis	*J Breast Cancer*	Does not address KQ1-KQ6
477	25311295	Kilchenmann	An evaluation of resource utilisation of single stage porcine acellular dermal matrix assisted breast reconstruction: A comparative study	*Breast*	NRCS <30 per arm
478	23389902	Kim	Immediate transverse rectus abdominis musculocutaneous (TRAM) flap breast reconstruction in underweight Asian patients	*Breast Cancer*	Copublication of included study with no new data
479	120349978	Kim	Nipple areola skin-sparing mastectomy with TRAM flap reconstruction: Single-center study	*Journal of Clinical Oncology*	Duplicate of another publication
480	23428931	Kim	Comparison of morbidity of donor site following pedicled muscle-sparing latissimus dorsi flap versus extended latissimus dorsi flap breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
481	20134317	Kim	Nipple-areola skin-sparing mastectomy with immediate transverse rectus abdominis musculocutaneous flap reconstruction is an oncologically safe procedure	*Breast Diseases*	Single group N enrolled <500
482	30282415	Kim	Breast reconstruction statistics in Korea from the Big Data Hub of the Health Insurance Review and Assessment Service	*Arch Plast Surg*	Does not address KQ1-KQ6
483	22186498	Kim	A meta-analysis of human acellular dermis and submuscular tissue expander breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
484	26090295	Kim	Individualized Risk of Surgical Complications: An Application of the Breast Reconstruction Risk Assessment Score	*Plast Reconstr Surg Glob Open*	No outcome of interest
485	31775207	Kim	Inlay graft of acellular dermal matrix to prevent incisional dehiscence after radiotherapy in prosthetic breast reconstruction	*Arch Plast Surg*	NRCS <30 per arm
486	28204936	Kim	Impact of Acellular Dermal Matrix (ADM) Use Under Mastectomy Flap Necrosis on Perioperative Outcomes of Prosthetic Breast Reconstruction	*Aesthetic Plast Surg*	NRCS <30 per arm
487	32332387	Kim	Inframammary Fold Incision Can Reduce Skin Flap Necrosis in Immediate Breast Reconstruction With Implant and Conjoined Fascial Flap	Ann Plast Surg	NRCS <30 per arm
488	32724804	Kim	Diametric Comparison between the Thoracodorsal Vessel and Deep Inferior Epigastric Vessel in Breast Reconstruction	Biomed Res Int	Single group N enrolled <500
489	22286439	Kobraei	Risk factors for adverse outcome following skin-sparing mastectomy and immediate prosthetic reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
490	30173716	Koh	Quality of life and shoulder function after latissimus dorsi breast reconstruction()	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
491	30859037	Komorowska-Timek	Subcutaneous Prosthetic Breast Reconstructions following Skin Reduction Mastectomy	*Plast Reconstr Surg Glob Open*	NRCS <30 per arm
492	24636099	Koolen	Effects of statins on ischemia-reperfusion complications in breast free flaps	*J Surg Res*	Not breast reconstruction
493	24636099	Koolen	Effects of statins on ischemia-reperfusion complications in breast free flaps	*Journal of Surgical Research*	Single group N enrolled <500
494	24512987	Korwar	Skin reducing mastectomy and immediate reconstruction: the effect of radiotherapy on complications and patient reported outcomes	*Eur J Surg Oncol*	NRCS not adjusted
495	33002979	Kotha	A Critical Examination of Length of Stay in Autologous Breast Reconstruction: A National Surgical Quality Improvement Program Analysis	Plast Reconstr Surg	Does not address KQ1-KQ6
496	33349523	Kouwenberg	Cost-utility analysis of four common surgical treatment pathways for breast cancer	European Journal of Surgical Oncology	Copublication of included study with no new data
497	30964213	Kracoff	Neo-adjuvant chemotherapy does not affect the immediate postoperative complication rate after breast reconstruction	*Breast J*	Does not address KQ1-KQ6
498	31066148	Kracoff	Does nipple sparing mastectomy affect the postoperative complication rate after breast reconstruction? Comparison of postoperative complications after nipple sparing mastectomy vs skin sparing mastectomy	*Breast J*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
499	33614536	Kraft	Polypropylene Mesh Complications in the Sublay Position After Abdominally Based Breast Reconstruction: Les complications des treillis de polypropylène en sous-couche après une reconstruction mammaire par voie abdominale	Plast Surg (Oakv)	NRCS not adjusted
500	11050764	Krause	Skin sparing mastectomy and immediate autologous reconstruction: oncological risks and aesthetic results	*Journal of cancer research and clinical oncology*	Single group N enrolled <500
501	25811560	Krishnan	The cost effectiveness of the DIEP flap relative to the muscle-sparing TRAM flap in postmastectomy breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
502	1387483	Kroll	A comparison of outcomes using three different methods of breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
503	8559819	Kroll	Comparison of resource costs between implant-based and TRAM flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
504	8559819	Kroll	Comparison of resource costs between implant-based and TRAM flap breast reconstruction	*Plastic and Reconstructive Surgery*	Duplicate of another publication
505	7850550	Kroll	Rationale for elective contralateral mastectomy with immediate bilateral reconstruction	*Ann Surg Oncol*	NRCS not adjusted
506	11335809	Kroll	Comparison of cost for DIEP and free TRAM flap breast reconstructions	*Plast Reconstr Surg*	NRCS not adjusted
507	9618094	Kroll	Does prior irradiation increase the risk of total or partial free-flap loss?	*J Reconstr Microsurg*	Single group N enrolled <500
508	8700982	Kroll	Choice of flap and incidence of free flap success	*Plast Reconstr Surg*	NRCS not adjusted
509	7638285	Kroll	Abdominal wall strength, bulging, and hernia after TRAM flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
510	22842406	Kronowitz	Current status of autologous tissue-based breast reconstruction in patients receiving postmastectomy radiation therapy	*Plast Reconstr Surg*	Narrative review/ Commentary
511	16404237	Kronowitz	Determining the optimal approach to breast reconstruction after partial mastectomy	*Plast Reconstr Surg*	NRCS <30 per arm
512	14663219	Kronowitz	Optimizing autologous breast reconstruction in thin patients	*Plast Reconstr Surg*	NRCS not adjusted
513	20465509	Kropf	Influence of the recipient vessel on fat necrosis after breast reconstruction with a free transverse rectus abdominis myocutaneous flap	*Scand J Plast Reconstr Surg Hand Surg*	Does not address KQ1-KQ6
514	29504033	Kubo	Complication analysis of complete versus partial coverage of tissue expanders using serratus anterior musculofascial flaps in immediate breast reconstruction	*Surg Today*	NRCS not adjusted
515	26372685	Kulkarni	Venous Thrombosis in Handsewn versus Coupled Venous Anastomoses in 857 Consecutive Breast Free Flaps	*J Reconstr Microsurg*	NRCS not adjusted
516	30231269	Kung	Radiation-Induced Skin Changes after Postmastectomy Radiation Therapy: A Pilot Study on Indicators for Timing of Delayed Breast Reconstruction	*J Reconstr Microsurg*	NRCS <30 per arm

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
517	31332635	Kupstas	Effect of Surgery Type on Time to Adjuvant Chemotherapy and Impact of Delay on Breast Cancer Survival: A National Cancer Database Analysis	*Ann Surg Oncol*	Single group >500, but no complications data
518	28328628	Kuykendall	Unilateral Versus Bilateral Breast Reconstruction: Is Less Really More?	*Ann Plast Surg*	NRCS not adjusted
519	27714840	Kwok	An analysis of free flap failure using the ACS NSQIP database. Does flap site and flap type matter?	*Microsurgery*	Does not address KQ1-KQ6
520	29452440	Kwok	Operative Time and Flap Failure in Unilateral and Bilateral Free Flap Breast Reconstruction	*J Reconstr Microsurg*	Does not address KQ1-KQ6
521	26054659	Kwok	National trends and complication rates after bilateral mastectomy and immediate breast reconstruction from 2005 to 2012	*American Journal of Surgery*	Duplicate of another publication
522	26054659	Kwok	National trends and complication rates after bilateral mastectomy and immediate breast reconstruction from 2005 to 2012	*Am J Surg*	Does not address KQ1-KQ6
523	30085346	Kwok	Immediate Unilateral Breast Reconstruction using Abdominally Based Flaps: Analysis of 3,310 Cases	*J Reconstr Microsurg*	NRCS not adjusted
524	109199616	Kwok	National trends and complication rates after bilateral mastectomy and immediate breast reconstruction from 2005 to 2012	*American Journal of Surgery*	Duplicate of another publication
525	26794627	Lagares-Borrego	A comparison of long-term cost and clinical outcomes between the two-stage sequence expander/prosthesis and autologous deep inferior epigastric flap methods for breast reconstruction in a public hospital	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
526	30178391	Lagendijk	Patient-Reported Outcome Measures May Add Value in Breast Cancer Surgery	*Ann Surg Oncol*	Single group N enrolled <500
527	29139613	Lago	Nipple-sparing mastectomy as treatment for patients with ductal carcinoma in situ: A 10-year follow-up study	*Breast Journal*	Single group N enrolled <500
528	30145648	Lai	Robotic Nipple-Sparing Mastectomy and Immediate Breast Reconstruction with Gel Implant	*Ann Surg Oncol*	Duplicate of another publication
529	29750759	Lam	Immediate Two-Stage Prosthetic Breast Reconstruction Failure: Radiation Is Not the Only Culprit	*Plast Reconstr Surg*	Does not address KQ1-KQ6
530	23676964	Lam	The effects of postmastectomy adjuvant radiotherapy on immediate two-stage prosthetic breast reconstruction: a systematic review	*Plast Reconstr Surg*	Narrative review/ Commentary
531	29062656	Lam	Two-Stage Prosthetic Breast Reconstruction after Mastectomy with or without Prior Postmastectomy Radiotherapy	*Plast Reconstr Surg Glob Open*	Single group N enrolled <500
532	12560692	Langstein	Breast cancer recurrence after immediate reconstruction: patterns and significance	*Plast Reconstr Surg*	Does not address KQ1-KQ6
533	20395795	Lanier	The effect of acellular dermal matrix use on complication rates in tissue expander/implant breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
534	CN-01301217	Laporta	Breast Reconstruction in Elderly Patients: risk Factors, Clinical Outcomes, and Aesthetic Results	*Journal of reconstructive microsurgery*	Duplicate of another publication
535	28061518	Laporta	Breast Reconstruction in Elderly Patients: Risk Factors, Clinical Outcomes, and Aesthetic Results	*Journal of Reconstructive Microsurgery*	Duplicate of another publication

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
536	23559355	Largent	Clinical trial outcomes of high- and extra high-profile breast implants	*Aesthet Surg J*	Not breast reconstruction
537	31316828	Laura	Postsurgical Ultrasound Evaluation of Patients with Prosthesis in Acellular Dermal Matrix: Results from Monocentric Experience	*Int J Surg Oncol*	NRCS <30 per arm
538	33337991	Lazzaroni	Association of anti-RNA polymerase III antibody with silicone breast implants rupture in a multicentre series of Italian patients with systemic sclerosis	Clin Exp Rheumatol	Single group N enrolled <500
539	32337778	Le	Impact of socioeconomic status on psychological functioning in survivorship following breast cancer and reconstruction	Breast Journal	Does not address KQ1-KQ6
540	26936318	Leckenby	Poly Implant Prothese (PIP) experience in the United Kingdom: A prospective cohort study into the accuracy of diagnostic imaging findings in comparison to operative findings of 1029 implants	*J Plast Reconstr Aesthet Surg*	Not breast reconstruction
541	26543648	Leduey	Comparison of the Explantation Rate of Poly Implant Prothese, Allergan, and Perouse Silicone Breast Implants within the First Four Years after Reconstructive Surgery before the Poly Implant Prothese Alert by the French Regulatory Authority	*Int J Breast Cancer*	>=10% augmentation reconstruction only
542	29068921	Lee	Evidence-Based Clinical Practice Guideline: Autologous Breast Reconstruction with DIEP or Pedicled TRAM Abdominal Flaps	*Plast Reconstr Surg*	Narrative review/ Commentary
543	20395800	Lee	Postmastectomy radiation therapy and breast reconstruction: an analysis of complications and patient satisfaction	*Ann Plast Surg*	NRCS not adjusted
544	20009825	Lee	Establishment of perforator flap programs for breast reconstruction: the New England program experience	*Plast Reconstr Surg*	NRCS not adjusted
545	19651073	Lee	Patient-reported outcomes of breast reconstruction after mastectomy: a systematic review	*J Am Coll Surg*	Does not address KQ1-KQ6
546	30431446	Lee	Nipple-sparing Mastectomy and Immediate Breast Reconstruction After Recurrence From Previous Breast Conservation Therapy	*Ann Plast Surg*	NRCS not adjusted
547	31964119	Lee	Ultrasonic dissection versus electrocautery for immediate prosthetic breast reconstruction	*Arch Plast Surg*	Single group N enrolled <500
548	26863006	Lee	Comparison of Long-Term Outcomes of Postmastectomy Radiotherapy between Breast Cancer Patients with and without Immediate Flap Reconstruction	*PLoS One*	Single group N enrolled <500
549	26161312	Lee	Use of latissimus dorsi muscle onlay patch alternative to acellular dermal matrix in implant-based breast reconstruction	*Gland Surg*	NRCS <30 per arm
550	28544393	Lee	Comparison of 5-year oncological outcomes of breast cancer based on surgery type	*ANZ J Surg*	Single group N enrolled <500
551	22323920	Lee	Does Immediate Breast Reconstruction after Mastectomy affect the Initiation of Adjuvant Chemotherapy?	*J Breast Cancer*	Single group N enrolled <500
552	26791137	Lee	Technique and outcomes of laparoscopic bulge repair after abdominal free flap reconstruction	*Microsurgery*	NRCS not adjusted
553	23094245	Lee	Reliability of reconstructed breast flap after chemotherapy and radiotherapy in immediate breast reconstruction	*Arch Plast Surg*	Single group N enrolled <500
554	31246795	Lee	Predictors for Prolonged Drainage following Tissue Expander-Based Breast Reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
555	28255833	Lee	Optimal Sequencing of Postmastectomy Radiotherapy and Two Stages of Prosthetic Reconstruction: A Meta-analysis	*Ann Surg Oncol*	Does not address KQ1-KQ6
556	25536199	Lee	Effects of Obesity on Postoperative Complications After Breast Reconstruction Using Free Muscle-Sparing Transverse Rectus Abdominis Myocutaneous, Deep Inferior Epigastric Perforator, and Superficial Inferior Epigastric Artery Flap: A Systematic Review and Meta-analysis	*Ann Plast Surg*	Does not address KQ1-KQ6
557	26374273	Lee	Prosthetic breast reconstruction in previously irradiated breasts: A meta-analysis	*J Surg Oncol*	Does not address KQ1-KQ6
558	26499053	Lee	Comparison of one-stage vs two-stage prosthesis-based breast reconstruction: a systematic review and meta-analysis	*Am J Surg*	Systematic review
559	26438439	Lee	Updated Evidence of Acellular Dermal Matrix Use for Implant-Based Breast Reconstruction: A Meta-analysis	*Ann Surg Oncol*	Narrative review/ Commentary
560	28509698	Lee	A Meta-analysis of Studies Comparing Outcomes of Diverse Acellular Dermal Matrices for Implant-Based Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
561	29718895	Lee	Long-term outcomes of patients with breast cancer after nipple-sparing mastectomy/skin-sparing mastectomy followed by immediate transverse rectus abdominis musculocutaneous flap reconstruction	*Medicine (United States)*	Duplicate of another publication
562	29718895	Lee	Long-term outcomes of patients with breast cancer after nipple-sparing mastectomy/skin-sparing mastectomy followed by immediate transverse rectus abdominis musculocutaneous flap reconstruction: Comparison with conventional mastectomy in a single center study	*Medicine (Baltimore)*	Single group >500, but no complications data
563	22872842	Lee	Outcome of management of local recurrence after immediate transverse rectus abdominis myocutaneous flap breast reconstruction	*Arch Plast Surg*	NRCS <30 per arm
564	23283525	Lee	Adjuvant chemotherapy reduces the incidence of abdominal hypertrophic scarring following immediate TRAM breast reconstruction	*Breast Cancer Res Treat*	Copublication of included study with no new data
565	27121604	Lee	Risk factors of mastectomy skin flap necrosis in immediate breast reconstruction using low abdominal flaps	*J Plast Surg Hand Surg*	No outcome of interest
566	33009147	Lee	The Hybrid Latissimus Dorsi Flap in Immediate Breast Reconstruction: A Comparative Study With the Abdominal-Based Flap	Ann Plast Surg	Single group N enrolled <500
567	32246465	Lee	Influence of complications following total mastectomy and immediate reconstruction on breast cancer recurrence	Br J Surg	Does not address KQ1-KQ6
568	23788143	Lentz	Radiation therapy and expander-implant breast reconstruction: an analysis of timing and comparison of complications	*Ann Plast Surg*	NRCS <30 per arm
569	21136255	Leone	Factors affecting symmetrization of the contralateral breast: a 7-year unilateral postmastectomy breast reconstruction experience	*Aesthetic Plast Surg*	No outcome of interest
570	32452097	Leser	Complication rates among women undergoing preventive mastectomy: An Austrian registry	Breast J	Single group N enrolled <500
571	21301299	Levine	Perforator flap breast reconstruction after unsatisfactory implant reconstruction	*Ann Plast Surg*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
572	22964681	Levine	Outcomes of delayed abdominal-based autologous reconstruction versus latissimus dorsi flap plus implant reconstruction in previously irradiated patients	*Ann Plast Surg*	NRCS not adjusted
573	24076695	Levine	Buried flap reconstruction after nipple-sparing mastectomy: advancing toward single-stage breast reconstruction	*Plastic and reconstructive surgery*	Single group N enrolled <500
574	32243319	Levy	Poly-4-Hydroxybutyric Acid Mesh Compares Favorably With Acellular Dermal Matrix in Tissue Expander-Based Breast Reconstruction	Ann Plast Surg	NRCS not adjusted
575	31274754	Li	Assessment of Factors for Complication in Autologous Breast Reconstruction.'	*Plast Reconstr Surg*	Narrative review/ Commentary
576	31256950	Li	Comparison of prepectoral and subpectoral breast reconstruction after mastectomies: A systematic review and meta analysis	*Eur J Surg Oncol*	Does not address KQ1-KQ6
577	31095530	Li	Pyoderma Gangrenosum After Abdominal Free Tissue Transfer for Breast Reconstruction: Case Series and Management Guidelines	*Ann Plast Surg*	Single group N enrolled <500
578	20578076	Lim	Oncological safety of skin sparing mastectomy followed by immediate reconstruction for locally advanced breast cancer	*J Surg Oncol*	NRCS <30 per arm
579	22456353	Lin	Implant-based, two-stage breast reconstruction in the setting of radiation injury: an outcome study	*Plast Reconstr Surg*	NRCS <30 per arm
580	22743867	Lindegren	Postmastectomy breast reconstruction in the irradiated breast: a comparative study of DIEP and latissimus dorsi flap outcome	*Plast Reconstr Surg*	NRCS not adjusted
581	31538064	Lindenblatt	A systematic review of donor site aesthetic and complications after deep inferior epigastric perforator flap breast reconstruction	*Gland Surg*	Systematic review
582	12621181	Lipa	Breast reconstruction in older women: advantages of autogenous tissue	*Plast Reconstr Surg*	NRCS <30 per arm
583	26165574	Lisa	Comparison of Delayed and Immediate Tissue Expander Breast Reconstruction in the Setting of Postmastectomy Radiation Therapy	*Ann Plast Surg*	Narrative review/ Commentary
584	24831775	Liu	Quality of life and patient satisfaction after microsurgical abdominal flap versus staged expander/implant breast reconstruction: a critical study of unilateral immediate breast reconstruction using patient-reported outcomes instrument BREAST-Q	*Breast Cancer Res Treat*	NRCS not adjusted
585	None	Liu	Contraction of reconstructive effects following mastectomy between expandable prosthesis and autologous tissue	*Chinese Journal of Cancer Prevention and Treatment*	NRCS <30 per arm
586	25680100	Liu	Comparison of the postoperative incidence rate of capsular contracture among different breast implants: a cumulative meta-analysis	*PLoS One*	Not breast reconstruction
587	31939242	Liu	[Multivariable analysis for flap-related complications in autologous breast reconstruction and economic analysis of intraoperative indocyanine green angiography]	Zhongguo Xiu Fu Chong Jian Wai Ke Za Zhi	NRCS not adjusted
588	32095924	Livingston-Rosanoff	Evaluation of Long-Term Satisfaction with Breast Surgery in Patients Treated for Ductal Carcinoma In Situ: A Population-Based Longitudinal Cohort Study	*Ann Surg Oncol*	No outcome of interest

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
589	30308615	Lohmander	Implant Based Breast Reconstruction With Acellular Dermal Matrix: Safety Data From an Open-label, Multicenter, Randomized, Controlled Trial in the Setting of Breast Cancer Treatment	*Ann Surg*	Does not address KQ1-KQ6
590	32762012	Lohmander	Quality of life and patient satisfaction after implant-based breast reconstruction with or without acellular dermal matrix: randomized clinical trial	BJS Open	Does not address KQ1-KQ6
591	29707460	Loo	Comparing the Outcome of Different Biologically Derived Acellular Dermal Matrices in Implant-based Immediate Breast Reconstruction: A Meta-analysis of the Literatures	*Plast Reconstr Surg Glob Open*	Narrative review/ Commentary
592	24867714	Lopez	The impact of conflicts of interest in plastic surgery: an analysis of acellular dermal matrix, implant-based breast reconstruction	*Plastic and reconstructive surgery*	Narrative review/ Commentary
593	24867714	Lopez	The impact of conflicts of interest in plastic surgery: an analysis of acellular dermal matrix, implant-based breast reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
594	12087236	Losken	Trends in unilateral breast reconstruction and management of the contralateral breast: the Emory experience	*Plast Reconstr Surg*	Does not address KQ1-KQ6
595	15156978	Losken	Factors that influence the completion of breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
596	23542858	Losken	Time to completion of nipple reconstruction: what factors are involved?	*Ann Plast Surg*	NRCS <30 per arm
597	21451387	Losken	Autologous fat grafting in secondary breast reconstruction	*Ann Plast Surg*	Single group N enrolled <500
598	25878934	Luce	Tissue Expander versus Tissue Expander and Latissimus Flap in Morbidly Obese Breast Reconstruction Patients	*Plast Reconstr Surg Glob Open*	Single group N enrolled <500
599	25389715	Lynch	A Comparison of Dermal Autograft and Acellular Dermal Matrix in Tissue Expander Breast Reconstruction: Long-term Aesthetic Outcomes and Capsular Contracture	*Ann Plast Surg*	NRCS <30 per arm
600	28743588	Magill	Determining the outcomes of post-mastectomy radiation therapy delivered to the definitive implant in patients undergoing one- and two-stage implant-based breast reconstruction: A systematic review and meta-analysis	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
601	32172527	Magno-Padron	A Nationwide Analysis of Early and Late Readmissions following Free Tissue Transfer for Breast Reconstruction	*J Reconstr Microsurg*	No outcome of interest
602	27826483	Major	The Effect of Timing on Breast Reconstruction Outcomes in Diabetic Women	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
603	26579526	Malata	Decision Making in Double-Pedicled DIEP and SIEA Abdominal Free Flap Breast Reconstructions: An Algorithmic Approach and Comprehensive Classification	*Front Surg*	Single group N enrolled <500
604	19342994	Man	Abdominal wall following free TRAM or DIEP flap reconstruction: a meta-analysis and critical review	*Plast Reconstr Surg*	Narrative review/ Commentary
605	33627231	Mandelbaum	National trends and predictors of mastectomy with immediate breast reconstruction	Am J Surg	Does not address KQ1-KQ6
606	32712889	Mandelbaum	National Trends in Immediate Breast Reconstruction: An Analysis of Implant-Based Versus Autologous Reconstruction After Mastectomy	Ann Surg Oncol	NRCS not adjusted
607	31044105	Manrique	Surgical Outcomes of Prepectoral Versus Subpectoral Implant-based Breast Reconstruction in Young Women	*Plast Reconstr Surg Glob Open*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
608	31416221	Manrique	Two-Staged Implant-Based Breast Reconstruction: A Long-Term Outcome Study in a Young Population	*Medicina (Kaunas)*	Single group N enrolled <500
609	31985613	Manrique	Prepectoral Two-Stage Implant-Based Breast Reconstruction with and without Acellular Dermal Matrix: Do We See a Difference?	*Plast Reconstr Surg*	NRCS <30 per arm
610	31633546	Manrique	Single-Stage Direct-to-Implant Breast Reconstruction: A Comparison Between Subpectoral Versus Prepectoral Implant Placement	*Annals of plastic surgery*	NRCS not adjusted
611	31633546	Manrique	Single-Stage Direct-to-Implant Breast Reconstruction: A Comparison Between Subpectoral Versus Prepectoral Implant Placement	*Ann Plast Surg*	NRCS not adjusted
612	31985613	Manrique	Prepectoral Two-Stage Implant-Based Breast Reconstruction with and without Acellular Dermal Matrix: Do We See a Difference?	Plastic and reconstructive surgery	NRCS <30 per arm
613	3768653	Mansel	Cosmetic results of immediate breast reconstruction post-mastectomy: a follow-up study	*Br J Surg*	NRCS not adjusted
614	3768653	Mansel	Cosmetic results of immediate breast reconstruction post-mastectomy: A follow-up study	*British Journal of Surgery*	NRCS not adjusted
615	31187585	Manum	Variables associated with length of stay in patients undergoing mastectomy and delayed-immediate breast reconstruction with tissue expander	*Breast J*	Single group N enrolled <500
616	31238166	Manyam	Long-Term Outcomes After Autologous or Tissue Expander/Implant-Based Breast Reconstruction and Postmastectomy Radiation for Breast Cancer	*Pract Radiat Oncol*	Duplicate of another publication
617	31238166	Manyam	Long-Term Outcomes After Autologous or Tissue Expander/Implant-Based Breast Reconstruction and Postmastectomy Radiation for Breast Cancer	*Practical Radiation Oncology*	NRCS not adjusted
618	31264293	Manyam	Long-term complications and reconstruction failures in previously radiated breast cancer patients receiving salvage mastectomy with autologous reconstruction or tissue expander/implant-based reconstruction	*Breast J*	NRCS not adjusted
619	139349741	Manyam	Long-term complications and reconstruction failures in previously radiated breast cancer patients receiving salvage mastectomy with autologous reconstruction or tissue expander/implant-based reconstruction	*Breast Journal*	Duplicate of another publication
620	21782310	Marchac	[A cost analysis of DIEP flap in breast reconstruction]	*Ann Chir Plast Esthet*	No outcome of interest
621	29176408	Marcusa	Prescription Opioid Use among Opioid-Naive Women Undergoing Immediate Breast Reconstruction	*Plast Reconstr Surg*	No outcome of interest
622	None	Marongiu	A human-derived acellular dermal matrix for breast reconstruction: The first European experience	European Journal of Cancer	Single group N enrolled <500
623	27047779	Marsh	Three routine free flaps per day in a single operating theatre: principles of a process mapping approach to improving surgical efficiency	*Gland Surg*	Does not address KQ1-KQ6
624	25347626	Martin	Use of fenestrations in acellular dermal allograft in two-stage tissue expander/implant breast reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
625	33133958	Martinez	Outpatient Microsurgical Breast Reconstruction	Plast Reconstr Surg Glob Open	NRCS not adjusted
626	28051266	Maruccia	One-stage breast reconstruction techniques in elderly patients to preserve quality of life	*Eur Rev Med Pharmacol Sci*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
627	24665051	Masoomi	Predictive risk factors of free flap thrombosis in breast reconstruction surgery	*Microsurgery*	Does not address KQ1-KQ6
628	31309057	Masoomi	Frequency and Predictors of 30-Day Surgical Site Complications in Autologous Breast Reconstruction Surgery	*World J Plast Surg*	Copublication of included study with no new data
629	31620328	Masoomi	Effect of Anemia in Postoperative Outcomes of Autologous Breast Reconstruction Surgery	*World J Plast Surg*	Does not address KQ1-KQ6
630	25642875	Masoomi	Does immediate tissue expander placement increase immediate postoperative complications in patients with breast cancer?	*Am Surg*	Does not address KQ1-KQ6
631	25357045	Masoomi	Perioperative outcomes of autologous breast reconstruction surgery in teaching versus nonteaching hospitals	*Plast Reconstr Surg*	Copublication of included study with no new data
632	26054302	Masoomi	Comparison of perioperative outcomes of autologous breast reconstruction surgeries	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
633	104822047	Massey	O-94 Patient reported outcomes following post mastectomy breast reconstruction	*EJC Supplements*	Single group N enrolled <500
634	19730293	Massey	Perforator flaps: Recent experience, current trends, and future directions based on 3974 microsurgical breast reconstructions	*Plastic and Reconstructive Surgery*	Narrative review/ Commentary
635	19730293	Massey	Perforator flaps: recent experience, current trends, and future directions based on 3974 microsurgical breast reconstructions	*Plast Reconstr Surg*	Does not address KQ1-KQ6
636	23083621	Matos	Fat necrosis in the breast after reconstruction with transverse rectus abdominis myocutaneous flap: MRI features	*European Journal of Radiology*	Single group N enrolled <500
637	26193963	Matsen	Skin Flap Necrosis After Mastectomy With Reconstruction: A Prospective Study	*Ann Surg Oncol*	Single group N enrolled <500
638	29617492	Matsumoto	Influence of advanced age on postoperative outcomes and total loss following breast reconstruction: a critical assessment of 560 cases	*Rev Col Bras Cir*	Does not address KQ1-KQ6
639	28195672	Matthews	Predictors of satisfaction and quality of life following post-mastectomy breast reconstruction	*Psychooncology*	Single group N enrolled <500
640	32332527	Mauch	Does Pregnancy Predict Incisional Hernia Repair after Abdominally Based Autologous Breast Reconstruction? A Retrospective Review of 890 Free Flaps	Plast Reconstr Surg	Copublication of included study with no new data
641	25717116	Maxwell	Ten-year results from the Natrelle 410 anatomical form-stable silicone breast implant core study	*Aesthet Surg J*	Single group N enrolled <500
642	32948492	Mayer	The value of preoperative computed tomography angiography (CT-A) in patients undergoing delayed latissimus dorsi flap breast reconstruction after axillary lymph node dissection or irradiation and suspicion of pedicle injury	J Plast Reconstr Aesthet Surg	Single group N enrolled <500
643	109500657	Mays	Surgical Outcomes in Elderly Patients Undergoing Mastectomy With and Without Reconstruction for Breast Cancer	*Journal of the American College of Surgeons*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
644	21136577	McCarthy	Patient satisfaction with postmastectomy breast reconstruction: a comparison of saline and silicone implants	*Cancer*	Duplicate of another publication
645	3566108	McCraw	An early appraisal of the methods of tissue expansion and the transverse rectus abdominis musculocutaneous flap in reconstruction of the breast following mastectomy	*Ann Plast Surg*	Single group N enrolled <500
646	3566108	McCraw	An early appraisal of the methods of tissue expansion and the transverse rectus abdominis musculocutaneous flap in reconstruction of the breast following mastectomy	*Annals of Plastic Surgery*	NRCS not adjusted
647	27627058	McGuire	Risk Factor Analysis for Capsular Contracture, Malposition, and Late Seroma in Subjects Receiving Natrelle 410 Form-Stable Silicone Breast Implants	*Plast Reconstr Surg*	Copublication of included study with no new data
648	12900602	Mehrara	Alternative venous outflow vessels in microvascular breast reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
649	28847440	Menez	Multicenter evaluation of quality of life and patient satisfaction after breast reconstruction, a long-term retrospective study	*Ann Chir Plast Esthet*	NRCS not adjusted
650	27776942	Mennie	National trends in immediate and delayed post-mastectomy reconstruction procedures in England: A seven-year population-based cohort study	*Eur J Surg Oncol*	Does not address KQ1-KQ6
651	30683449	Mets	Persistent disparities in breast cancer surgical outcomes among hispanic and African American patients	*Eur J Surg Oncol*	Does not address KQ1-KQ6
652	32823954	Meyer	The Value of Morphometric Measurements in Risk Assessment for Donor-Site Complications after Microsurgical Breast Reconstruction	J Clin Med	NRCS <30 per arm
653	18235363	Michy	[What surgical procedure for immediate breast reconstruction after preoperative radiotherapy and chemotherapy?]	*J Chir (Paris)*	NRCS not adjusted
654	22768687	Mijatovic	[Quality of life after breast reconstruction]	*Lijec Vjesn*	Unable to retrieve article
655	29538000	Mikhaylov	Ketorolac and Hematoma Incidence in Postmastectomy Implant-Based Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
656	9858162	Miller	Absence of longitudinal changes in rheumatologic parameters after silicone breast implantation: a prospective 13-year study	*Plast Reconstr Surg*	NRCS not adjusted
657	25607768	Miller	Immediate Implant Reconstruction Is Associated With a Reduced Risk of Lymphedema Compared to Mastectomy Alone: A Prospective Cohort Study	*Ann Surg*	Does not address KQ1-KQ6
658	17255654	Miller	Microvascular breast reconstruction in the diabetic patient	*Plast Reconstr Surg*	Does not address KQ1-KQ6
659	31663934	Mirhaidari	Prepectoral Versus Subpectoral Direct to Implant Immediate Breast Reconstruction	*Ann Plast Surg*	NRCS not adjusted
660	22094760	Mirzabeigi	Trials and tribulations with the inferior gluteal artery perforator flap in autologous breast reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
661	30789475	Mirzabeigi	Locoregional Cancer Recurrence after Breast Reconstruction: Detection, Management, and Secondary Reconstructive Strategies	*Plast Reconstr Surg*	NRCS <30 per arm
662	23542828	Mirzabeigi	An assessment of the risks and benefits of immediate autologous breast reconstruction in patients undergoing postmastectomy radiation therapy	*Ann Plast Surg*	Does not address KQ1-KQ6
663	25539292	Mirzabeigi	Predicting and managing donor-site wound complications in abdominally based free flap breast reconstruction: improved outcomes with early reoperative closure	*Plast Reconstr Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
664	10863769	Missana	[Radiotherpay and immediate breast reconstruction with myocutaneous flap in breast cancer of reserved prognosis]	*Ann Chir Plast Esthet*	Unable to retrieve article
665	10863769	Missana	Radiotherapy and immediate breast reconstruction with myocutaneous flap in breast cancer of reserved prognosis	*Annales de Chirurgie Plastique Esthetique*	Unable to retrieve article
666	24495186	Mlodinow	Risk factors for mastectomy flap necrosis following immediate tissue expander breast reconstruction	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
667	24025652	Mlodinow	Predictors of readmission after breast reconstruction: a multi-institutional analysis of 5012 patients	*Ann Plast Surg*	Duplicate of another publication
668	7851550	Modena	Mastectomy and immediate breast reconstruction: Oncological considerations and evaluation of two different methods relating to 88 cases	*European Journal of Surgical Oncology*	NRCS not adjusted
669	22795362	Mohan	Trends in tertiary breast reconstruction: literature review and single centre experience	*Breast*	Narrative review/ Commentary
670	32892804	Mohan	Autologous Breast Reconstruction in Low Body Mass Index Patients: Strategies for Maximizing Skin Envelope and Breast Volume	Clin Plast Surg	Single group N enrolled <500
671	31628083	Moller	The reconstructive journey: Description of the breast reconstruction pathway in a high-volume UK-based microsurgical centre	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
672	31568276	Momeni	A Matched-Pair Analysis of Prepectoral with Subpectoral Breast Reconstruction: Is There a Difference in Postoperative Complication Rate?	*Plast Reconstr Surg*	NRCS not adjusted
673	27355266	Momoh	Tradeoffs Associated With Contralateral Prophylactic Mastectomy in Women Choosing Breast Reconstruction: Results of a Prospective Multicenter Cohort	*Ann Surg*	Copublication of included study with no new data
674	21629047	Momoh	Delayed autologous breast reconstruction after postmastectomy radiation therapy: is there an optimal time?	*Ann Plast Surg*	Does not address KQ1-KQ6
675	21659842	Momoh	Analysis of complications and patient satisfaction in pedicled transverse rectus abdominis myocutaneous and deep inferior epigastric perforator flap breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
676	110864088	Momoh	Breast reconstruction in patients with unilateral breast cancer who choose contralateral prophylactic mastectomy: an assessment of postoperative morbidity	*Journal of the American College of Surgeons*	Does not address KQ1-KQ6
677	21843920	Monrigal	Mastectomy with immediate breast reconstruction after neoadjuvant chemotherapy and radiation therapy. A new option for patients with operable invasive breast cancer. Results of a 20 years single institution study	*Eur J Surg Oncol*	NRCS not adjusted
678	32205491	Monroig	Do Postoperative Prophylactic Antibiotics Reduce Highly Virulent Infections?: An Analysis of 660 Tissue Expander Breast Reconstructions	*Ann Plast Surg*	Does not address KQ1-KQ6
679	3432841	Montoreano	Latissimus dorsi and rectus abdominis breast reconstruction postmastectomy: musculocutaneous breast reconstruction	*Semin Surg Oncol*	NRCS not adjusted
680	33220897	Moon	Adverse Events Associated with Breast Implants: The Role of Bacterial Infection and Biofilm	Clin Plast Surg	Narrative review/Commentary

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
681	None	Moon	Can pregnancy following muscle-sparing transverse abdominis myocutaneous (MS-TRAM) flaps be safe on abdominal wall?	Clinical and Experimental Obstetrics and Gynecology	Case report or series of case reports
682	17312480	Mosahebi	Aesthetic outcome of different techniques of reconstruction following nipple-areola-preserving envelope mastectomy with immediate reconstruction	*Plastic and Reconstructive Surgery*	NRCS <30 per arm
683	32332524	Mosharrafa	Direct-to-Implant Breast Reconstruction with Simultaneous Nipple-Sparing Mastopexy Utilizing an Inferiorly Based Adipodermal Flap: Our Experience with Prepectoral and Subpectoral Techniques	Plast Reconstr Surg	Narrative review/Commentary
684	27798949	Mull	Impact of Time Interval between Radiation and Free Autologous Breast Reconstruction	*J Reconstr Microsurg*	Does not address KQ1-KQ6
685	28445351	Mundy	Breast Cancer and Reconstruction: Normative Data for Interpreting the BREAST-Q	*Plast Reconstr Surg*	Does not address KQ1-KQ6
686	32097289	Mundy	The Evolution of Breast Satisfaction and Well-Being after Breast Cancer: A Propensity-Matched Comparison to the Norm	*Plast Reconstr Surg*	Does not address KQ1-KQ6
687	32766077	Mundy	Optimizing Intraoperative Evaluation of Mastectomy Skin Flap Viability	Plast Reconstr Surg Glob Open	Case report or series of case reports
688	18317121	Munhoz	Assessment of immediate conservative breast surgery reconstruction: a classification system of defects revisited and an algorithm for selecting the appropriate technique	*Plast Reconstr Surg*	Single group N enrolled <500
689	30824169	Murphy	Returns to the operating room after breast surgery at a tertiary care medical center	*Am J Surg*	Not breast reconstruction
690	31297826	Murphy	Pain and opioid prescriptions vary by procedure after breast surgery	*J Surg Oncol*	Does not address KQ1-KQ6
691	30745085	Murphy	A comparison of patient reported outcome measures in patients who received both DIEP flap and PAP flap breast reconstructions	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
692	29901587	Myung	Quantitative analysis of shoulder function and strength after breast reconstruction: A retrospective cohort study	*Medicine (Baltimore)*	NRCS not adjusted
693	130212782	Myung	Quantitative analysis of shoulder function and strength after breast reconstruction: A retrospective cohort study	*Medicine*	NRCS not adjusted
694	33692412	Myung	Validating machine learning approaches for prediction of donor related complication in microsurgical breast reconstruction: a retrospective cohort study	Sci Rep	Duplicate of another publication
695	33692412	Myung	Validating machine learning approaches for prediction of donor related complication in microsurgical breast reconstruction: a retrospective cohort study	Sci Rep	Single group >500, but no harms data
696	19952629	Nahabedian	AlloDerm performance in the setting of prosthetic breast surgery, infection, and irradiation	*Plast Reconstr Surg*	Single group N enrolled <500
697	29166344	Nahabedian	Two-Stage Prosthetic Breast Reconstruction: A Comparison Between Prepectoral and Partial Subpectoral Techniques	*Plast Reconstr Surg*	NRCS not adjusted
698	11786798	Nahabedian	Contour abnormalities of the abdomen after breast reconstruction with abdominal flaps: the role of muscle preservation	*Plast Reconstr Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
699	21251120	Nahabedian	Breast reconstruction in women under 30: a 10-year experience	*Breast J*	Narrative review/ Commentary
700	18443503	Nahabedian	The impact of breast reconstruction on the oncologic efficacy of radiation therapy: a retrospective analysis	*Ann Plast Surg*	NRCS not adjusted
701	12142662	Nahabedian	Breast Reconstruction with the free TRAM or DIEP flap: patient selection, choice of flap, and outcome	*Plast Reconstr Surg*	NRCS not adjusted
702	15220572	Nahabedian	Factors associated with anastomotic failure after microvascular reconstruction of the breast	*Plast Reconstr Surg*	Single group N enrolled <500
703	15692347	Nahabedian	Breast reconstruction with the DIEP flap or the muscle-sparing (MS-2) free TRAM flap: is there a difference?	*Plast Reconstr Surg*	NRCS not adjusted
704	33202009	Nahabedian	What Are the Long-Term Aesthetic Issues in Prepectoral Breast Reconstruction?	Aesthet Surg J	NRCS <30 per arm
705	30847663	Nakagomi	Lateral thoracoaxillar dermal-fat flap for breast conserving surgery: the changes of the indication and long-term results	*Breast Cancer*	Not breast reconstruction
706	15943735	Nano	Qualitative assessment of breast reconstruction in a specialist breast unit	*ANZ J Surg*	NRCS not adjusted
707	31055108	Naoum	The Impact of Chest Wall Boost on Reconstruction Complications and Local Control in Patients Treated for Breast Cancer	*Int J Radiat Oncol Biol Phys*	Does not address KQ1-KQ6
708	32607638	Naoum	Optimal Reconstruction Type and PMRT Timing for Breast Cancer Patients treated by Neoadjuvant Chemotherapy and Mastectomy	*International Journal of Radiation Oncology, Biology, Physics*	Does not address KQ1-KQ6
709	CN-01580972	Nct	Direct to Implant Breast Reconstruction Based Pre- or Retropectoral	*https://clinicaltrials.gov/show/NCT03143335*	Protocol/methods with no results
710	CN-01701127	Nct	SEroma Reduction pOst MAstectomy 'SEROMA Study'	*https://clinicaltrials.gov/show/NCT03738527*	Not breast reconstruction
711	CN-01517046	Nct	The Use of an Acellular Dermal Matrix in a Two-Staged Breast Reconstruction	*https://clinicaltrials.gov/show/NCT00616824*	Protocol/methods with no results
712	CN-01581816	Nct	Prospective Trial of Subcutaneous Versus Subpectoral 2-Staged Implant-Based Breast Reconstruction	*https://clinicaltrials.gov/show/NCT02775409*	Protocol/methods with no results
713	CN-01794765	Nct	Delayed-immediate Versus Delayed Breast Reconstruction in Breast Cancer Patients With Mastectomy and Radiation Therapy	*https://clinicaltrials.gov/show/NCT03730922*	Protocol/methods with no results
714	CN-01794855	Nct	Standard Silicone-based vs. B-Lite® Light Weight Breast Implant After Total Mastectomy and Radiotherapy for Breast Cancer	*https://clinicaltrials.gov/show/NCT03737500*	Protocol/methods with no results

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
715	CN-01543662	Nct	Breast Reconstruction With Acellular Dermal Matrix in the Setting of Breast Cancer Treatment	*https://clinicaltrials.gov/show/NCT02061527*	Protocol/methods with no results
716	CN-02082997	Nct	Pre- Versus Sub-pectoral Implant-based Breast Reconstruction After Skin-sparing Mastectomy or Nipple-sparing Mastectomy	*https://clinicaltrials.gov/show/NCT04293146*	Protocol/methods with no results
717	CN-02089009	Nct	ERAS in Autologous Breast Reconstruction: a Pilot RCT	*https://clinicaltrials.gov/show/NCT04306003*	Protocol/methods with no results
718	CN-01522432	Nct	Hypofractionated Radiation Therapy After Mastectomy in Preventing Recurrence in Patients With Stage IIa-IIIa Breast Cancer	*https://clinicaltrials.gov/show/NCT03414970*	Protocol/methods with no results
719	CN-01944992	Nct	Pre-pectoral Versus Sub-pectoral Implant Placement in Immediate Breast Reconstruction	*https://clinicaltrials.gov/show/NCT03959709*	Protocol/methods with no results
720	21601458	Nedumpara	Impact of immediate breast reconstruction on breast cancer recurrence and survival	*Breast*	Single group N enrolled <500
721	CN-01940884	Negenborn	Short-term cost-effectiveness of one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage expander-implant reconstruction from a multicentre randomized clinical trial	*British journal of surgery*	Duplicate of another publication
722	30835827	Negenborn	Short-term cost-effectiveness of one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage expander-implant reconstruction from a multicentre randomized clinical trial	*Br J Surg*	Does not address KQ1-KQ6
723	CN-01930174	Negenborn	Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial	*The lancet. Oncology*	Duplicate of another publication
724	30104147	Negenborn	Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial	*Lancet Oncol*	Does not address KQ1-KQ6
725	25557724	Nelson	Wound healing complications after autologous breast reconstruction: a model to predict risk	*J Plast Reconstr Aesthet Surg*	Copublication of included study with no new data
726	25456289	Nelson	Intraoperative perfusion management impacts postoperative outcomes: an analysis of 682 autologous breast reconstruction patients	*J Plast Reconstr Aesthet Surg*	Copublication of included study with no new data
727	28084138	Nelson	Intraoperative vasopressors and thrombotic complications in free flap breast reconstruction	*J Plast Surg Hand Surg*	Copublication of included study with no new data
728	23886556	Nelson	Delayed autologous breast reconstruction: factors which influence patient decision making	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
729	21042098	Nelson	A Comparison between DIEP and muscle-sparing free TRAM flaps in breast reconstruction: a single surgeon's recent experience	*Plast Reconstr Surg*	NRCS not adjusted
730	30431541	Nelson	Function and Strength after Free Abdominally Based Breast Reconstruction: A 10-Year Follow-Up	*Plast Reconstr Surg*	NRCS <30 per arm
731	10560853	Newman	Feasibility of immediate breast reconstruction for locally advanced breast cancer	*Ann Surg Oncol*	Single group N enrolled <500
732	21184070	Newman	The true incidence of near-term postoperative complications in prosthetic breast reconstruction utilizing human acellular dermal matrices: a meta-analysis	*Aesthetic Plast Surg*	Narrative review/ Commentary
733	27633549	Ng	Trends in Post-Mastectomy Reconstruction in an Asian Population: A 12-Year Institutional Review	*Breast J*	Does not address KQ1-KQ6
734	120533760	Ng	Trends in Post-Mastectomy Reconstruction in an Asian Population: A 12-Year Institutional Review	*Breast Journal*	Duplicate of another publication
735	33634944	Ng	Immediate prepectoral implant reconstruction using TiLOOP Bra Pocket results in improved patient satisfaction over dual plane reconstruction	ANZ journal of surgery	NRCS not adjusted
736	20628580	Nguyen	Infectious Complications Leading to Explantation in Implant-Based Breast Reconstruction With AlloDerm	*Eplasty*	NRCS not adjusted
737	22791106	Nguyen	Effect of immediate reconstruction on postmastectomy surgical site infection	*Ann Surg*	Does not address KQ1-KQ6
738	27010582	Nickel	Effect of Noninfectious Wound Complications after Mastectomy on Subsequent Surgical Procedures and Early Implant Loss	*J Am Coll Surg*	NRCS not adjusted
739	25455801	Niddam	[Breast reconstruction by latissimus dorsi flap: Towards an evolution of ideas]	*Ann Chir Plast Esthet*	NRCS not adjusted
740	8004611	Noda	Breast reconstruction	*Cancer*	NRCS not adjusted
741	108158587	NR	Breast reconstruction improves well-being and quality of life	*Johns Hopkins Medical Letter: Health After 50*	Unable to retrieve article
742	25840544	Nwaogu	Venous Thromboembolism after Breast Reconstruction in Patients Undergoing Breast Surgery: An American College of Surgeons NSQIP Analysis	*J Am Coll Surg*	Does not address KQ1-KQ6
743	9492663	Nyren	Risk of connective tissue disease and related disorders among women with breast implants: a nation-wide retrospective cohort study in Sweden	*Bmj*	Not breast reconstruction
744	29948462	O' Halloran	Neoadjuvant chemoradiation and breast reconstruction: the potential for improved outcomes in the treatment of breast cancer	*Ir J Med Sci*	Single group N enrolled <500
745	29927832	O'Connell	Comparison of Immediate versus Delayed DIEP Flap Reconstruction in Women Who Require Postmastectomy Radiotherapy	*Plast Reconstr Surg*	NRCS not adjusted
746	30923359	O'Connell	The impact of immediate breast reconstruction on the time to delivery of adjuvant therapy: the iBRA-2 study	*Br J Cancer*	Does not address KQ1-KQ6
747	30923359	O'Connell	The impact of immediate breast reconstruction on the time to delivery of adjuvant therapy: the iBRA-2 study	*British Journal of Cancer*	Duplicate of another publication
748	27013145	O'Neill	Usability of the internal mammary recipient vessels in microvascular breast reconstruction	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
749	32152777	O'Neill	Development and Evaluation of a Machine Learning Prediction Model for Flap Failure in Microvascular Breast Reconstruction	*Ann Surg Oncol*	Does not address KQ1-KQ6
750	30489498	Offodile	Assessing the Quality of Microvascular Breast Reconstruction Performed in the Urban Safety-Net Setting: A Doubly Robust Regression Analysis	*Plast Reconstr Surg*	Does not address KQ1-KQ6
751	29044475	Offodile	The site of care matters: An examination of the relationship between high Medicaid burden hospitals and the use, cost, and complications of immediate breast reconstruction after mastectomy	*Cancer*	Does not address KQ1-KQ6
752	25676466	Offodile	Racial disparities in the type of postmastectomy reconstruction chosen	*J Surg Res*	Does not address KQ1-KQ6
753	127216390	Offodile	The site of care matters: An examination of the relationship between high Medicaid burden hospitals and the use, cost, and complications of immediate breast reconstruction after mastectomy	*Cancer (0008543X)*	Duplicate of another publication
754	29052108	Ogita	Risk factors for complications among breast cancer patients treated with post-mastectomy radiotherapy and immediate tissue-expander/permanent implant reconstruction: a retrospective cohort study	*Breast Cancer*	Does not address KQ1-KQ6
755	30225915	Oh	Patient-reported outcomes of breast reconstruction in older women: Audit of a large metropolitan public/private practice in Sydney, Australia	*Psychooncology*	NRCS <30 per arm
756	26965305	Oh	Patterns and outcomes of breast reconstruction in older women - A systematic review of the literature	*Eur J Surg Oncol*	Does not address KQ1-KQ6
757	3308352	Olbrisch	[Tissue expander in breast reconstruction. Experiences and results with more than 300 expanders]	*Chirurg*	Unable to retrieve article
758	33214118	Oleru	The impact of hepatitis B and C diagnoses on surgical outcomes following mastectomy and breast reconstruction	J Plast Reconstr Aesthet Surg	Does not address KQ1-KQ6
759	32195865	Olinger	Outcomes of Immediate Implant-Based Mastectomy Reconstruction in Women with Previous Breast Radiation	*Plast Reconstr Surg*	Does not address KQ1-KQ6
760	32195865	Olinger	Outcomes of Immediate Implant-Based Mastectomy Reconstruction in Women with Previous Breast Radiotherapy	Plast Reconstr Surg	Duplicate of another publication
761	31146506	Oliver	Postmastectomy Radiation Therapy (PMRT) before and after 2-Stage Expander-Implant Breast Reconstruction: A Systematic Review	*Medicina (Kaunas)*	Narrative review/ Commentary
762	18209153	Olsen	Hospital-associated costs due to surgical site infection after breast surgery	*Arch Surg*	Does not address KQ1-KQ6
763	26036877	Olsen	Incidence of Surgical Site Infection Following Mastectomy With and Without Immediate Reconstruction Using Private Insurer Claims Data	*Infect Control Hosp Epidemiol*	NRCS not adjusted
764	32221200	Opsomer	Lumbar Flap versus the Gold Standard: Comparison to the DIEP Flap	Plast Reconstr Surg	NRCS not adjusted
765	30616243	Orr	Bleeding After Free Flap-Based Breast Reconstruction: A NSQIP Analysis	*J Reconstr Microsurg*	Does not address KQ1-KQ6
766	26612083	Orzalesi	Nipple sparing mastectomy: Surgical and oncological outcomes from a national multicentric registry with 913 patients (1006 cases) over a six year period	*Breast*	Does not address KQ1-KQ6
767	26287324	Otte	[The DIEP Flap as Method of Choice in Breast Reconstruction - Results and Protocol for Succesful Reconstruction]	*Handchir Mikrochir Plast Chir*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
768	26855905	Otte	Conservative mastectomies and Immediate-DElayed AutoLogous (IDEAL) breast reconstruction: the DIEP flap	*Gland Surg*	Single group >500, but no complications data
769	25692294	Ouyang	Effect of implant vs. tissue reconstruction on cancer specific survival varies by axillary lymph node status in breast cancer patients	*PLoS One*	NRCS not adjusted
770	32113960	Oxley	Successful same day discharge after immediate post-mastectomy alloplastic breast reconstruction: A single tertiary centre retrospective audit	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
771	23542834	Ozturk	Breast reconstruction with abdominal-based free flaps in high body mass index population: postoperative complications and impact of weight loss	*Ann Plast Surg*	Single group N enrolled <500
772	22238939	Pak	[Results of single-stage reconstructive surgery in breast cancer patients (a report of 1143 cases)]	*Vopr Onkol*	Unable to retrieve article
773	31438594	Palubicka	Surgical Site Infection after Breast Surgery: A Retrospective Analysis of 5-Year Postoperative Data from a Single Center in Poland	*Medicina (Kaunas)*	Single group N enrolled <500
774	26817890	Pan	Predictors for Reconstruction and Mood Disorder Associated With Reconstruction in Patients With Breast Cancer and Mastectomy: A Retrospective Cohort Study	*Medicine (Baltimore)*	Does not address KQ1-KQ6
775	29510420	Panayi	Impact of Obesity on Outcomes in Breast Reconstruction: A Systematic Review and Meta-Analysis	*J Reconstr Microsurg*	Does not address KQ1-KQ6
776	26165884	Pannucci	Loupes-Only Microsurgery is a Safe Alternative to the Operating Microscope: An Analysis of 1,649 Consecutive Free Flap Breast Reconstructions	*J Reconstr Microsurg*	Does not address KQ1-KQ6
777	33567574	Papa	Protocol for Prevention and Monitoring of Surgical Site Infections in Implant-Based Breast Reconstruction: Preliminary Results	Medicina (Kaunas)	Single group N enrolled <500
778	16437226	Papadopulos	[Quality of life and patient satisfaction after breast reconstruction]	*Chirurg*	NRCS not adjusted
779	27187252	Parabkaharan	Comparison of Reconstructive Outcomes in Breast Cancer Patients With Preexisting Subpectoral Implants: Implant-Sparing Mastectomy With Delayed Implant Exchange Versus Immediate Tissue Expander Reconstruction	*Ann Plast Surg*	Single group N enrolled <500
780	30881804	Parikh	Cortiva Versus AlloDerm Ready-to-use in Prepectoral and Submuscular Breast Reconstruction: Prospective Randomized Clinical Trial Study Design and Early Findings	*Plast Reconstr Surg Glob Open*	Single group N enrolled <500
781	29511877	Park	The use of acellular dermal matrix in immediate two-stage prosthetic breast reconstruction provides protection from postmastectomy radiation therapy: a clinicopathologic perspective	*J Mater Sci Mater Med*	NRCS not adjusted
782	32629834	Park	Intraoperative Intercostal Nerve Block for Postoperative Pain Control in Pre-Pectoral versus Subpectoral Direct-to-Implant Breast Reconstruction: A Retrospective Study	Medicina (Kaunas)	NRCS not adjusted
783	33586091	Park	Is mastectomy with immediate reconstruction safe for patients undergoing neoadjuvant chemotherapy? A nationwide study from Korean Breast Cancer Society	Breast Cancer	Does not address KQ1-KQ6
784	23018685	Parks	Human acellular dermis versus no acellular dermis in tissue expansion breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
785	18093828	Patani	Oncological safety and patient satisfaction with skin-sparing mastectomy and immediate breast reconstruction	*Surg Oncol*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
786	23897324	Patel	Microvascular autologous breast reconstruction in the context of radiation therapy: comparing two reconstructive algorithms	*Plast Reconstr Surg*	Single group N enrolled <500
787	21734543	Patel	Management of massive mastectomy skin flap necrosis following autologous breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
788	24572859	Patel	Reinforcement of the abdominal wall following breast reconstruction with abdominal flaps: a comparison of synthetic and biological mesh	*Plast Reconstr Surg*	Does not address KQ1-KQ6
789	29761885	Patel	Immediate breast reconstruction for women having inflammatory breast cancer in the United States	*Cancer Med*	Single group N enrolled <500
790	32294076	Patel	Comparing Prepectoral Versus Subpectoral Tissue Expander Placement Outcomes in Delayed-Immediate Autologous Breast Reconstruction	Ann Plast Surg	Does not address KQ1-KQ6
791	31942389	Patrinely	Acellular Dermal Matrix Performance Compared with Latissimus Dorsi Myocutaneous Flap in Expander-Based Breast Reconstruction	*Plast Reconstr Surg Glob Open*	NRCS not adjusted
792	28740767	Peiris	The Effect of the Timing of Radiotherapy on Clinical and Patient-Reported Outcomes After Latissimus Dorsi Breast Reconstruction: A 10-Year Study	*Plast Reconstr Surg Glob Open*	NRCS not adjusted
793	29788682	Pek	Immediate breast reconstruction following nipple-sparing mastectomy in an asian population: Aesthetic outcomes and mitigating nipple-areolar complex necrosis	*Archives of Plastic Surgery*	NRCS <30 per arm
794	29788682	Pek	Immediate breast reconstruction following nipple-sparing mastectomy in an Asian population: Aesthetic outcomes and mitigating nipple-areolar complex necrosis	*Arch Plast Surg*	Single group N enrolled <500
795	24732652	Peled	Impact of total skin-sparing mastectomy incision type on reconstructive complications following radiation therapy	*Plast Reconstr Surg*	Does not address KQ1-KQ6
796	22526909	Peled	Outcomes after total skin-sparing mastectomy and immediate reconstruction in 657 breasts	*Annals of Surgical Oncology*	Does not address KQ1-KQ6
797	20855759	Peled	Impact of chemotherapy on postoperative complications after mastectomy and immediate breast reconstruction	*Archives of Surgery*	NRCS not adjusted
798	28671888	Peled	Complications After Total Skin-Sparing Mastectomy and Expander-Implant Reconstruction: Effects of Radiation Therapy on the Stages of Reconstruction	*Ann Plast Surg*	NRCS not adjusted
799	26170194	Peled	Expanding the Indications for Total Skin-Sparing Mastectomy: Is It Safe for Patients with Locally Advanced Disease?	*Ann Surg Oncol*	Does not address KQ1-KQ6
800	19325334	Persichetti	Implant breast reconstruction after salvage mastectomy in previously irradiated patients	*Ann Plast Surg*	NRCS not adjusted
801	23542851	Pestana	Factors affecting complications in radiated breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
802	8060065	Peters	Factors affecting the rupture of silicone-gel breast implants	*Ann Plast Surg*	Duplicate of another publication
803	8060065	Peters	Factors affecting the rupture of silicone-gel breast implants	*Ann Plast Surg*	Single group N enrolled <500
804	7702307	Peters	Calcification of breast implant capsules: incidence, diagnosis, and contributing factors	*Ann Plast Surg*	Single group N enrolled <500
805	1340174	Petit	[Immediate mammary reconstruction in the radical treatment of cancer of the breast]	*Ann Chir Plast Esthet*	Unable to retrieve article
806	18210199	Petit	Oncological results of immediate breast reconstruction: long term follow-up of a large series at a single institution	*Breast Cancer Res Treat*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
807	31538071	Phan	The use of Patient Reported Outcome Measures in assessing patient outcomes when comparing autologous to alloplastic breast reconstruction: a systematic review	*Gland Surg*	Does not address KQ1-KQ6
808	33299693	Phillips	Is Tissue Expansion Worth It? Comparative Outcomes of Skin-preserving versus Delayed Autologous Breast Reconstruction	Plast Reconstr Surg Glob Open	Single group N enrolled <500
809	26165569	Pinell-White	Patient-Reported Quality of Life After Breast Reconstruction: A One-Year Longitudinal Study Using the WHO-QOL Survey	*Ann Plast Surg*	NRCS <30 per arm
810	16996422	Pinsolle	Complications analysis of 266 immediate breast reconstructions	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
811	28619483	Piper	Characterizing infections in prosthetic breast reconstruction: A validity assessment of national health databases	*J Plast Reconstr Aesthet Surg*	Single group >500, but no complications data
812	23486127	Piper	Total skin-sparing mastectomy: a systematic review of oncologic outcomes and postoperative complications	*Ann Plast Surg*	Does not address KQ1-KQ6
813	19806332	Piroth	Immediate reconstruction with an expander/implant following ablatio mammae because of breast cancer : side effects and cosmetic results after adjuvant chest wall radiotherapy	*Strahlenther Onkol*	Single group N enrolled <500
814	10063590	Plogmeier	[Breast reconstruction: autologous tissue versus implant]	*Zentralbl Chir*	NRCS not adjusted
815	11711934	Polednak	Type of breast reconstructive surgery among breast cancer patients: a population-based study	*Plast Reconstr Surg*	No outcome of interest
816	32420245	Polotto	One-step prepectoral breast reconstruction with porcine dermal matrix-covered implant: a protective technique improving the outcome in post-mastectomy radiation therapy setting	Gland Surg	Does not address KQ1-KQ6
817	31868761	Porter	Comparison of Saline Expanders and Air Expanders for Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
818	104983367	Potter	Reporting clinical outcomes of breast reconstruction: a systematic review	*JNCI: Journal of the National Cancer Institute*	Does not address KQ1-KQ6
819	26109277	Potter	Systematic review and critical appraisal of the impact of acellular dermal matrix use on the outcomes of implant-based breast reconstruction	*Br J Surg*	Narrative review/ Commentary
820	24011501	Potter	Early complications and implant loss in implant-based breast reconstruction with and without acellular dermal matrix (Tecnoss Protexa(R)): a comparative study	*Eur J Surg Oncol*	NRCS not adjusted
821	30639093	Potter	Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study	*The Lancet Oncology*	Duplicate of another publication
822	30507480	Potter	Quality of life after breast reconstruction-the BRIOS study	*Lancet Oncology*	Duplicate of another publication
823	7761519	Pouhaer	Cosmetic results and complications in breast cancer patients after total mastectomy with circular incision and immediate breast reconstruction	*Plast Reconstr Surg*	Narrative review/ Commentary
824	7761519	Pouhaer	Cosmetic results and complications in breast cancer patients after total mastectomy with circular incision and immediate breast reconstruction	*Plastic and Reconstructive Surgery*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
825	32726819	Prantl	Impact of Smoking Status in Free Deep Inferior Epigastric Artery Perforator Flap Breast Reconstruction: A Multicenter Study	J Reconstr Microsurg	Copublication of included study with no new data
826	33346536	Prantl	Effect of Radiation Therapy on Microsurgical Deep Inferior Epigastric Perforator Flap Breast Reconstructions: A Matched Cohort Analysis of 4577 Cases	Ann Plast Surg	Copublication of included study with no new data
827	18434824	Preminger	The influence of AlloDerm on expander dynamics and complications in the setting of immediate tissue expander/implant reconstruction: a matched-cohort study	*Ann Plast Surg*	NRCS not adjusted
828	29419662	Pu	The role of postmastectomy radiation therapy in patients with immediate prosthetic breast reconstruction: A meta-analysis	*Medicine (Baltimore)*	Does not address KQ1-KQ6
829	31495035	Punglia	Patient-preferred outcomes measurement after post-mastectomy radiation therapy and immediate reconstruction	*Breast J*	Single group N enrolled <500
830	124339287	Pusic	Patient-Reported Outcomes 1 Year After Immediate Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium Study	*Journal of Clinical Oncology*	Duplicate of another publication
831	26219243	Pyfer	Early Postoperative Outcomes in Breast Conservation Surgery Versus Simple Mastectomy with Implant Reconstruction: A NSQIP Analysis of 11,645 Patients	*Ann Surg Oncol*	Does not address KQ1-KQ6
832	31668432	Qi	Does Choice of Reconstruction Type Affect Survival in Patients With Metastatic Breast Cancer?	*J Surg Res*	Does not address KQ1-KQ6
833	31467545	Qian	A Systematic Review and Meta-Analysis on Microsurgical Safety and Efficacy of Profunda Artery Perforator Flap in Breast Reconstruction	*J Oncol*	Does not address KQ1-KQ6
834	25652054	Qin	Assessing Outcomes and Safety of Inpatient Versus Outpatient Tissue Expander Immediate Breast Reconstruction	*Ann Surg Oncol*	Does not address KQ1-KQ6
835	25652054	Qin	Assessing Outcomes and Safety of Inpatient Versus Outpatient Tissue Expander Immediate Breast Reconstruction	*Annals of Surgical Oncology*	Duplicate of another publication
836	24961932	Qin	Differential impact of non-insulin-dependent diabetes mellitus and insulin-dependent diabetes mellitus on breast reconstruction outcomes	*Breast Cancer Res Treat*	NRCS not adjusted
837	29384865	Qin	Postoperative outcomes of breast reconstruction after mastectomy	*Medicine (United States)*	Duplicate of another publication
838	28992647	Qiu	Surgical Duration Impacts Venous Thromboembolism Risk in Microsurgical Breast Reconstruction	*J Reconstr Microsurg*	Does not address KQ1-KQ6
839	33437474	Quilichini	Mastectomy with immediate breast reconstruction: Results of a mono-centric 4-years cohort	Ann Med Surg (Lond)	No outcome of interest
840	27047785	Quinn	Prosthetic breast reconstruction: indications and update	*Gland Surg*	Narrative review/ Commentary
841	27622099	Qureshi	Direct Hospital Cost of Outcome Pathways in Implant-Based Reconstruction with Acellular Dermal Matrices	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
842	28235218	Razdan	National Breast Reconstruction Utilization in the Setting of Postmastectomy Radiotherapy	*J Reconstr Microsurg*	Does not address KQ1-KQ6
843	26910695	Razdan	Cost-Effectiveness Analysis of Breast Reconstruction Options in the Setting of Postmastectomy Radiotherapy Using the BREAST-Q	*Plast Reconstr Surg*	No outcome of interest

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
844	21617433	Reddy	Bilateral autologous reconstruction from different sites: indications and outcomes after DIEP and SGAP flaps	*Plast Reconstr Surg*	Case report or series of case reports
845	20429922	Reefy	Oncological outcome and patient satisfaction with skin-sparing mastectomy and immediate breast reconstruction: a prospective observational study	*BMC Cancer*	NRCS not adjusted
846	31858435	Reinders	Higher reconstruction failure and less patient-reported satisfaction after post mastectomy radiotherapy with immediate implant-based breast reconstruction compared to immediate autologous breast reconstruction	*Breast Cancer*	Duplicate of another publication
847	31858435	Reinders	Higher reconstruction failure and less patient-reported satisfaction after post mastectomy radiotherapy with immediate implant-based breast reconstruction compared to immediate autologous breast reconstruction	*Breast Cancer*	NRCS <30 per arm
848	23714788	Reish	Infection following implant-based reconstruction in 1952 consecutive breast reconstructions: salvage rates and predictors of success	*Plastic and reconstructive surgery*	Duplicate of another publication
849	23714788	Reish	Infection following implant-based reconstruction in 1952 consecutive breast reconstructions: salvage rates and predictors of success	*Plast Reconstr Surg*	Copublication of included study with no new data
850	25811561	Reish	Breast reconstruction outcomes after nipple-sparing mastectomy and radiation therapy	*Plast Reconstr Surg*	Does not address KQ1-KQ6
851	31620344	Rezaei	Latissimus Dorsi Musculocutaneous Flap Inset Innovation in Breast Reconstruction	*World J Plast Surg*	NRCS <30 per arm
852	33470628	Rhemtulla	Incisional Hernia Incidence, Repair Techniques, and Outcomes Based on 1600 Consecutive Patients Receiving Abdominally Based Autologous Breast Reconstruction	Ann Plast Surg	Copublication of included study with no new data
853	29383613	Riba	Surgical Risk Factors for the Delayed Initiation of Adjuvant Chemotherapy in Breast Cancer	*Ann Surg Oncol*	Does not address KQ1-KQ6
854	21780554	Ribuffo	Cagliari University Hospital (CUH) protocol for immediate alloplastic breast reconstruction and unplanned radiotherapy. A preliminary report	*Eur Rev Med Pharmacol Sci*	Single group N enrolled <500
855	26166643	Ribuffo	Does postoperative radiation therapy represent a contraindication to expander-implant based immediate breast reconstruction? An update 2012-2014	*Eur Rev Med Pharmacol Sci*	Narrative review/ Commentary
856	32860077	Ribuffo	Dual-Plane Retro-pectoral Versus Pre-pectoral DTI Breast Reconstruction: An Italian Multicenter Experience	Aesthetic Plast Surg	NRCS not adjusted
857	29341294	Ricci	Topical nitroglycerin for the treatment of intraoperative microsurgical vasospasm	*Microsurgery*	Does not address KQ1-KQ6
858	28296715	Ricci	Evaluating the Use of Tissue Oximetry to Decrease Intensive Unit Monitoring for Free Flap Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
859	27135144	Ricci	A Novel Free Flap Monitoring System Using Tissue Oximetry with Text Message Alerts	*J Reconstr Microsurg*	Does not address KQ1-KQ6
860	23018695	Richter	A comparison of a new skin closure device and intradermal sutures in the closure of full-thickness surgical incisions	*Plast Reconstr Surg*	Single group N enrolled <500
861	30691788	Rifkin	Impact of Diabetes on 30-Day Complications in Mastectomy and Implant-Based Breast Reconstruction	*J Surg Res*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
862	30691788	Rifkin	Impact of Diabetes on 30-D Complications in Mastectomy and Implant-Based Breast Reconstruction	*Journal of Surgical Research*	Duplicate of another publication
863	26375459	Rimler	The effects of radiation therapy on perfusion of free versus pedicle transverse rectus abdominis myocutaneous (TRAM) flaps in vivo	*J Plast Reconstr Aesthet Surg*	Narrative review/ Commentary
864	29724621	Rindom	Shoulder-related donor site morbidity and patient-reported satisfaction after delayed breast reconstruction with pedicled flaps from the back: A comparative analysis	*Journal of Plastic, Reconstructive and Aesthetic Surgery*	NRCS not adjusted
865	26818271	Rinker	A Comparison of Methods to Assess Mastectomy Flap Viability in Skin-Sparing Mastectomy and Immediate Reconstruction: A Prospective Cohort Study	*Plast Reconstr Surg*	NRCS <30 per arm
866	26202563	Roberts	Once is Rarely Enough: A Population-Based Study of Reoperations after Postmastectomy Breast Reconstruction	*Ann Surg Oncol*	NRCS not adjusted
867	32964476	Roberts	Reoperation cascade in postmastectomy breast reconstruction and its associated factors: Results from a long-term population-based study	*J Surg Oncol*	Does not address KQ1-KQ6
868	32839117	Robertson	Reconstructive trends following mastectomies in Scotland: A comparison with England	Surgeon	Does not address KQ1-KQ6
869	27182693	Rocco	Different types of implants for reconstructive breast surgery	*Cochrane Database Syst Rev*	Systematic review
870	25339608	Rochlin	Postmastectomy radiation therapy and immediate autologous breast reconstruction: integrating perspectives from surgical oncology, radiation oncology, and plastic and reconstructive surgery	*J Surg Oncol*	Narrative review/ Commentary
871	30973838	Rochlin	The Power of Patient Norms: Postoperative Pathway Associated With Shorter Hospital Stay After Free Autologous Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
872	26275493	Rodriguez-Unda	Low incidence of complications using polyglactin 910 (Vicryl) mesh in breast reconstruction: A systematic review	*J Plast Reconstr Aesthet Surg*	Systematic review
873	11994594	Rogers	Radiation effects on breast reconstruction with the deep inferior epigastric perforator flap	*Plast Reconstr Surg*	Single group N enrolled <500
874	29968023	Romanoff	A Comparison of Patient-Reported Outcomes After Nipple-Sparing Mastectomy and Conventional Mastectomy with Reconstruction	*Ann Surg Oncol*	Single group N enrolled <500
875	23395741	Romics Jr	Oncologic safety of skin-sparing mastectomy followed by immediate breast reconstruction: Rate and localization of recurrences, and impact of reconstruction techniques	*Orvosi Hetilap*	Unable to retrieve article
876	22634689	Roostaeian	Comparison of immediate implant placement versus the staged tissue expander technique in breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
877	27018662	Roostaeian	Impact of Prior Tissue Expander/Implant on Postmastectomy Free Flap Breast Reconstruction	*Plast Reconstr Surg*	>=10% revision reconstruction only
878	24572867	Roostaeian	The effect of prior abdominal surgery on abdominally based free flaps in breast reconstruction	*Plast Reconstr Surg*	Copublication of included study with no new data
879	2147095	Rosen	Clinical experience with immediate breast reconstruction using tissue expansion or transverse rectus abdominis musculocutaneous flaps	*Ann Plast Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
880	11147117	Rouzier	[Autologous breast reconstruction with latissimus dorsi flap]	*Ann Chir Plast Esthet*	Unable to retrieve article
881	10974078	Rowland	Role of breast reconstructive surgery in physical and emotional outcomes among breast cancer survivors	*JNCI: Journal of the National Cancer Institute*	Single group N enrolled <500
882	31821317	Rubilar	Autologous versus prosthetic reconstruction for women with breast cancer who will undergo post-reconstruction radiotherapy	*Medwave*	Narrative review/ Commentary
883	139349747	Rudolph	Operative risk stratification in the obese female undergoing implant-based breast reconstruction	*Breast Journal*	>=10% revision reconstruction only
884	20223055	Rusby	Immediate breast reconstruction after mastectomy: what are the long-term prospects?	*Ann R Coll Surg Engl*	NRCS <30 per arm
885	28382097	Ryu	Oncologic Outcomes after Immediate Breast Reconstruction Following Total Mastectomy in Patients with Breast Cancer: A Matched Case-Control Study	*J Breast Cancer*	Does not address KQ1-KQ6
886	19407609	Sacks	Rib-sparing internal mammary vessel harvest for microvascular breast reconstruction in 100 consecutive cases	*Plast Reconstr Surg*	NRCS not adjusted
887	28274406	Sacotte	Assessing long-term complications in patients undergoing immediate postmastectomy breast reconstruction and adjuvant radiation	*Pract Radiat Oncol*	NRCS not adjusted
888	31395398	Sada	Mastectomy and immediate breast reconstruction in the elderly: Trends and outcomes	*Surgery*	Does not address KQ1-KQ6
889	29485605	Sadideen	The Safety of Early Adjuvant Internal Mammary Lymph Node Irradiation following Mastectomy and Immediate Autologous Reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
890	129664178	Sae Byul	Long-term outcomes of patients with breast cancer after nipple-sparing mastectomy/skin-sparing mastectomy followed by immediate transverse rectus abdominis musculocutaneous flap reconstruction: Comparison with conventional mastectomy in a single center study	*Medicine*	Duplicate of another publication
891	24354013	Saha	Post-mastectomy reconstruction: a risk-stratified comparative analysis of outcomes	*Breast*	Does not address KQ1-KQ6
892	24354013	Saha	Post-mastectomy reconstruction: A risk-stratified comparative analysis of outcomes	*Breast*	Does not address KQ1-KQ6
893	19387162	Sailon	Free transverse rectus abdominis myocutaneous and deep inferior epigastric perforator flaps for breast reconstruction: a systematic review of flap complication rates and donor-site morbidity	*Ann Plast Surg*	Systematic review
894	18090738	Saint-Cyr	Internal mammary perforator recipient vessels for breast reconstruction using free TRAM, DIEP, and SIEA flaps	*Plast Reconstr Surg*	Does not address KQ1-KQ6
895	17519690	Saint-Cyr	Changing trends in recipient vessel selection for microvascular autologous breast reconstruction: an analysis of 1483 consecutive cases	*Plast Reconstr Surg*	Does not address KQ1-KQ6
896	21705282	Sajid	Prevention of postoperative seroma-related morbidity by quilting of latissimus dorsi flap donor site: a systematic review	*Clin Breast Cancer*	Does not address KQ1-KQ6
897	21858596	Salgarello	DIEP flap donor site versus elective abdominoplasty short-term complication rates: a meta-analysis	*Aesthetic Plast Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
898	21617451	Salgarello	Breast fat grafting with platelet-rich plasma: a comparative clinical study and current state of the art	*Plast Reconstr Surg*	Does not address KQ1-KQ6
899	16508729	Salhab	Skin-sparing mastectomy and immediate breast reconstruction: patient satisfaction and clinical outcome	*Int J Clin Oncol*	NRCS <30 per arm
900	27975034	Salibian	Subcutaneous Implant-based Breast Reconstruction with Acellular Dermal Matrix/Mesh: A Systematic Review	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
901	32997369	Salibian	Comparing outcomes between stacked/conjoined and non-stacked/conjoined abdominal microvascular unilateral breast reconstruction	Microsurgery	Does not address KQ1-KQ6
902	28949034	Samargandi	Comparing the thoracodorsal and internal mammary vessels as recipients for microsurgical autologous breast reconstruction: A systematic review and meta-analysis	*Microsurgery*	Does not address KQ1-KQ6
903	26483861	Sanati-Mehrizy	A Comparison of Postoperative Outcomes in Immediate Versus Delayed Reconstruction After Mastectomy	*Eplasty*	Does not address KQ1-KQ6
904	28005734	Sanati-Mehrizy	Risk Factors Leading to Free Flap Failure: Analysis From the National Surgical Quality Improvement Program Database	*J Craniofac Surg*	Single group N enrolled <500
905	28234813	Sandberg	Molecular Profiling Using Breast Cancer Subtype to Plan for Breast Reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
906	26872025	Sando	The Early Years of Practice: An Assessment of Operative Efficiency and Cost of Free Flap and Implant Breast Reconstruction at an Academic Institution	*J Reconstr Microsurg*	NRCS not adjusted
907	27806906	Santosa	Effect of Patient Age on Outcomes in Breast Reconstruction: Results from a Multicenter Prospective Study	*J Am Coll Surg*	Copublication of included study with no new data
908	25289224	Sarhane	Preoperative Anemia and Postoperative Outcomes in Immediate Breast Reconstructive Surgery: A Critical Analysis of 10,958 Patients from the ACS-NSQIP Database	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
909	117554091	Sari	Radiation Therapy Outcomes After Skin-Sparing Mastectomy and Implant-Based Breast Reconstruction	*International Journal of Radiation Oncology, Biology, Physics*	Does not address KQ1-KQ6
910	17440339	Saulis	A retrospective analysis of patient satisfaction with immediate postmastectomy breast reconstruction: comparison of three common procedures	*Plast Reconstr Surg*	NRCS not adjusted
911	30589770	Sbitany	Prepectoral Breast Reconstruction in the Setting of Postmastectomy Radiation Therapy: An Assessment of Clinical Outcomes and Benefits	*Plast Reconstr Surg*	NRCS <30 per arm
912	22456352	Sbitany	Strategies for recognizing and managing intraoperative venous congestion in abdominally based autologous breast reconstruction	*Plast Reconstr Surg*	No outcome of interest
913	28574950	Sbitany	Prepectoral Breast Reconstruction: A Safe Alternative to Submuscular Prosthetic Reconstruction following Nipple-Sparing Mastectomy	*Plast Reconstr Surg*	NRCS not adjusted
914	19952627	Sbitany	Acellular dermis-assisted prosthetic breast reconstruction versus complete submuscular coverage: a head-to-head comparison of outcomes	*Plast Reconstr Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
915	22094735	Sbitany	Acellular dermis-assisted prosthetic breast reconstruction: a systematic and critical review of efficacy and associated morbidity	*Plast Reconstr Surg*	Does not address KQ1-KQ6
916	25057918	Sbitany	Tissue Expander Reconstruction After Total Skin-Sparing Mastectomy: Defining the Effects of Coverage Technique on Nipple/Areola Preservation	*Ann Plast Surg*	NRCS not adjusted
917	25158699	Sbitany	Immediate implant-based breast reconstruction following total skin-sparing mastectomy: defining the risk of preoperative and postoperative radiation therapy for surgical outcomes	*Plast Reconstr Surg*	NRCS not adjusted
918	11981192	Scevola	Drains and seromas in TRAM flap breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
919	30570559	Schaeffer	Early Functional Outcomes After Prepectoral Breast Reconstruction: A Case-Matched Cohort Study	*Ann Plast Surg*	NRCS <30 per arm
920	28194591	Schaverien	Complications in DIEP Flap Breast Reconstruction After Mastectomy for Breast Cancer: A Prospective Cohort Study Comparing Unilateral and Bilateral Reconstructions	*Ann Surg Oncol*	Narrative review/ Commentary
921	23886555	Schaverien	Is immediate autologous breast reconstruction with postoperative radiotherapy good practice?: a systematic review of the literature	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
922	24652691	Schaverien	Effect of obesity on outcomes of free autologous breast reconstruction: a meta-analysis	*Microsurgery*	Does not address KQ1-KQ6
923	17720644	Schaverien	Comparison of outcomes and donor-site morbidity in unilateral free TRAM versus DIEP flap breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
924	19050512	Scholz	Long-term outcomes after primary breast reconstruction using a vertical skin pattern for skin-sparing mastectomy	*Plast Reconstr Surg*	NRCS not adjusted
925	9531705	Schondorf	[Plastic reconstructive surgical methods in breast saving therapy of breast carcinoma: our concept of modified quadrantectomy]	*Zentralbl Gynakol*	NRCS not adjusted
926	1325065	Schuster	Breast reconstruction in women treated with radiation therapy for breast cancer: Cosmesis, complications, and tumor control	*Plastic and Reconstructive Surgery*	NRCS <30 per arm
927	33425590	Schwartz	Early Expander-to-Implant Exchange after Postmastectomy Reconstruction Reduces Rates of Subsequent Major Infectious Complications	Plast Reconstr Surg Glob Open	Single group N enrolled <500
928	28538553	Sebai	The Effect of Resident Involvement on Postoperative Short-Term Surgical Outcomes in Immediate Breast Reconstruction: A National Surgical Quality Improvement Program Study of 24,005 Patients	*Plast Reconstr Surg*	Does not address KQ1-KQ6
929	None	Seddon	Versatility, clinical outcomes and mammographic follow-up of Chest Wall Perforator Flaps (CWPF): A single-centre experience	European Journal of Cancer	Single group N enrolled <500
930	27049776	Seidenstuecker	Myosonographic study of abdominal wall dynamics to assess donor site morbidity after microsurgical breast reconstruction with a DIEP or an ms-2 TRAM flap	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
931	21364411	Seidenstuecker	Morbidity of microsurgical breast reconstruction in patients with comorbid conditions	*Plast Reconstr Surg*	NRCS not adjusted
932	27894917	Seigle-Murandi	Incidence of breast implant rupture in a 12-year retrospective cohort: Evidence of quality discrepancy depending on the range	*J Plast Reconstr Aesthet Surg*	>=10% augmentation reconstruction only

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
933	21042100	Selber	A prospective study comparing the functional impact of SIEA, DIEP, and muscle-sparing free TRAM flaps on the abdominal wall: Part II. Bilateral reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
934	16641623	Selber	Risk factors and complications in free TRAM flap breast reconstruction	*Ann Plast Surg*	Single group >500, but no complications data
935	18626349	Selber	A head-to-head comparison between the muscle-sparing free TRAM and the SIEA flaps: is the rate of flap loss worth the gain in abdominal wall function?	*Plast Reconstr Surg*	NRCS not adjusted
936	26111310	Selber	Critical Evaluation of Risk Factors and Early Complications in 564 Consecutive Two-Stage Implant-Based Breast Reconstructions Using Acellular Dermal Matrix at a Single Center	*Plast Reconstr Surg*	Single group N enrolled <500
937	28106627	Seth	Outcomes After Elevation of Serratus Anterior Fascia During Prosthetic Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
938	32855081	Sewart	Does mesh improve patient satisfaction and health-related quality of life after implant-based breast reconstruction? A multicentre prospective cohort study	European Journal of Cancer	Does not address KQ1-KQ6
939	28954300	Sewart	The impact of radiotherapy on patient-reported outcomes of immediate implant-based breast reconstruction: Results of a prospective multicentre cohort study	European Journal of Cancer	Copublication of included study with no new data
940	33078212	Sgarzani	Sub-muscular Reconstruction after NAC Sparing Mastectomy: Direct to Implant Breast Reconstruction with Human ADM Versus Tissue Expander	Aesthetic Plast Surg	NRCS not adjusted
941	22693373	Shaikh	Post mastectomy immediate breast reconstruction 13 years experience in a single centre	*Indian J Surg Oncol*	Duplicate of another publication
942	15096928	Shaikh-Naidu	Determinants of aesthetic satisfaction following TRAM and implant breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
943	32032723	Shammas	Assessing the Utility of Post-Mastectomy Imaging after Breast Reconstruction	*J Am Coll Surg*	Does not address KQ1-KQ6
944	32032723	Shammas	Assessing the Utility of Post-Mastectomy Imaging after Breast Reconstruction	*J Am Coll Surg*	Duplicate of another publication
945	31460998	Shammas	Immediate Breast Reconstruction Allows for the Timely Initiation of Post-Mastectomy Radiation Therapy	*Plast Reconstr Surg*	Duplicate of another publication
946	31460998	Shammas	Immediate Breast Reconstruction Allows for the Timely Initiation of Postmastectomy Radiation Therapy	*Plast Reconstr Surg*	Does not address KQ1-KQ6
947	142362112	Shammas	Assessing the Utility of Post-Mastectomy Imaging after Breast Reconstruction	*Journal of the American College of Surgeons*	Duplicate of another publication
948	29845051	Shash	Laparoscopic Harvesting of Omental Flaps for Breast Reconstruction-A Review of the Literature and Outcome Analysis	*Plast Surg (Oakv)*	Does not address KQ1-KQ6
949	31338643	Sheckter	The impact of hospital volume on patient safety indicators following post-mastectomy breast reconstruction in the US	*Breast Cancer Res Treat*	No outcome of interest
950	32390251	Shen	Prolonged Opioid Use After Surgery for Early-Stage Breast Cancer	Oncologist	Does not address KQ1-KQ6
951	117523175	Shoichiro	The Impact of Chemotherapy on Complications Associated with Mastectomy and Immediate Autologous Tissue Reconstruction	*American Surgeon*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
952	20195965	Shridharani	Breast sensation after breast reconstruction: a systematic review	*J Reconstr Microsurg*	Does not address KQ1-KQ6
953	26910655	Shubinets	Surgically Treated Hernia following Abdominally Based Autologous Breast Reconstruction: Prevalence, Outcomes, and Expenditures	*Plast Reconstr Surg*	NRCS not adjusted
954	25003427	Shuck	Impact of Connective Tissue Disease on Oncologic Breast Surgery and Reconstruction	*Ann Plast Surg*	NRCS <30 per arm
955	32442071	Shumway	Integration of Breast Reconstruction and Postmastectomy Radiotherapy	J Clin Oncol	Systematic review
956	26001862	Silva	The Effect of Contralateral Prophylactic Mastectomy on Perioperative Complications in Women Undergoing Immediate Breast Reconstruction: A NSQIP Analysis	*Ann Surg Oncol*	Does not address KQ1-KQ6
957	31077489	Simpson	Incidence of complications following two-stage expander/implant breast reconstruction: The impact of cancer diagnosis in prophylactic mastectomy	*Breast J*	NRCS <30 per arm
958	28953716	Singh	Five-Year Safety Data for More than 55,000 Subjects following Breast Implantation: Comparison of Rare Adverse Event Rates with Silicone Implants versus National Norms and Saline Implants	*Plast Reconstr Surg*	>=10% augmentation reconstruction only
959	31342362	Singh	Neoadjuvant Radiotherapy to Facilitate Immediate Breast Reconstruction: A Systematic Review and Current Clinical Trials	*Ann Surg Oncol*	Does not address KQ1-KQ6
960	8790856	Singletary	Skin-sparing mastectomy with immediate breast reconstruction: the M. D. Anderson Cancer Center experience	*Ann Surg Oncol*	Does not address KQ1-KQ6
961	28027221	Sinha	Late Surgical-Site Infection in Immediate Implant-Based Breast Reconstruction	*Plast Reconstr Surg*	Copublication of included study with no new data
962	29978367	Sinnott	Impact of Postmastectomy Radiation Therapy in Prepectoral Versus Subpectoral Implant-Based Breast Reconstruction	*Ann Surg Oncol*	Does not address KQ1-KQ6
963	31348330	Siotos	Survival and Disease Recurrence Rates among Breast Cancer Patients following Mastectomy with or without Breast Reconstruction	*Plast Reconstr Surg*	Does not address KQ1-KQ6
964	30489499	Siotos	Cost-Effectiveness Analysis of Silicone versus Saline Implant-Based Breast Reconstruction Using the BREAST-Q	*Plast Reconstr Surg*	NRCS not adjusted
965	29475791	Siotos	Breast reconstruction and risk of arm lymphedema development: A meta-analysis	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
966	26881927	Skovsted Yde	Acellular dermal matrices in breast reconstructions - a literature review	*J Plast Surg Hand Surg*	Narrative review/ Commentary
967	27678203	Smith	Cost and Complications of Local Therapies for Early-Stage Breast Cancer	*J Natl Cancer Inst*	Does not address KQ1-KQ6
968	30093286	Smith	Human acellular dermis increases surgical site infection and overall complication profile when compared with submuscular breast reconstruction: An updated meta-analysis incorporating new products()	*J Plast Reconstr Aesthet Surg*	Narrative review/ Commentary
969	132785107	Smith	Early Toxicity and Patient Reported Outcomes of Post-Mastectomy Pencil-Beam Scanning Proton Therapy in Women with Immediate Tissue Expander Breast Reconstruction	*International Journal of Radiation*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
				Oncology, Biology, Physics	
970	25089217	Smith	Functional morbidity following latissimus dorsi flap breast reconstruction	*J Adv Pract Oncol*	Narrative review/ Commentary
971	31980737	Sobti	Evaluation of capsular contracture following immediate prepectoral versus subpectoral direct-to-implant breast reconstruction	Sci Rep	NRCS <30 per arm
972	7801137	Solomon	A clinical and laboratory profile of symptomatic women with silicone breast implants	*Semin Arthritis Rheum*	Single group N enrolled <500
973	24878776	Song	Impact of neoadjuvant chemotherapy on immediate breast reconstruction: a meta-analysis	*PLoS One*	Does not address KQ1-KQ6
974	29076316	Song	Salvage of Infected Breast Implants	*Arch Plast Surg*	Does not address KQ1-KQ6
975	32203988	Song	Current status of and trends in post-mastectomy breast reconstruction in Korea	*Arch Plast Surg*	Does not address KQ1-KQ6
976	29781241	Sosin	Timing of radiation therapy in nipple-sparing mastectomy influences outcomes and patient-reported quality of life	*Breast J*	NRCS not adjusted
977	133048109	Sosin	Timing of radiation therapy in nipple-sparing mastectomy influences outcomes and patient-reported quality of life	*Breast Journal*	NRCS <30 per arm
978	12420617	Soubirac	[Deflation of breast implants, pre-filled with saline or hydrogel. Results and analysis of 650 treated patients]	*Ann Chir Plast Esthet*	NRCS not adjusted
979	127250790	Soumian	Early Outcomes Of Immediate Breast Reconstructions Using Acellular Dermal Matrix After Mastectomy For Breast Cancer	*Journal of Cancer Research & Therapeutics*	NRCS not adjusted
980	18626353	Spear	Options in reconstructing the irradiated breast	*Plast Reconstr Surg*	NRCS <30 per arm
981	19083539	Spear	Considerations of previous augmentation in subsequent breast reconstruction	*Aesthet Surg J*	NRCS <30 per arm
982	15622237	Spear	The effect of radiation on pedicled TRAM flap breast reconstruction: outcomes and implications	*Plast Reconstr Surg*	NRCS not adjusted
983	12832882	Spear	Resource cost comparison of implant-based breast reconstruction versus TRAM flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
984	23676517	Spear	Long-term outcomes of failed prosthetic breast reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
985	24867717	Spear	Natrelle round silicone breast implants: Core Study results at 10 years	*Plast Reconstr Surg*	Single group N enrolled <500
986	18626348	Spear	A retrospective analysis of outcomes using three common methods for immediate breast reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
987	22743866	Spear	Two-stage prosthetic breast reconstruction using AlloDerm including outcomes of different timings of radiotherapy	*Plast Reconstr Surg*	Does not address KQ1-KQ6
988	12560691	Spiegel	Recurrence following treatment of ductal carcinoma in situ with skin-sparing mastectomy and immediate breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
989	32097295	Srinivasa	Obesity and Breast Reconstruction: Complications and Patient-Reported Outcomes in a Multicenter, Prospective Study	*Plast Reconstr Surg*	Copublication of included study with no new data
990	29068918	Srinivasa	Direct-to-Implant versus Two-Stage Tissue Expander/Implant Reconstruction: 2-Year Risks and Patient-Reported Outcomes from a Prospective, Multicenter Study	*Plast Reconstr Surg*	Does not address KQ1-KQ6
991	30516558	Steffenssen	A Systematic Review and Meta-analysis of Functional Shoulder Impairment After Latissimus Dorsi Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
992	30516558	Steffenssen	A Systematic Review and Meta-analysis of Functional Shoulder Impairment After Latissimus Dorsi Breast Reconstruction	*Annals of plastic surgery*	Does not address KQ1-KQ6
993	32195171	Steiner	Interdisciplinary Treatment of Breast Cancer After Mastectomy With Autologous Breast Reconstruction Using Abdominal Free Flaps in a University Teaching Hospital-A Standardized and Safe Procedure	*Front Oncol*	NRCS not adjusted
994	32195171	Steiner	Interdisciplinary Treatment of Breast Cancer After Mastectomy With Autologous Breast Reconstruction Using Abdominal Free Flaps in a University Teaching Hospital – A Standardized and Safe Procedure	Frontiers in Oncology	NRCS not adjusted
995	26961987	Stevens	Nine-Year Core Study Data for Sientra's FDA-Approved Round and Shaped Implants with High-Strength Cohesive Silicone Gel	*Aesthet Surg J*	Single group N enrolled <500
996	25948657	Stevens	Eight-year follow-up data from the U.S. clinical trial for Sientra's FDA-approved round and shaped implants with high-strength cohesive silicone gel	*Aesthet Surg J*	Single group N enrolled <500
997	16772913	Stevens	A comparison of 500 prefilled textured saline breast implants versus 500 standard textured saline breast implants: is there a difference in deflation rates?	*Plast Reconstr Surg*	NRCS not adjusted
998	8337271	Stevenson	TRAM flap breast reconstruction and contralateral reduction or mastopexy	*Plast Reconstr Surg*	Single group N enrolled <500
999	29489546	Sue	Mastectomy Skin Necrosis After Breast Reconstruction: A Comparative Analysis Between Autologous Reconstruction and Implant-Based Reconstruction	*Ann Plast Surg*	NRCS not adjusted
1000	28301366	Sue	Management of Mastectomy Skin Necrosis in Implant Based Breast Reconstruction	*Ann Plast Surg*	NRCS not adjusted
1001	33618944	Suh	A comparative study of pre- or subpectoral expander position with the fenestrated Acellular dermal matrix anterior coverage, on drainage volume and Seroma Formation after Non-Nipple-Sparing Mastectomy	J Plast Reconstr Aesthet Surg	NRCS <30 per arm
1002	18594356	Sullivan	True incidence of all complications following immediate and delayed breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
1003	18594356	Sullivan	True incidence of all complications following immediate and delayed breast reconstruction	*Plastic and Reconstructive Surgery*	NRCS not adjusted
1004	33482758	Sung Mi	Does chemotherapy or radiotherapy affect the postoperative complication in breast cancer patients who underwent immediate breast reconstruction with tissue expander?	BMC Cancer	Duplicate of another publication
1005	26098457	Sutton	Incidence of Internal Mammary Lymph Nodes with Silicone Breast Implants at MR Imaging after Oncoplastic Surgery	*Radiology*	No outcome of interest

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1006	NR	Syed	Do modern methods of post-mastectomy immediate breast reconstruction for breast cancer delay adjuvant therapy?	*European Journal of Oncology*	NRCS not adjusted
1007	21840780	Tadiparthi	Two-stage delayed breast reconstruction with an expander and free abdominal tissue transfer: outcomes of 65 consecutive cases by a single surgeon	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
1008	23806906	Tadiparthi	An analysis of the motivating and risk factors for conversion from implant-based to total autologous breast reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
1009	26210234	Taghizadeh	Does post-mastectomy radiotherapy affect the outcome and prevalence of complications in immediate DIEP breast reconstruction? A prospective cohort study	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
1010	16529044	Tamaki	[Immediate breast reconstruction following to skin-sparing mastectomy]	*Nihon Rinsho*	Does not address KQ1-KQ6
1011	30562406	Tan	A cost-effectiveness analysis of DIEP vs free MS-TRAM flap for microsurgical breast reconstruction	*J Surg Oncol*	NRCS not adjusted
1012	23730591	Tan	The deep inferior epigastric perforator and pedicled transverse rectus abdominis myocutaneous flap in breast reconstruction: a comparative study	*Arch Plast Surg*	NRCS <30 per arm
1013	26202557	Tang	Nipple-Sparing Mastectomy in Irradiated Breasts: Selecting Patients to Minimize Complications	*Ann Surg Oncol*	Does not address KQ1-KQ6
1014	29697604	Tang	Facebook Facts: Breast Reconstruction Patient-Reported Outcomes Using Social Media	*Plast Reconstr Surg*	NRCS not adjusted
1015	27014551	Tanos	Locally Advanced Breast Cancer: Autologous Versus Implant-based Reconstruction	*Plast Reconstr Surg Glob Open*	NRCS not adjusted
1016	25940160	Teisch	Latissimus dorsi flap versus pedicled transverse rectus abdominis myocutaneous breast reconstruction: outcomes	*J Surg Res*	No outcome of interest
1017	30708063	Tejera Hernandez	Inverse radiotherapy planning in reconstructive surgery for breast cancer	*Int J Surg*	Single group N enrolled <500
1018	31140187	Teoh	Evaluation of the Role of Neoadjuvant Radiotherapy in the Management of Patients Treated with Mastectomy and Immediate Autologous Breast Reconstruction	*J Reconstr Microsurg*	Narrative review/ Commentary
1019	32892333	Teotia	Intraoperative Microvascular Complications in Autologous Breast Reconstruction: The Effects of Resident Training on Microsurgical Outcomes	J Reconstr Microsurg	Single group N enrolled <500
1020	9739832	Tepavicharova	[The comparative characteristics of methods for breast reconstruction after a mastectomy]	*Khirurgiia (Sofiia)*	Unable to retrieve article
1021	31280491	Tevis	Postoperative complications in combined gynecologic, plastic, and breast surgery: An analysis from National Surgical Quality Improvement Program	*Breast J*	Not breast reconstruction
1022	31933584	Thangarajah	Comparison of Subpectoral versus Prepectoral Immediate Implant Reconstruction after Skin- and Nipple-Sparing Mastectomy in Breast Cancer Patients: A Retrospective Hospital-Based Cohort Study	*Breast Care (Basel)*	NRCS <30 per arm
1023	15114125	Thoma	Comparison of the deep inferior epigastric perforator flap and free transverse rectus abdominis myocutaneous flap in postmastectomy reconstruction: a cost-effectiveness analysis	*Plast Reconstr Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1024	31033841	Thomas	An Assessment of Bleeding Complications Necessitating Blood Transfusion across Inpatient Plastic Surgery Procedures: A Nationwide Analysis Using the National Surgical Quality Improvement Program Database	*Plast Reconstr Surg*	Does not address KQ1-KQ6
1025	18224376	Thomson	A prospective longitudinal study of cosmetic outcome in immediate latissimus dorsi breast reconstruction and the influence of radiotherapy	*Ann Surg Oncol*	NRCS <30 per arm
1026	26360138	Thorarinsson	A retrospective review of the incidence of various complications in different delayed breast reconstruction methods	*J Plast Surg Hand Surg*	NRCS not adjusted
1027	28861376	Thorarinsson	Patient determinants as independent risk factors for postoperative complications of breast reconstruction	*Gland Surg*	Does not address KQ1-KQ6
1028	28740762	Thorarinsson	Long-Term Health-Related Quality of Life after Breast Reconstruction: Comparing 4 Different Methods of Reconstruction	*Plast Reconstr Surg Glob Open*	NRCS not adjusted
1029	28122466	Thorarinsson	Blood loss and duration of surgery are independent risk factors for complications after breast reconstruction	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
1030	32945960	Ticha	Patient-Reported Outcomes of Three Different Types of Breast Reconstruction with Correlation to the Clinical Data 5 Years Postoperatively	Aesthetic Plast Surg	NRCS not adjusted
1031	28684286	Tomouk	Donor site morbidity in DIEP free flap breast reconstructions: A comparison of unilateral, bilateral, and bipedicled surgical procedure types	*J Plast Reconstr Aesthet Surg*	Single group N enrolled <500
1032	31987776	Tondu	Breast reconstruction after nipple-sparing mastectomy in the large and/or ptotic breast: A systematic review of indications, techniques, and outcomes	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
1033	23810309	Tong	Clinical outcomes of percutaneous drainage of breast fluid collections after mastectomy with expander-based breast reconstruction	*Journal of Vascular and Interventional Radiology*	Does not address KQ1-KQ6
1034	104090246	Tong	Clinical outcomes of percutaneous drainage of breast fluid collections after mastectomy with expander-based breast reconstruction	*Journal of Vascular & Interventional Radiology*	Single group N enrolled <500
1035	22531404	Tong	The transition from pedicle transverse rectus abdominis myocutaneous to perforator flap: what is the cost of opportunity?	*Ann Plast Surg*	NRCS not adjusted
1036	17701730	Tonseth	Patient-reported outcomes after breast reconstruction with deep inferior epigastric perforator flaps	*Scand J Plast Reconstr Surg Hand Surg*	NRCS not adjusted
1037	31711862	Toyserkani	Autologous versus implant-based breast reconstruction: A systematic review and meta-analysis of Breast-Q patient-reported outcomes	*J Plast Reconstr Aesthet Surg*	Systematic review
1038	23692931	Tran	Risk factors associated with venous thromboembolism in 49,028 mastectomy patients	*Breast*	Does not address KQ1-KQ6
1039	23692931	Tran	Risk factors associated with venous thromboembolism in 49,028 mastectomy patients	*Breast*	Does not address KQ1-KQ6
1040	28591940	Tran	Cost analysis of postmastectomy reconstruction: A comparison of two staged implant reconstruction using tissue expander and acellular dermal matrix with abdominal-based perforator free flaps	*J Surg Oncol*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1041	28591935	Tran	Cost analysis of postmastectomy reconstruction: A comparison of two staged implant reconstruction using tissue expander and acellular dermal matrix with abdominal based perforator free flaps	*J Surg Oncol*	Narrative review/ Commentary
1042	10946929	Tran	Postoperative adjuvant irradiation: effects on tranverse rectus abdominis muscle flap breast reconstruction	*Plast Reconstr Surg*	Single group N enrolled <500
1043	None	Tsai	Breast reconstruction modality and outcomes after mastectomy	*Formosan Journal of Surgery*	NRCS not adjusted
1044	28916881	Tsay	A 3D Mammometric Comparison of Implant-Based Breast Reconstruction With and Without Acellular Dermal Matrix (ADM)	*Aesthetic Plast Surg*	NRCS <30 per arm
1045	24469159	Tsoi	Safety of tissue expander/implant versus autologous abdominal tissue breast reconstruction in postmastectomy breast cancer patients: a systematic review and meta-analysis	*Plast Reconstr Surg*	Systematic review
1046	24745568	Tsoi	Systematic review on the patient-reported outcomes of tissue-expander/implant vs autologous abdominal tissue breast reconstruction in postmastectomy breast cancer patients	*J Am Coll Surg*	Narrative review/ Commentary
1047	24679114	Tuggle	Increased hospital volume is associated with improved outcomes following abdominal-based breast reconstruction	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
1048	11391187	Tzafetta	Evaluation of the factors related to postmastectomy breast reconstruction	*Plast Reconstr Surg*	NRCS <30 per arm
1049	28806290	Uda	Clinical and Quantitative Isokinetic Comparison of Abdominal Morbidity and Dynamics following DIEP versus Muscle-Sparing Free TRAM Flap Breast Reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
1050	17051098	Ulusal	Simultaneous endoscope-assisted contralateral breast augmentation with implants in patients undergoing postmastectomy breast reconstruction with abdominal flaps	*Plast Reconstr Surg*	Single group N enrolled <500
1051	32381984	Umezaki	[The Approach of Breast Reconstruction for Breast Cancer in Our Hospital]	Gan To Kagaku Ryoho	Unable to retrieve article
1052	29968032	Upadhyaya	Outcomes of Autologous Fat Grafting in Mastectomy Patients Following Breast Reconstruction	*Ann Surg Oncol*	Single group N enrolled <500
1053	24987526	Valdatta	Acellular dermal matrices and radiotherapy in breast reconstruction: a systematic review and meta-analysis of the literature	*Plast Surg Int*	Narrative review/ Commentary
1054	26975786	van Huizum	Immediate breast reconstruction with a myocutaneous latissimus dorsi flap and implant following skin-sparing salvage mastectomy after irradiation as part of breast-conserving therapy	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted
1055	None	van Vuuren	Patient satisfaction and complication rate after mastectomy with immediate two-stage breast reconstruction as compared to mastectomy without immediate breast reconstruction	*Surgical Practice*	Single group N enrolled <500
1056	31280700	Vania	Can pedicled TRAM flap be a satisfying alternative to free TRAM in developing countries? - a systematic review and meta-analysis	*Acta Chir Belg*	Does not address KQ1-KQ6
1057	27771262	Vanschoonbeek	Outcome after urgent microvascular revision of free DIEP, SIEA and SGAP flaps for autologous breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1058	25913487	Vargas	Mastectomy skin necrosis after microsurgical breast reconstruction	*J Surg Res*	Single group N enrolled <500
1059	25891675	Vargas	Tumescent mastectomy technique in autologous breast reconstruction	*J Surg Res*	Single group N enrolled <500
1060	25891675	Vargas	Tumescent mastectomy technique in autologous breast reconstruction	*Journal of Surgical Research*	Duplicate of another publication
1061	31513715	Vasconcelos	Acellular dermal matrices safety in breast reconstruction-Is it truly associated with higher rates of complications? A large single-surgeon cohort analysis	*Breast J*	NRCS not adjusted
1062	18626347	Vega	500 Consecutive patients with free TRAM flap breast reconstruction: A single surgeon's experience	*Plastic and Reconstructive Surgery*	Duplicate of another publication
1063	18626347	Vega	500 Consecutive patients with free TRAM flap breast reconstruction: a single surgeon's experience	*Plast Reconstr Surg*	Single group >500, but no complications data
1064	32705515	Venkatesh	Direct-to-Implant Breast Reconstruction in Patients Undergoing Post-Mastectomy Radiotherapy	Ann Surg Oncol	Narrative review/Commentary
1065	25506538	Vieira	A Multi-institutional Analysis of Insurance Status as a Predictor of Morbidity Following Breast Reconstruction	*Plast Reconstr Surg Glob Open*	Does not address KQ1-KQ6
1066	31335468	Viezel-Mathieu	Acellular Dermal Matrix-sparing Direct-to-implant Prepectoral Breast Reconstruction: A Comparative Study Including Cost Analysis	*Ann Plast Surg*	NRCS not adjusted
1067	21451370	Vogel	Breast cancer in women under age 40 years: treatment by total mastectomy and reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
1068	31577663	Voineskos	Giving Meaning to Differences in BREAST-Q Scores: Minimal Important Difference for Breast Reconstruction Patients	*Plast Reconstr Surg*	NRCS not adjusted
1069	28293504	Vollbach	An Appraisal of Internal Mammary Artery Perforators as Recipient Vessels in Microvascular Breast Reconstruction-An Analysis of 515 Consecutive Cases	*Plast Reconstr Surg Glob Open*	Single group N enrolled <500
1070	27353390	Wade	The importance of the unit of analysis: Commentary on Beugels et al. (2016). Complications in unilateral versus bilateral deep inferior epigastric artery perforator flap breast reconstructions: A multicentre study	*J Plast Reconstr Aesthet Surg*	Narrative review/ Commentary
1071	23542852	Wagner	A classification system for fat necrosis in autologous breast reconstruction	*Ann Plast Surg*	NRCS not adjusted
1072	31076195	Wagner	A systematic review of complications in prepectoral breast reconstruction	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
1073	29876176	Walia	Prepectoral Versus Subpectoral Tissue Expander Placement: A Clinical and Quality of Life Outcomes Study	*Plast Reconstr Surg Glob Open*	NRCS <30 per arm
1074	20679822	Wan	Inclusion of mesh in donor-site repair of free TRAM and muscle-sparing free TRAM flaps yields rates of abdominal complications comparable to those of DIEP flap reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
1075	25054245	Wang	Lessons learned from the American College of Surgeons National Surgical Quality Improvement Program Database: has centralized data collection improved immediate breast reconstruction outcomes and safety?	*Plast Reconstr Surg*	NRCS not adjusted
1076	25942235	Wang	Abstract 124: outcomes of total skin-sparing mastectomy and reconstruction in 924 breasts over 11 years	*Plast Reconstr Surg*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1077	25052246	Wang	Total skin-sparing mastectomy and immediate breast reconstruction: an evolution of technique and assessment of outcomes	*Ann Surg Oncol*	Does not address KQ1-KQ6
1078	31020469	Wang	Post-mastectomy immediate breast reconstruction is oncologically safe in well-selected T4 locally advanced breast cancer: a large population-based study and matched case-control analysis	*Breast Cancer Research and Treatment*	Does not address KQ1-KQ6
1079	31020469	Wang	Post-mastectomy immediate breast reconstruction is oncologically safe in well-selected T4 locally advanced breast cancer: a large population-based study and matched case-control analysis	*Breast Cancer Res Treat*	Does not address KQ1-KQ6
1080	24902911	Wang	Meta-analysis of the safety and factors contributing to complications of MS-TRAM, DIEP, and SIEA flaps for breast reconstruction	*Aesthetic Plast Surg*	Systematic review
1081	32807619	Wang	Autologous tissue reconstruction after mastectomy – A cross-sectional survey of 110 hospitals in China	European Journal of Surgical Oncology	Does not address KQ1-KQ6
1082	20855759	Warren Peled	Impact of chemotherapy on postoperative complications after mastectomy and immediate breast reconstruction	*Arch Surg*	NRCS not adjusted
1083	27187684	Warschkow	A population-based analysis of secondary malignancies in breast cancer patients receiving breast reconstruction	*Br J Cancer*	No outcome of interest
1084	30329056	Watad	Silicone breast implants and the risk of autoimmune/rheumatic disorders: a real-world analysis	*Int J Epidemiol*	Not mastectomy for breast cancer
1085	23783060	Weichman	Sterile 'ready-to-use' AlloDerm decreases postoperative infectious complications in patients undergoing immediate implant-based breast reconstruction with acellular dermal matrix	*Plast Reconstr Surg*	Single group N enrolled <500
1086	29369110	Weinstein	Moffitt Cancer Center Experience of Tissue Expander Breast Reconstruction: Does Acellular Dermal Matrix Increase Return to the Operating Room?	*Ann Plast Surg*	NRCS not adjusted
1087	30109538	Weiss	Reconstruction in the Metastatic Breast Cancer Patient: Results from the National Cancer Database	*Ann Surg Oncol*	Does not address KQ1-KQ6
1088	32605294	Weitgasser	Bilateral Simultaneous Breast Reconstruction with DIEP- and TMG Flaps: Head to Head Comparison, Risk and Complication Analysis	J Clin Med	NRCS not adjusted
1089	109550161	Weller	Effects of Radiation Therapy on Long-term Toxicity and Reconstruction Failure Following Mastectomy and Autologous Reconstruction	*International Journal of Radiation Oncology, Biology, Physics*	Does not address KQ1-KQ6
1090	24691317	Wes	Do Prior Abdominal Surgeries Increase Complications in Abdominally Based Breast Reconstructions?	*Ann Plast Surg*	Copublication of included study with no new data
1091	11039373	Wilkins	Prospective analysis of psychosocial outcomes in breast reconstruction: one-year postoperative results from the Michigan Breast Reconstruction Outcome Study	*Plast Reconstr Surg*	Single group N enrolled <500
1092	27906762	Wilkins	Complications in Postmastectomy Breast Reconstruction: One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study	*Annals of Surgery*	Duplicate of another publication

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1093	9326776	Williams	The effects of radiation treatment after TRAM flap breast reconstruction	*Plastic and Reconstructive Surgery*	Copublication of included study with no new data
1094	9326776	Williams	The effects of radiation treatment after TRAM flap breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
1095	32113147	Wilting	Three-dimensional evaluation of breast volume changes following autologous free flap breast reconstruction over six months'	*Breast*	Single group N enrolled <500
1096	24673121	Wink	Direct-to-implant breast reconstruction: an analysis of 1612 cases from the ACS-NSQIP surgical outcomes database	*J Plast Surg Hand Surg*	Does not address KQ1-KQ6
1097	25798391	Winocour	Early Surgical Site Infection Following Tissue Expander Breast Reconstruction with or without Acellular Dermal Matrix: National Benchmarking Using National Surgical Quality Improvement Program	*Arch Plast Surg*	Copublication of included study with no new data
1098	30507480	Winters	Quality of life after breast reconstruction-the BRIOS study	*Lancet Oncology*	Narrative review/ Commentary
1099	31121016	Wixtrom	Device-Specific Findings of Imprinted-Texture Breast Implants: Characteristics, Risks, and Benefits	*Aesthet Surg J*	Single group N enrolled <500
1100	31155830	Wohlgemuth	Risk of breast implant-associated anaplastic large cell lymphoma in patients submitted to breast implantation: A systematic review	*Breast J*	Systematic review
1101	10493686	Wolfe	Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis	*J Rheumatol*	Unable to retrieve article
1102	NR	Wolfswinkel	Complications of abdominal-based free flaps for breast reconstruction in obese patients: A meta-analysis and case series	*European Journal of Plastic Surgery*	Does not address KQ1-KQ6
1103	138986907	Wong	IMRT is Associated with Lower Reconstruction Failure and Complication Rates Following Post-Mastectomy Radiation to a Reconstructed Breast	*International Journal of Radiation Oncology, Biology, Physics*	Single group N enrolled <500
1104	31342383	Wong	National Patterns of Breast Reconstruction and Nipple-Sparing Mastectomy for Breast Cancer, 2005-2015	*Ann Surg Oncol*	Does not address KQ1-KQ6
1105	32537347	Wood	Complications after Perforated versus Nonperforated Acellular Dermal Matrix Use in Direct-to-Implant Breast Reconstruction: A Propensity Score Analysis	Plast Reconstr Surg Glob Open	Single group N enrolled <500
1106	33137841	Woodward	Nipple-sparing mastectomy: A review of outcomes at a single institution	Breast J	Single group N enrolled <500
1107	24200701	Wormald	The increased risk of adverse outcomes in bilateral deep inferior epigastric artery perforator flap breast reconstruction compared to unilateral reconstruction: a systematic review and meta-analysis	*J Plast Reconstr Aesthet Surg*	Does not address KQ1-KQ6
1108	31348326	Wormer	Reducing Expansion Visits in Immediate Implant-Based Breast Reconstruction: A Comparative Study of Prepectoral and Subpectoral Expander Placement	*Plast Reconstr Surg*	NRCS not adjusted
1109	24691350	Wu	Racial differences in ischemic complications of pedicled versus free abdominal flaps for breast reconstruction	*Ann Plast Surg*	Case report or series of case reports
1110	18953926	Wu	[A retrospective study of 129 cases with immediate breast reconstruction after skin-sparing mastectomy for breast cancer]	*Zhonghua Wai Ke Za Zhi*	Single group N enrolled <500

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1111	18766032	Wu	Comparison of donor-site morbidity of SIEA, DIEP, and muscle-sparing TRAM flaps for breast reconstruction	*Plast Reconstr Surg*	NRCS not adjusted
1112	29631098	Wu	Breast reconstruction with Alloderm Ready to Use: A meta-analysis of nine observational cohorts	*Breast*	Narrative review/ Commentary
1113	30034254	Wu	Comparison of survival outcomes of locally advanced breast cancer patients receiving postmastectomy radiotherapy with and without immediate breast reconstruction: A population-based analysis	*Cancer Management and Research*	Does not address KQ1-KQ6
1114	30034254	Wu	Comparison of survival outcomes of locally advanced breast cancer patients receiving post-mastectomy radiotherapy with and without immediate breast reconstruction: a population-based analysis	*Cancer Manag Res*	Does not address KQ1-KQ6
1115	29846217	Wu	Evaluating the Impact of Resident Participation and the July Effect on Outcomes in Autologous Breast Reconstruction	*Ann Plast Surg*	Does not address KQ1-KQ6
1116	31461141	Wu	Breast Cancer Recurrence in the Nipple-Areola Complex After Nipple-Sparing Mastectomy With Immediate Breast Reconstruction for Invasive Breast Cancer	*JAMA Surg*	Does not address KQ1-KQ6
1117	139809975	Wu	Breast Cancer Recurrence in the Nipple-Areola Complex After Nipple-Sparing Mastectomy With Immediate Breast Reconstruction for Invasive Breast Cancer	*JAMA Surgery*	Case report or series of case reports
1118	33665246	Wu	Data on distant metastasis and survival after locoregional recurrence following nipple-sparing mastectomy and immediate breast reconstruction	Data Brief	Single group N enrolled <500
1119	33495030	Wu	Locoregional recurrence following nipple-sparing mastectomy with immediate breast reconstruction: Patterns and prognostic significance	Eur J Surg Oncol	NRCS not adjusted
1120	25162244	Wurzer	[Is there a psychological and physiological difference between DIEP- and free TRAM-flap? A retrospective patient survey]	*Handchir Mikrochir Plast Chir*	NRCS <30 per arm
1121	26285643	Xavier Harmeling	The effect of immediate breast reconstruction on the timing of adjuvant chemotherapy: a systematic review	*Breast Cancer Res Treat*	Narrative review/ Commentary
1122	31985610	Xue	Follow-Up Study: One-Step Salvage of Infected Prosthetic Breast Reconstructions Using Antibiotic-Impregnated Polymethylmethacrylate Plates and Concurrent Tissue Expander Exchange	*Plast Reconstr Surg*	Single group N enrolled <500
1123	33526379	Yamashita	Long-Term Oncologic Safety of Nipple-Sparing Mastectomy With Immediate Reconstruction	Clin Breast Cancer	Does not address KQ1-KQ6
1124	26562294	Yang	The Type of Breast Reconstruction May Not Influence Patient Satisfaction in the Chinese Population: A Single Institutional Experience	*PLoS One*	NRCS not adjusted
1125	28833134	Yang	Changes in shoulder muscle activity pattern on surface electromyography after breast cancer surgery	*J Surg Oncol*	NRCS <30 per arm
1126	22493623	Yang	Surgical techniques for personalized oncoplastic surgery in breast cancer patients with small- to moderate-sized breasts (part 2): volume replacement	*J Breast Cancer*	Does not address KQ1-KQ6
1127	31775208	Yang	Considerations for patient selection: Prepectoral versus subpectoral implant-based breast reconstruction	*Arch Plast Surg*	NRCS not adjusted
1128	33389980	Yang	Post-mastectomy radiation therapy in breast reconstruction: a patterns of care study of the Korean Radiation Oncology Group	Radiat Oncol J	NRCS not adjusted

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1129	33483782	Yazar	Invited Response on: Nipple-Sparing Mastectomy and Immediate Implant-Based Reconstruction with or Without Skin Reduction in Patients with Large Ptotic Breasts: A Case-Matched Analysis	Aesthetic Plast Surg	Does not address KQ1-KQ6
1130	9843345	Yeh	Immediate breast reconstruction in breast cancer: morbidity and outcome	*Am Surg*	NRCS <30 per arm
1131	CN-02175345	Yehia	Reconstruction Outcomes in a Multi-Institution Prospective Phase II Hypofractionated Post-Mastectomy Radiation Therapy Trial	International journal of radiation oncology biology physics	NRCS not adjusted
1132	26618122	Yim	Outcomes of Take-Back Operations in Breast Reconstruction with Free Lower Abdominal Flaps	*Arch Plast Surg*	Does not address KQ1-KQ6
1133	25620484	Ying	Current trends of breast reconstruction after mastectomy for breast cancer patients in China: A survey report	*Chinese Journal of Oncology*	Duplicate of another publication
1134	29102781	Yoon	Outcomes of immediate versus delayed breast reconstruction: Results of a multicenter prospective study	*Breast*	Does not address KQ1-KQ6
1135	31342370	Young	Outcomes of > 1300 Nipple-Sparing Mastectomies with Immediate Reconstruction: The Impact of Expanding Indications on Complications	*Ann Surg Oncol*	Does not address KQ1-KQ6
1136	27508508	Youssef	Use of Acellular Dermal Matrix versus Latissimus Dorsi Flap for Breast Reconstruction: Clinical and Patient-Reported Outcomes	*Breast J*	NRCS <30 per arm
1137	27070347	Yu	Comparison of Histological Characteristics of Acellular Dermal Matrix Capsules to Surrounding Breast Capsules in Acellular Dermal Matrix-Assisted Breast Reconstruction	*Ann Plast Surg*	NRCS <30 per arm
1138	30132338	Yun	Breast Reconstruction and Radiation Therapy	*Cancer Control*	Narrative review/ Commentary
1139	128167261	Yun	The role of postmastectomy radiation therapy in patients with immediate prosthetic breast reconstruction: A meta-analysis	*Medicine*	Does not address KQ1-KQ6
1140	138986910	Zhang	The Impact of Radiotherapy on Complications and Reconstruction Failures in Patients Undergoing Mastectomy and Breast Reconstruction	*International Journal of Radiation Oncology, Biology, Physics*	Single group N enrolled <500
1141	16883889	Zhao	[Clinic applications of primary breast reconstruction with a subpectoral silicone tissue expander]	*Zhonghua Zheng Xing Wai Ke Za Zhi*	Single group N enrolled <500
1142	26377821	Zhao	A Meta-analysis of Postoperative Complications of Tissue Expander/Implant Breast Reconstruction Using Acellular Dermal Matrix	*Aesthetic Plast Surg*	Systematic review
1143	28000160	Zheng	Radiotherapy and nipple-areolar complex necrosis after nipple-sparing mastectomy: a systematic review and meta-analysis	*Radiol Med*	Does not address KQ1-KQ6
1144	24888814	Zhong	Barriers to immediate breast reconstruction in the Canadian Universal Health Care System: Zhong T, Fernandes KA, Saskin R, et al (Univ Health Network, Toronto, Ontario, Canada; Inst for Clinical Evaluative Sciences, Toronto, Ontario, Canada; Et al) J Clin Oncol 32:2133-2141, 2014	*Breast Diseases*	Does not address KQ1-KQ6

No.	PMID or Other Identifier	First Author Last Name	Title	Journal	Reason for Exclusion
1145	CN-00915067	Zhong	The Multi Centre Canadian Acellular Dermal Matrix Trial (MCCAT): study protocol for a randomized controlled trial in implant-based breast reconstruction	*Trials*	Duplicate of another publication
1146	24165392	Zhong	The Multi Centre Canadian Acellular Dermal Matrix Trial (MCCAT): study protocol for a randomized controlled trial in implant-based breast reconstruction	*Trials*	Protocol/methods with no results
1147	CN-01120691	Zhong	The Multi Centre Canadian Acellular Dermal Matrix Trial (MCCAT): study protocol for a randomized controlled trial in implant-based breast reconstruction	*Trials*	Duplicate of another publication
1148	103996301	Zhong	The Multi Centre Canadian Acellular Dermal Matrix Trial (MCCAT): study protocol for a randomized controlled trial in implant-based breast reconstruction	*Trials*	Duplicate of another publication
1149	26922050	Zhu	Comparison of subcutaneous versus submuscular expander placement in the first stage of immediate breast reconstruction	*J Plast Reconstr Aesthet Surg*	NRCS <30 per arm
1150	22017572	Zucatto	Immediate breast reconstruction using free transverse rectus abdominis myocutaneous flap: impact on breast cancer recurrence after mastectomy	*Breast J*	Single group N enrolled <500

Abbreviations: PMID = PubMed identifier, KQ = Key Question, NR = not reported, NRCS = nonrandomized comparative study.

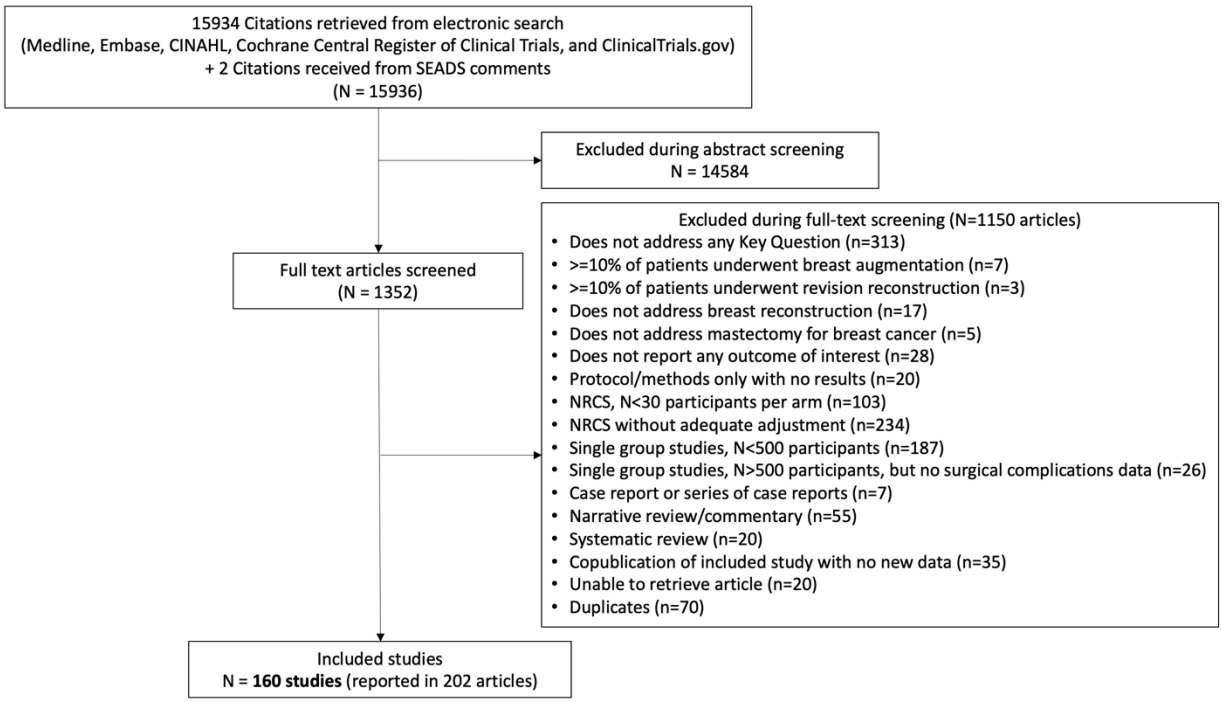
Colors: Header rows are shaded orange. The color does not add unique information.

Appendix C. Results: Design, Arm, and Sample Details

Results of Literature Searches

As illustrated by Figure C-1, our primary electronic search retrieved a combined 15,936 unique citations. Of these, 1,352 were deemed potentially relevant and retrieved in full text. After full-text screening, we identified 160 eligible studies that were reported in 202 articles.

Figure C-1. Flow diagram for studies



Abbreviations: NRCS = nonrandomized comparative study, SEADS = Submit Supplemental Evidence and Data for Systematic Reviews.

Description of Included Studies

Overall Summary of Study Characteristics

The 160 included studies (reported in 202 articles[1-202]) were published between 1989 and 2021. All told, the studies enrolled and followed patients between 1977 and 2020. The 160 studies comprised eight RCTs, 83 NRCSs (observational cohort studies), and 69 single group studies.

The 160 included studies included a total of 459,228 patients. The 160 studies comprised eight RCTs with 570 patients (ranging from 34 to 150 patients each), 83 NRCSs with 202,862 patients (ranging from 70 to 32,897 patients each), and 69 single group studies with 275,218 patients (ranging from 501 to 56,522 patients each).

Appendix Tables C-1 to C-7 summarize the design and arm details of all 160 studies. Although the tables are organized by KQ, we describe all 160 studies here. Ninety studies (56%) were conducted exclusively in the U.S., 12 (8%) exclusively in South Korea, 7 (4%) exclusively in Canada, 7 (4%) exclusively in Sweden, 6 (4%) exclusively in China, 5 (3%) exclusively in the U.K., 4 (3%) exclusively in France, 4 (3%) exclusively in Germany, and 4 (3%) exclusively in

the Netherlands. Other common countries included Belgium and Italy (3 studies [2%] each) and Japan (2 studies [1%]). One study each (1%) was conducted in Australia, Denmark, Finland, India, Portugal, Taiwan, and Turkey. Six studies (4%) were conducted in multiple countries, each of which included the U.S. and Canada.

Among all 160 studies, 94 (59%) were single-center studies, while 56 (35%) involved multiple centers (10 studies [6%] did not report number of centers). A large proportion of the studies either were not funded (48/160 studies; 30%) or did report information about funding sources (72/160 studies; 45%). Among the remaining 40 studies, 33 studies were funded by nonindustry sources, and 9 studies were funded by industry sources (2 studies were funded by both).

Summary of Patient Characteristics

Almost half of studies (72/160; 45%) did not report any data about the ages for the entire study population. When reported, average patient ages ranged from 42.1 to 58.3 years. The youngest and oldest enrolled patients were 18 years and 83 years, respectively.

A large proportion of the studies (96/160; 61%) did not report any data about body mass index (BMI) for the entire study population. When reported, average BMIs ranged from 21.9 to 34.5 kg/m^2. The lowest and highest BMIs among enrolled patients were 14.4 kg/m^2 and 60.3 kg/m^2, respectively.

Only 27 studies reported data about patient race. Most patients were white/Caucasian, with percentages ranging from 63.2% to 97.9%. Black/African Americans were the next most common, ranging from 1.3% to 15.0%.

Only 8 studies reported on whether the breast cancer being treated was the first or a repeat occurrence. All patients in all 8 studies were being treated for their first breast cancer.

Only 36 studies reported data about whether the mastectomy that patients (in the entire study population) received was for therapeutic or prophylactic purposes. Among most of these studies, the mastectomy was therapeutic for the majority of patients (ranging from 73.6% to 100%). However, in 2 studies, the majority of patients received mastectomy for therapeutic purposes (64.6% and 55.5%).

Risk of Bias Assessments

Appendix Tables D-1 to D-4 summarize the risk of bias assessment of all 160 studies. Among the 8 RCTs, we rated 4 at overall high risk of bias and 4 at overall moderate risk of bias. The main reasons for high risk of bias ratings were the lack of blinding of participants and care providers, incompleteness of outcome data, or evidence of selective outcome reporting. Among the 83 NRCSs, we rated 63 at overall high risk of bias, 19 at overall moderate risk of bias, and 1 at overall low risk of bias. The main reasons for high risk of bias ratings were the lack of blinding of participants, care providers, and outcomes assessors or evidence of serious risk of confounding. Among the 69 Single group studies, we rated 1 at overall high risk of bias, 14 at overall moderate risk of bias, and 54 at overall low risk of bias. The main reasons for moderate risk of bias ratings were because the interventions were not clearly described or consistently delivered or that the outcomes were not prespecified, clearly defined, and consistently assessed.

Table C-1. Key Question 1: Implant-based versus autologous reconstruction – comparative studies, summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Abedi, 2016, 25003437, Canada	NRCS (None) (2003-2011)	High	I: BR	IBR	NR	Timing: Imm (100) Stages: >1 (87) Chemo: Before (28.7)/After (16.6) Radio: Before (13.4)/After (15.1)	404	48.3 (9.6)	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	AR (all)	N/A	Timing: Imm (100) Stages: NR Chemo: Before (47.5)/After (13.7) Radio: Before (38.9)/After (3.2)	314	50 (8.2)	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	AR with DIEP	N/A	NR	NR	NR	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	AR with TRAM	N/A	Timing: Imm (100)	NR	NR	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	Total	N/A	.	718	NR	NR	NR	NR
Brito, 2020, No PMID, Portugal	NRCS (NR) (2014-2018)	High	I: IBR or AR with pedicled TRAM or LD-flap E: Hybrid IBR and AR (other than LD)	IBR	NR	TIMING: Imm (95.6)/Del (4.4) RADIO: Timing NR (14.7)	68	45.5 (9.2)	NR	1st: 100	NR
	NRCS (NR) (2014-2018)	High	I: IBR or AR with pedicled TRAM or LD-flap E: Hybrid IBR and AR (other than LD)	AR	N/A	RADIO: Timing NR (61.3)	111	50.2 (8.5)	NR	1st: 100	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2014-2018)	High	I: IBR or AR with pedicled TRAM or LD-flap E: Hybrid IBR and AR (other than LD)	Total	N/A	N/A	179	49.1	NR	1st: 100	NR
Brorson 2020a, 32807615, Sweden	RCT (Non-industry) (2008-2020)	High	I: Age≥18 years; unilateral mastectomy E: Current smoker; BMI >30	IBR	NR	Laterality: Uni (100) Timing: Del (100) Stages: 1 (100) Chemo: Before (18.6)	80	55.7 (9.0)	NR	NR	Stage 0: 19.1 Stage I: 36.8 Stage II: 42.6 Stage III: 1.5
	RCT (Non-industry) (2008-2020)	High	I: Age≥18 years; unilateral mastectomy E: Current smoker; BMI >30	AR	N/A	Laterality: Uni (100) Timing: Del (100) Chemo: Before (23.6)	70	55.1 (7.0)	NR	NR	Stage 0: 14.5 Stage I: 25.5 Stage II: 60.0 Stage III: 0
	RCT (Non-industry) (2008-2020)	High	I: Age≥18 years; unilateral mastectomy E: Current smoker; BMI >30	Total	N/A	N/A	150	NR	NR	NR	NR
Carramaschi, 1989, 2602589, France	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	IBR	MATERIAL: Silicone (100)	Laterality: Uni (97.8)/Bi (2.2) Timing: Imm (11)/Del (89) Stages: 1 (92.2)/>1 (7.8) Chemo: NR Radio: NR	166	NR	NR	NR	NR
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	AR (all)	N/A	NR	74	NR	NR	NR	NR
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	AR with TRAM	N/A	NR	40	NR	NR	NR	NR
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	AR with LD	N/A	NR	34	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	Total	N/A	N/A	240	46.6 (NR); Range: 24, 70	NR	NR	Stage III (18)
Chetta, 2017, 28002254, US	NRCS (NR) (2009-2012)	High	I: Age >=18 years, BR for breast cancer/high risk/family history of breast cancer E: Combination of procedures (e.g., IBR plus AR)	IBR	NR	Timing: Imm (83)/Del (17)/ Radio: Before (25)/After (75)	3846	18-34 years (6%), 35-44 years (26%), 45-54 years (40%), 55-64 years (22%), ≥65 years (21%)	NR	NR	NR
	NRCS (NR) (2009-2012)	High	I: Age >=18 years, BR for breast cancer/high risk/family history of breast cancer E: Combination of procedures (e.g., IBR plus AR)	AR	N/A	Timing: Imm (52)/Del (48) Radio: Before (64)/After (36)	935	18-34 years (5%), 35-44 years (23%), 45-54 years (42%), 55-64 years (24%), ≥65 years (5%)	NR	NR	NR
	NRCS (NR) (2009-2012)	High	I: Age >=18 years, BR for breast cancer/high risk/family history of breast cancer E: Combination of procedures (e.g., IBR plus AR)	Total	N/A	N/A	4781	NR	NR	NR	NR
Dauplat, 2021, 33622886, France	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR or AR after therapeutic mastectomy E: Another concurrent cancer	IBR	NR	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (14) RADIO: Timing NR (10)	205	NR	NR	NR	Ther (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR or AR after therapeutic mastectomy E: Another concurrent cancer	AR with TRAM	N/A	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (40) RADIO: Timing NR (17)	30	NR	NR	NR	Ther (100)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR or AR after therapeutic mastectomy E: Another concurrent cancer	AR with LD and implant	NR	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (17) RADIO: Timing NR (14)	91	NR	NR	NR	Ther (100)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR or AR after therapeutic mastectomy E: Another concurrent cancer	AR with LD and no implant	N/A	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (32) RADIO: Timing NR (7)	78	NR	NR	NR	Ther (100)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR or AR after therapeutic mastectomy E: Another concurrent cancer	Total	N/A	N/A	404	NR	NR	NR	Ther (100)
de Araujo, 2016, 27673527, US	NRCS (NR) (2002-2012)	High	I: Age >=18 years with unilateral chest wall radiotherapy followed by bilateral mastectomy and immediate bilateral BR E: Bilateral chest wall radiotherapy	IBR	NR	Laterality: Bi (100) Radio: Before (100)	38	NR	NR	NR	Stage NR (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2002-2012)	High	I: Age >=18 years with unilateral chest wall radiotherapy followed by bilateral mastectomy and immediate bilateral BR E: Bilateral chest wall radiotherapy	AR	N/A	Laterality: Bi (100) Stages: 1 (100) Radio: Before (100)	32	NR	NR	NR	Stage NR (100)
	NRCS (NR) (2002-2012)	High	I: Age >=18 years with unilateral chest wall radiotherapy followed by bilateral mastectomy and immediate bilateral BR E: Bilateral chest wall radiotherapy	Total	N/A	N/A	70	51.2 (8.2)	NR	NR	Stage NR (100)
Eltahir, 2015, 25539295, Netherlands	NRCS (NR) (2006-2010)	Moderate	I: Age >=18 years E: Presence of metastasis or severe illness, reconstruction failure	IBR	NR	Timing: Mixed (100)	45	Median 42; IQR 22, 59	NR	NR	Stage II (95.3), Stage III (4.7)
	NRCS (NR) (2006-2010)	Moderate	I: Age >=18 years E: Presence of metastasis or severe illness, reconstruction failure	AR	N/A	Timing: Mixed (100)	47	Median 49; Range 31, 74	NR	NR	Stage II (71.4), Stage III (28.6)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2006-2010)	Moderate	I: Age >=18 years E: Presence of metastasis or severe illness, reconstruction failure	Total	N/A	N/A	92	NR	NR	NR	NR
Fischer, 2013, 23629074, US	NRCS (NR) (2005-2008)	High	I: Did not receive postoperative radiation therapy, age<65 years, BMI 25-35mg/kg2	IBR	PLANE: Total submuscular (100)	Laterality: Uni (40)/Bi (60) Stages: 1 (100) Chemo: After (21.7) Radio: Before (16.7)	60	46.3 (9.5)	NR	NR	NR
	NRCS (NR) (2005-2008)	High	I: Did not receive postoperative radiation therapy, age<65 years, BMI 25-35mg/kg2	AR	N/A	Laterality: Uni (36.6)/Bi (63.4) Stages: >1 (100) Chemo: After (26.8) Radio: Before (28.9)	142	50 (7.9)	NR	NR	NR
	NRCS (NR) (2005-2008)	High	I: Did not receive postoperative radiation therapy, age<65 years, BMI 25-35mg/kg2	Total	N/A	N/A	202	NR	NR	NR	NR
Fischer, 2014, 24916480, US	NRCS (NR) (2005-2011)	High	I: AR with free flap or TE/Implant BR	IBR	PLANE: Total submuscular (100)	Laterality: Uni (40)/Bi (60) Timing: Imm (90.3)/Del (7.1) Stages: >1 (100) Chemo: Before (30.3)/After (47.7)/No chemotherapy (22.0) Radio: Before (16.8)/After (16.8)/None(66.4)	155	47.9 (11.6)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2005-2011)	High	I: AR with free flap or TE/Implant BR	AR	N/A	Laterality: Uni (38.1)/Bi (61.9) Timing: Imm (89.7)/Del (10.3) Stages: 1 (100) Chemo: Before (25.2)/After (40.0)/No chemotherapy (34.8) Radio: Before (16.8)/After (28.4)/None(54.8)	155	48.5 (9.1)	NR	NR	NR
	NRCS (NR) (2005-2011)	High	I: AR with free flap or TE/Implant BR	Total	N/A	N/A	310	NR	NR	NR	NR
Fischer, 2015, 26366550, US	NRCS (Non-industry) (2007-2012)	High	I: Age >=18 years with postmastectomy BR E: Known metastatic disease and where the discharge disposition was recorded as unknown or death	IBR (Direct to Implant)	NR	Laterality: Uni (57.7)/Bi (42.3) Timing: Imm (100) Chemo: NR Radio: NR	1717	52.7 (11.4)	NR	NR	Stage 0 (23), Stage NR (77)
	NRCS (Non-industry) (2007-2012)	High	I: Age >=18 years with postmastectomy BR E: Known metastatic disease and where the discharge disposition was recorded as unknown or death	IBR (TE/IBR)	NR	Laterality: Uni (61.9)/Bi (38.1) Timing: Imm (100) Chemo: NR Radio: NR	10690	51.8 (10.7)	NR	NR	Stage 0 (20.2), Stage NR (79.8)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2007-2012)	High	I: Age >=18 years with postmastectomy BR E: Known metastatic disease and where the discharge disposition was recorded as unknown or death	AR	N/A	Laterality: Uni (70.5)/Bi (29.5) Timing: Imm (100) Stages: 1 (100) Chemo: NR Radio: NR	2747	52.2 (9.9)	NR	NR	Stage 0 (20), Stage NR (80)
	NRCS (Non-industry) (2007-2012)	High	I: Age >=18 years with postmastectomy BR E: Known metastatic disease and where the discharge disposition was recorded as unknown or death	Total	N/A	N/A	1515 4	NR	NR	NR	NR
Garbay, 1992, 1624727, France	NRCS (NR) (1979-1990)	High	I: BR	IBR	NR	Timing: Imm (29)/Del (71) Stages: 1 (29)/>1 (71)	224	NR	NR	NR	NR
	NRCS (NR) (1979-1990)	High	I: BR	AR with TRAM	N/A	NR	63	NR	NR	NR	NR
	NRCS (NR) (1979-1990)	High	I: BR	AR with LD	N/A	NR	36	NR	NR	NR	NR
	NRCS (NR) (1979-1990)	High	I: BR	Total	N/A	N/A	323	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Garvey, 2012, 23096600, US	NRCS (NR) (2005-2013)	Moderate	I: Obese patients (BMI≥30 kg/m2) E: "Delayed-delayed" or "delayed-immediate" BR	IBR	SIZE: Mean 702 cc, SD 130	Timing: Imm (91.4)/Del (8.6) Stages: 1 (3.4)/>1 (96.6) Chemo: Before (29.4)/After (13.1) Radio: Before (3.6)/After (11.1)	NR	52.2 (10.3)	NR	NR	NR
	NRCS (NR) (2005-2013)	Moderate	I: Obese patients (BMI≥30 kg/m2) E: "Delayed-delayed" or "delayed-immediate" BR	AR	N/A	Timing: Imm (71)/Del (29) Chemo: Before (52.4)/After (7.1) Radio: Before (31)/Timing NR (6.2)	NR	48.9 (8.9)	NR	NR	NR
	NRCS (NR) (2005-2013)	Moderate	I: Obese patients (BMI≥30 kg/m2) E: "Delayed-delayed" or "delayed-immediate" BR	Total	N/A	N/A	700	50 (NR); Range 26, 78	NR	NR	NR
Ha, 2020, 32000718, South Korea	NRCS (NR) (2010-2014)	High	I: Immediate BR E: Phyllodes tumor, angiosarcoma, or metastatic cancer at initial presentation; prophylactic mastectomy; prior history of breast cancer; major complications such as flap loss or implant loss that may delay adequate postoperative anti-cancer treatment	IBR	NR	Timing: Imm (100) Chemo: Timing NR (55)/No chemotherapy (45) Radio: Timing NR (79)/None(21)	247	41 (8.73)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2010-2014)	High	I: Immediate BR E: Phyllodes tumor, angiosarcoma, or metastatic cancer at initial presentation; prophylactic mastectomy; prior history of breast cancer; major complications such as flap loss or implant loss that may delay adequate postoperative anti-cancer treatment	AR	N/A	Timing: Imm (100) Chemo: Timing NR (47)/No chemotherapy (53) Radio: Timing NR (80)/None(20)	249	43 (6.99)	NR	NR	NR
	NRCS (NR) (2010-2014)	High	I: Immediate BR E: Phyllodes tumor, angiosarcoma, or metastatic cancer at initial presentation; prophylactic mastectomy; prior history of breast cancer; major complications such as flap loss or implant loss that may delay adequate postoperative anti-cancer treatment	Total	N/A	N/A	496	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Hangge, 2019, 31606126, US	NRCS (None) (2010-2017)	High	I: Mastectomy with immediate 1-stage IBR, 2-stage IBR, or AR	IBR (Direct to Implant)	NR	Laterality: Uni (31)/Bi (69) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (24)/No chemotherapy (76) Radio: Timing NR (17)/None(83)	193	50.9 (11)	W (86), B (3), A (6), H (5), Others (1)	NR	Stage 0 (21), Stage I (50), Stage II (34), Stage III (13), Stage IV (3)
	NRCS (None) (2010-2017)	High	I: Mastectomy with immediate 1-stage IBR, 2-stage IBR, or AR	IBR (TE/IBR)	NR	Laterality: Uni (29)/Bi (71) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (23)/No chemotherapy (77) Radio: Timing NR (21)/None(79)	146	51.5 (11.3)	W (87), B (1), A (3), H (9)	NR	Stage 0 (20), Stage I (42), Stage II (44), Stage III (12), Stage IV (2)
	NRCS (None) (2010-2017)	High	I: Mastectomy with immediate 1-stage IBR, 2-stage IBR, or AR	AR	N/A	Laterality: Uni (47)/Bi (53) Timing: Imm (100) Stages: >1 (100) Chemo: Timing NR (28)/No chemotherapy (72) Radio: Timing NR (13)/None(87)	60	55.9 (7.8)	W (77), B (7), A (7), H (10)	NR	Stage 0 (25), Stage I (49), Stage II (33), Stage III (13), Stage IV (4)
	NRCS (None) (2010-2017)	High	I: Mastectomy with immediate 1-stage IBR, 2-stage IBR, or AR	Total	N/A	N/A	399	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Jiang, 2013, 24349366, US	NRCS (Non-industry) (1998-2002)	High	I: Unilateral breast cancer E: Partial or subcutaneous mastectomy; Histological grade IV (SEER program code: undifferentiated or anaplastic) cancer	IBR	NR	Laterality: Uni (100) Timing: Imm (100) Radio: Timing NR (16.9)/None(79.7)	1412	<45 years (34.9%), 45-64 years (55.9%), >64 years (9.1%)	W (88.6), B (5.8), Others (5.5)	NR	NR
	NRCS (Non-industry) (1998-2002)	High	I: Unilateral breast cancer E: Partial or subcutaneous mastectomy; Histological grade IV (SEER program code: undifferentiated or anaplastic) cancer	AR	N/A	Laterality: Uni (100) Timing: Imm (100) Stages: 1 (100) Radio: Timing NR (19.9)/None(76.1)	2649	<45 years (34.3%), 45-64 years (58.3%), >64 years (7.4%)	W (83.5), B (11.5), Others (5.1)	NR	NR
	NRCS (Non-industry) (1998-2002)	High	I: Unilateral breast cancer E: Partial or subcutaneous mastectomy; Histological grade IV (SEER program code: undifferentiated or anaplastic) cancer	Total	N/A	N/A	4061	NR	NR	NR	NR
Kouwenberg, 2019, 30270015, Netherlands	NRCS (None) (2008-2017)	Moderate	I: Mastectomy for breast cancer E: Distant metastasis	IBR	NR	Laterality: Uni (67.2)/Bi (32.8) Chemo: Before (49.3)/After (50.7) Radio: Timing NR (28.4)/None(71.6)	67	55 (11.63)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2008-2017)	Moderate	I: Mastectomy for breast cancer E: Distant metastasis	AR	N/A	Laterality: Uni (65.7)/Bi (32.8) Chemo: Timing NR (59.7)/No chemotherapy (40.3) Radio: Timing NR (23.9)/None(76.1)	67	55 (9.49)	NR	NR	NR
	NRCS (None) (2008-2017)	Moderate	I: Mastectomy for breast cancer E: Distant metastasis	Total	N/A	N/A	134	NR	NR	NR	NR
Kouwenberg, 2020, 32590633, Netherlands	NRCS (None) (2008-2018)	Moderate	I: Mastectomy for breast cancer	IBR	NR	Laterality: Uni (71.1)/Bi (28.9) Timing: Imm (47.6)/Del (52.0)/NR (0.4) Chemo: Timing NR (43.9) Radio: Timing NR (22.6)	296	60.1 (10.0)	NR	NR	NR
	NRCS (None) (2008-2018)	Moderate	I: Mastectomy for breast cancer	AR	N/A	Laterality: Uni (85.4)/Bi (14.6) Timing: Imm (15.6)/Del (82.6)/NR (1.8) Chemo: Timing NR (47.6) Radio: Timing NR (30.6)	179	59.6 (9.7)	NR	NR	NR
	NRCS (None) (2008-2018)	Moderate	I: Mastectomy for breast cancer	Total	N/A	N/A	475	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Kulkarni, 2017, 28713853, US & Canada	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	IBR (all)	NR	NR	1846	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	IBR (Direct to Implant)	NR	NR	79	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	IBR (TE/IBR)	NR	NR	942	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR (all)	N/A	NR	821	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with DIEP	N/A	NR	463	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with TRAM	N/A	NR	94	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with TRAM	N/A	NR	111	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with LD	N/A	NR	80	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with SIEA	N/A	NR	73	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	Total	N/A	N/A	2667	49.7 (10.1)	W (87.8), B (6.5), A (4.7), Others (1)	NR	Ther (89.7), Proph (10.3)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Laporta, 2017, 28061518, Italy	NRCS (None) (2004-2014)	High	I: BR following mastectomy E: Local recurrence needing surgical revision	IBR	NR	NR	NR	NR	NR	1st: 100	NR
	NRCS (None) (2004-2014)	High	I: BR following mastectomy E: Local recurrence needing surgical revision	AR	N/A	Stages: 1 (100)	NR	NR	NR	1st: 100	NR
	NRCS (None) (2004-2014)	High	I: BR following mastectomy E: Local recurrence needing surgical revision	Total	N/A	N/A	993	50.6 (NR)	NR	NR	NR
Lei, 2020, 32481367, China	NRCS (NR) (2012-2016)	Moderate	I: Single-stage IBR or AR after mastectomy	IBR	NR	Timing: Imm (100) Chemo: Timing NR (76.1)	226	NR	NR	NR	Stage I: 52.2 Stage II: 47.8
	NRCS (NR) (2012-2016)	Moderate	I: Single-stage IBR or AR after mastectomy	AR	N/A	Timing: Imm (100) Chemo: Timing NR (72.9)	83	NR	NR	NR	Stage I: 45.9 Stage II: 54.1
	NRCS (NR) (2012-2016)	Moderate	I: Single-stage IBR or AR after mastectomy	Total	N/A	N/A	309	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Liu, 2014, 24558063, US	NRCS (Non-industry) (2007-2011)	High	I: TE/IBR or AR; without pre/postoperative radiotherapy E: Patients with previous aesthetic or reconstructive breast surgery, patients who were active smokers, and patients with a follow-up duration of <6 months after their breast reconstruction	IBR	NR	Laterality: Uni (45.8)/Bi (54.2) Timing: Imm (91.1)/Del (8.9) Chemo: Timing NR (34.1)/No chemotherapy (65.9) Radio: Timing NR (100)	179	46.9 (10.1)	NR	NR	NR
	NRCS (Non-industry) (2007-2011)	High	I: TE/IBR or AR; without pre/postoperative radiotherapy E: Patients with previous aesthetic or reconstructive breast surgery, patients who were active smokers, and patients with a follow-up duration of <6 months after their breast reconstruction	AR	N/A	Laterality: Uni (60)/Bi (40) Timing: Imm (65.3)/Del (34.7) Stages: 1 (100) Chemo: Timing NR (42.7)/No chemotherapy (57.3) Radio: Timing NR (100)	75	52.1 (8)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2007-2011)	High	I: TE/IBR or AR; without pre/postoperative radiotherapy E: Patients with previous aesthetic or reconstructive breast surgery, patients who were active smokers, and patients with a follow-up duration of <6 months after their breast reconstruction	Total	N/A	N/A	254	NR	NR	NR	NR
Mak, 2020, 32665188, China	NRCS (NR) (2008-2013)	Moderate	I: Immediate reconstruction	IBR	NR	Laterality: Uni (70)/Bi (30) Timing: Imm (100) Chemo: Timing NR (46.7) Radio: Timing NR (23.3)	30	Median: 39.2 SD: 7.1	NR	NR	NR
	NRCS (NR) (2008-2013)	Moderate	I: Immediate reconstruction	AR	N/A	Timing: Uni (96.2)/Bi (3.8) Timing: Imm (100) Chemo: Timing NR (65.3) Radio: Timing NR (48.8)	213	Median: 46.3 SD: 7.9	NR	NR	NR
	NRCS (NR) (2008-2013)	Moderate	I: Immediate reconstruction	Total	N/A	N/A	243	Median: 45.4 SD: 8.1	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
McCarthy, 2014, 24201740, US	NRCS (NR) (2003-2008)	Moderate	I: Age >=21 years; immediate postmastectomy two-stage TE/IBR, or immediate postmastectomy AR E: Prior irradiation; delayed postmastectomy BR; combined AR and IBR; local recurrence of breast cancer; and/or history of complex regional pain syndrome	IBR	NR	Laterality: Uni (51.8)/Bi (48.2) Timing: Imm (100) Stages: >1 (100) Chemo: Timing NR (62) Radio: Timing NR (100)	141	Median 50; Range 26, 79	NR	NR	NR
	NRCS (NR) (2003-2008)	Moderate	I: Age >=21 years; immediate postmastectomy two-stage TE/IBR, or immediate postmastectomy AR E: Prior irradiation; delayed postmastectomy BR; combined AR and IBR; local recurrence of breast cancer; and/or history of complex regional pain syndrome	AR	N/A	Laterality: Uni (78.9)/Bi (21.1) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (40.8) Radio: Timing NR (100)	74	Median 52; Range 25, 69	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2003-2008)	Moderate	I: Age >=21 years; immediate postmastectomy two-stage TE/IBR, or immediate postmastectomy AR E: Prior irradiation; delayed postmastectomy BR; combined AR and IBR; local recurrence of breast cancer; and/or history of complex regional pain syndrome	Total	N/A	N/A	218	NR	NR	NR	NR
Merchant, 2015, 26111325, US	NRCS (NR) (2005-2009)	High	I: Immediate BR E: Simultaneous TE/IBR and AR	IBR	NR	Timing: Imm (100)	10437	NR	NR	NR	NR
	NRCS (NR) (2005-2009)	High	I: Immediate BR E: Simultaneous TE/IBR and AR	AR	N/A	Timing: Imm (100) Stages: 1 (100)	2329	NR	NR	NR	NR
	NRCS (NR) (2005-2009)	High	I: Immediate BR E: Simultaneous TE/IBR and AR	Total	N/A	N/A	12766	18-39 years (10.6%), 40-59 years (65.8%), ≥60 years (23.5%)	W (70.9), B (4.5), A (8.6), H (9.9)	NR	NR
Mioton, 2013, 23562485, US	NRCS (None) (2006-2010)	Moderate	I: AR or TE/IBR	IBR	NR	Timing: Imm (92.1)/Del (7.9)	9786	51.02 (10.56)	W (80.5), B (6.3), A (2.5), Others (10.8)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2006-2010)	Moderate	I: AR or TE/IBR	AR	N/A	Timing: Imm (20.7)/Del (79.3)	3296	51.8 (9.702)	W (76.8), B (11), A (2.9), Others (9.3)	NR	NR
	NRCS (None) (2006-2010)	Moderate	I: AR or TE/IBR	Total	N/A	N/A	13082	NR	NR	NR	NR
Momeni, 2018, 29095189, US	NRCS (None) (2008-2013)	High	I: BR following mastectomy for breast cancer E: Lumpectomy and breast reconstruction or lumpectomy and mastectomy; multiple reconstructive procedures	IBR	NR	NR	16851	NR	NR	NR	NR
	NRCS (None) (2008-2013)	High	I: BR following mastectomy for breast cancer E: Lumpectomy and breast reconstruction or lumpectomy and mastectomy; multiple reconstructive procedures	AR	N/A	Stages: 1 (100)	4622	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2008-2013)	High	I: BR following mastectomy for breast cancer E: Lumpectomy and breast reconstruction or lumpectomy and mastectomy; multiple reconstructive procedures	Total	N/A	N/A	21473	NR	NR	NR	NR
Naoum, 2020a, 31756414, US	NRCS (NR) (1997-2017)	High	I: BR E: Neoadjuvant chemotherapy; local recurrence, bilateral cancer; different BR on each breast	IBR	NR	Timing: Imm (99.8)/Del (0.2) Stages: 1 (100) Chemo: After (38)/No chemotherapy (62) Radio: Timing NR (41.1)/None(58.9)	416	51.3 (NR)	NR	NR	NR
	NRCS (NR) (1997-2017)	High	I: BR E: Neoadjuvant chemotherapy; local recurrence, bilateral cancer; different BR on each breast	AR	N/A	Timing: Imm (85.7)/Del (14.3) Stages: 1 (100) Chemo: After (62.7)/No chemotherapy (37.3) Radio: Timing NR (39.2)/None(60.8)	311	49.1 (NR)	NR	NR	NR
	NRCS (NR) (1997-2017)	High	I: BR E: Neoadjuvant chemotherapy; local recurrence, bilateral cancer; different BR on each breast	Total	N/A	N/A	727	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Naoum, 2020b, 32607638, US	NRCS (None) (2000-2017)	High	I: Reconstruction with neoadjuvant chemotherapy and PMRT	IBR DTI	ADM: Yes (98.4)/No (1.6)	Laterality: Uni (24.4)/Bi (75.6) Timing: Imm (99.2)/Del (0.8) Stages: 1 (100) Chemo: After (100) Radio: After (100)	127	Median: 42.9 (IQR 38.0, 50.9)	NR	NR	Stage 0: 23.6 Stage I: 12.6 Stage II: 38.6 Stage III: 23.6 Stage IV: 1.6
	NRCS (None) (2000-2017)	High	I: Reconstruction with neoadjuvant chemotherapy and PMRT	IBR TE/I	ADM: Yes (60.0)/No (40.0)	Laterality: Uni (34.1)/Bi (65.9) Timing: Imm (92.9)/Del (7.1) Stages: >1 (100) Chemo: After (100) Radio: After (100)	85	Median: 44.5 (IQR 38.1, 50.6)	NR	NR	Stage 0: 12.9 Stage I: 11.8 Stage II: 50.6 Stage III: 24.7 Stage IV: 0
	NRCS (None) (2000-2017)	High	I: Reconstruction with neoadjuvant chemotherapy and PMRT	AR	N/A	Laterality: Uni (67.0)/Bi (33.0) Timing: Imm (31.8)/Del (68.2) Stages: 1 (100) Chemo: After (100) Radio: After (100)	88	Median: 47.3 (IQR 40.8, 52.0)	NR	NR	Stage 0: 13.6 Stage I: 17.0 Stage II: 31.8 Stage III: 36.4 Stage IV: 1.1
	NRCS (None) (2000-2017)	High	I: Reconstruction with neoadjuvant chemotherapy and PMRT	Total	N/A	N/A	300	Median: 45.0 (IQR 38.6, 51.2)	NR	NR	Stage 0: 17.6 Stage I: 13.6 Stage II: 40.0 Stage III: 27.6 Stage IV: 1.0
Nasser, 2018, 30204678, US	NRCS (Non-industry) (2009-2012)	High	I: Adult women; BR E: Delayed BR; LD flaps; Simultaneous AR and IBR	IBR	NR	Timing: Imm (100)	28124	NR	NR	NR	NR
	NRCS (Non-industry) (2009-2012)	High	I: Adult women; BR E: Delayed BR; LD flaps; Simultaneous AR and IBR	AR	N/A	Timing: Imm (100) Stages: 1 (100)	4773	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2009-2012)	High	I: Adult women; BR E: Delayed BR; LD flaps; Simultaneous AR and IBR	Total	N/A	N/A	3289 7	NR	NR	NR	NR
Nelson, 2019, 31356276, US	NRCS (Non-industry) (2009-2017)	High	I: Age>=18 years; BR after therapeutic or prophylactic mastectomy	IBR	NR	Laterality: Uni (31.89)/Bi (68.11) Timing: Imm (99.93)/Del (0.07) Chemo: Before (41.41)/After (0.27)/No chemotherapy (58.19) Radio: Before (8.15)/After (17.67)/None(74.18)	2932	49.53 (10.05)	W (85.54), B (6.55), A (5.05), Others (2.86)	NR	NR
	NRCS (Non-industry) (2009-2017)	High	I: Age>=18 years; BR after therapeutic or prophylactic mastectomy	AR	N/A	Laterality: Uni (58.33)/Bi (41.67) Timing: Imm (58.93)/Del (39.29) Chemo: Before (30.95)/After (3.27)/No chemotherapy 65.48) Radio: Before (9.82)/After (23.81)/Timing NR (66.37)/None(66.37)	336	29.92 (8.11)	W (74.11), B (13.39), A (4.46), Others (8.04)	NR	NR
	NRCS (Non-industry) (2009-2017)	High	I: Age>=18 years; BR after therapeutic or prophylactic mastectomy	Total	N/A	N/A	3268	49.57 (9.87)	W (63.19), B (7.25), A (4.99), Others (3.4)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Palve, 2020, 32468337, Finland	NRCS (Non-industry) (2008-2019)	Moderate	I: Breast reconstruction	IBR	NR	Timing: Imm (49)/Del (51)	51	NR	NR	NR	NR
	NRCS (Non-industry) (2008-2019)	Moderate	I: Breast reconstruction	AR	N/A	Timing: Imm (15)/Del (85)	283	NR	NR	NR	NR
	NRCS (Non-industry) (2008-2019)	Moderate	I: Breast reconstruction	Total	N/A	N/A	334	NR	NR	NR	NR
Qin, 2018, 29384865, China	NRCS (Non-industry) (2009-2015)	High	I: Immediate or delayed unilateral BR following mastectomy E: Not received standard adjuvant treatment; bilateral BR; synchronous bilateral invasive breast cancer or metachronous contralateral breast cancer	IBR	NR	Laterality: Uni (100) Timing: Imm (100) Stages: 1 (100) Chemo: Before (16.7)/After (70.1) Radio: Timing NR (16.7)	54	41.2 (5.4)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2009-2015)	High	I: Immediate or delayed unilateral BR following mastectomy E: Not received standard adjuvant treatment; bilateral BR; synchronous bilateral invasive breast cancer or metachronous contralateral breast cancer	IBR	NR	Laterality: Uni (100) Timing: Del (100) Stages: >1 (100) Chemo: Before (31.6)/After (73.7) Radio: Timing NR (73.7)	38	38.7 (4.8)	NR	NR	NR
	NRCS (Non-industry) (2009-2015)	High	I: Immediate or delayed unilateral BR following mastectomy E: Not received standard adjuvant treatment; bilateral BR; synchronous bilateral invasive breast cancer or metachronous contralateral breast cancer	AR	N/A	Laterality: Uni (100) Chemo: Before (18.6)/After (71.2) Radio: Timing NR (33.9)	59	43.2 (6.5)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2009-2015)	High	I: Immediate or delayed unilateral BR following mastectomy E: Not received standard adjuvant treatment; bilateral BR; synchronous bilateral invasive breast cancer or metachronous contralateral breast cancer	Total	N/A	N/A	151	NR	NR	NR	NR
Roth, 2007, 17413877, US	NRCS (NR) (1994-1998)	High	I: Unilateral or bilateral TE/IBR or AR with TRAM flap	IBR	NR	NR	69	48.5 (9)	NR	NR	NR
	NRCS (NR) (1994-1998)	High	I: Unilateral or bilateral TE/IBR or AR with TRAM flap	AR	N/A	Stages: 1 (100)	225	48.5 (8.7)	NR	NR	NR
	NRCS (NR) (1994-1998)	High	I: Unilateral or bilateral TE/IBR or AR with TRAM flap	Total	.	.	294	NR	W (89), B (4), A (1), H (1), Others (5)	NR	NR
Shiraishi, 2020, 32589082, Japan	NRCS (None) (NR-NR)	High	I: First-time, immediate IBR with TE or AR with DIEP E: Implant or flap loss	IBR	NR	Timing: Imm (100) Stages: >1 (100)	56	NR	NR	1st: 100	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (20XX-20XX)	High	I: First-time, immediate IBR with TE or AR with DIEP E: Implant or flap loss	AR	N/A	Timing: Imm (100)	34	NR	NR	1st: 100	NR
	NRCS (None) (20XX-20XX)	High	I: First-time, immediate IBR with TE or AR with DIEP E: Implant or flap loss	Total	N/A	N/A	90	53.2 (13.0)	NR	1st: 100	NR
Simon, 2020, 33363007, Italy	NRCS (NR) (2016-2019)	Moderate	I: IBR or AR with LD flap	IBR	NR	Laterality: Uni (100) Timing: Imm (100)	68	NR	NR	NR	NR
	NRCS (NR) (2016-2019)	Moderate	I: IBR or AR with LD flap	AR	N/A	Laterality: Uni (100) Timing: Imm (100)	139	NR	NR	NR	NR
	NRCS (NR) (2016-2019)	Moderate	I: IBR or AR with LD flap	Total	N/A	N/A	207	NR	NR	NR	NR
Tallroth, 2020, 33436336, Sweden	RCT (None) (2012-2018)	Moderate	I: Delayed reconstruction without prior radiation therapy	IBR	NR	Laterality: Uni (100) Timing: Del (100) Chemo: Timing NR (45)/No (55)	29	55.8 (8.9)	NR	NR	NR
	RCT (None) (2012-2018)	Moderate	I: Delayed reconstruction without prior radiation therapy	AR	N/A	Laterality: Uni (100) Timing: Del (100) Chemo: Timing NR (57)/No (43)	29	52.3 (10.0)	NR	NR	NR
	RCT (None) (2012-2018)	Moderate	I: Delayed reconstruction without prior radiation therapy	Total	N/A	N/A	73	53.7 (9.4)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Woo, 2018, 30360958, South Korea	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	IBR	NR	Timing: Imm (100) Chemo: Before (5.4)/After (48) Radio: Before (4)/After (13.5)	NR	NR	NR	NR	NR
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	AR (all)	N/A	Timing: Imm (100)	NR	NR	NR	NR	NR
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	AR with DIEP	N/A	Timing: Imm (100) Chemo: Before (2.3)/After (40.9) Radio: Before (2.2)/After (14.8)	NR	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	AR with LD	N/A	Timing: Imm (100) Chemo: Before (8.6)/After (43.6) Radio: After (9.4)	NR	NR	NR	NR	NR
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	Total	N/A	N/A	420	43 (7.4)	NR	NR	NR
Wu, 2021, 33740204, South Korea	NRCS (None) (2010-2016)	High	I: Neoadjuvant chemotherapy followed by mastectomy and reconstruction	IBR	Surface: Smo(12.3)/ Tex (87.7)	Timing: Imm (100) Stages: 1 (87)/>1 (13) Chemo: Before (100)/After (13.8) Chemo: After (45.7)	138	Median 40 (IQR 24, 60)	NR	1st: 100	NR
	NRCS (None) (2010-2016)	High	I: Neoadjuvant chemotherapy followed by mastectomy and reconstruction	AR	N/A	Timing: Imm (100) Chemo: Before (100)/After (9.4) Chemo: After (48.9)	276	Median 41 (IQR 23, 61)	NR	1st: 100	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2010-2016)	High	I: Neoadjuvant chemotherapy followed by mastectomy and reconstruction	Total	N/A	N/A	414	NR	NR	1st: 100	NR
Xu, 2018, 30261115, China	NRCS (Non-industry) (2012-2016)	Moderate	I: Immediate IBR or AR E: Delayed BR or preoperative neoadjuvant chemotherapy; more than one type of BR	IBR	NR	Timing: Imm (100) Stages: 1 (100)	326	45.2 (NR)	NR	NR	Stage 0 (14.4), Stage NR (85)
	NRCS (Non-industry) (2012-2016)	Moderate	I: Immediate IBR or AR E: Delayed BR or preoperative neoadjuvant chemotherapy; more than one type of BR	AR	N/A	Timing: Imm (100) Stages: 1 (100)	100	50.8 (NR)	NR	NR	Stage 0 (11), Stage NR (89)
	NRCS (Non-industry) (2012-2016)	Moderate	I: Immediate IBR or AR E: Delayed BR or preoperative neoadjuvant chemotherapy; more than one type of BR	Total	N/A	N/A	426	NR	NR	NR	NR
Yueh, 2009, 19228537, US	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	IBR	NR	NR	87	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR (all)	N/A	Stages: 1 (100)	675	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with DIEP	N/A	Stages: 1 (100)	420	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with TRAM	N/A	Stages: 1 (100)	143	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with LD	N/A	Stages: 1 (100)	112	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	Total	N/A	N/A	762	NR	NR	NR	NR
Zhang, 2019, 30675702, China	NRCS (NR) (2001-2015)	High	I: Age 18–65 years; BR with or without PMRT E: Prophylactic mastectomy and BR; radiotherapy for local-regional recurrences; bilateral BR	IBR	NR	Laterality: Uni (100)	394	NR	NR	NR	NR
	NRCS (NR) (2001-2015)	High	I: Age 18–65 years; BR with or without PMRT E: Prophylactic mastectomy and BR; radiotherapy for local-regional recurrences; bilateral BR	AR	N/A	Laterality: Uni (100) Stages: 1 (100)	438	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2001-2015)	High	I: Age 18–65 years; BR with or without PMRT E: Prophylactic mastectomy and BR; radiotherapy for local-regional recurrences; bilateral BR	Total	N/A	N/A	832	<40 years (60%), ≥40 years (40%)	NR	NR	NR

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

W = White or Caucasian, B = Black or African American, A = Asian, H = Hispanic or Latino.

Proph = prophylactic, Ther = therapeutic.

Abbreviations: AR = autologous reconstruction, BR = breast reconstruction, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, IQR = interquartile range, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PMRT = postmastectomy radiation therapy, RCT = randomized controlled trial, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TE/I = tissue expander/implant, Ther = therapeutic, TRAM = transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-2. Key Question 1: Implant-based versus autologous reconstruction – single group studies, summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Acosta, 2011, 21046538, Sweden	SGS (NR) (2000-2009)	High	I: ASA classification 1 or 2	AR	N/A	Laterality: Uni (85.6)/Bi (14.4) Timing: Imm (16)/Del (84) Radio: Before (54.7)	543	51 (8.7)	NR	NR	Stage I (40), Stage II (53), Stage III (7)
Albornoz, 2013, 23897346, US	SGS (None) (1998-2010)	Low	I: Breast cancer or increased risk of breast cancer who underwent mastectomy and immediate AR E: Delayed BR; LD flaps; Simultaneous AR and IBR	AR	N/A	Laterality: Uni (85.4)/Bi (14.6) Timing: Imm (100) Stages: 1 (100)	21016	≤39 years (12%), 40–49 years (36.5%), 50–59 years (35%), ≥60 years (16.5%)	W (77.4), B (10.5), A (2.7), H (6.4), Others (3)	NR	NR
Andree, 2012, 23197233, Germany	SGS (NR) (2004-2011)	Low	I: Skin-sparing or subcutaneous mastectomy, with free AR	AR	N/A	Timing: Imm (100) Stages: 1 (100)	940	NR	NR	NR	Stage NR (100)
Banuelos, 2020, 31663932, US	SGS (None) (2015-2017)	Low	I: Immediate tissue expander/IBR	IBR	NR	Timing: Imm (100)	768	50 (10.9)	NR	NR	NR
Beugels, 2018, 29399731, Netherlands	SGS (NR) (2010-2017)	Low	I: AR with DIEP flap E: AR with stacked unilateral or mixed bilateral (immediate on one side and delayed on the other side)	AR	N/A	Laterality: Uni (76.5)/Bi (23.5) Timing: Imm (39.5)/Del (60.5) Stages: 1 (100) Chemo: Timing NR (56.3) Radio: After (3)/Timing NR (42.6)	737	50.9 (NR)	NR	NR	Ther (76.5), Proph (23.5)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Brooks, 2012, 22098451, US	SGS (NR) (2000-2006)	Low	I: Multi-stage IBR E: Immediate IBR	IBR	PLANE: Total submuscular (100)	Laterality: Uni (68.8)/Bi (31.2) Timing: Del (100) Stages: >1 (100) Chemo: Timing NR (49.4)/No chemotherapy (50.6) Radio: Before (3.7)/After (9.5)/None (86.7)	560	<50 years (58.3%), >50 years (41.7%)	NR	NR	Ther (73.6), Proph (22.4)
Chang, 2000, 10809092, US	SGS (NR) (1989-1998)	Low	I: AR with TRAM flap	AR	N/A	Chemo: Before (78.8) Radio: Before (13.3)	718	<40 years (22.8%), 40-49 (44.8%), ≥50 years (32.3%)		NR	NR
Chang, 2011, 21407063, US	SGS (None) (2002-2009)	Low	I: AR with free flap	AR	N/A	Laterality: Uni (58.9)/Bi (41.1)	650	Mean 58.3	NR	NR	NR
Chang, 2016, 25003429, US	SGS (None) (2000-2010)	Low	I: AR with free flap	AR	N/A	Laterality: Uni (54.3)/Bi (45.7) Timing: Imm (35.5)/Del (64.5)	1608	49.04 (9.1)	NR	NR	NR
Chen, 2014, 25620484, China	SGS (NR) (2012-2012)	Low	I: IBR with or without ADM	IBR	NR	NR	1860	NR	NR	NR	NR
Chen, 2016, 27930584, Taiwan	SGS (None) (1998-2013)	Low	I: Immediate IBR E: AR or delayed BR	IBR	PLANE: Total submuscular (7.9)	Timing: Imm (100) Stages: 1 (5)/>1 (95) (52.2)/No chemotherapy (47.8) (7.4)/None (92.6)	569	42.1 (NR)	NR	NR	Stage 0 (22.8), Stage I (32.7), Stage II (32.2), Stage III (10.9), Stage IV (0.4)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Chen, 2018a, 29596085, US	SGS (None) (2010-2014)	Low	I: Age >=18 years, immediate IBR	IBR	NR	Laterality: Uni (47.5)/Bi (52.5) Timing: Imm (100) Chemo: Before (5.2) Radio: Before (5)	23048	51.7 (NR)	W (77.4), B (8.5), A (2.9), H (6.8), Other 1 (0.3), Other 2 (4.2)	NR	NR
Chen, 2018b, 29596085, US	SGS (None) (2010-2014)	Low	I: Age >=18 years, immediate AR	AR	N/A	Laterality: Uni (56.9)/Bi (43.1) Timing: Imm (100) Stages: 1 (100) Chemo: Before (5.9) Radio: Before (75.2)	19496	52.7 (NR)	W (68.8), B (14.3), A (4.4), H (8.4), Other 1 (0.1), Other 2 (0.4)	NR	NR
Cleveland, 2013, 23945529, US	SGS (None) (2005-2011)	Low	I: AR	AR	N/A	Laterality: Uni (45.1)/Bi (54.9) Timing: Imm (75.5)/Del (21.3)/Mixed (3.2) Stages: 1 (100)	812	50.2 (NR)	NR	NR	NR
Collier, 2019, 31461001, US	SGS (NR) (2013-2014)	Moderate	I: Age >=18 years, IBR	IBR	NR	NR	18338	51.68 (NR)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Cordeiro, 2006, 16980842, US	SGS (NR) (1992-2004)	Moderate	I: Two-stage TE/implant BR E: Combined AR plus TE/implant BR	IBR	MATERIAL: Silicone (12.2)/Saline 87.8% SURFACE: Textured (100) SHAPE: Anatomic/Teardrop (100) SIZE: NR PLANE: Total submuscular (100)	Laterality: Uni (75.3)/Bi (24.7) Timing: Imm (96.3)/Del (2.1)/Mixed (1.6) Stages: >1 (100) Chemo: Before (38.2) Radio: Before (5.6)/After (15.3)	1221	NR	NR	NR	NR
Cordeiro, 2012, 22286416, US	SGS (NR) (1997-2018)	Low	I: Two-stage TE/implant BR E: Combined AR plus TE/implant BR, postoperative/perioperative radiation therapy, history of irradiation because of Hodgkin disease, delayed BR	IBR	SURFACE: Textured (100) PLANE: Total submuscular (100)	Timing: Imm (100) Stages: >1 (100) (7.1)/None(92.9)	1699	NR	NR	NR	NR
Cordeiro, 2015b, 26090764, US	SGS (Industry) (2005-2012)	Low	I: Age >=18 years E: Breast cancer without mastectomy, abscess/infection, any disease known to impact wound healing	IBR	MATERIAL: Silicone (100) SURFACE: Textured (100) SHAPE: Anatomic/Teardrop (100) SIZE: NR PLANE: Partial submuscular (57.8)/Total submuscular (37.7)	Laterality: Uni (24.2)/Bi (76) Timing: Imm (86.6)/Del (12.8) Stages: 1 (8.2)/>1 (91.8)	2795	Median 50; Range 18, 82	W (88.1), B (3.7), A (2.7), H (2.3), Others (1)	NR	Proph (40.9)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Coroneos, 2019, 30222598, US	SGS (NR) (2007-2009)	Low	I: Age >=18 years	IBR	MATERIAL: Silicone (100)	NR	5031	NR	NR	NR	NR
Daly, 2020, 31994156, US	SGS (NR) (2004-2015)	Low	I: AR with DIEP flap	AR	N/A	Laterality: Uni (54.5)/Bi (45.5) Timing: Imm (100) Stages: 1 (100) Radio: Before (34.8)/After (5.5)/None (59.7)	818	50.1 (NR)	NR	NR	NR
Enajat, 2010, 19790180, Sweden	SGS (None) (2000-2008)	Low	I: AR with DIEP flap E: AR with flaps supplied by more than one artery (stacked or bipedicled flaps)	AR	N/A	Laterality: Uni (87.4)/Bi (12.6) Timing: Imm (13.8)/Del (86.2)	501	50.6 (8.7)	NR	NR	NR
Fitzgerald, 2016, 27047776, UK	SGS (NR) (2010-2014)	Low	I: Microsurgical BR	AR	N/A	Laterality: Uni (89.2)/Bi (10.8) Timing: Imm (70)/Del (30) Stages: 1 (100)	1064	50 (NR)	NR	NR	NR
Gfrerer, 2015, 25626807, US	SGS (NR) (2004-2013)	Low	I: IBR E: AR with or without implants, bilateral prophylactic mastectomy for risk reduction, h/o radiation therapy to the chest wall not associated with breast cancer treatment	IBR	NR	Laterality: Uni (28.7)/Bi (72.2) Timing: Imm (59.8)/Del (40.2) Chemo: Timing NR (25) Radio: Timing NR (11.3)	3142	47.6 (9.6)	NR	NR	NR
Gill, 2004, 15083015, US	SGS (NR) (1992-2002)	Moderate	I: AR with DIEP flap	AR	N/A	Laterality: Uni (60.7)/Bi (39.3) Timing: Imm (59.9)/Del (40.1)	609	48.9 (NR); Range 16, 74	NR	NR	Ther (87.7), Proph (12.3)
Haddock, 2019, 31461004, US	SGS (NR) (2010-2018)	Moderate	I: AR with free flap	AR	N/A	Timing: Imm (43.66)/Del (55.17) Chemo: Before (12.4) Radio: Timing NR (19.8)	509	54 (NR)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Haddock, 2020, 33487570, US	SGS (None) (2009-2018)	Low	I: IR with unilateral, bilateral, or bipedicled DIEP	AR	N/A	Laterality: Uni (100)	644	NR	NR	NR	NR
Hamdi, 2010, 20679823, US	SGS (NR) (2002-2009)	Low	I: AR	AR	N/A	Stages: 1 (100)	688	NR	NR	NR	NR
Hamdi, 2011, 20576480, Belgium	SGS (NR) (2002-2009)	Low	I: IBR	IBR	NR	NR	688	NR	NR	NR	NR
Hansen, 2018, 29778821, US	SGS (NR) (2004-2015)	Low	I: Immediate 1-stage BR	IBR	NR	Laterality: Uni (50.4)/Bi (49.6) Timing: Imm (100) Stages: 1 (100) Radio: Before (9.3)/After (31.7)	903	49 (NR)	NR	NR	NR
Heo, 2018, 30039735, South Korea	SGS (NR) (2012-2017)	Low	I: AR with a free TRAM flap E: AR with bi-pedicled flap, bilateral simultaneous reconstruction, DIEP flap, muscle-sparing type 0 TRAM flap, and use of foreign materials such as ADM or mesh	AR	N/A	Laterality: Uni (100) Timing: Imm (82)/Del (18) Stages: 1 (100) Chemo: Before (11.9)/After (76.4)/No chemotherapy (11.7)	615	48.4 (7.8)	NR	NR	NR
Hunsicker, 2017, 26849284, US	SGS (Industry) (2001-2014)	Low	I: Immediate, direct-to-implant, BR with ADM E: Delayed, 2-stage TE/IBR, expandable implants	IBR	SIZE: Mean 484.8, SD 123.8, Range 100, 800 PLANE: Partial submuscular (100)	Laterality: Uni (100) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (73.7) Radio: Timing NR (88.4)	863	47 (10); Range 21, 77	NR	NR	Ther (35.4), Proph (64.6)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Jo, 2020, 33386262, South Korea	SGS (None) (2010-2019)	Low	I: AR with DIEP after therapeutic mastectomy without PMRT	AR	N/A	NR	615	47.2 (0.3)	NR	NR	NR
Huo, 2016, 27697676, US	SGS (Non-industry) (2009-2012)	Low	I: Age <65 years E: Radiation therapy within 3 months before mastectomy; metastatic disease	IBR	NR	NR	1332	NR	NR	NR	NR
Kanuri, 2014, 24675199, US	SGS (NR) (2004-2011)	Low	I: Immediate IBR E: Delayed IBR; AR	IBR	ADM: Yes (66.3), No (33.7)	Timing: Imm (100)	508	NR	NR	NR	NR
Kato, 2013, 24011080, Japan	SGS (NR) (2005-2011)	Low	I: TE/IBR E: Bilateral breast cancer; AR; cancer recurrence; BR after mastectomy for reasons other than breast cancer	IBR	MATERIAL: Silicone (100)	Timing: Imm (54.9)/Del (45.1) Stages: >1 (100) Chemo: Before (9.8)/After (23.8)/No chemotherapy (66.4) Radio: Before (0.1)/After (5)/None(94.9)	981	<50 years (64.7%), ≥50 years (35.3%)	NR	1st: 100	NR
Langer, 2010, 20980954, Germany	SGS (NR) (2004-2009)	Low	I: AR with free flaps	AR	N/A	Laterality: Uni (88.7)/Bi (11.3) Chemo: Timing NR (53.9) Radio: Timing NR (43.7)	635	Mean 50.3 (NR); Range 25, 77	NR	NR	NR
Lantieri, 2015, 26238173, France	SGS (NR) (1994-2014)	Moderate	I: AR with DIEP flap	AR	N/A	Laterality: Uni (91.4)/Bi (8.6)	1048	NR	NR	NR	NR
Law, 2018, 30463754, US	SGS (None) (2007-2015)	Low	I: TE/IBR E: AR; diabetes	IBR	NR	NR	11039	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Lee, 2021a, 32974692, South Korea	SGS (NR) (2010-2016)	Low	I: Immediate TE/IBR E: Hybrid IBR and AR, adjuvant chemotherapy	IBR	Surface: Smooth (44.3)/Textured (55.7) Shape: Round (44.3)/Anatomic (55.7) Size: Mean 331, SD 102.1 Plane: Prepectoral (100) ADM: Yes (60.0), No (40.0)	Laterality: Uni (93.5)/Bi (6.5) Timing: Imm (100) Stages: 2 (100) Chemo: Before (2.3)/After (39.5) Radio: After (10.9)	568	43.7 (7.3)	NR	NR	NR
Liao, 2008, 18349626, US	SGS (NR) (2000-2006)	Low	I: AR with TRAM flap E: AR with other flaps, e.g., LD, perforator flaps	AR	N/A	Laterality: Uni (84.5)/Bi (15.5) Stages: 1 (100)	679	49 (NR)	NR	NR	Stage 0 (34.8), Stage I (28), Stage II (27.4), Stage III (8.8), Stage IV (0.9)
Lovecchio, 2015, 24691330, US	SGS (None) (2004-2013)	Low	I: TE/IBR	IBR	NR	Laterality: NR Timing: NR Stages: >1 (100) Chemo: Timing NR (51.8) Radio: Before (10)/After (20)	1275	47 (NR); Range 41, 56	NR	NR	NR
Masoomi, 2019, 31331721, US	SGS (None) (2012-2014)	Low	I: AR	AR	N/A	Stages: 1 (100) Chemo: Before (11.7) Radio: Before (16.7)	55850	52 (10); >65 years (11.3%)	W (71), B (13.5), A (3.1), H (8.2), Other 1 (0.3), Other 2 (3.9)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Mehrara, 2006, 17016173, US	SGS (NR) (1991-2002)	Moderate	I: Microvascular BR	AR	N/A	Laterality: Uni (73.5)/Bi (26.5) Timing: Imm (58)/Del (42) Stages: 1 (58)/>1 (42) Chemo: Before (7.7)	952	Median 48.9; Range 21, 79	NR	NR	NR
Mirzabeigi, 2015, 25811579, US	SGS (NR) (2008-2012)	Low	I: AR with free flap E: AR with other commonly used free flaps (e.g., gluteal or transverse upper gracilis)	AR	N/A	Laterality: Uni (43)/Bi (57) Stages: 1 (100) Chemo: Before (40.4) Radio: Before (29.3)	858	51.1 (NR)	NR	NR	NR
Munder, 2021, 32565553, Germany	SGS (NR) (2004-2014)	Low	I: AR with DIEP flap E: Previous abdominal or thoracic surgery and abdominal scarring	AR	N/A	Laterality: Uni (86.7)/Bi (13.3) Timing: Imm (100) Chemo: Timing NR (67.6) Radio: Timing NR (58.7)	1124	50.0 (8.7)	NR	NR	NR
Nelson, 2014, 25046665, US	SGS (None) (2005-2011)	Moderate	I: AR with free flap	AR	N/A	Chemo: After (28.3) Radio: After (19.1)	848	NR	W (77.6), B (15), A (2), H (1.9), Others (3.5)	NR	NR
O'Neill, 2019, 31196805, Canada	SGS (None) (2009-2018)	Low	I: AR with free flap	AR	N/A	Laterality: Uni (47.9)/Bi (52.1) Timing: Imm (41)/Del (59) Chemo: Timing NR (54.3) Radio: Timing NR (50.6)	960	50.5 (8.9)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Parikh, 2018, 30204676, US	SGS (NR) (2005-2015)	Low	I: Immediate TE/IBR or direct-to-implant BR, with placement of AlloDerm RTU or FD ADM. E: Delayed IBR without use of ADM; ADM or mesh product other than AlloDerm RTU or FD; Prepectoral BR; Concomitant AR	IBR	NR	Laterality: Uni (41.3)/Bi (58.7) Timing: Imm (100) Stages: 1 (8.2)/>1 (91.8) Chemo: Before (26.1)/After (35.6)/No chemotherapy (38.3) Radio: Before ()/After (34.2)/None(65.8)	1285	49.6 (NR)	NR	NR	Stage 0 (11.2), Stage I (32.4), Stage II (30.3), Stage III (26.1)
Park, 2019, 30863940, South Korea	SGS (NR) (2009-2017)	Moderate	I: Immediate BR E: Antihypertensive medication only a month before the surgery or had undergone a change in their treatment regimen within a month before the surgery; patients with hypertension not on pertinent medications	IBR	NR	Laterality: Uni (95.8)/Bi (4.2) Timing: Imm (100) Stages: >1 (100) Chemo: Timing NR (7.7)/No chemotherapy (92.3) Radio: Timing NR (3.5)/None(96.5)	999	43.6 (NR)	NR	NR	NR
Phan, 2020, 31124177, UK	SGS (NR) (2010-2014)	Low	I: AR with free flap	AR	N/A	Laterality: Uni (89)/Bi (11) Timing: Imm (66)/Del (34)	1070	NR	NR	NR	NR
Polanco, 2021, 33745850, US	SGS (Non-industry) (2010-2017)	Low	I: Age ≥18 years; AR with free, muscle-sparing, or pedicled TRAM, DIEP, or SIEA E: Hybrid IBR and AR	AR	N/A	Laterality: Uni (57.5)/Bi (42.5) Timing: Imm (58.9)/Del (41.1) Stages: 1 (100)	777	Median: 51 (IQR 44, 56)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Potter, 2019, 30639093, UK	SGS (Non-industry) (2014-2016)	Moderate	I: Age >=16 years; Immediate IBR E: Combined IBR and AR; delayed BR; revisional surgery	IBR	SIZE: Median 390 g, IQR 260, 583, Range 39, 2300	Laterality: Uni (74)/Bi (26) Timing: Imm (100) Stages: 1 (78)/>1 (21) Chemo: Before (11)/No chemotherapy (88)	2108	Median 49; IQR 43, 57; Range 16, 83	NR	NR	Stage I (59), Stage II (37), Stage III (3)
Prantl, 2020, 32895743, Germany	SGS (Non-industry) (2011-2019)	Low	I: AR with DIEP flap	AR	N/A	Laterality: Uni (58.6)/Bi (41.4) Timing: Imm (24.8)/Del (75.2) Stages: 1 (100) Chemo: Before (58.9) Radio: Before (18.5)	3926	51.2	NR	NR	NR
Rogoff, 2020, 32243320, US	SGS (NR) (2001-2018)	Low	I: TE/IBR	IBR	ADM: Yes (64.9)/No (35.1)	Laterality: Uni (60.3)/Bi (39.7) Timing: Imm (100) Stages: 2 (100) Chemo: Before (16.9)/After (32.1) Radio: Before (4.8) /After (19.9)	627	53.1	NR	NR	NR
Rubio, 2019, 30665841, Belgium	SGS (None) (2008-2011)	Low	I: AR	AR	N/A	Timing: Imm (40.7)/Del (59.3) Stages: 1 (100)	56522	51.2 (9.8)	W (72.4), B (11.7), A (2.9), H (9.8), Other 1 (0.3), Other 2 (3)	NR	NR
Salibian, 2019, 31333984, US	SGS (NR) (2006-2018)	Low	I: Immediate alloplastic BR	IBR	NR	Laterality: NR Timing: Imm (100) Stages: NR Chemo: NR Radio: NR	1045	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Seidenstuecker, 2016, 27017243, Belgium	SGS (None) (2004-2010)	Moderate	I: AR with DIEP flap	AR	N/A	Timing: Imm (100) Stages: 1 (100)	931	NR	NR	NR	NR
Selber, 2009, 19935283, US	SGS (None) (1992-2007)	Low	I: AR with free TRAM, DIEP, or SIEA flaps	AR	N/A	Laterality: Uni (58.6)/Bi (41.3) Timing: Imm (77.7)/Del (19)/Mixed (2.3) Stages: 1 (100) Chemo: After (16.2) Radio: After (7.9)	1031	<65 years (94.7%), ≥65 years (5.3%)	NR	NR	NR
Seth, 2015, 25180955, US	SGS (Industry; Non-industry) (1999-2008)	Low	I: TE/IBR	IBR	NR	Timing: Imm (93.4)/Del (6.6) Stages: >1 (100) Radio: Timing NR (25.1)/None(74.9)	893	48.8 (NR)	NR	NR	NR
Sewart, 2021, 33609398, UK	SGS (Non-industry) (2014-2016)	Low	I: Age ≥18 years; Immediate IBR E: Hybrid IBR and AR; revision reconstruction	IBR	Plane: Prepectoral (1.6)/Partial submuscular (7.5)	Laterality: Uni (75.1)/Bi (24.9) Timing: Imm (100) Stages: 1 (78.6)/2 (21.4) Chemo: Timing NR (33.1) Radio: Timing NR (28.3)	891	Median: 50 (IQR 45, 58)	NR	NR	Ther (82.2), Proph (17.8)
Shaikh, 2010, 22693373, India	SGS (NR) (1996-2008)	Low	I: AR with TRAM or LD flaps	AR	N/A	Timing: Imm (100)	546	NR	NR	NR	Stage NR (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Singh, 2012, 22342636, US	SGS (Industry) (2008-2009)	Low	I: IBR E: initial reconstruction included a flap or other AR procedure, preexisting breast implant complications, unrelated surgery concurrent with initial reconstruction, death during the 18 month post-index period, TE reconstruction in which the tissue expander exchange procedure could not be identified from available coded claims.	IBR	NR	Timing: Imm (100) Stages: 1 (7.2)/>1 (92.8) Radio: Timing NR (17.8)	1316	49.1 (NR)	NR	NR	NR
Singh, 2021, 33564597, US	SGS (None) (NR-2020)	Low	I: Age ≥18 years; Immediate IBR E: Pregnant	IBR	NR	Timing: Imm (50)/Del (50) Stages: 1 (50)/2 (50)	1740	51.9	W (97.9)	NR	NR
Song, 2016, 26637165, US	SGS (Industry; Non-industry) (2002-2012)	Low	I: AR	AR	N/A	Laterality: Uni (68.5)/Bi (31.5) Timing: Imm (65.1)/Del (32.2)/Mixed (2.5) Stages: 1 (100) Chemo: Before (40.8)/After (14)/No chemotherapy (46.4) Radio: Before (38.8)/After (6.1)/None(54.5)	1809	Range 16, 78; <65 years (96.8%), ≥65 years (3.2%)	W (42.2), B (1.9), A (4.5), H (0.4), Other 1 (1.8), Other 2 (1.2)	NR	None (5.4), Stage 0 (26.6), Stage NR (63.7)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Tran, 2018, 29794694, US	SGS (NR) (2004-2015)	Low	I: AR	AR	N/A	Laterality: Uni (52.3)/Bi (47.7) Timing: Imm (NR)/Del (34.8)/Mixed (NR) Stages: 1 (100) Chemo: Timing NR (48.2)/No chemotherapy (51.8) Radio: Timing NR (38.2)/None(61.8)	853	50.1 (8.6)	NR	NR	Stage 0 (42.1), Stage I (23.7), Stage II (21), Stage III (10), Stage IV (3.3)
Warren, 2020, 33040748, US	SGS (Non-industry) (2011-2015)	Moderate	I: Age ≥18 years E: Likely to have antibiotics at discharge; length of stay ≥90 days	IBR	NR	Timing: Imm (100)	1924	NR	NR	NR	NR
Watterson, 1995, 7761505, Australia	SGS (NR) (1981-1991)	Moderate	NR	AR	N/A	Laterality: Uni (68.9)/Bi (31.1) Timing: Imm (27)/Del (73)	556	46 (NR); Range 24, 69	NR	NR	NR
Williams, 1995, 7794079, US	SGS (NR) (1981-1993)	Moderate	I: AR with TRAM flap	AR	N/A	NR	680	>60 years (5.4%)	NR	NR	NR
Yoo, 2014, 24852813, South Korea	SGS (None) (2001-2010)	Moderate	I: AR with TRAM flap	AR	N/A	NR	964	NR	NR	NR	NR

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

W = White or Caucasian, B = Black or African American, A = Asian, H = Hispanic or Latino.

Proph = prophylactic, Ther = therapeutic.

Abbreviations: AR = autologous reconstruction, BR = breast reconstruction, DIEP = Deep inferior epigastric perforator, IBR = implant-based reconstruction, IQR = interquartile range, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PMRT = postmastectomy radiation therapy, RCT = randomized controlled trial, SD = standard deviation, SIEA = Superficial inferior epigastric artery perforator, TE/I = tissue expander/implant, Ther = therapeutic, TRAM = Transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-3. Key Question 2: Timing of chemotherapy and radiation therapy relative to IBR or AR – summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Cordeiro, 2015a, 25742523, US	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	IBR before radiation	NR	Laterality: Uni (71.6)/Bi (28.4) Stages: >1 (100)	NR	46.3 (8.9)	NR	NR	NR
	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	IBR after radiation	NR	Laterality: Uni (57)/Bi (43) Stages: >1 (100)	NR	46.1 (10.6)	NR	NR	NR
	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	Total	N/A	N/A	1143	NR	NR	NR	NR
Eriksson, 2013, 24258257, Sweden	NRCS (NR) (2007-2011)	High	I: Immediate IBR E: Only risk-reducing surgery	IBR before radiation	PLANE: Partial submuscular (100)	Timing: Imm (100) Chemo: After (57.57)/No chemotherapy (42.11)	304	Median 46; Range 21, 74	NR	NR	Stage 0 (9.54), Stage NR (90.46)
	NRCS (NR) (2007-2011)	High	I: Immediate IBR E: Only risk-reducing surgery	IBR after radiation	PLANE: Partial submuscular (100)	Timing: Imm (100) Chemo: After (32.25)/No chemotherapy (65.63)	64	Median 55; Range 28, 75	NR	NR	Stage 0 (28.13), Stage NR (70.31)
	NRCS (NR) (2007-2011)	High	I: Immediate IBR E: Only risk-reducing surgery	Total	N/A	N/A	368	NR	NR	NR	NR
Hirsch, 2014, 25347643, US	NRCS (NR) (1998-2008)	High	I: Immediate TE/IBR	IBR before radiation	NR	Timing: Imm (100) Stages: >1 (100)	NR	NR	NR	NR	NR
	NRCS (NR) (1998-2008)	High	I: Immediate TE/IBR	IBR after radiation	NR	Timing: Imm (100) Stages: >1 (100)	NR	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (1998-2008)	High	I: Immediate TE/IBR	Total	N/A	N/A	876	Mean 48.1; Range 16.1, 57.6	NR	NR	NR
Stein, 2020, 32561384, Canada	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	IBR before radiation	SIZE: Mean 406 cc	Laterality: NR Timing: Imm (100) Stages: 1 (53.9)/>1 (46.1) Chemo: Before (100) Radiation: Before (100)	76	47.2 (NR)	NR	NR	NR
	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	IBR after radiation	SIZE: Mean 444 cc	Laterality: NR Timing: Imm (100) Stages: 1 (50)/>1 (50) Chemo: After (100) Radiation: After (100)	54	54.7 (NR)	NR	NR	NR
	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	Total	N/A	N/A	130	50.3 (NR)	NR	NR	NR
Yoon, 2020, 32332528, US & Canada	NRCS (Non-industry) (2012-2015)	Moderate	I: Immediate TE/ IBR with PMRT	IBR before radiation	NR	Laterality: Uni (38.8)/Bi (61.2) Timing: Imm (100) Stages: >1 (100) Chemo: Before (92.5)/After (7.5) Radiation: After (100)	80	45.3 (10.1)	W (93.6), Others (6.4)	NR	NR
	NRCS (Non-industry) (2012-2015)	Moderate	I: Immediate TE/ IBR with PMRT	IBR after radiation	NR	Laterality: Uni (42.6)/Bi (57.4) Timing: Imm (100) Stages: >1 (100) Chemo: Before (60.8)/After (39.2) Radiation: Before (100)	237	47.4 (10.4)	W (87.6), Others (12.4)	NR	NR
	NRCS (Non-industry) (2012-2015)	Moderate	I: Immediate TE/ IBR with PMRT	Total	N/A	N/A	317	NR	NR	NR	NR

Note: Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral (“Uni”) or bilateral (“Bi”). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate (“Imm”) or delayed (“Del”). Chemo: Timing of chemotherapy relative to reconstruction.

Abbreviations: BR = breast reconstruction, IBR = implant-based reconstruction, IQR = interquartile range, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, SD = standard deviation, TE/I = tissue expander/implant, Ther = therapeutic.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-4. Key Question 3: Comparison of materials for IBR – summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Antony, 2014, 24135689, US	NRCS (None) (1997-2007)	High	I: 2-staged bilateral IBR	IBR with silicone	NR	Laterality: Bi (100) Stages: >1 (100)	NR	NR	NR	NR	Stage NR (100)
	NRCS (None) (1997-2007)	High	I: 2-staged bilateral IBR	IBR with saline	NR	Laterality: Bi (100) Stages: >1 (100)	NR	NR	NR	NR	Stage NR (100)
	NRCS (None) (1997-2007)	High	I: 2-staged bilateral IBR	Total	N/A	N/A	365	47 (9.4)	NR	NR	Stage NR (100)
Cordeiro, 2015a, 25742523, US	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	IBR with silicone	NR	Stages: >1 (100)	NR	NR	NR	NR	NR
	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	IBR with saline	NR	Stages: >1 (100)	NR	NR	NR	NR	NR
	NRCS (Industry) (2003-2012)	High	I: IBR E: Combined AR plus TE/implant BR, perioperative radiation therapy, delayed BR	Total	N/A	N/A	1143	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Le, 2005, 15743498, US	NRCS (Non-industry) (1993-1994)	High	I: Age <65 years; early-stage/unstaged first primary breast cancer treated with mastectomy E: Missing implant information; bilateral implants of discordant types	IBR with silicone	NR	NR	333	NR	NR	NR	NR
	NRCS (Non-industry) (1993-1994)	High	I: Age <65 years; early-stage/unstaged first primary breast cancer treated with mastectomy E: Missing implant information; bilateral implants of discordant types	IBR with saline	NR	NR	149	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (1993-1994)	High	I: Age <65 years; early-stage/unstaged first primary breast cancer treated with mastectomy E: Missing implant information; bilateral implants of discordant types	IBR with double lumen implants	NR	NR	314	NR	NR	NR	NR
	NRCS (Non-industry) (1993-1994)	High	I: Age <65 years; early-stage/unstaged first primary breast cancer treated with mastectomy E: Missing implant information; bilateral implants of discordant types	Total	N/A	N/A	796	NR	W (94.2), B (1.3), A (1.6), H (2)	NR	NR
Macadam, 2010, 20009795, Canada	NRCS (Non-industry) (NR)	High	I: IBR	IBR with silicone	NR	Laterality: Uni (40)/Bi (60) Timing: Imm (82.67)/Del (17.33) Chemo: Timing NR (60)/No chemotherapy (40) Radio: Timing NR (37.33)/None(62.67)	75	52.27 (9.54); <45 years (25.33%), ≥45 years (74.67%)	W (34.78), A (57.97), Others (7.25)	NR	None (5.33), Stage 0 (42.67), Stage NR (52)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (NR)	High	I: IBR	IBR with saline	SURFACE: Smooth (100) SHAPE: Round (100)	Laterality: Uni (44.12)/Bi (55.88) Timing: Imm (61.76)/Del (35.29)/Mixed (2.94) Chemo: Timing NR (47.06)/No chemotherapy (52.94) Radio: Timing NR (38.24)/None(71.76)	68	55.62 (9.14); <45 years (14.49%), ≥45 years (85.51%)	W (23.64), A (74.6), Others (4.76)	NR	None (4.48), Stage 0 (35.82), Stage NR (59.7)
	NRCS (Non-industry) (NR)	High	I: IBR	Total	N/A	N/A	143	NR	NR	NR	NR
McCarthy, 2010, 21136577, US & Canada	NRCS (NR) (2006-2007)	High	I: Age >=21 years; IBR	IBR with silicone	NR	Laterality: Uni (47.2)/Bi (52.8) Timing: Imm (65.9)/Del (34.1) Radio: Before (25)/After (23.3)	176	53.7 (11)	W (92), B (1.1), A (1.7), Others (5.2)	NR	NR
	NRCS (NR) (2006-2007)	High	I: Age >=21 years; IBR	IBR with saline	NR	Laterality: Uni (60.1)/Bi (39.9) Timing: Imm (74.2)/Del (25.8) Radio: Before (20.3)/After (19.3)	306	51.3 (10.4)	W (87.8), B (4), A (4), Others (4.2)	NR	NR
	NRCS (NR) (2006-2007)	High	I: Age >=21 years; IBR	Total	N/A	N/A	482	NR	NR	NR	NR

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

Abbreviations: BR = breast reconstruction, IBR = implant-based reconstruction, IQR = interquartile range, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, SD = standard deviation, TE/I = tissue expander/implant, Ther = therapeutic.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-5. Key Question 4: Comparison of anatomic planes for IBR – summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Lee, 2021b, 33691448, South Korea	RCT (None) (2018-2019)	Moderate	I: Age 30-60; Immediate IBR E: Advanced-stage III or IV breast cancer	Prepectoral	MATERIAL: Silicone (100) SURFACE: Textured (100) ADM: Yes (100)	Laterality: Uni (100) Timing: Imm (100) Chemo: Timing NR (30) Radio: Timing NR (25)	20	46.2 (7.1)	NR	NR	Stage 0: 30 Stage I: 30 Stage II: 40
	RCT (None) (2018-2019)	Moderate	I: Age 30-60; Immediate IBR E: Advanced-stage III or IV breast cancer	Partial submuscular	MATERIAL: Silicone (100) SURFACE: Textured (100) ADM: Yes (100)	Laterality: Uni (100) Timing: Imm (100) Chemo: Timing NR (42.9) Radio: Timing NR (35.7)	14	46.8 (4.4)	NR	NR	Stage 0: 21.4 Stage I: 42.9 Stage II: 35.7
	RCT (None) (2018-2019)	Moderate	I: Age 30-60; Immediate IBR E: Advanced-stage III or IV breast cancer	Total	N/A	N/A	34	NR	NR	NR	NR
Avila, 2020, 33234947, US	NRCS (None) (2014-2018)	High	I: IBR	Prepectoral	NR	Laterality: Uni (14.8)/Bi (85.2) Timing: Imm (97)/Del (3) Stages: 1 (73.9)/ 2 (26.1) Chemo: Before (15.3) Radio: Timing NR (3.5)	203	46.5 (10.0)	NR	NR	NR
	NRCS (None) (2014-2018)	High	I: IBR	Total submuscular	NR	Laterality: Uni (12.9)/Bi (87.1) Timing: Imm (97)/Del (3) Stages: 1 (33.2)/ 2 (66.8) Chemo: Before (14.4) Radio: Timing NR (0.5)	202	45.9 (10.4)	NR	NR	NR
	NRCS (None) (2014-2018)	High	I: IBR	Total	N/A	N/A	405	46.2 (10.2)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Cattelani, 2018, 29275104, Italy	NRCS (NR) (2015-2016)	High	I: Age <75 years, no previous radiation, BMI <30 kg/m2 E: T4 or Mþ breast tumors	Prepectoral	MATERIAL: Silicone (100) SURFACE: Textured (100) SHAPE: Anatomic/Teardrop (100) SIZE: Mean 390.9 ml, Range 180, 570	Laterality: Uni (82.05)/Bi (17.95) Timing: Imm (100) Stages: 1 (100) Chemo: Before (10.26)/After (28.21)/No chemotherapy (61.53) Radio: Timing NR (13.04)/None(86.96)	39	52.9 (NR); Range 36, 71	NR	NR	NR
	NRCS (NR) (2015-2016)	High	I: Age <75 years, no previous radiation, BMI <30 kg/m2 E: T4 or Mþ breast tumors	Total submuscular	SURFACE: Textured (100) SIZE: Mean 361.5 ml, Range 190, 650	Laterality: Uni (82.22)/Bi (17.78) Timing: Imm (100) Stages: 1 (73.3)/>1 (26.7) Chemo: Before (8.89)/After (37.78)/No chemotherapy (53.33) Radio: Timing NR (20.76)/None(79.24)	45	52.3 (NR); Range 26, 75	NR	NR	NR
	NRCS (NR) (2015-2016)	High	I: Age <75 years, no previous radiation, BMI <30 kg/m2 E: T4 or Mþ breast tumors	Total	N/A	N/A	84	NR	NR	NR	NR
Gabriel, 2020, 32195862, US	NRCS (None) 2009-2017)	High	I: Immediate two-stage IBR; BMI >=30 E: Revision reconstruction	Prepectoral	NR	Laterality: Uni (52.7)/Bi (47.3) Timing: Imm (100) Chemo: Before (13.2)/After (5.9) Radio: Before (3.9)/After (1.6)	68	Median: 49 (IQR 33, 76)	NR	NR	NR
	NRCS (None) 2009-2017)	High	I: Immediate two-stage IBR; BMI >=30 E: Revision reconstruction	Partial submuscular	NR	Laterality: Uni (50.8)/Bi (49.2) Chemo: Before (12.3)/After (30.8) Radio: Before (3.1)/After (10.9)	65	Median: 53 (IQR 28, 73)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) 2009-2017)	High	I: Immediate two-stage IBR; BMI >=30 E: Revision reconstruction	Total	N/A	N/A	133	NR	NR	NR	NR
Kim, 2020, 33066236, South Korea	NRCS (None) 2015-2020)	Moderate	I: Immediate unilateral single-stage IBR with ADM E: Previous breast surgery or radiation therapy	Prepectoral	Size: Mean 249.0 cc (SD 104.8) ADM: Yes (100)	Laterality: Uni (100) Timing: Imm (100) Stages: 1 (100) Chemo: Before (5.7)/After (32.1) Radio: Timing NR (11.3)	53	47.7 (7.5)	NR	1st: 100	Stage I: 73.6 Stage II: 20.8 Stage III: 5.7
	NRCS (None) 2015-2020)	Moderate	I: Immediate unilateral single-stage IBR with ADM E: Previous breast surgery or radiation therapy	Partial submuscular	Size: Mean 268.1 cc (SD 103.0) ADM: Yes (100)	Laterality: Uni (100) Timing: Imm (100) Stages: 1 (100) Chemo: Before (10.5)/After (43.0) Radio: Timing NR (18.4)	114	46.6 (8.7)	NR	1st: 100	Stage I: 66.7 Stage II: 21.0 Stage III: 10.2
	NRCS (None) 2015-2020)	Moderate	I: Immediate unilateral single-stage IBR with ADM E: Previous breast surgery or radiation therapy	Total	N/A	N/A	167	NR	NR	1st: 100	NR
Kraenzlin, 2021, 32568752, US	NRCS (None) 2016-2018)	High	I: Adults; IBR with TE	Prepectoral	NR	Laterality: Uni (40.8)/Bi (59.2) Timing: Del (100) Stages: >1 (100) Chemo: Before (21.9)/After (13.6) Radio: Before (11.8)/After (7.1)	169	48.8	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) 2016-2018)	High	I: Adults; IBR with TE	Total submuscular	NR	Laterality: Uni (47.0)/Bi (53.0) Timing: Del (100) Stages: >1 (100) Chemo: Before (26.5)/After (17.1) Radio: Before (28.2)/After (10.3)	117	49.4	NR	NR	NR
	NRCS (None) 2016-2018)	High	I: Adults; IBR with TE	Total	N/A	N/A	286	NR	NR	NR	NR
Nealon, 2020a, 32032345, US	NRCS (None) (2014-2018)	High	I: Direct-to-implant BR	Prepectoral	SURFACE: Smooth (100) SHAPE: Round (100) SIZE: Mean 468.2 ml, SD 174.7	Laterality: Uni (39.5)/Bi (60.5) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (38.6)/No chemotherapy (61.4) Radio: Timing NR (36.8)/None(63.2)	114	52.7 (12.4); Median 51.5; IQR 47.8, 62	NR	NR	Stage I (43.9), Stage II (17.5), Stage III (6.1)
	NRCS (None) (2014-2018)	High	I: Direct-to-implant BR	Total submuscular	SURFACE: Smooth (100) SHAPE: Round (100) SIZE: Mean 417.2 ml, SD 141.8	Laterality: Uni (32.4)/Bi (67.6) Timing: Imm (100) Stages: 1 (100) Chemo: Timing NR (31.7)/No chemotherapy (68.3) Radio: Timing NR (36.7)/None(63.3)	142	50.7 (10.4); Median 51; IQR 43.8, 58	NR	NR	Stage I (44.4), Stage II (18.3), Stage III (7), Stage IV (1.4)
	NRCS (None) (2014-2018)	High	I: Direct-to-implant BR	Total	N/A	N/A	256	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Ozgur, 2020, 33223365, Turkey	NRCS (NR) (2012-2015)	High	I: Immediate single-staged IBR after therapeutic mastectomy	Partial submuscular	Size: Mean 375.7 mm^3 (SD 75.7)	Laterality: Uni (82.4)/Bi (17.6) Timing: Imm (100) Stages: 1 (100) Chemo: Before (33.0) Radio: Before (3.3)/After (56.0)	83	43.7 (10.2)	NR	1st: 96.7 Recurrent: 3.3	Therapeutic: 100
	NRCS (NR) (2012-2015)	High	I: Immediate single-staged IBR after therapeutic mastectomy	Total submuscular	Size: Mean 373 mm^3 (SD 80.9)	Laterality: Uni (82.9)/Bi (17.1) Timing: Imm (100) Stages: 1 (100) Chemo: Before (32.5) Radio: Before (9.4)/After (55.6)	107	43.0 (9.4)	NR	1st: 90.6 Recurrent: 9.4	Therapeutic: 100
	NRCS (NR) (2012-2015)	High	I: Immediate single-staged IBR after therapeutic mastectomy	Total	N/A	N/A	190	NR	NR	NR	Therapeutic: 100

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

Abbreviations: BR = breast reconstruction, IBR = implant-based reconstruction, IQR = interquartile range, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, SD = standard deviation, SIEA = Superficial inferior epigastric artery perforator, TE/I = tissue expander/implant, Ther = therapeutic, TRAM = Transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-6. Key Question 5: Use versus nonuse of human ADM for IBR – summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
McCarthy, 2012, 23096987, NCT00639106, US	RCT (Non-industry) (NR)	Moderate	I: Age >=21 years; immediate TE/IBR E: Single-stage IBR and/or combined AR + TE/IBR; prior irradiation to the ipsilateral breast/chest; history of prior axillary lymph node dissection	IBR with human ADM	PLANE: Total submuscular (100)	Laterality: Uni (48)/Bi (52) Timing: Imm (100) Stages: >1 (100) Chemo: Before (6)/After (30)/No chemotherapy (64)	36	IQR 29, 69	NR	NR	NR
	RCT (Non-industry) (NR)	Moderate	I: Age >=21 years; immediate TE/IBR E: Single-stage IBR and/or combined AR + TE/IBR; prior irradiation to the ipsilateral breast/chest; history of prior axillary lymph node dissection	IBR without human ADM	NR	Laterality: Uni (44)/Bi (56) Timing: Imm (100) Stages: >1 (100) Chemo: Before (6)/After (25)/No chemotherapy (69)	33	IQR 32, 72	NR	NR	NR
	RCT (Non-industry) (NR)	Moderate	I: Age >=21 years; immediate TE/IBR E: Single-stage IBR and/or combined AR + TE/IBR; prior irradiation to the ipsilateral breast/chest; history of prior axillary lymph node dissection	Total	N/A	N/A	69	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Wendel, 2013, none, US	RCT (Non-industry) (2007-2011)	High	I: TE/IBR	IBR with human ADM	NR	NR	20	NR	NR	NR	NR
	RCT (Non-industry) (2007-2011)	High	I: TE/IBR	IBR without human ADM	NR	NR	16	NR	NR	NR	NR
	RCT (Non-industry) (2007-2011)	High	I: TE/IBR	Total	N/A	N/A	36	18-65 years (83.3%), ≥65 years (16.7%)	NR	NR	NR
Brooke, 2012, 22868313, US	NRCS (None) (2000-2010)	High	I: TE/IBR E: Prior major breast surgery or BR	IBR with use of human ADM	NR	Laterality: Uni (31.3)/Bi (68.7) Stages: >1 (100)	131	50 (12.1)	NR	NR	Stage NR (100)
	NRCS (None) (2000-2010)	High	I: TE/IBR E: Prior major breast surgery or BR	IBR without use of human ADM	NR	Laterality: Uni (47.6)/Bi (52.4) Stages: >1 (100) Chemo: Timing NR (38)	42	46 (10.7)	NR	NR	Stage NR (100)
	NRCS (None) (2000-2010)	High	I: TE/IBR E: Prior major breast surgery or BR	Total	N/A	N/A	173	49.7 (10.7)	NR	NR	Stage NR (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Cattelani, 2018, 29275104, Italy	NRCS (NR) (2015-2016)	High	I: Age < 75 years, no previous radiotherapy, BMI <30 kg/m2 E: T4 or Mþ breast tumors, previous surgery of the same breast	IBR with prepectoral placement	MATERIAL: Silicone (100) SURFACE: Textured (100) SHAPE: Anatomic/Teardrop (100) SIZE: Mean 390.9 ml, Range 180, 570 PLANE: Prepectoral (100)	Laterality: Uni (82.05)/Bi (17.95) Timing: Imm (100) Stages: 1 (100) Chemo: Before (10.26)/After (28.21)/No chemotherapy (61.53) Radio: Timing NR (13.04)/None(86.96)	39	52.9 (NR); Range 36, 71	NR	NR	NR
	NRCS (NR) (2015-2016)	High	I: Age < 75 years, no previous radiotherapy, BMI <30 kg/m2 E: T4 or Mþ breast tumors, previous surgery of the same breast	IBR with total submuscular placement	SURFACE: Textured (100) SIZE: Mean 361.5 ml, Range 190, 650 PLANE: Total submuscular (100)	Laterality: Uni (82.22)/Bi (17.78) Timing: Imm (100) Stages: 1 (73.3)/>1 (26.7) Chemo: Before (8.89)/After (37.78)/No chemotherapy (53.33) Radio: Timing NR (20.76)/None(79.24)	45	52.3 (NR); Range 26, 75	NR	NR	NR
	NRCS (NR) (2015-2016)	High	I: Age < 75 years, no previous radiotherapy, BMI <30 kg/m2 E: T4 or Mþ breast tumors, previous surgery of the same breast	Total	N/A	N/A	84	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Chun, 2010, 20124828, US	NRCS (NR) (2002-2008)	High	I: Immediate TE/implant or AR + TE/implant E: Delayed AR	IBR with use of human ADM	NR	Timing: Imm (100) Chemo: Before (14.9)/After (19)/No chemotherapy (66.1) Radio: Before (8.7)/After (6.5)/None(85.9)	269 breasts	47 (10.5)	NR	NR	Stage 0 (71.4), Stage I (4.1), Stage II (12.3), Stage III (12.3)
	NRCS (NR) (2002-2008)	High	I: Immediate TE/implant or AR + TE/implant E: Delayed AR	IBR without use of human ADM	NR	Timing: Imm (100) Chemo: Before (8.2)/After (30.8)/No chemotherapy (61) Radio: Before (5.2)/After (8.6)/None(86.2)	146 breasts	46.2 (8.4)	NR	NR	Stage 0 (66.4), Stage I (8.2), Stage II (13.7), Stage III (11.6)
	NRCS (NR) (2002-2008)	High	I: Immediate TE/implant or AR + TE/implant E: Delayed AR	Total	N/A	N/A	283	NR	NR	NR	NR
Craig, 2019, 29800083, US	NRCS (None) (2004-2014)	Low	I: TE/implant BR E: Pre-mastectomy radiation therapy	IBR with human ADM	NR	Timing: Imm (100) Stages: >1 (100) Radio: After (15.3)	NR	49 (10.6); Range 29, 68	NR	NR	Ther (100)
	NRCS (None) (2004-2014)	Low	I: TE/implant BR E: Pre-mastectomy radiation therapy	IBR without human ADM	NR	Timing: Imm (100) Stages: >1 (100) Radio: After (14.2)	NR	48.4 (10.6); Range 28, 72	NR	NR	Ther (100)
	NRCS (None) (2004-2014)	Low	I: TE/implant BR E: Pre-mastectomy radiation therapy	Total	N/A	N/A	957	NR	NR	NR	NR
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS (Non-industry) (2012-2015)	Moderate	I: TE/IBR	IBR with human ADM	NR	Laterality: Uni (38.9)/Bi (61.1) Timing: Imm (100) Stages: >1 (100) Chemo: Before (69.8)/After (30.2) Radiation: Before (3.7)/After (21.3)	738	48.7 (10.5)	NR	NR	Ther (85.8), Proph (14.2)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2012-2015)	Moderate	I: TE/IBR	IBR without human ADM	NR	Laterality: Uni (38.8)/Bi (61.2) Timing: Imm (100) Stages: >1 (100) Chemo: Before (61.9)/After (38.1) Radiation: Before (5.9)/After (20.9)	713	48.1 (10.1)	NR	NR	Ther (93.3), Proph (6.7)
	NRCS (Non-industry) (2012-2015)	Moderate	I: TE/IBR	Total	N/A	N/A	1451	48.4 (10.3)	NR	NR	Ther (89.5), Proph (10.5)
Hirsch, 2014, 25347643, US	NRCS (NR) (1998-2008)	Low	L: Immediate TE/IBR	IBR with human ADM	NR	Timing: Imm (100) Stages: >1 (100)	201	NR	NR	NR	NR
	NRCS (NR) (1998-2008)	Low	L: Immediate TE/IBR	IBR without human ADM	NR	Timing: Imm (100) Stages: >1 (100)	675	NR	NR	NR	NR
	NRCS (NR) (1998-2008)	Low	L: Immediate TE/IBR	Total	N/A	N/A	876	Mean 48.1; Range 16.1, 57.6	NR	NR	NR
Ibrahim, 2013, 24165587, US	NRCS (None) (2005-2011)	Moderate	I: Immediate or delayed TE/IBR E: AR with or without ADM	IBR with human ADM	NR	NR	3283	50.7 (10.6)	W (83), B (5.7), A (2.9), H (0.3), Other 1 (0.1), Other 2 (0.2), Other 3 (7.9)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2005-2011)	Moderate	I: Immediate or delayed TE/IBR E: AR with or without ADM	IBR without human ADM	NR	NR	15714	51.3 (10.8)	W (78.7), B (6.6), A (28), H (0.8), Other 1 (0.1), Other 2 (0.2), Other 3 (11)	NR	NR
	NRCS (None) (2005-2011)	Moderate	I: Immediate or delayed TE/IBR E: AR with or without ADM	Total	N/A	N/A	18977	51.2 (10.7)	W (79.4), B (6.4), A (2.8), H (0.1), Other 1 (0.1), Other 2 (0.2), Other 3 (10.3)	NR	NR
Lee, 2020, No PMID, South Korea	NRCS (NR) (27738380 10-2016938)	High	I: Immediate unilateral TE/IBR	IBR with human ADM	NR	Laterality: Uni (100) Timing: Imm (100) Stages: >1 (100)	738	NR	NR	NR	NR
	NRCS (NR) (2010-2018)	High	I: Immediate unilateral TE/IBR	IBR without human ADM	NR	Laterality: Uni (100) Timing: Imm (100) Stages: >1 (100)	693	NR	NR	NR	NR
	NRCS (NR) (2010-2018)	High	I: Immediate unilateral TE/IBR	Total	N/A	N/A	1431	43.8 (7.5)	NR	NR	NR
Liu, 2011, 21228744, US	NRCS (NR) (2004-2011)	High	I: Immediate IBR E: Delayed reconstruction; AR	IBR with human ADM	NR	Timing: Imm (100) Radio: NR (9.8)/None(90.2)	266	NR	NR	NR	NR
	NRCS (NR) (2004-2011)	High	I: Immediate IBR E: Delayed reconstruction; AR	IBR without human ADM	NR	Timing: Imm (100) Radio: Timing NR (10.4)/None(89.6)	242	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2004-2011)	High	I: Immediate IBR E: Delayed reconstruction; AR	Total	N/A	N/A	508	NR	NR	NR	NR
Nealon, 2020b, 31605310, US	NRCS (None) (2008-2018)	High	I: Unilateral breast cancer, bilateral mastectomy, and immediate IBR E: Bilateral AR; Delayed contralateral prophylactic mastectomy and BR	IBR with human ADM	NR	Timing: Imm (100)	1488 breasts	NR	NR	NR	NR
	NRCS (None) (2008-2018)	High	I: Unilateral breast cancer, bilateral mastectomy, and immediate IBR E: Bilateral AR; Delayed contralateral prophylactic mastectomy and BR	IBR without human ADM	NR	Timing: Imm (100)	668 breasts	NR	NR	NR	NR
	NRCS (None) (2008-2018)	High	I: Unilateral breast cancer, bilateral mastectomy, and immediate IBR E: Bilateral AR; Delayed contralateral prophylactic mastectomy and BR	Total	N/A	N/A	1117	NR	NR	NR	NR
Pannucci, 2013, 23508050, US	NRCS (Non-industry) (2008-2011)	Moderate	I: TE/IBR E: Mastopexy/breast augmentation	IBR with human ADM	NR	NR	3450	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2008-2011)	Moderate	I: TE/IBR E: Mastopexy/breast augmentation	IBR without human ADM	NR	NR	10799	NR	NR	NR	NR
	NRCS (Non-industry) (2008-2011)	Moderate	I: TE/IBR E: Mastopexy/breast augmentation	Total	N/A	N/A	14249	<40 years (15%), 40-60 years (57.5%), ≥60 years (21.1%)	NR	NR	NR
Peled, 2012, 22634688, US	NRCS (NR) (2006-2010)	High	I: Immediate TE/IBR	IBR with human ADM	SURFACE: Textured (100) PLANE: Total submuscular (100)	Timing: Imm (100) Stages: >1 (100) Chemo: Before (36)/After (21)/No chemotherapy (43) Radio: Before (9)/After (14)/None(77)	65	48.2 (NR)	NR	NR	Ther (55), Proph (45)
	NRCS (NR) (2006-2010)	High	I: Immediate TE/IBR	IBR without human ADM	PLANE: Total submuscular (100)	Timing: Imm (100) Stages: >1 (100) Chemo: Before (44.4)/After (23.3)/No chemotherapy (32.3) Radio: Before (4.4)/After (23.3)/None(72.3)	63	44.6 (NR)	NR	NR	Ther (66.7), Proph (33.3)
	NRCS (NR) (2006-2010)	High	I: Immediate TE/IBR	Total	N/A	N/A	128	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Qureshi, 2016, 27465177, US	NRCS (Industry) (2003-2009)	High	I: TE/IBR E: Concomitant or prior ipsilateral AR; immediate implant; ADM other than AlloDerm Regenerative Tissue Matrix (LifeCell Corp., Branchburg, N.J.); concurrent congenital or acquired ipsilateral breast deformity; patients with plans for future AR	IBR with human ADM	SURFACE: Textured (100) SHAPE: Round (100)	Laterality: Uni (53.6)/Bi (46.5) Timing: Imm (93.2)/Del (6.8) Chemo: Timing NR (47.5) Radio: Timing NR (24.4)	295	49.6 (10.3)	NR	NR	NR
	NRCS (Industry) (2003-2009)	High	I: TE/IBR E: Concomitant or prior ipsilateral AR; immediate implant; ADM other than AlloDerm Regenerative Tissue Matrix (LifeCell Corp., Branchburg, N.J.); concurrent congenital or acquired ipsilateral breast deformity; patients with plans for future AR	IBR without human ADM	SURFACE: Textured (100) SHAPE: Round (100)	Laterality: Uni (55.9)/Bi (45) Timing: Imm (83.1)/Del (16.9) Chemo: Timing NR (51.7) Radio: Timing NR (35.6)	118	50.8 (9.7)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Industry) (2003-2009)	High	I: TE/IBR E: Concomitant or prior ipsilateral AR; immediate implant; ADM other than AlloDerm Regenerative Tissue Matrix (LifeCell Corp., Branchburg, N.J.); concurrent congenital or acquired ipsilateral breast deformity; patients with plans for future AR	Total	N/A	N/A	413	NR	NR	NR	NR
Safran, 2020, 32221195, Canada	NRCS (None) (2016-2018)	High	I: Immediate, direct-to-implant prepectoral IBR E: Previously failed IBR; extensive skin envelope radiation damage; locally advanced breast cancer; extensive skin excision; delayed IBR or AR	IBR with human ADM	PLANE: Prepectoral (100)	Timing: Imm (100) Stages: 1 (100)	243	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2016-2018)	High	I: Immediate, direct-to-implant prepectoral IBR E: Previously failed IBR; extensive skin envelope radiation damage; locally advanced breast cancer; extensive skin excision; delayed IBR or AR	IBR without human ADM	PLANE: Prepectoral (100)	Timing: Imm (100) Stages: 1 (100)	70	NR	NR	NR	NR
	NRCS (None) (2016-2018)	High	I: Immediate, direct-to-implant prepectoral IBR E: Previously failed IBR; extensive skin envelope radiation damage; locally advanced breast cancer; extensive skin excision; delayed IBR or AR	Total	N/A	N/A	313	48.6 (11.6)	NR	NR	Ther (44.4), Proph (55.6)
Seth, 2012, 23018687, US	NRCS (Non-industry) (2006-2008)	High	I: Immediate TE/IBR E: Combination of AR and TE/IBR (e.g., LD flap)	IBR with human ADM	SIZE: Mean 444.2 ml, SD 132.7 PLANE: Total submuscular (100)	Laterality: Uni (55)/Bi (45) Timing: Imm (100) Radio: Before (4.5)/After (24.6)	199 Breasts	49.5 (11)	NR	NR	NR
	NRCS (Non-industry) (2006-2008)	High	I: Immediate TE/IBR E: Combination of AR and TE/IBR (e.g., LD flap)	IBR without human ADM	SIZE: Mean 437.3 ml, SD 132.2 PLANE: Total submuscular (100)	Laterality: Uni (60)/Bi (40) Timing: Imm (100) Radio: Before (6.4)/After (18.8)	293 breasts	47.4 (10.1)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2006-2008)	High	I: Immediate TE/IBR E: Combination of AR and TE/IBR (e.g., LD flap)	Total	N/A	N/A	417	NR	NR	NR	NR
Sobti, 2018, 29481386, US	NRCS (NR) (2014-2016)	High	I: TE/IBR	IBR with human ADM	NR	Laterality: Uni (25.1)/Bi (74.9) Chemo: Timing NR (13.9) Radio: Timing NR (9.5)	338	46.4 (9.8)	NR	NR	NR
	NRCS (NR) (2014-2016)	High	I: TE/IBR	IBR without human ADM	NR	Laterality: Uni (43.4)/Bi (56.6) Chemo: Timing NR (17) Radio: Timing NR (3.7)	376	46.7 (9.4)	NR	NR	NR
	NRCS (NR) (2014-2016)	High	I: TE/IBR	Total	N/A	N/A	714	46.5 (9.6)	NR	NR	NR
Stein, 2020, 32561384, Canada	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	IBR with human ADM	SIZE: Mean 446 cc	Timing: Imm (100) Stages: 1 (67.4)/>1 (32.6) Radiation: Before (58.2)/After (41.8)	89	51.1 (NR)	NR	NR	NR
	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	IBR without human ADM	SIZE: Mean 369 cc	Timing: Imm (100) Stages: 1 (19.5)/>1 (80.5) Radiation: Before (56.1)/After (43.9)	41	48.6 (NR)	NR	NR	NR
	NRCS (None) (2010-2019)	High	I: Immediate IBR with radiation	Total	N/A	N/A	130	50.3 (NR)	NR	NR	NR
Vardanian, 2011, 22030500, US	NRCS (None) (2000-2008)	High	I: IBR E: Delayed BR; combination of AR and TE/IBR	IBR with human ADM	NR	Laterality: Uni (31)/Bi (69) Timing: Imm (100)	123	49 (11)	NR	NR	None (6.5), Stage NR (93.5)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2000-2008)	High	I: IBR E: Delayed BR; combination of AR and TE/IBR	IBR without human ADM	NR	Laterality: Uni (39)/Bi (61) Timing: Imm (100)	80	47 (10)	NR	NR	None (16.3), Stage 0 (83.7)
	NRCS (None) (2000-2008)	High	I: IBR E: Delayed BR; combination of AR and TE/IBR	Total	N/A	N/A	203	NR	NR	NR	NR
Weichman, 2012, 22544088, US	NRCS (NR) (2007-2010)	Moderate	I: Immediate two-stage, IBR E: Immediate permanent IBR, AR, combination, or delayed BR	IBR with human ADM	NR	Timing: Imm (100) Stages: >1 (100) Chemo: Before (14.2)/After (31.3)/No chemotherapy (54.5) Radio: Before (7.8)/After (6.4)/None(85.8)	442 breasts	51.08 (11.7)	NR	NR	Stage 0 (13.1), Stage I (19.2), Stage II (17.4), Stage III (5.4), Stage IV (0.045)
	NRCS (NR) (2007-2010)	Moderate	I: Immediate two-stage, IBR E: Immediate permanent IBR, AR, combination, or delayed BR	IBR without human ADM	PLANE: Total submuscular (100)	Timing: Imm (100) Stages: >1 (100) Chemo: Before (16.7)/After (28.6)/No chemotherapy (54.7) Radio: Before (8.7)/After (7.9)/None(83.4)	186 breasts	49.09 (11.58)	NR	NR	Stage 0 (18.8), Stage I (18.8), Stage II (17.7), Stage III (8.6)
	NRCS (NR) (2007-2010)	Moderate	I: Immediate two-stage, IBR E: Immediate permanent IBR, AR, combination, or delayed BR	Total	N/A	N/A	407	NR	NR	NR	NR
Woo, 2017, 28509694, South Korea	NRCS (None) (2010-2016)	High	I: Immediate TE/IBR E: Direct-to-implant BR; AR; or delayed BR	IBR with human ADM	NR	Timing: Imm (100) Stages: >1 (100) Chemo: After (43.2) Radio: Before (3)/After (13.6)/None(83.4)	199	42.9 (6.9)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Implant Details (%) (Only Reported Details)	Reconstruction Details (%) (Only Reported Details)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2010-2016)	High	I: Immediate TE/IBR E: Direct-to-implant BR; AR; or delayed BR	IBR without human ADM	PLANE: Total submuscular (100)	Timing: Imm (100) Stages: >1 (100) Chemo: After (36.7) Radio: Before (3.0)/After (16.6)/None(80.4)	199	42.8 (7.2)	NR	NR	NR
	NRCS (None) (2010-2016)	High	I: Immediate TE/IBR E: Direct-to-implant BR; AR; or delayed BR	Total	N/A	N/A	398	NR	NR	NR	NR

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

W = White or Caucasian, B = Black or African American, A = Asian, H = Hispanic or Latino.

Proph = prophylactic, Ther = therapeutic.

Abbreviations: AR = autologous reconstruction, BR = breast reconstruction, IBR = implant-based reconstruction, IQR = interquartile range, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PMRT = postmastectomy radiation therapy, RCT = randomized controlled trial, SD = standard deviation, TE/I = tissue expander/implant, Ther = therapeutic.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table C-7. Key Question 6: Comparison of flap types for autologous reconstruction – summary of design, arm, and sample details

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Abedi, 2016, 25003437, Canada	NRCS (None) (2003-2011)	High	I: BR	AR with DIEP	NR	NR	NR	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	AR with TRAM	TIMING: Imm (100)	NR	NR	NR	NR	NR
	NRCS (None) (2003-2011)	High	I: BR	Total	TIMING: Imm (100) CHEMO: Before (47.5)/After (13.7) RADIO: Before (38.9)/After (3.2)	314	50 (8.2)	NR	NR	NR
Baumann, 2010, 20440154, US	NRCS (NR) (2001-2006)	High	I: Free flap AR	AR with DIEP	STAGES: 1 (100)	71	NR	NR	NR	NR
	NRCS (NR) (2001-2006)	High	I: Free flap AR	AR with TRAM	STAGES: 1 (100)	120	NR	NR	NR	NR
	NRCS (NR) (2001-2006)	High	I: Free flap AR	AR with SIEA	STAGES: 1 (100)	37	NR	NR	NR	NR
	NRCS (NR) (2001-2006)	High	I: Free flap AR	Total	N/A	228	NR	NR	NR	NR
Brandberg, 2000, 10626972, Sweden	RCT (Non-industry) (1994-1996)	High	I: Age <=79; free of recurrence E: Poorly controlled diabetes and secondary complications, immunosuppressive treatment, family history or previous rheumatic disease	AR with TRAM	LATERALITY: Uni (100) TIMING: Del (100) STAGES: >1 (100) RADIO: Timing NR (48)	29	52 (9.2)	NR	1st: 100	Ther (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	RCT (Non-industry) (1994-1996)	High	I: Age <=79; free of recurrence E: Poorly controlled diabetes and secondary complications, immunosuppressive treatment, family history or previous rheumatic disease	AR with LD	LATERALITY: Uni (100) TIMING: Del (100) STAGES: >1 (100) RADIO: Timing NR (47)	30	54 (8.9)	NR	1st: 100	Ther (100)
	RCT (Non-industry) (1994-1996)	High	I: Age <=79; free of recurrence E: Poorly controlled diabetes and secondary complications, immunosuppressive treatment, family history or previous rheumatic disease	AR with LTD	LATERALITY: Uni (100) TIMING: Del (100) STAGES: >1 (100) RADIO: No (100)	16	52 (8.5)	NR	1st: 100	Ther (100)
	RCT (Non-industry) (1994-1996)	High	I: Age <=79; free of recurrence E: Poorly controlled diabetes and secondary complications, immunosuppressive treatment, family history or previous rheumatic disease	Total	N/A	75	NR	NR	1st: 100	Ther (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Brorson 2020b, 32807615, Sweden	RCT (Non-industry) (2008-2020)	High	I: Age 18-60; Unilateral mastectomy E: Current smoker; BMI >30	AR with DIEP	LATERALITY: Uni (100) TIMING: Del (100) STAGES: 1 (100) CHEMO: Before (91.2)	44	49.3 (6.4)	NR	NR	Stage 1 (6.5) Stage 2 (45.2) Stage 3 (48.4)
	RCT (Non-industry) (2008-2020)	High	I: Age 18-60; Unilateral mastectomy E: Current smoker; BMI >30	AR with LD	LATERALITY: Uni (100) TIMING: Del (100) STAGES: 1 (100) CHEMO: Before (75.0)	39	51.9 (8.3)	NR	NR	Stage 1 (2.9) Stage 2 (32.4) Stage 3 (64.7)
	RCT (Non-industry) (2008-2020)	High	I: Age 18-60; Unilateral mastectomy E: Current smoker; BMI >30	Total	N/A	83	NR	NR	NR	NR
Carramaschi, 1989, 2602589, France	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	AR with TRAM	NR	40	NR	NR	NR	NR
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	AR with LD	NR	34	NR	NR	NR	NR
	NRCS (NR) (1982-1986)	High	I: Postmastectomy BR	Total	N/A	74	NR	NR	NR	NR
Dauplat, 2021, 33622886, France	NRCS (None) (2007-2009)	Moderate	I: Unilateral AR after therapeutic mastectomy E: Another concurrent cancer	AR with TRAM	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (40) RADIO: Timing NR (17)	30	NR	NR	NR	Ther (100)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral AR after therapeutic mastectomy E: Another concurrent cancer	AR with LD and implant	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (17) RADIO: Timing NR (14)	91	NR	NR	NR	Ther (100)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral AR after therapeutic mastectomy E: Another concurrent cancer	AR with LD and no implant	LATERALITY: Uni (100) TIMING: Imm (100) CHEMO: Timing NR (32) RADIO: Timing NR (7)	78	NR	NR	NR	Ther (100)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2007-2009)	Moderate	I: Unilateral IBR after therapeutic mastectomy E: Another concurrent cancer	Total	N/A	199	NR	NR	NR	Ther (100)
Erdmann-Sager, 2018, 29019862, US, Canada	NRCS (Non-industry) (2012-2015)	Moderate	I: First-time, unilateral or bilateral BR	AR with DIEP	LATERALITY: Uni (57.8)/Bi (42.2) TIMING: Imm (84)/Del (16) CHEMO: After (28.3)/No chemotherapy (71.7) RADIO: Before (22.5)/After (19.1)/None(58.4)	445	51.1 (8.8)	NR	NR	Ther (88.5), Proph (11.5)
	NRCS (Non-industry) (2012-2015)	Moderate	I: First-time, unilateral or bilateral BR	AR with TRAM	LATERALITY: Uni (63.5)/Bi (36.5) TIMING: Imm (76.5)/Del (23.5) CHEMO: After (46.5)/No chemotherapy (53.5) RADIO: Before (15.5)/After (36.6)/None(47.9)	115	52.2 (8.6)	NR	NR	Ther (91.3), Proph (8.7)
	NRCS (Non-industry) (2012-2015)	Moderate	I: First-time, unilateral or bilateral BR	AR with TRAM	LATERALITY: Uni (80.9)/Bi (19.1) TIMING: Imm (88.8)/Del (11.2) CHEMO: After (22.5)/No chemotherapy (77.5) RADIO: Before (30.3)/After (14.6)/None(55.1)	89	53.6 (8.5)	NR	NR	Ther (95.5), Proph (4.5)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2012-2015)	Moderate	I: First-time, unilateral or bilateral BR	AR with SIEA	LATERALITY: Uni (66.2)/Bi (33.8) TIMING: Imm (91.5)/Del (8.5) CHEMO: After (11.3)/No chemotherapy (88.7) RADIO: Before (40)/After (1.7)/None(58.3)	71	53.3 (8.2)	NR	NR	Ther (91.5), Proph (8.5)
	NRCS (Non-industry) (2012-2015)	Moderate	I: First-time, unilateral or bilateral BR	Total	N/A	791	NR	NR	NR	NR
Garbay, 1992, 1624727, France	NRCS (NR) (1979-1990)	High	I: BR	AR with TRAM	NR	63	NR	NR	NR	NR
	NRCS (NR) (1979-1990)	High	I: BR	AR with LD	NR	36	NR	NR	NR	NR
	NRCS (NR) (1979-1990)	High	I: BR	Total	N/A	99	NR	NR	NR	NR
Israeli, 2014, 24572840, US	NRCS (Industry) (2008-2009)	High	I: AR E: Revision BR; AR with TRAM flap involving an TE/I	AR with TRAM	RADIO: Before (4.4)/After (13.5)	252	50.7 (7.65)	NR	NR	NR
	NRCS (Industry) (2008-2009)	High	I: AR E: Revision BR; AR with TRAM flap involving an TE/I	AR with LD	RADIO: Before (6.3)/After (11.6)	302	50 (8.94)	NR	NR	NR
	NRCS (Industry) (2008-2009)	High	I: AR E: Revision BR; AR with TRAM flap involving an TE/I	Total	N/A	554	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Knox, 2016, 26267400, Canada	NRCS (NR) (2002-2013)	High	I: Unilateral or bilateral AR with DIEP or pedicled TRAM flap E: History of abdominal hernia or bulge	AR with DIEP	LATERALITY: Uni (59.3)/Bi (49.8) TIMING: Imm (63.1)/Del (33.9)/Mixed (3.1) STAGES: 1 (100) CHEMO: Before (51.5)/After (9.2)/No chemotherapy (39.3) RADIO: Before (47.7)/After (7.7)/None(44.6)	130	49 (8.4); Range 16, 72	NR	NR	Stage 0 (16.2), Stage NR (77.7), Proph (5.4)
	NRCS (NR) (2002-2013)	High	I: Unilateral or bilateral AR with DIEP or pedicled TRAM flap E: History of abdominal hernia or bulge	AR with TRAM	LATERALITY: Uni (82.2)/Bi (17.8) TIMING: Imm (74.5)/Del (24.9)/Mixed (0.5) STAGES: 1 (100) CHEMO: Before (48)/After (11.9)/No chemotherapy (40.1) RADIO: Before (45.6)/After (11.9)/None(42.5)	377	50.2 (8); Range 29, 71	NR	NR	Stage 0 (28.7), Stage NR (58.1), Proph (1.3)
	NRCS (NR) (2002-2013)	High	I: Unilateral or bilateral AR with DIEP or pedicled TRAM flap E: History of abdominal hernia or bulge	Total	N/A	507	NR	NR	NR	NR
Kroll, 2000, 10987463, US	NRCS (NR) (1989-2000)	High	I: AR with DIEP/free TRAM flap	AR with DIEP	NR	NR	NR	NR	NR	NR
	NRCS (NR) (1989-2000)	High	I: AR with DIEP/free TRAM flap	AR with TRAM	NR	NR	NR	NR	NR	NR
	NRCS (NR) (1989-2000)	High	I: AR with DIEP/free TRAM flap	Total	N/A	241	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Kulkarni, 2017, 28713853, US, Canada	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with DIEP	NR	463	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with TRAM	NR	94	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with TRAM	NR	111	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with LD	NR	80	NR	NR	NR	NR
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	AR with SIEA	NR	73	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2011-2016)	Moderate	I: Age >=18 years; first-time, immediate or delayed, bilateral or unilateral postmastectomy BR	Total	N/A	821	NR	NR	NR	NR
Macadam, 2016, 26910656, US, Canada, Japan, Lebanon	NRCS (Non-industry) (2002-2012)	High	I: AR E: AR with a combination of flaps	AR with DIEP	LATERALITY: Uni (57.2)/Bi (42.8) TIMING: Imm (58.2)/Del (37.1)/Mixed (4.6) STAGES: 1 (100) CHEMO: Before (43.8)/After (8.8)/No chemotherapy (48.6) RADIO: Before (39.2)/After (3.1)/None(58)	670	49 (8.4)	W (83.2), B (3.5), A (8), H (1.3), Other 1 (2.4), Other 2 (1.6)	NR	None (8.8), Stage 0 (23.4), Stage NR (67.8); Proph (8.5)
	NRCS (Non-industry) (2002-2012)	High	I: AR E: AR with a combination of flaps	AR with TRAM	LATERALITY: Uni (79.2)/Bi (20.8) TIMING: Imm (71.5)/Del (27.8)/Mixed (0.7) STAGES: 1 (100) CHEMO: Before (31.7)/After (21.1)/No chemotherapy (49.7) RADIO: Before (27.5)/After (8.5)/None(64.1)	144	47.8 (7.7)	W (81.4), B (7.1), Others (11.4)	NR	None (4.2), Stage 0 (35.2), Stage NR (60.6); Proph (4.2)

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (2002-2012)	High	I: AR E: AR with a combination of flaps	AR with TRAM	LATERALITY: Uni (79.2)/Bi (20.8) TIMING: Imm (70.7)/Del (28)/Mixed (1.3) STAGES: 1 (100) CHEMO: Before (42.5)/After (16.7)/No chemotherapy (44.4) RADIO: Before (40.2)/After (9.8)/None(50.8)	683	50.3 (8.2)	W (83.6), B (2.5), A (7.9), H (0.6), Other 1 (1.4), Other 2 (4)	NR	None (2.8), Stage 0 (31.8), Stage NR (65.5); Proph (2.3)
	NRCS (Non-industry) (2002-2012)	High	I: AR E: AR with a combination of flaps	AR with TRAM	LATERALITY: Uni (63.1)/Bi (36.9) TIMING: Imm (65.1)/Del (33.9)/Mixed (1) STAGES: 1 (100) CHEMO: Before (36.3)/After (16.4)/No chemotherapy (49) RADIO: Before (42.1)/After (2.7)/None(55.5)	293	49.6 (7.9)	W (80.2), B (6), A (4.3), Other 1 (8.6), Other 2 (0.9)	NR	None (4.8), Stage 0 (26.6), Stage NR (68.5); Proph (4.5)
	NRCS (Non-industry) (2002-2012)	High	I: AR E: AR with a combination of flaps	Total	N/A	1790	NR	NR	NR	NR
Massenburg, 2015, 26487657, US	NRCS (NR) (2005-2012)	High	I: AR	AR with TRAM	NR	2464	52 (9)	W (82.3), B (12.4), A (3.3), H (1.4), Others (0.6)	NR	NR
	NRCS (NR) (2005-2012)	High	I: AR	AR with LD	NR	2085	52.8 (10.9)	W (83.8), B (12.2), A (2.6), H (0.4), Others (0.7)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2005-2012)	High	I: AR	Total	N/A	4549	51.8 (9.7)	W (82.3), B (13), A (3.4), H (0.7), Others (0.6)	NR	NR
Mennie, 2015, 25839173, UK	NRCS (Industry; Non-industry) (2006-2012)	High	I: AR E: Other types of immediate or delayed BR	AR with DIEP	LATERALITY: Uni (87.6)/Bi (12.4) STAGES: 1 (100)	5144	NR	NR	NR	NR
	NRCS (Industry; Non-industry) (2006-2012)	High	I: AR E: Other types of immediate or delayed BR	AR with TRAM	LATERALITY: Uni (91.9)/Bi (8.1) STAGES: 1 (100)	1963	NR	NR	NR	NR
	NRCS (Industry; Non-industry) (2006-2012)	High	I: AR E: Other types of immediate or delayed BR	AR with TRAM	LATERALITY: Uni (91.3)/Bi (8.7) STAGES: 1 (100)	922	NR	NR	NR	NR
	NRCS (Industry; Non-industry) (2006-2012)	High	I: AR E: Other types of immediate or delayed BR	Total	N/A	7929	16-45 years (29.2%), 46–50 years (23.4%), 51-55 years (20.5%), 56-60 years (13.9%), ≥60 years (13%)	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
Rindom, 2019, 31515191, Denmark	RCT (Industry) (2013-2015)	Moderate	I: Age >=18, unilateral, delayed BR	AR with LD	LATERALITY: Uni (100) TIMING: Del (100) STAGES: 1 (100) CHEMO: Timing NR (77.78) RADIO: Timing NR (50)	25	54.2; Range 41, 71	NR	NR	Ther (94.45), Proph (5.55)
	RCT (Industry) (2013-2015)	Moderate	I: Age >=18, unilateral, delayed BR	AR with TAP	LATERALITY: Uni (100) TIMING: Del (100) STAGES: >1 (13.64) CHEMO: Timing NR (68.18) RADIO: Timing NR (77.27)	25	55.8; Range 35, 70	NR	NR	Ther (100)
	RCT (Industry) (2013-2015)	Moderate	I: Age >=18, unilateral, delayed BR	Total	N/A	50	NR	NR	NR	
Woo, 2018, 30360958, South Korea	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	AR with DIEP	TIMING: Imm (100) CHEMO: Before (2.3)/After (40.9) RADIO: Before (2.2)/After (14.8)	NR	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	AR with LD	TIMING: Imm (100) CHEMO: Before (8.6)/After (43.6) RADIO: After (9.4)	NR	NR	NR	NR	NR
	NRCS (NR) (2008-2013)	High	I: Immediate BR E: Direct-to-implant BR; combination of AR and TE/IBR (e.g., LD flap); AR with TRAM flap,; history of shoulder joint morbidity, such as adhesive capsulitis or rotator cuff disease	Total	N/A	NR	NR	NR	NR	NR
Yueh, 2009, 19228537, US	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with DIEP	STAGES: 1 (100)	420	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with TRAM	STAGES: 1 (100)	143	NR	NR	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	AR with LD	STAGES: 1 (100)	112	NR	NR	NR	NR
	NRCS (Non-industry) (1996-2006)	High	I: Therapeutic or prophylactic mastectomy E: BR for breast augmentation only	Total	N/A	675	NR	NR	NR	NR
Zhong, 2014, 24675183, Canada	NRCS (Non-industry) (2009-2012)	High	I: AR with DIEP or free TRAM flaps	AR with DIEP	STAGES: 1 (100)	244	NR	NR	NR	NR
	NRCS (Non-industry) (2009-2012)	High	I: AR with DIEP or free TRAM flaps	AR with TRAM	STAGES: 1 (100)	48	NR	NR	NR	NR
	NRCS (Non-industry) (2009-2012)	High	I: AR with DIEP or free TRAM flaps	Total	N/A	292	50.1 (8.6)	NR	NR	NR
Zoghbi Y, 2017, 28052051, US	NRCS (None) (2010-2011)	High	I: AR with DIEP or free TRAM flaps	AR with DIEP	NR	9699	50 (13)	W (70.8), B (11.2), A (3.6), H (10.9), Others (3.5)	NR	NR
	NRCS (None) (2010-2011)	High	I: AR with DIEP or free TRAM flaps	AR with TRAM	NR	6137	50 (13)	W (67.2), B (13.8), A (3.7), H (11.3), Others (3.6)	NR	NR

Study, Publication Year, PMID, Country	Design (Funding) (Study Years)	Risk of Bias	Eligibility Criteria	Arm	Reconstruction Details (%)	N	Age in Years, Mean (SD) or as Specified	Race (%)	Breast Cancer Occurrence %	Cancer Stage or Mastectomy Purpose (%)
	NRCS (None) (2010-2011)	High	I: AR with DIEP or free TRAM flaps	Total	N/A	15836	50 (13); Median 50	W (69.5), B (12.2), A (3.6), H (11.1), Others (3.6)	NR	NR

Blue coloring is only to visually separate different studies.

I: inclusion criteria, E: exclusion criteria

Laterality: whether the reconstruction was unilateral ("Uni") or bilateral ("Bi"). Stages: Whether the reconstruction was completed in 1 stage or >1 stages. Timing: Timing of reconstruction relative to mastectomy, i.e., immediate ("Imm") or delayed ("Del"). Chemo: Timing of chemotherapy relative to reconstruction. Radio: Timing of radiation therapy relative to reconstruction.

W = White or Caucasian, B = Black or African American, A = Asian, H = Hispanic or Latino.

Proph = prophylactic, Ther = therapeutic.

Abbreviations: AR = autologous reconstruction, BR = breast reconstruction, DIEP = Deep inferior epigastric perforator, IBR = implant-based reconstruction, IQR = interquartile range, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PMRT = postmastectomy radiation therapy, RCT = randomized controlled trial, SD = standard deviation, SIEA = Superficial inferior epigastric artery perforator, TAP = thoracodorsal artery perforator, TE/I = tissue expander/implant, Ther = therapeutic, TRAM = Transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Appendix D. Results: Risk of Bias

Table D-1. Risk of bias assessment for all Key Questions – randomized controlled trials

KQ	Study, Year, PMID	Random Sequence Generation	Allocation Concealment	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1	Brorson 2020a, 32807615	Low	Low	High	High	High	N/A	High	Low	Low	Yes	Yes	Yes	**High**
1	Tallroth, 2020, 33436336	Unclear	Unclear	High	High	Low	Unclear	Low	Low	Low	Yes	Yes	Yes	**Moderate**
4	Lee, 2021b, 33691448	Unclear	Unclear	High	High	Unclear	N/A	Unclear	Unclear	Low	Yes	Yes	Yes	**Moderate**
5	McCarthy, 2012, 23096987	Low	Low	High	High	Low	Low	Low	High	Low	Yes	Yes	Yes	**Moderate**
5	Wendel, 2013, none	Unclear	Unclear	High	High	Low	N/A	High	High	Low	No	No	No	**High**
6	Brandberg, 2000, 10626972	Low	Low	High	High	High	High	High	High	Low	Yes	Yes	Yes	**High**
6	Brorson 2020b, 32807615	Low	Low	High	High	High	N/A	High	Low	Low	Yes	Yes	Yes	**High**
6	Rindom, 2019, 31515191	Low	Low	High	High	High	High	Low	Low	Low	Yes	Yes	Yes	**Moderate**

Abbreviations: KQ = Key Question, PMID = PubMed identifier. Ratings are color coded for emphasis only. The colors do not impart unique information.
From the Cochrane Risk of Bias Tool (each item rated as Low, High, Unclear, or N/A [not applicable])

- Random sequence generation (selection bias): Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.
- Allocation concealment (selection bias): Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
- Blinding of participants (performance bias): Performance bias due to knowledge of the allocated interventions by participants during the study.
- Blinding of personnel/care providers (performance bias): Performance bias due to knowledge of the allocated interventions by personnel/care providers during the study.
- Blinding of outcome assessor (detection bias): Detection bias due to knowledge of the allocated interventions by outcome assessors during the study.
- Incomplete outcome data (attrition bias): Attrition bias due to amount, nature, or handling of incomplete outcome data.
- Selective outcome reporting (outcome reporting bias): Bias arising from outcomes being selectively reported based on the direction and/or strength of the results.

- Other Bias: Bias due to problems not covered elsewhere in the table.

From the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool (each item rated as Yes, No, or Unclear)

- Eligibility criteria prespecified and clearly described: Potentially related to selection bias.
- Intervention clearly described and delivered consistently: Potentially related to performance bias.
- Outcomes prespecified, clearly defined, valid, reliable, and assessed consistently: Potentially related to detection bias.

Overall risk of bias assessed as **HIGH**, **MODERATE**, or **LOW.**

Table D-2. Risk of bias assessment for all Key Questions – nonrandomized comparative studies, confounding and selection bias

KQ	Study, Year, PMID	1.1 Potential for Any Confounding?	1.2 Potential for Time-Varying Confounding?	1.3 Intervention Switches Related to Prognostic Factors?	1.4 Appropriate Analysis Method for Confounding?	1.5 Appropriate Confounding Variables Used?	1.6 Inappropriate Control of Post-Intervention Variables?	Judgment – Risk of Bias Related to Confounding	2.1 Participant Selection Based on Post-Intervention Variables?	2.2 Post-Intervention Variables Associated with Intervention?	2.3 Post-Intervention Variables Associated with Outcome?	2.4 Start and Follow-Up (Duration) Coincide	2.5 Appropriate Adjustment for Selection Bias	Judgment – Risk of Bias Related to Selection Bias
1	Brito, 2020, No PMID	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Chetta, 2017, 28002254	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	de Araujo, 2016, 27673527	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Eltahir, 2015, 25539295	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	PY	N/A	Low
1	Fischer, 2013, 23629074	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Fischer, 2014, 24916480	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Fischer, 2015, 26366550	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Garvey, 2012, 23096600	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	Y	N/A	Low
1	Ha, 2020, 32000718	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	N	PN	Serious
1	Hangge, 2019, 31606126	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	PY	N/A	Low
1	Jiang, 2013, 24349366	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Kouwenberg, 2019, 30270015	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	PN	PY	Moderate
1	Kouwenberg, 2020, 32590633	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	PY	N/A	Low
1	Laporta, 2017, 28061518	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Lei, 2020, 32481367	Yes	No	N/A	Y	Y	Y	Moderate	N	N/A	N/A	Y	N/A	Low
1	Liu, 2014, 24558063	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Mak, 2020, 32665188	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	McCarthy, 2014, 24201740	Yes	No	N/A	Y	PY	Y	Moderate	PN	N/A	N/A	N	PN	Moderate
1	Merchant, 2015, 26111325	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Mioton, 2013, 23562485	Yes	No	N/A	Y	Y	N	Low	PN	N/A	N/A	PY	N/A	Low
1	Momeni, 2018, 29095189	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Naoum, 2020a, 31756414	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Naoum, 2020b, 32607638	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	PY	N/A	Moderate
1	Nasser, 2018, 30204678	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Nelson, 2019, 31356276	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Palve, 2020, 32468337	Yes	No	N/A	Y	Y	Y	Moderate	N	N/A	N/A	Y	N/A	Low
1	Qin, 2018, 29384865	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	N	PN	Moderate
1	Roth, 2007, 17413877	Yes	No	N/A	N	N/A	N	Critical	N	N/A	N/A	Y	N/A	Low
1	Shiraishi, 2020, 32589082	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Simon, 2020, 33363007	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	Y	N/A	Low

KQ	Study, Year, PMID	1.1 Potential for Any Confounding?	1.2 Potential for Time-Varying Confounding?	1.3 Intervention Switches Related to Prognostic Factors?	1.4 Appropriate Analysis Method for Confounding?	1.5 Appropriate Confounding Variables Used?	1.6 Inappropriate Control of Post-Intervention Variables?	Judgment – Risk of Bias Related to Confounding	2.1 Participant Selection Based on Post-Intervention Variables?	2.2 Post-Intervention Variables Associated with Intervention?	2.3 Post-Intervention Variables Associated with Outcome?	2.4 Start and Follow-Up (Duration) Coincide	2.5 Appropriate Adjustment for Selection Bias	Judgment – Risk of Bias Related to Selection Bias
1	Wu, 2021, 33740204	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1	Xu, 2018, 30261115	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	Y	N/A	Low
1	Zhang, 2019, 30675702	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1, 6	Abedi, 2016, 25003437	Yes	No	N/A	N	N/A	Y	Serious	N	N/A	N/A	Y	N/A	Low
1, 6	Carramaschi, 1989, 2602589	Yes	No	N/A	N	N/A	N	Critical	N	N/A	N/A	N	N	Low
1, 6	Dauplat, 2021, 33622886	Yes	No	N/A	Y	Y	Y	Moderate	N	N/A	N/A	Y	N/A	Low
1, 6	Garbay, 1992, 1624727	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
1, 6	Kulkarni, 2017, 28713853	Yes	No	N/A	Y	Y	PN	Low	PN	N/A	N/A	Y	N/A	Low
1, 6	Woo, 2018, 30360958	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	PY	N/A	Low
1, 6	Yueh, 2009, 19228537	Yes	No	N/A	N	N/A	N	Critical	N	N/A	N/A	Y	N/A	Low
2	Eriksson, 2013, 24258257	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	N	PY	Moderate
2	Yoon, 2020, 32332528	Yes	No	N/A	Y	PY	N	Low	N	N/A	N/A	N	PY	Moderate
2, 3	Cordeiro, 2015a, 25742523	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	N	PY	Moderate
2, 5	Hirsch, 2014, 25347643	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
2, 5	Stein, 2020, 32561384	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	N	PY	Moderate
3	Antony, 2014, 24135689	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
3	Le, 2005, 15743498	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
3	Macadam, 2010, 20009795	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Moderate
3	McCarthy, 2010, 21136577	Yes	No	N/A	Y	PY	Y	Moderate	N	N/A	N/A	N	PY	Moderate
4	Avila, 2020, 33234947	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
4	Gabriel, 2020, 32195862	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
4	Kim, 2020, 33066236	Yes	No	N/A	Y	Y	Y	Moderate	N	N/A	N/A	Y	N/A	Low
4	Kraenzlin, 2021, 32568752	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
4	Nealon, 2020a, 32032345	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
4	Ozgur, 2020, 33223365	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	PY	N/A	Low
4, 5	Cattelani, 2018, 29275104	Yes	No	N/A	PN	N/A	N	Critical	N	N/A	N/A	Y	N/A	Low
5	Brooke, 2012, 22868313	Yes	No	N/A	N	Y	N	Serious	N	N/A	N/A	PY	N/A	Low
5	Chun, 2010, 20124828	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
5	Craig, 2019, 29800083	Yes	No	N/A	Y	Y	N	Low	PY	Y	Y	N	N	Moderate
5	Ibrahim, 2013, 24165587	Yes	No	N/A	Y	PY	PN	Low	PN	N/A	N/A	PY	N/A	Low
5	Ganesh Kumar, 2021, 33172826	Yes	No	N/A	Y	Y	PN	Low	PN	N/A	N/A	PY	N/A	Low

KQ	Study, Year, PMID	1.1 Potential for Any Confounding?	1.2 Potential for Time-Varying Confounding?	1.3 Intervention Switches Related to Prognostic Factors?	1.4 Appropriate Analysis Method for Confounding?	1.5 Appropriate Confounding Variables Used?	1.6 Inappropriate Control of Post-Intervention Variables?	Judgment – Risk of Bias Related to Confounding	2.1 Participant Selection Based on Post-Intervention Variables?	2.2 Post-Intervention Variables Associated with Intervention?	2.3 Post-Intervention Variables Associated with Outcome?	2.4 Start and Follow-Up (Duration) Coincide	2.5 Appropriate Adjustment for Selection Bias	Judgment – Risk of Bias Related to Selection Bias
5	Lee, 2020, No PMID	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
5	Liu, 2011, 21228744	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	PY	N/A	Low
5	Nealon, 2020b, 31605310	Yes	No	N/A	N	N/A	N	Critical	N	N/A	N/A	Y	N/A	Low
5	Pannucci, 2013, 23508050	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	Y	N/A	Low
5	Peled, 2012, 22634688	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
5	Qureshi, 2016, 27465177	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
5	Safran, 2020, 32221195	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Moderate
5	Seth, 2012, 23018687	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	N	Y	Low
5	Sobti, 2018, 29481386	Yes	No	N/A	N	N/A	Y	Serious	N	N/A	N/A	Y	N/A	Low
5	Vardanian, 2011, 22030500	Yes	No	N/A	PN	N/A	N	Serious	Y	PN	N/A	Y	N/A	Low
5	Weichman, 2012, 22544088	Yes	No	N/A	PY	PY	N	Low	N	N/A	N/A	Y	N/A	Low
5	Woo, 2017, 28509694	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Baumann, 2010, 20440154	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Erdmann-Sager, 2018, 29019862	Yes	No	N/A	Y	Y	N	Low	PN	N/A	N/A	PY	N/A	Low
6	Israeli, 2014, 24572840	Yes	No	N/A	N	N/A	N	Serious	Y	PN	N/A	Y	N/A	Low
6	Knox, 2016, 26267400	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Kroll, 2000, 10987463	Yes	No	N/A	N	N/A	PN	Serious	PY	Y	PN	PY	N/A	Moderate
6	Macadam, 2016, 26910656	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Massenburg, 2015, 26487657	Yes	No	N/A	Y	Y	N	Low	N	N/A	N/A	PY	N/A	Low
6	Mennie, 2015, 25839173	Yes	No	N/A	PN	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Zhong, 2014, 24675183	Yes	No	N/A	N	N/A	N	Serious	N	N/A	N/A	Y	N/A	Low
6	Zoghbi, 2017, 28052051	Yes	No	N/A	Y	PN	N	Moderate	N	N/A	N/A	PY	N/A	Low

Abbreviations: KQ = Key Question, N/A = Not applicable, NI = no information, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PN = probably no, PY = probably yes.

Judgements are color coded for emphasis only. The colors do not impart unique information. Signaling questions are not color coded for simplicity and because they are only used to inform the judgements.

Responses to Risk of Bias in Nonrandomized Studies of Interventions (ROBINS-I) signaling questions 1.1 to 1.6 and 2.1 to 2.5 are in regular font. (each item rated as Yes, PY, NI, PN, No, or N/A)

Overall judgements about confounding and selection bias are in **bold font**. Each judgement is rated as **Low**, **Moderate**, **Serious**, **Critical**, or **NI**.

Table D-3. Risk of bias assessment for all Key Questions – nonrandomized comparative studies, assessment of remaining biases, quality, and overall risk of bias

KQ	Study, Year, PMID	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1	Brito, 2020, No PMID	High	High	High	Low	Low	Low	Low	Yes	Yes	Yes	**High**
1	Chetta, 2017, 28002254	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	de Araujo, 2016, 27673527	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Eltahir, 2015, 25539295	High	Unclear	N/A	Unclear	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Fischer, 2013, 23629074	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Fischer, 2014, 24916480	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Fischer, 2015, 26366550	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Garvey, 2012, 23096600	High	High	High	N/A	Low	Low	Low	Yes	Unclear	Yes	**Moderate**
1	Ha, 2020, 32000718	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Hangge, 2019, 31606126	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Jiang, 2013, 24349366	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Kouwenberg, 2019, 30270015	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Kouwenberg, 2020, 32590633	High	High	High	High	Unclear	Low	Low	Yes	Unclear	Yes	**Moderate**
1	Laporta, 2017, 28061518	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Lei, 2020, 32481367	High	High	High	N/A	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Liu, 2014, 24558063	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Mak, 2020, 32665188	High	High	N/A	Low	Low	Low	Low	No	Yes	Yes	**Moderate**

KQ	Study, Year, PMID	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1	McCarthy, 2014, 24201740	High	High	N/A	High	Low	Low	Low	Yes	Unclear	Yes	**Moderate**
1	Merchant, 2015, 26111325	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**High**
1	Mioton, 2013, 23562485	High	High	High	High	Low	Low	Low	Unclear	Unclear	Yes	**Moderate**
1	Momeni, 2018, 29095189	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**High**
1	Naoum, 2020a, 31756414	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Naoum, 2020b, 32607638	High	High	N/A	Low	Low	Low	Low	Yes	Yes	Yes	**High**
1	Nasser, 2018, 30204678	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**High**
1	Nelson, 2019, 31356276	High	High	N/A	Unclear	Low	Low	High	Yes	Yes	Yes	**High**
1	Palve, 2020, 32468337	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Qin, 2018, 29384865	High	High	High	High	Low	High	Low	Yes	Unclear	No	**High**
1	Roth, 2007, 17413877	High	High	N/A	Unclear	Low	Low	Low	Yes	Yes	Yes	**High**
1	Shiraishi, 2020, 32589082	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1	Simon, 2020, 33363007	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Wu, 2021, 33740204	High	High	N/A	Low	Unclear	Low	Low	Yes	Yes	Yes	**High**
1	Xu, 2018, 30261115	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1	Zhang, 2019, 30675702	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1, 6	Abedi, 2016, 25003437	Unclear	Unclear	High	N/A	Low	Low	Low	No	Yes	Yes	**High**
1, 6	Carramaschi, 1989, 2602589	Low	Low	Low	N/A	Low	Low	Low	Yes	Yes	Unclear	**High**

KQ	Study, Year, PMID	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1, 6	Dauplat, 2021, 33622886	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**Moderate**
1, 6	Garbay, 1992, 1624727	High	High	N/A	High	Low	Low	Low	No	No	Yes	**High**
1, 6	Kulkarni, 2017, 28713853	High	High	High	High	Unclear	Low	Low	Yes	Yes	Yes	**Moderate**
1, 6	Woo, 2018, 30360958	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
1, 6	Yueh, 2009, 19228537	High	High	N/A	Unclear	Low	Low	Low	Yes	Yes	Yes	**High**
2	Eriksson, 2013, 24258257	High	High	Low	Low	Low	Low	Low	Yes	No	Yes	**High**
2	Yoon, 2020, 32332528	High	High	High	High	Low	Low	Low	Yes	Yes	Unclear	**Moderate**
2, 3	Cordeiro, 2015a, 25742523	High	High	High	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
2, 5	Hirsch, 2014, 25347643	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
2, 5	Stein, 2020, 32561384	High	High	N/A	Low	Low	Low	Low	Yes	Yes	Yes	**High**
3	Antony, 2014, 24135689	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
3	Le, 2005, 15743498	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**High**
3	Macadam, 2010, 20009795	High	High	N/A	Unclear	Low	Low	Low	Yes	Yes	Yes	**High**
3	McCarthy, 2010, 21136577	High	High	N/A	High	Low	Low	Low	Unclear	Unclear	Yes	**High**
4	Avila, 2020, 33234947	High	High	Unclear	Low	Low	Low	Low	Yes	Yes	Yes	**High**
4	Gabriel, 2020, 32195862	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**High**
4	Kim, 2020, 33066236	High	High	High	N/A	Low	Low	Low	Yes	Yes	Yes	**Moderate**

KQ	Study, Year, PMID	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
4	Kraenzlin, 2021, 32568752	High	High	High	High	Low	High	Low	Yes	Yes	Yes	**High**
4	Nealon, 2020a, 32032345	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
4	Ozgur, 2020, 33223365	High	High	N/A	Low	Low	Low	Low	Yes	Yes	Yes	**High**
4, 5	Cattelani, 2018, 29275104	High	High	Unclear	Unclear	Low	Low	Low	Yes	Yes	Yes	**High**
5	Brooke, 2012, 22868313	High	High	High	N/A	High	Low	Low	Yes	Yes	Yes	**High**
5	Chun, 2010, 20124828	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Craig, 2019, 29800083	Low	Low	Low	Low	Unclear	Low	Low	Yes	Unclear	Yes	**Low**
5	Ibrahim, 2013, 24165587	High	High	High	High	Low	Low	Low	Yes	Unclear	Yes	**Moderate**
5	Ganesh Kumar, 2021, 33172826	High	High	High	High	Low	Low	Low	Yes	Unclear	Yes	**Moderate**
5	Lee, 2020, No PMID	High	High	N/A	Low	Low	Low	Low	Yes	Yes	Yes	**High**
5	Liu, 2011, 21228744	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Nealon, 2020b, 31605310	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Pannucci, 2013, 23508050	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**Moderate**
5	Peled, 2012, 22634688	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Qureshi, 2016, 27465177	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Safran, 2020, 32221195	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Seth, 2012, 23018687	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Sobti, 2018, 29481386	Low	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**

KQ	Study, Year, PMID	Blinding of Participants	Blinding of Personnel/ Care Providers	Blinding of Outcome Assessors (Objective Outcomes)	Blinding of Outcome Assessors (Subjective Outcomes)	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
5	Vardanian, 2011, 22030500	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
5	Weichman, 2012, 22544088	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Unclear	**Moderate**
5	Woo, 2017, 28509694	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
6	Baumann, 2010, 20440154	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
6	Erdmann-Sager, 2018, 29019862	High	High	High	High	Low	Low	Low	Yes	Unclear	Yes	**Moderate**
6	Israeli, 2014, 24572840	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
6	Knox, 2016, 26267400	High	High	Unclear	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
6	Kroll, 2000, 10987463	High	High	N/A	High	Low	Low	Low	Yes	Yes	Yes	**High**
6	Macadam, 2016, 26910656	High	High	Low	Unclear	Low	Low	Unclear	Yes	Yes	Yes	**High**
6	Massenburg, 2015, 26487657	High	High	High	High	Low	Unclear	Low	No	Unclear	Yes	**High**
6	Mennie, 2015, 25839173	High	High	Low	N/A	Low	Low	Low	Yes	Yes	Yes	**High**
6	Zhong, 2014, 24675183	High	High	Low	N/A	Low	Low	Unclear	Yes	Yes	Yes	**High**
6	Zoghbi, 2017, 28052051	High	High	High	High	Unclear	Low	Low	Yes	Unclear	Yes	**High**

Abbreviations: KQ = Key Question, N/A = not applicable, NRCS = nonrandomized comparative study, PMID = PubMed identifier.
Ratings are color coded for emphasis only. The colors do not impart unique information.
From the Cochrane Risk of Bias Tool (each item rated as Low, High, Unclear, or N/A)

- Blinding of participants (performance bias): Performance bias due to knowledge of the allocated interventions by participants during the study.
- Blinding of personnel/care providers (performance bias): Performance bias due to knowledge of the allocated interventions by personnel/care providers during the study.
- Blinding of outcome assessor (detection bias): Detection bias due to knowledge of the allocated interventions by outcome assessors during the study.
- Incomplete outcome data (attrition bias): Attrition bias due to amount, nature or handling of incomplete outcome data.
- Selective outcome reporting (outcome reporting bias): Bias arising from outcomes being selectively reported based on the direction and/or strength of the results.
- Other BiaStages: Bias due to problems not covered elsewhere in the table.

From the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool (each item rated as Yes, No, Unclear, or No Data)

- Eligibility criteria prespecified and clearly described: potentially related to selection bias.
- Intervention clearly described and delivered consistently: potentially related to performance bias.
- Outcomes prespecified, clearly defined, valid, reliable, and assessed consistently: potentially related to detection bias.

Overall risk of bias assessed as **HIGH**, **MODERATE**, or **LOW**.

Table D-4. Risk of bias and quality assessment for all Key Questions – single group studies

KQ	Study, Year, PMID	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1	Acosta, 2011, 21046538	Low	High	Low	No	Yes	No	**High**
1	Albornoz, 2013, 23897346	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Andree, 2012, 23197233	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Banuelos, 2020, 31663932	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Beugels, 2018, 29399731	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Brooks, 2012, 22098451	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chang, 2000, 10809092	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chang, 2011, 21407063	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chang, 2016, 25003429	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chen, 2014, 25620484	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chen, 2016, 27930584	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chen, 2018a, 29596085	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Chen, 2018b, 29596085	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Cleveland, 2013, 23945529	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Collier, 2019, 31461001	Low	Low	Unclear	Yes	Yes	Yes	**Moderate**
1	Cordeiro, 2006, 16980842	Unclear	Low	Low	Yes	Yes	Yes	**Moderate**
1	Cordeiro, 2012, 22286416	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Cordeiro, 2015b, 26090764	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Coroneos, 2019, 30222598	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Daly, 2020, 31994156	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Enajat, 2010, 19790180	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Fitzgerald, 2016, 27047776	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Gfrerer, 2015, 25626807	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Gill, 2004, 15083015	Low	Low	Unclear	Yes	Unclear	Yes	**Moderate**
1	Haddock, 2019, 31461004	Low	Low	Low	No	Yes	Yes	**Moderate**
1	Haddock, 2020, 33487570	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Hamdi, 2010, 20679823	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Hamdi, 2011, 20576480	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Hansen, 2018, 29778821	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Heo, 2018, 30039735	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Hunsicker, 2017, 26849284	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Huo, 2016, 27697676	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Jo, 2020, 33386262	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Kanuri, 2014, 24675199	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Kato, 2013, 24011080	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Langer, 2010, 20980954	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Lantieri, 2015, 26238173	Low	Low	Low	Unclear	Unclear	No	**Moderate**

KQ	Study, Year, PMID	Incomplete Outcome Data	Selective Outcome Reporting	Other Bias	Eligibility Criteria Prespecified and Clearly Described	Intervention Clearly Described and Consistently Delivered	Outcomes Prespecified, Clearly Defined, Valid, Reliable, and Consistently Assessed	Overall RoB
1	Law, 2018, 30463754	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Lee, 2021a, 32974692	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Liao, 2008, 18349626	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Lovecchio, 2015, 24691330	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Masoomi, 2019, 31331721	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Mehrara, 2006, 17016173	Low	Low	Low	Unclear	No	Yes	**Moderate**
1	Mirzabeigi, 2015, 25811579	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Munder, 2021, 32565553	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Nelson, 2014, 25046665	Low	Unclear	Low	Yes	Unclear	Yes	**Moderate**
1	O'Neill, 2019, 31196805	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Parikh, 2018, 30204676	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Park, 2019, 30863940	Low	Low	Low	Yes	Yes	Unclear	**Moderate**
1	Phan, 2020, 31124177	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Polanco, 2021, 33745850	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Potter, 2019, 30639093	Low	Low	Low	Yes	No	Yes	**Moderate**
1	Prantl, 2020, 32895743	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Rogoff, 2020, 32243320	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Rubio, 2019, 30665841	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Salibian, 2019, 31333984	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Seidenstuecker, 2016, 27017243	Unclear	Unclear	Low	Yes	Yes	Yes	**Moderate**
1	Selber, 2009, 19935283	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Seth, 2015, 25180955	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Sewart, 2021, 33609398	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Shaikh, 2010, 22693373	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Singh, 2012, 22342636	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Singh, 2021, 33564597	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Song, 2016, 26637165	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Tran, 2018, 29794694	Low	Low	Low	Yes	Yes	Yes	**Low**
1	Watterson, 1995, 7761505	Low	Low	Low	No	Yes	Yes	**Moderate**
1	Warren, 2020, 33040748	Low	Low	Low	Yes	No	Yes	**Moderate**
1	Williams, 1995, 7794079	Low	Low	Low	No	Yes	Yes	**Moderate**
1	Yoo, 2014, 24852813	Low	Low	Low	Unclear	Unclear	Yes	**Moderate**

Abbreviations: KQ = Key Question, PMID = PubMed identifier, RoB = risk of bias.
Ratings are color coded for emphasis only.
From the Cochrane Risk of Bias Tool (each item rated as Low, High, Unclear, N/A)

- Incomplete outcome data (attrition bias): Attrition bias due to amount, nature or handling of incomplete outcome data.
- Selective outcome reporting (outcome reporting bias): Bias arising from outcomes being selectively reported based on the direction and/or strength of the results.
- Other BiaStages: Bias due to problems not covered elsewhere in the table.

From the National Heart, Lung, and Blood Institute (NHLBI) Quality Assessment Tool (each item rated as Yes, No, Unclear, or No Data)

- Eligibility criteria prespecified and clearly described: potentially related to selection bias.
- Intervention clearly described and delivered consistently: potentially related to performance bias.
- Outcomes prespecified, clearly defined, valid, reliable, and assessed consistently: potentially related to detection bias.

Overall risk of bias assessed as **HIGH**, **MODERATE**, **LOW**.

Appendix E. Results: Summary Tables for Outcomes

Table E-1.1. Summary Table – Key Question 1: IBR versus AR – continuous outcomes (general quality of life, psychosocial well-being, sexual well-being, patient satisfaction with breasts, and patient satisfaction with outcome)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	IBR, N	IBR, Mean (SD)	AR, N	AR, Mean (SD)	AR Versus IBR, Effect Size (95% CI)	P Value
Kouwenberg, 2019, 30270015, Netherlands	NRCS	Moderate	General QoL	EQ-5D-5L utilities score (0-1)	NR	All	67	0.85 (0.18)	67	0.87 (0.14)	NR	0.7
Kouwenberg, 2020, 32590633, Netherlands	NRCS	Moderate	General QoL	EQ-5D-5L utilities score (0-1)	>6 mo	All	296	0.85 (0.30)	179	0.85 (0.20)	NR	NS
	NRCS	Moderate	General QoL	EQ-5D-5L VAS (0-100)	>6 mo	All	296	77.6 (18.4)	179	79.2 (16.7)	NR	NS
	NRCS	Moderate	General QoL	EORTC QLQC30: Global health status (0-100)	>6 mo	All	296	80.2 (18.4)	179	81.4 (14.7)	NR	NS
Roth, 2007, 17413877, US	NRCS	High	General QoL	FACT-B: Functional well-being (0-28)	2 y	All	35	23.3 (NR)	55	24.1 (NR)	NR	NS
	NRCS	High	General QoL	SF-36: Role emotional (0-100)	2 y	All	35	86.7 (NR)	55	86.1 (NR)	NR	NS
	NRCS	High	General QoL	SF-36: Vitality (0-100)	2 y	All	35	65.7 (NR)	55	62.4 (NR)	NR	NS
	NRCS	High	General QoL	SF-36: General mental health (0-100)	2 y	All	35	77.6 (NR)	55	77 (NR)	NR	NS
	NRCS	High	General QoL	Body Image (9-45)	2 y	All	35	32.5 (NR)	55	35.3 (NR)	NR	NS
Tallroth, 2020, 33436336, Sweden	RCT	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	5.3 y	All	28	78.8 (20.1)	42	79.1 (21.5)	MD 0.3 (−6.7, 7.3)	0.93
Eltahir, 2015, 25539295, Netherlands	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	2.2 y	All	45	77.2 (18.1)	47	74.0 (17.8)	adjMD 4.6 (−2.8, 12.0)	0.22
	NRCS	Moderate	Psychosocial WB	SF-36: Social functioning (0-100)	2.2 y	All	NR	NR	NR	NR	adjMD −1.21 (−8.44, 6.02)	0.74

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	IBR, N	IBR, Mean (SD)	AR, N	AR, Mean (SD)	AR Versus IBR, Effect Size (95% CI)	P Value
Kouwenberg, 2020, 32590633, Netherlands	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	>6 mo	All	296	71.6 (20.2)	179	75.8 (19.5)	NR	<0.05
	NRCS	Moderate	Psychosocial WB	EORTC QLQC30: Social function (0-100)	>6 mo	All	296	87.5 (27.2)	179	88.0 (17.1)	NR	NS
	NRCS	Moderate	Psychosocial WB	EORTC QLQC30: Emotional function (0-100)	>6 mo	All	296	85.0 (23.3)	179	87.0 (17.1)	NR	NS
	NRCS	Moderate	Psychosocial WB	EORTC QLQC30: Cognitive function (0-100)	>6 mo	All	296	85.0 (23.7)	179	83.7 (21.5)	NR	NS
	NRCS	Moderate	Psychosocial WB	EORTC QLQC30: Role function (0-100)	>6 mo	All	296	86.0 (28.1)	179	84.0 (21.8)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	1 y	All	791	71.8 (19)	386	74.7 (19.2)	adjMD 3.70 (0.73, 6.76)	0.015
	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	2 y	All	1490	74.5 (18.9)	523	75.8 (19)	adjMD 3.27 (1.25, 5.29)	NR
	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	2 y	Unilateral	600	74.6 (18.7)	317	76.8 (18.9)	adjMD 3.84 (NR)	NR
	NRCS	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	2 y	Bilateral	994	74.5 (19)	224	73.4 (19)	adjMD 0.91 (NR)	NR
	NRCS	Moderate	Psychosocial WB	PROMIS: Anxiety (0-100)	1 y	All	775	49.7 (9.4)	383	50.4 (9.6)	adjMD 0.70 (−0.75, 2.08)	0.36
	NRCS	Moderate	Psychosocial WB	PROMIS: Depression (0-100)	1 y	All	776	47.3 (8)	385	47.9 (8.2)	adjMD 0.40 (−0.70, 1.45)	0.50
Roth, 2007, 17413877, US	NRCS	High	Psychosocial WB	FACT-B: Social/ family WB (0-28)	2 y	All	35	19.3 (NR)	55	20.3 (NR)	NR	0.24
	NRCS	High	Psychosocial WB	SF-36: Social functioning (0-100)	2 y	All	35	87.9 (NR)	55	87.7 (NR)	NR	≥0.05

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	IBR, N	IBR, Mean (SD)	AR, N	AR, Mean (SD)	AR Versus IBR, Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	RCT	Moderate	Sexual WB	BREAST-Q: Sexual well-being (0-100)	5.3 y	All	28	58.4 (23.1)	42	67.1 (28.1)	MD 8.7 (0.2, 17.2)	0.046
Eltahir, 2015, 25539295, Netherlands	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual well-being (0-100)	2.2 y	All	45	61.14 (24.17)	47	60.89 (20.82)	adjMD 6.44 (−3.56, 16.5)	0.20
Kouwenberg, 2020, 32590633, Netherlands	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual well-being (0-100)	>6 mo	All	296	56.4 (30.7)	179	63.3 (30.4)	NR	<0.05
	NRCS	Moderate	Sexual WB	EORTC QLQBR23: Sexual functioning (0-100)	>6 mo	All	296	33.4 (29.4)	179	32.0 (27.3)	NR	<0.05
	NRCS	Moderate	Sexual WB	EORTC QLQBR23: Sexual enjoyment (0-100)	>6 mo	All	296	63.8 (32.5)	179	64.2 (33.8)	NR	NS
Kulkarni, 2017, 28713853, US & Canada	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual WB (0-100)	1 y	All	756	53 (21.1)	370	55.4 (19.8)	adjMD 4.50 (1.52, 7.48)	0.003
	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual WB (0-100)	2 y	All	1490	53.9 (21.3)	523	57.1 (21.7)	adjMD 5.53 (−2.95, 8.11)	NR
	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual WB (0-100)	2 y	Unilateral	600	52.8 (20.5)	317	58.9 (20.6)	adjMD 11.42 (NR)	<0.001
	NRCS	Moderate	Sexual WB	BREAST-Q: Sexual WB (0-100)	2 y	Bilateral	994	54.7 (21.5)	214	54.4 (23)	adjMD 4.2 (NR)	<0.001
Tallroth, 2020, 33436336, Sweden	RCT	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	5.3 y	All	28	63.4 (11.8)	42	72.1 (17.7)	MD 8.7 (3.8, 13.6)	0.001
	RCT	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with nipples (0-100)	5.3 y	All	28	65.4 (21.8)	42	67.7 (24.9)	MD 2.3 (−5.5, 10.1)	0.56
Brito, 2020, No PMID, Portugal	NRCS	High	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	NR	All	68	56.3 (17.1)	111	64.1 (17.1)	NR	0.004
Eltahir, 2015, 25539295, Netherlands	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2.2 y	All	45	65.51 (17.55)	47	75.19 (17.09)	adjMD 8.16 (1.18, 15.2)	0.023
	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with nipples (0-100)	2.2 y	All	45	63.62 (33.99)	47	65.31 (27.82)	adjMD 1.70 (−14.2, 17.6)	0.83
Kouwenberg, 2020,	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	>6 mo	All	296	59.4 (19.3)	179	71.3 (17.7)	NR	<0.05

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	IBR, N	IBR, Mean (SD)	AR, N	AR, Mean (SD)	AR Versus IBR, Effect Size (95% CI)	P Value
32590633, Netherlands	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with nipples (0-100)	>6 mo	All	296	55.0 (48.7)	179	63.0 (29.0)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	1 y	All	795	64.0 (16.8)	388	67.8 (17.2)	adjMD 6.30 (3.41, 9.09)	<0.001
	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	All	1490	64.2 (18)	523	68.5 (18.3)	adjMD 7.94 (5.68, 10.2)	NR
	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	Unilateral	600	61.2 (18)	317	68.3 (18.1)	adjMD 9.85 (NR)	0.001
	NRCS	Moderate	Satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	Bilateral	994	66.1 (17.7)	214	68.9 (18.6)	adjMD 5.13 (2.07, 8.17)*	0.001
Tallroth, 2020, 33436336, Sweden	RCT	Moderate	Satisfaction with outcome	BREAST-Q: Satisfaction with outcome (0-100)	5.3 y	All	28	79.4 (14.2)	42	82.3 (21.4)	MD 2.9 (−3.1, 8.9)	0.34
Eltahir, 2015, 25539295, Netherlands	NRCS	Moderate	Satisfaction with outcome	BREAST-Q: Satisfaction with outcome (0-100)	2.2 y	All	45	74.5 (19.0)	47	81.8 (18.7)	adjMD 4.9 (−3.1, 12.9)	0.23
Kouwenberg, 2020, 32590633, Netherlands	NRCS	Moderate	Satisfaction with outcome	BREAST-Q: Satisfaction with outcome (0-100)	>6 mo	All	296	66.4 (23.7)	179	75.8 (22.2)	NR	<0.05

Abbreviations: adj = adjusted, CI = confidence interval, QoL = quality of life, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation, VAS = Visual Analog Scale, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.
* Confidence interval calculated based on the reported P value.

Table E-1.2. Summary Table – Key Question 1: IBR versus AR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Design	Overall RoB	Outcome Measurement	Time Point	Group	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	RCT	Moderate	BREAST-Q: Chest (0-100)	5.3 y	IBR	All	28	72.0 (21.5)	Ref	Ref
	RCT	Moderate	BREAST-Q: Chest (0-100)	5.3 y	AR	All	42	79.6 (21.1)	MD 7.6 (0.3, 14.9)	0.041
Eltahir, 2015, 25539295, Netherlands	NRCS	Moderate	BREAST-Q: Physical WB (0-100)	2.2 y	IBR	All	45	71.89 (15.06)	Ref	Ref
	NRCS	Moderate	BREAST-Q: Physical WB (0-100)	2.2 y	AR	All	47	77.13 (17.11)	adjMD −2.60 (−9.77, 4.57)	0.47
	NRCS	Moderate	SF-36: Physical function (0-100)	2.2 y	IBR	All	45	NR	Ref	Ref
	NRCS	Moderate	SF-36: Physical function (0-100)	2.2 y	AR	All	NR	NR	adjMD 2.13 (−4.20, 8.46)	0.51
Kouwenberg, 2020, 32590633, Netherlands	NRCS	Moderate	BREAST-Q: Chest (0-100)	>6 mo	IBR	All	296	72.6 (17.8)	Ref	Ref
	NRCS	Moderate	BREAST-Q: Chest (0-100)	>6 mo	AR	All	179	75.8 (15.4)	NR	<0.05
	NRCS	Moderate	EORTC QLQC30 (0-100)	>6 mo	IBR	All	296	88.0 (20.6)	Ref	Ref
	NRCS	Moderate	EORTC QLQC30 (0-100)	>6 mo	AR	All	179	85.6 (15.7)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	NRCS	Moderate	BREAST-Q: Chest (0-100)	1 y	IBR (all)	All	791	76.7 (14.5)	Ref	Ref
	NRCS	Moderate	BREAST-Q: Chest (0-100)	1 y	AR (all)	All	386	74.9 (15.1)	adjMD 1.60 (−0.57, 3.68)	0.003
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	IBR (all)	All	NR	NR	NR	NR
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	IBR (all)	Unilateral	600	77.2 (13.8)	NR	NR
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	IBR (all)	Bilateral	994	77.3 (14.6)	NR	NR
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	AR (all)	All	NR	NR	NR	NR
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	AR (all)	Unilateral	317	76.3 (15.4)	vs. IBR (Unilateral): adjMD 1.77 (−1.17, 4.71)*	0.24
	NRCS	Moderate	BREAST-Q: Chest (0-100)	2 y	AR (all)	Bilateral	224	74.5 (15.4)	vs. IBR (Bilateral): adjMD 0.57 (−1.40, 2.54)*	0.57
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	IBR (all)	All	1490	NR	NR	NR
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	IBR DTI	All	93	NR	Ref	Ref

Study, Year, PMID, Country	Design	Overall RoB	Outcome Measurement	Time Point	Group	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Kulkarni, continued	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	IBR TE	All	1263	NR	Ref	Ref
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	AR (all)	All	1523	75.6 (15.4)	vs. IBR (all): adjMD 1.69 (0.13, 3.24)	NR
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	AR with DIEP	All	350	NR	vs. IBR (TE): adjMD −1.44 (−4.11, 1.23)*	0.29
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	AR with free TRAM	All	87	NR	vs. IBR (TE): adjMD −0.62 (−4.78, 3.54)*	0.77
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	2 y	AR with pedicled TRAM	All	77	NR	vs. IBR (TE): adjMD −3.93 (−8.15, 0.29)*	0.068
	NRCS	Moderate	PROMIS: Pain interference (0-100)	2 y	IBR (all)	All	773	46 (7.5)	Ref	Ref
	NRCS	Moderate	PROMIS: Pain interference (0-100)	2 y	AR (all)	All	384	48.4 (8.4)	adjMD 1.10 (0.01, 2.25)	0.048
	NRCS	Moderate	PROMIS: Physical function (0-100)	1 y	IBR (all)	All	777	52.2 (6.8)	Ref	Ref
	NRCS	Moderate	PROMIS: Physical function (0-100)	1 y	AR (all)	All	385	50.1 (7.2)	adjMD −0.60 (−1.51, 0.39)	0.25
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	IBR (all)	All	NR	NR	NR	NR
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	IBR (all)	Unilateral	600	52.6 (6.5)	NR	NR
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	IBR (all)	Bilateral	994	52.8 (6.3)	NR	NR
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	AR (all)	All	NR	NR	NR	NR
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	AR (all)	Unilateral	317	51.3 (7.3)	vs. IBR (unilateral): adjMD −0.14 (−1.42, 1.14)*	0.83
	NRCS	Moderate	PROMIS: Physical function (0-100)	2 y	AR (all)	Bilateral	214	49.8 (7.6)	vs. IBR (bilateral): adjMD −1.21 (−2.47, 0.05)*	0.06
McCarthy, 2014, 24201740, US	NRCS	Moderate	BREAST-Q: Physical WB (0-100)	1-5 y	IBR	All	141	76.5 (16)	Ref	Ref
	NRCS	Moderate	BREAST-Q: Physical WB (0-100)	1-5 y	AR	All	74	82.5 (15.3)	NR	<0.05

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, DTI = direct to implant, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PROMIS: Patient Reported Outcomes Measurement Information System, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* Confidence interval calculated based on the reported P value.

Table E-1.3. Summary Table – Key Question 1: IBR versus AR – NRCSs, categorical outcomes (physical well-being and recurrence of breast cancer)

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Measurement	Time Point	IBR, n/N (%)	AR, n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Nelson, 2019, 31356276, US	High	Physical WB	Higher BREAST-Q: Chest	1 y	NR/1342 (NR)	NR/194 (NR)	0.96 (0.67, 1.38)	NS
	High	Physical WB	Higher BREAST-Q: Chest	3 y	NR/1085 (NR)	NR/98 (NR)	1.4 (0.83, 2.34)	NS
	High	Physical WB	Higher BREAST-Q: Chest	5 y	NR/743 (NR)	NR/41 (NR)	4.52 (2.03, 10.1)	<0.001
	High	Physical WB	Higher BREAST-Q: Chest	7 y	NR/377 (NR)	NR/19 (NR)	3.08 (1.03, 9.15)	0.043
Ha, 2020, 32000718, South Korea	High	Breast cancer recurrence	High histologic grade (Grade III) breast cancer	4.8 y	14/247 (5.7)	24/249 (9.6)	3.39 (1.23, 9.32)	0.018
	High	Breast cancer recurrence	Locoregional breast cancer	4.8 y	9/247 (3.6)	11/249 (4.4)	NR	0.70
Kouwenberg, 2020, 32590633, Netherlands	Moderate	Breast cancer recurrence	Local recurrence	>6 mo	13/296 (4.5	7/179 (4.0)	0.89 (0.35, 2.26)	0.25
	Moderate	Breast cancer recurrence	Distant recurrence	>6 mo	13/296 (4.5)	8/179 (4.6)	1.02 (0.41, 2.51)	0.97
Wu, 2021, 33740204, South Korea	High	Breast cancer recurrence	NR	5.8 y	29/138 (21.0)	64/276 (23.2)	NR	0.62

Abbreviations: AR = autologous reconstruction, CI = confidence interval, mo = months, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, WB = well-being, y = years.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-1.4. Summary Table – Key Question 1: IBR versus AR – NRCSs, categorical outcomes (patient satisfaction with breasts and with outcome)

Study, Year, PMID, Country	Overall RoB	Outcome Measurement	Time Point	Group	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Lei, 2020, 32481367, China	High	Satisfied with breasts	2 mo	IBR	NR	Ref	Ref	Ref
	High	Satisfied with breasts	2 mo	AR	NR	vs. IBR	0.85 (0.36, 1.63)	0.40
Yueh, 2009, 19228537, US	High	Satisfied with breasts	NR	IBR	42/87 (48.3)	Ref	Ref	Ref
	High	Satisfied with breasts	NR	AR	NR/389 (NR)	vs. IBR	1.43 (1.18, 1.73)	NR
	High	Satisfied with breasts	NR	AR with TRAM	102/143 (71.3)	vs. IBR	3.49 (1.91, 6.40)	NR
	High	Satisfied with breasts	NR	AR with LD	68/112 (60.7)	vs. IBR	1.99 (1.09, 3.65)	NR
Lei, 2020, 32481367, China	High	Satisfied with surgical outcome	2 mo	IBR	NR	Ref	Ref	Ref
	High	Satisfied with surgical outcome	2 mo	AR	NR	vs. IBR	0.69 (0.45, 1.67)	0.33
Yueh, 2009, 19228537, US	High	Satisfied with surgical outcome	NR	IBR	49/87 (56.3)	Ref	Ref	Ref
	High	Satisfied with surgical outcome	NR	AR	NR/389 (NR)	vs. IBR	1.83 (1.11, 3.03)	NR
	High	Satisfied with surgical outcome	NR	AR with TRAM	98/143 (68.5)	vs. IBR	2.05 (1.13, 3.72)	NR
	High	Satisfied with surgical outcome	NR	AR with LD	63/112 (56.3)	vs. IBR	1.12 (0.64, 2.12)	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, mo = months, RCT = randomized controlled trial, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-1.5. Summary Table – Key Question 1: IBR versus AR – categorical outcomes, mortality, unplanned repeat hospitalizations, necrosis, thromboembolic events, wound dehiscence, delayed healing, seroma, and hematoma

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Description	Time Point	IBR n/N (%)	AR n/N (%)	Adjusted Odds Ratio (95% CI) for AR versus IBR	P Value
Jiang, 2013, 24349366, US	NRCS	High	Mortality	Overall mortality	8.9 y	241/1412 (17.1)	503/2649 (19.0)	0.96 (0.89, 1.04)	NR
	NRCS	High	Mortality	Breast cancer-specific mortality	8.9 y	209/1412 (14.8)	432/2649 (16.3)	0.95 (0.87, 1.04)	NR
Merchant, 2015, 26111325, US	NRCS	High	Unplanned repeat hospitalizations	Any unplanned readmission	1 mo	338/10437 (3.24)	95/2329 (4.08)	1.07 (0.95, 1.20)	NR
Mioton, 2013, 23562485, US	NRCS	Moderate	Unplanned repeat hospitalizations	Any unplanned readmission	1 mo	172/3960 (4.34)	56/1052 (5.32)	NR	NS
Nasser, 2018, 30204678	NRCS	High	Unplanned repeat hospitalizations	Unplanned ED visits	1 mo	NR/28124 (NR)	NR/4773 (NR)	1.11 (0.91, 1.25)	0.18
	NRCS	High	Unplanned repeat hospitalizations	Unplanned ED visits with pain-related diagnosis	1 mo	NR/28124 (NR)	NR/4773 (NR)	1.11 (0.83, 1.67)	0.41
Abedi, 2016, 25003437, Canada	NRCS	High	Necrosis	Mastectomy flap necrosis	1.6-1.9 y	70/606 (11.6)	60/395 (15.2)	0.66 (0.38, 1.16)	0.15
de Araujo, 2016, 27673527, US	NRCS	High	Necrosis	Major mastectomy flap necrosis	4.3 y	NR/38 (NR)	NR/32 (NR)	17.9 (0.52, 610.5)	0.11
Naoum, 2020a, 31756414, US	NRCS	High	Necrosis	Mastectomy flap necrosis	4-10 y	26/633 breasts (4.1)	16/342 breasts (4.7)	0.83 (0.19, 3.50)	0.8
	NRCS	High	Necrosis	Fat necrosis	4-10 y	1/633 breasts (0.2)	24/342 breasts (7.0)	21.2 (2.5, 174.5)	0.004
Woo, 2018, 30360958, South Korea	NRCS	High	Necrosis	Mastectomy flap necrosis	NR	14/60 (23.3)	7/70 (10)	0.31 (0.11, 0.86)	0.02
Brorson 2020a, 32807615, Sweden	RCT	High	Thromboembolic events	DVT	1 mo	0/66 (0)	0/51 (0)	No events	N/A
	RCT	High	Thromboembolic events	PE	1 mo	1/66 (1.5)	0/51 (0)	Not calculable (no events in AR group)	Not calculable
Tallroth, 2020, 3346336, Sweden	RCT	Moderate	Thromboembolic events	DVT	1 mo	1/28 (3.6)	0/42 (0)	Not calculable (no events in AR group)	Not calculable
	RCT	Moderate	Thromboembolic events	Arterial stop	1 mo	0/28 (0)	2/42 (4.8)	Not calculable (no events in IBR group)	Not calculable
	RCT	Moderate	Thromboembolic events	Venous stasis	1 mo	0/28 (0)	6/42 (14.3)	Not calculable (no events in IBR group)	Not calculable

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Description	Time Point	IBR n/N (%)	AR n/N (%)	Adjusted Odds Ratio (95% CI) for AR versus IBR	P Value
Mioton, 2013, 23562485, US	NRCS	Moderate	Thromboembolic events	DVT	1 mo	27/9786 (0.28)	20/3296 (0.61)	0.99 (0.41, 2.41)	NR
	NRCS	Moderate	Thromboembolic events	PE	1 mo	17/9786 (0.17)	17/3296 (0.52)	1.84 (0.71, 4.77)	NR
Momeni, 2018, 29095189, US	NRCS	High	Thromboembolic events	DVT or PE	3 mo	65/16851 (3.85)	815/4622 (17.63)	2.27 (1.79, 2.86)	NR
Garvey, 2012, 23096600, US	NRCS	Moderate	Wound dehiscence	NR	1.5 y	28/442 breasts (6.3)	25/548 breasts (4.6)	NR	0.25
Mioton, 2013, 23562485, US	NRCS	Moderate	Wound dehiscence	Wound disruption	1 mo	44*/9786 (0.44)	41*/3296 (1.24)	1.79 (0.83, 3.84)	NR
Fischer, 2013, 23629074, US	NRCS	High	Delayed healing	Delayed breast wound healing	4 y	9/60 (15)	52/142 (36.6)	2.2 (1.0, 5.2)	0.06
Garvey, 2012, 23096600, US	NRCS	Moderate	Delayed healing	NR	1.5 y	19/442 breasts (4.3)	41/548 breasts (7.5)	NR	0.01
Fischer, 2014, 24916480, US	NRCS	High	Seroma	Breast seroma	1.8-2.1 y	13/155 (8.1)	4/155 (2.8)	NR	0.009
Garvey, 2012, 23096600, US	NRCS	Moderate	Seroma	Breast seroma or hematoma	1.5 y	61/442 breasts (13.8)	27/548 breasts (4.9)	NR	<0.001
Fischer, 2014, 24916480, US	NRCS	High	Hematoma	Breast hematoma	1.8-2.1 mo	4/155 (2.4)	4/155 (2.8)	NR	1.0

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DVT = deep vein thrombosis, ED = emergency department, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PE = pulmonary embolism, PMID = PubMed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

*calculated

Table E-1.6. Summary Table – Key Question 1: IBR versus AR – NRCSs, categorical outcomes (unplanned repeat surgeries for revision, unplanned repeat surgeries for complications, pain, infections not explicitly implant related, and reconstructive failure)

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Description	Time Point	Group	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Fischer, 2014, 24916480, US	High	Unplanned repeat surgery for revision	Unplanned revision	<6 mo	IBR	All	8/155 (5.2)	Ref	Ref
	High	Unplanned repeat surgery for revision	Unplanned revision	<6 mo	AR	All	6/155 (3.9)	NR	0.56
	High	Unplanned repeat surgery for revision	Unplanned revision	<1 y	IBR	All	17/155 (11.0)	Ref	Ref
	High	Unplanned repeat surgery for revision	Unplanned revision	<1 y	AR	All	7/155 (4.5)	NR	0.017
	High	Unplanned repeat surgery for revision	Unplanned revision	<2 y	IBR	All	21/155 (13.5)	Ref	Ref
	High	Unplanned repeat surgery for revision	Unplanned revision	<2 y	AR	All	7/155 (4.5)	NR	0.003
Kulkarni, 2017, 28713853, US & Canada	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	IBR DTI	All	31/93 (33.3)	-	-
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	IBR TE	All	503/1263 (39.8)	Ref	Ref
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	AR with DIEP	All	223/350 (63.7)	vs. IBR with TE: 2.66 (1.83, 3.86)	<0.001
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	AR with free TRAM	All	56/87 (64.4)	vs. IBR with TE: 2.26 (1.35, 3.78)	0.002
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	AR with pedicled TRAM	All	40/77 (57.1)	vs. IBR with TE: 1.34 (0.75, 2.40)	0.33
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	AR with LD	All	41/64 (64.1)	vs. IBR with TE: 1.97 (1.07, 3.64)	0.031
	Moderate	Unplanned repeat surgery for revision	Unplanned revision	2 y	AR with SIEA	All	33/62 (53.2)	vs. IBR with TE: 1.83 (0.93, 3.60)	0.079
Zhang, 2019, 30675702, China	High	Unplanned repeat surgery for revision	Unplanned reoperation	4.9 y	IBR	All	230/394 (58.4)	Ref	Ref
	High	Unplanned repeat surgery for revision	Unplanned reoperation	4.9 y	AR	All	154/438 (35.2)	vs. IBR: 0.72 (0.50, 1.06)	0.093

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Description	Time Point	Group	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Hangge, 2013, 31606126, US	High	Unplanned repeat surgery for complications	NR	NR	IBR DTI	All	81/193 (42)	vs. AR: 2.03 (1.03, 3.98)	0.042
	High	Unplanned repeat surgery for complications	NR	NR	IBR TE	All	58/146 (40)	vs. AR: 1.81 (0.90, 3.64)	0.096
	High	Unplanned repeat surgery for complications	NR	NR	AR	All	17/60 (28)	Ref	Ref
Mioton, 2013, 23562485, US	Moderate	Unplanned repeat surgery for complications	NR	1 mo	IBR	All	662/9786 (6.76)	1.08 (0.88, 1.32)	NR
	Moderate	Unplanned repeat surgery for complications	NR	1 mo	AR	All	316/3296 (9.59)	Ref	Ref
Zhang, 2019, 30675702, China	High	Unplanned repeat surgery for complications	Urgent surgery for a compromised implant/flap	4.9 y	IBR	All	31/394 (7.9)	vs. AR: 0.63 (0.29, 1.37)	NR
	High	Unplanned repeat surgery for complications	Urgent surgery for a compromised implant/flap	4.9 y	AR	All	33/438 (7.5)	Ref	Ref
Kulkarni, 2017, 28713853, US & Canada	Moderate	Pain	VAS: Moderate to severe	2 y	IBR DTI	All	NR	-	-
	Moderate	Pain	VAS: Moderate to severe	2 y	IBR TE	All	NR	Ref	Ref
	Moderate	Pain	VAS: Moderate to severe	2 y	AR with DIEP	All	NR	vs. IBR with TE: 1.22 (0.73, 2.04)*	0.45
	Moderate	Pain	VAS: Moderate to severe	2 y	AR with free TRAM	All	NR	vs. IBR with TE: 1.73 (0.73, 4.08)*	0.21
	Moderate	Pain	VAS: Moderate to severe	2 y	AR with pedicled TRAM	All	NR	vs. IBR with TE: 1.64 (0.68, 3.95)*	0.27
	Moderate	Pain	VAS: Moderate to severe	2 y	AR with LD	All	NR	vs. IBR with TE: 0.94 (0.28, 3.14)*	0.92
	Moderate	Pain	VAS: Moderate to severe	2 y	AR with SIEA	All	NR	vs. IBR with TE: 1.43 (0.57, 3.62)*	0.45

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Description	Time Point	Group	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
de Araujo, 2016, 27673527, US	High	Infections not explicitly implant-related	SSI	4.3 y	IBR	All	NR/38 (NR)	vs. AR 0.86 (0.18, 4.11)	0.847
	High	Infections not explicitly implant-related	SSI	4.3 y	AR	All	NR/32 (NR)	Ref	Ref
Garvey, 2012, 23096600, US	Moderate	Infections not explicitly implant-related	Infections	1.5 y	IBR	All	50/442 breasts (11.3)	Ref	Ref
	Moderate	Infections not explicitly implant-related	Infections	1.5 y	AR	All	21/548 breasts (3.8)	vs. IBR: NR	<0.001
Kulkarni, 2017, 28713853, US & Canada	Moderate	Infections not explicitly implant-related	Breast WI	2 y	IBR	All	NR	NR	NR
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	IBR DTI	All	17/112 (15.2)	-	-
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	IBR TE	All	159/1525 (10.4)	Ref	Ref
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR (all)	All	NR	NR	NR
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR with DIEP	All	27/390 (6.9)	vs IBR TE: 0.44 (0.25, 0.78)	0.005
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR with free TRAM	All	5/95 (5.3)	vs IBR TE: 0.45 (0.17, 1.18)	0.10
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR with pedicled TRAM	All	8/85 (9.4)	vs IBR TE: 0.73 (0.31, 1.70)	0.46
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR with LD	All	6/71 (8.5)	vs IBR TE: 0.50 (0.15, 1.56)	0.23
	Moderate	Infections not explicitly implant-related	Breast WI	2 y	AR with SIEA	All	8/65 (12.3)	vs IBR TE: 0.67 (0.25, 1.82)	0.43
Mioton, 2013, 23562485, US	Moderate	Infections not explicitly implant-related	WI	1 mo	IBR	All	338/9786 (3.45)	Ref	Ref
	Moderate	Infections not explicitly implant-related	WI	1 mo	AR	All	180/3296 (5.46)	vs IBR: 1.40 (1.01, 1.96)	NR
	Moderate	Infections not explicitly implant-related	Superficial SSI	1 mo	IBR	All	163/9786 (1.67)	Ref	Ref
	Moderate	Infections not explicitly implant-related	Superficial SSI	1 mo	AR	All	97/3296 (2.95)	vs IBR: 1.20 (0.81, 1.76)	NR
	Moderate	Infections not explicitly implant-related	Deep SSI	1 mo	IBR	All	195/9786 (1.07)	Ref	Ref

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Description	Time Point	Group	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
	Moderate	Infections not explicitly implant-related	Deep SSI	1 mo	AR	All	65/3296 (1.97)	vs IBR: 1.81 (1.12, 2.94)	NR
Naoum, 2020a, 31756414, US	High	Infections not explicitly implant-related	NR	4-10 y	IBR	All	23/633 breasts (3.6)	Ref	Ref
	High	Infections not explicitly implant-related	NR	4-10 y	AR	All	9/342 breasts (2.6)	vs IBR: 0.77 (0.20, 2.50)	0.67
Naoum, 2020b, 32607638, US	High	Infections not explicitly implant-related	NR	4.3-6.3 y	IBR DTI	All	7/127 (5.5)	Ref	Ref
	High	Infections not explicitly implant-related	NR	4.3-6.3 y	IBR with TE	All	2/88 (2.2)	Ref	Ref
	High	Infections not explicitly implant-related	NR	4.3-6.3 y	AR	All	11/85 (13.0)	vs. IBR DTI: 3.2 (0.6, 16) vs. IBR with TE: 8.1 (1.7, 39)	0.20 0.009
Chetta, 2017, 28002254, US	High	Reconstructive failure	NR	1.3 mo	IBR	All	1101/3746 (29.4)	Ref	Ref
	High	Reconstructive failure	NR	1.3 mo	AR	All	40/935 (4.3)	vs IBR: 0.09 (0.07, 0.13)	<0.001
Fischer, 2013, 23629074, US	High	Reconstructive failure	Unplanned, nonaesthetic TE/I removal related to a complication	4 y	IBR	All	4/60 (7.3)	Ref	Ref
	High	Reconstructive failure	Flap loss	4 y	AR	All	2/142 (1.3)	vs IBR: 0.19 (0.04, 0.80)	0.03
Garvey, 2012, 23096600, US	Moderate	Reconstructive failure	NR	1.5 y	IBR	All	70/442 breasts (15.8)	Ref	Ref
	Moderate	Reconstructive failure	NR	1.5 y	AR	All	8/548 breasts (1.5)	vs IBR: NR	<0.001

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Description	Time Point	Group	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	Moderate	Reconstructive failure	NR	2 y	IBR (all)	All	NR	Ref	Ref
	Moderate	Reconstructive failure	NR	2 y	IBR (all)	Unilateral	41/600 (6.83)	NR	NR
	Moderate	Reconstructive failure	NR	2 y	IBR (all)	Bilateral	74/994 (7.44)	NR	NR
	Moderate	Reconstructive failure	NR	2 y	AR (all)	All	NR	NR	NR
	Moderate	Reconstructive failure	NR	2 y	AR (all)	Unilateral	4/317 (1.26)	vs. IBR (all): 0.12 (0.04, 0.36)	<0.001
	Moderate	Reconstructive failure	NR	2 y	AR (all)	Bilateral	4/224 (1.87)	vs. IBR (all): 0.14 (0.05, 0.45)	0.001
Mioton, 2013, 23562485, US	Moderate	Reconstructive failure	Implant or flap failure	1 mo	IBR	All	83/9786 (0.85)	Ref	Ref
	Moderate	Reconstructive failure	Implant or flap failure	1 mo	AR	All	103/3296 (3.13)	vs. IBR: 1.69 (1.08, 2.62)	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SSI = surgical site infection, TE = tissue expander, TRAM = transverse rectus abdominis myocutaneous, VAS = Visual Analog Scale, WI = wound infection, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Confidence interval calculated based on the reported P value.

Table E-1.7. Summary Table – Key Question 1: IBR versus AR – NRCSs, continuous outcomes (pain and analgesic use)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Overall RoB	Time Point	Group	N	Mean (SD)	Adjusted Mean Difference (95% CI)	P Value
Eltahir, 2015, 25539295, Netherlands	Pain	SF-36: Pain (0-100)	Moderate	2.2 y	IBR	NR	NR	Ref	Ref
	Pain	SF-36: Pain (0-100)	Moderate	2.2 y	AR	NR	NR	vs. IBR: 2.40 (−5.37, 10.2)	0.54
Kouwenberg, 2020, 32590633, Netherlands	Pain	EORTC QLQC30 Pain (0-100)	Moderate	>6 mo	IBR	296	15.9 (26.3)	Ref	Ref
	Pain	EORTC QLQC30 Pain (0-100)	Moderate	>6 mo	AR	179	17.2 (27.2)	NR	NS
Kulkarni, 2017, 28713853, US & Canada	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR (all)	463	NR	NR	NR

Study, Year, PMID, Country	Outcome	Outcome Measurement	Overall RoB	Time Point	Group	N	Mean (SD)	Adjusted Mean Difference (95% CI)	P Value
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR with DIEP	111	NR	vs. IBR (all): −1.20 (−2.11, −0.29)*	0.01
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR with free TRAM	94	NR	vs. IBR (all): 0.26 (−1.16, 1.69)*	0.72
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR with pedicled TRAM	NR	NR	vs. IBR (all): −1.04 (−2.53, 0.45)*	0.17
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): 0.35 (−1.37, 2.07)*	0.69
	Pain	MPQ-SF: Sensory (0-10)	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): 2.41 (0.38, 4.44)*	0.02
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	IBR Direct	96	4.2 (NR)	-	-
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	IBR TE	1329	5.7 (NR)	Ref	Ref
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR with DIEP	296	4.8 (NR)	vs. IBR TE: 1.10 (0.35, 1.85)*	0.004
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR with free TRAM	83	6.7 (NR)	vs. IBR TE: 2.48 (NR)	<0.001
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR with pedicled TRAM	91	5 (NR)	vs. IBR TE: 1.19 (−0.14, 2.52)*	0.08
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR with LD	62	5.4 (NR)	vs. IBR TE: 0.42 (−1.19, 2.03)*	0.61
	Pain	MPQ-SF: Sensory (0-10)	Moderate	3 mo	AR with SIEA	56	NR	vs. IBR TE: 2.37 (0.81, 3.94)*	0.003
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR with DIEP	463	NR	vs. IBR (all): 0.24 (−0.10, 0.58)*	0.16
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR with free TRAM	111	NR	vs. IBR (all): 0.37 (−0.15, 0.89)*	0.16
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR with pedicled TRAM	94	NR	vs. IBR (all): −0.01 (−0.79, 0.77)*	0.98
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): 0.47 (−0.17, 1.11)*	0.15
	Pain	MPQ-SF: Affective (0-10)	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): −0.03 (−0.97, 0.91)	0.95
Kulkarni, continued	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	IBR (all)	1263	NR	NR	NR
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	IBR Direct	93	NR	-	-
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	IBR TE	1263	NR	Ref	Ref
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR with DIEP	350	NR	vs. IBR TE: 0.33 (0.07, 0.59)*	0.013
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR with free TRAM	87	NR	vs. IBR TE: 0.84 (NR)	<0.001
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR with pedicled TRAM	77	NR	vs. IBR TE: 0.04 (−0.47, 0.55)*	0.877
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR with LD	64	NR	vs. IBR TE: −0.13 (−0.66, 0.40)*	0.63
	Pain	MPQ-SF: Affective (0-10)	Moderate	2 y	AR with SIEA	62	NR	vs. IBR TE: 1.24 (NR)	<0.0001
	Pain	VAS (0-10)	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref

Study, Year, PMID, Country	Outcome	Outcome Measurement	Overall RoB	Time Point	Group	N	Mean (SD)	Adjusted Mean Difference (95% CI)	P Value
	Pain	VAS (0-10)	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	VAS (0-10)	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	VAS (0-10)	Moderate	1 w	AR (all)	NR	NR	NR	NR
	Pain	VAS (0-10)	Moderate	1 w	AR with DIEP	463	NR	vs. IBR (all): −0.18 (−0.49, 0.13)*	0.25
	Pain	VAS (0-10)	Moderate	1 w	AR with free TRAM	111	NR	vs. IBR (all): −0.19 (−0.68, 0.30)*	0.45
	Pain	VAS (0-10)	Moderate	1 w	AR with pedicled TRAM	94	NR	vs. IBR (all): −0.72 (−1.27, −0.17)*	0.01
	Pain	VAS (0-10)	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): 0.01 (−0.51, 0.53)*	0.97
	Pain	VAS (0-10)	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): 0.21 (−0.42, 0.84)*	0.51
Roth, 2007, 17413877, US	Pain	VAS: Bodily pain (1-5)	High	2 y	IBR	48	2.2 (1.2)	Ref	Ref
	Pain	VAS: Bodily pain (1-5)	High	2 y	AR	159	2.2 (1.2)	vs IBR: NR	NS
	Pain	VAS: Breast pain (1-5)	High	2 y	IBR	48	2.1 (1.3)	Ref	Ref
	Pain	VAS: Breast pain (1-5)	High	2 y	AR	159	1.8 (1.1)	vs IBR: NR	NS
	Pain	VAS: Abdominal pain (1-5)	High	2 y	IBR	48	4.8 (0.8)	Ref	Ref
	Pain	VAS: Abdominal pain (1-5)	High	2 y	AR	159	4.0 (1.2)	vs IBR: NR	<0.0001
	Pain	VAS: Back pain (1-5)	High	2 y	IBR	48	4.0 (1.3)	Ref	Ref
	Pain	VAS: Back pain (1-5)	High	2 y	AR	159	3.7 (1.5)	vs IBR: NR	NS
Shiraishi, 2020, 32589082, Japan	Pain	MPQ-SF: Total (0-10)	High	1 y	IBR	56	NR	Ref	Ref
	Pain	MPQ-SF: Total (0-10)	High	1 y	AR	34	NR	1.08 (NR, NR)	NR
	Pain	MPQ-SF: Sensory (0-10)	High	1 y	IBR	56	NR	Ref	Ref
	Pain	MPQ-SF: Sensory (0-10)	High	1 y	AR	34	NR	0.80 (NR, NR)	NR
	Pain	MPQ-SF: Affective (0-10)	High	1 y	IBR	56	NR	Ref	Ref
	Pain	MPQ-SF: Affective (0-10)	High	1 y	AR	34	NR	0.28 (NR, NR)	NR
Shiraishi, 2020, 32589082, Japan	Analgesic use	Analgesic use score (0-5)	High	1 y	IBR	56	NR	Ref	Ref
	Analgesic use	Analgesic use score (0-5)	High	1 y	AR	34	NR	0.37 (NR, NR)	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MPQ-SF = McGill Pain Questionnaire-Short Form, MD = mean difference, MOS SF = Medical Outcomes Study Short Form, MPQ-SF = McGill Pain Questionnaire Short Form, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery, TE = tissue expander, TRAM = transverse rectus abdominis myocutaneous, VAS = Visual Analog Scale.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Confidence interval calculated based on the reported P value.

Table E-2.1. Summary Table – Key Question 2b: Timing of IBR in relation to radiation therapy – NRCSs, continuous outcomes (various)

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Measurement	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Adjusted MD (95% CI)	P Value
Cordeiro, 2015, 30270015, US	High	Physical WB	BREAST-Q: Physical WB (0-100)	3.3 y	84	72.5 (2.6)	22	73.4 (1.9)	NR	NS
Yoon, 2020, 32332528, US & Canada	Moderate	Physical WB	BREAST-Q: Physical WB (0-100)	2 y	80	NR	237	NR	−0.64 (−7.19, 5.90)	0.84
	Moderate	Physical WB	PROMIS: Physical function (0-100)	2 y	80	NR	237	NR	−0.04 (−2.40, 2.32)	0.97
Cordeiro, 2015, 30270015, US	High	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	3.3 y	84	71.1 (1.4)	22	72.3 (1.2)	NR	<0.01
Yoon, 2020, 32332528, US & Canada	Moderate	Psychosocial WB	BREAST-Q: Psychosocial WB (0-100)	2 y	80	NR	237	NR	0.48 (−7.72, 8.68)	0.91
Cordeiro, 2015, 30270015, US	High	Sexual WB	BREAST-Q: Sexual WB (0-100)	3.3 y	84	54.0 (0.9)	22	55.4 (0.7)	NR	<0.01
Yoon, 2020, 32332528, US & Canada	Moderate	Sexual WB	BREAST-Q: Sexual WB (0-100)	2 y	80	NR	237	NR	−1.00 (−8.41, 6.40)	0.78
	Moderate	Sexual WB	EORTC: Sexual function	2 y	80	NR	237	NR	−1.40 (−8.58, 5.77)	0.70
Cordeiro, 2015, 30270015, US	High	Satisfaction with breast	BREAST-Q: Satisfaction with breast (0-100)	3.3 y	84	56.2 (3.3)	22	57.2 (3.1)	NR	NS
Yoon, 2020, 32332528, US & Canada	Moderate	Satisfaction with breast	BREAST-Q: Satisfaction with breast (0-100)	2 y	80	NR	237	NR	−3.89 (−11.0, 3.23)	0.28
Cordeiro, 2015, 30270015, US	High	Satisfaction with outcome	BREAST-Q: Satisfaction with outcome (0-100)	3.3 y	84	68.4 (3.8)	22	70.2 (3.0)	NR	0.02
Yoon, 2020, 32332528, US & Canada	Moderate	Pain	PROMIS: Pain interference (0−100)	2 y	80	NR	237	NR	2.86 (−1.05, 6.77)	0.14

Abbreviations: CI = confidence interval, EORTC = European Organization for Research and Treatment of Cancer, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, PROMIS = Patient-Reported Outcomes Measurement Information System, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-2.2. Summary Table – Key Question 2b: Timing of IBR in relation to radiation therapy – NRCSs, categorical outcomes (various)

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Measurement	Time Point	IBR Before Radiation (%)	IBR After Radiation (%)	Effect Size (95% CI) Before Versus After Radiation	P Value
Eriksson, 2013, 24258257, Sweden	High	Unplanned repeat surgeries for revision	NR	3.6 y	NR	NR	adjHR 0.94 (0.63, 1.40)	NR
Hirsch, 2014, 25347643, US	High	Necrosis	NR	3.1 y	NR	NR	adjOR 0.96 (0.68, 1.35)	0.94
Yoon, 2020, 32332528, US & Canada	Moderate	Infections (not explicitly implant-related)	Major (IV antibiotics)	2 y	5/46 (10.9%)	7/104 (6.7%)	NR	0.40
	Moderate	Infections (not explicitly implant-related)	Minor (oral antibiotics)	2 y	3/46 (6.5%)	7/104 (6.7%)	NR	0.96
Yoon, 2020, 32332528, US & Canada	Moderate	Wound dehiscence	NR	2 y	0/46 (0%)	5/104 (4.8%)	NR	0.32
Yoon, 2020, 32332528, US & Canada	Moderate	Seroma	NR	2 y	2/46 (4.4%)	8/104 (7.7%)	NR	0.46
Yoon, 2020, 32332528, US & Canada	Moderate	Capsular contracture	NR	2 y	1/46 (2.2%)	3/104 (2.9%)	NR	0.80
Hirsch, 2014, 25347643, US	High	Hematoma	NR	3.1 y	NR	NR	adjOR 0.56 (0.22, 1.45)	0.39
Yoon, 2020, 32332528, US & Canada	Moderate	Hematoma	NR	2 y	1/46 (2.2%)	4/104 (3.9%)	NR	0.63
Hirsch, 2014, 25347643, US	High	Composite/unspecified harms	Any complication	3.5 y	NR	NR	adjOR 0.81 (0.56, 1.17)	NR
	High	Composite/unspecified harms	Operative complications	3.5 y	NR	NR	adjOR 0.92 (0.59, 1.45)	NR
	High	Composite/unspecified harms	Nonoperative complications	3.5 y	NR	NR	adjOR 0.90 (0.60, 1.34)	NR
Stein, 2020, 32561384, Canada	High	Composite/unspecified harms	Any complication	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 0.82 (0.03, 2.19)	0.69
	High	Composite/unspecified harms	Major complications	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 0.62 (0.21, 1.86)	0.40
	High	Composite/unspecified harms	Minor complications	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 1.29 (0.41, 4.03)	0.65
Yoon, 2020, 32332528, US & Canada	Moderate	Composite/unspecified harms	Any complication	2 y	33/80 (41.3)	95/237 (40.1)	NR	0.85
	Moderate	Composite/unspecified harms	Major complications	2 y	26/80 (32.5)	82/237 (34.6)	NR	0.73

Abbreviations: adj = adjusted, CI = confidence interval, hosp. = hospitalization, HR = hazard ratio, IBR = implant-based reconstruction, IV = intravenous, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, OR = odds ratio, PMID = PubMed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-3.1. Summary Table – Key Question 3: Comparisons of implant materials for IBR – NRCSs, continuous outcomes (general quality of life, physical well-being, psychosocial well-being, sexual well-being, satisfaction with outcome, and satisfaction with breasts)

Study, Year, PMID	RoB	Outcome	Outcome Measurement	Time Point (y)	Silicone, N	Silicone, Mean (SD)	Saline, N	Saline, Mean (SD)	Effect Size (95% CI)	P Value
Macadam, 2010, 20009795, Canada	High	General quality of life	EORTC QLQC30 (0-100): Global health status	2.6-4.5	72	79.9 (18.1)	67	74.9 (20.9)	NR	0.13
	High	Physical WB	BREAST-Q (0-100): Physical WB	2.6-4.5	74	76.2 (14.9)	68	73.4 (16.3)	NR	0.28
	High	Psychosocial WB	BREAST-Q (0-100): Psychosocial WB	2.6-4.5	75	77.6 (18.6)	67	70.8 (18.8)	NR	0.03
	High	Sexual WB	BREAST-Q (0-100): Sexual WB	2.6-4.5	71	54.4 (19.8)	65	47.6 (20.9)	NR	0.056
	High	Satisfaction with outcome	BREAST-Q (0-100): Satisfaction with outcome	2.6-4.5	75	75.4 (17.6)	68	69.5 (22.6)	NR	0.082
	High	Satisfaction with breasts	BREAST-Q (0-100): Satisfaction with breast	2.6-4.5	75	63.8 (15.2)	67	56.9 (15.1)	NR	0.008
McCarthy, 2010, 21136577, US & Canada	High	Satisfaction with breasts	BREAST-Q (0-100): Satisfaction with breast	2.4-3.3	176	58.0 (20.3)	306	52.5 (20.4)	adjMD 4.1 (1.31*, 6.89*)	0.004

Abbreviations: adj = adjusted, CI = confidence interval, EORTC QLQC3 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30, IBR = implant-based reconstruction, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Calculated.

Table E-3.2. Summary Table – Key Question 3: Comparisons of implant materials for IBR – NRCSs, categorical outcomes (mortality, implant failure/loss, and capsular contracture)

Study, Year, PMID, Country	Overall RoB	Outcome	Outcome Measurement	Time Point (y)	Implant Material	n/N (%)	Effect Size (95% CI)	P Value
Le, 2005, 15743498, US	High	Mortality	Breast cancer mortality	12.4	Silicone	NR	Ref	Ref
	High	Mortality	Breast cancer mortality	12.4	Saline	NR	vs. Silicone: adjHR 1.01 (0.44, 2.34)	NR
	High	Mortality	Breast cancer mortality	12.4	Double lumen	NR	vs. Silicone: adjHR 1.49 (0.83, 2.70)	NR
	High	Mortality	Non-breast cancer mortality	12.4	Silicone	NR	Ref	Ref
	High	Mortality	Non-breast cancer mortality	12.4	Saline	NR	vs. Silicone: adjHR 1.75 (0.29, 10.39)	NR
	High	Mortality	Non-breast cancer mortality	12.4	Double lumen	NR	vs. Silicone: adjHR 3.13 (0.91, 10.78)	NR
Cordeiro, 2015a, 25742523, US	High	Implant failure/loss	TE and implant loss	3.3	Silicone	NR/159	adjOR 0.61 (0.36, 1.07)	NS
	High	Implant failure/loss	TE and implant loss	3.3	Saline	NR/129	Ref	Ref
Antony, 2014, 24135689, US	High	Capsular contracture	Baker Grade III or IV	3-5	Silicone	NR/179	Ref	Ref
	High	Capsular contracture	Baker Grade III or IV	3-5	Saline	NR/166	NR	NS

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, HR = hazard ratio, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-4.1. Summary Table – Key Question 4: Comparisons of anatomic planes of implant placement for IBR – continuous outcomes (various)

Study, Year, PMID, Country	Design	RoB	Outcome	Outcome Measurement	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	RCT	Moderate	Physical WB	SF-36 (0–100): PCS	6 mo	Prepectoral	20	45.2 (7.1)	Ref	Ref
	RCT	Moderate	Physical WB	SF-36 (0–100): PCS	6 mo	Partial Submuscular	14	45.2 (7.1)	NR	0.689
Cattelani, 2018, 29275104, Italy	NRCS	High	Physical WB	Constant Murley (0–100): Upper limb	1 d	Prepectoral	39	71.6 (8.9)	Ref	Ref
	NRCS	High	Physical WB	Constant Murley (0–100): Upper limb	1 d	Total Submuscular	45	60.4 (10.5)	NR	<0.001
	NRCS	High	Physical WB	Constant Murley (0–100): Upper limb	7 d	Prepectoral	39	65.7 (9.3)	Ref	Ref
	NRCS	High	Physical WB	Constant Murley (0–100): Upper limb	7 d	Total Submuscular	45	52.4 (12.2)	NR	<0.001
	NRCS	High	Physical WB	DASH (0-100)	1 y	Prepectoral	39	9.9 (17.9)	Ref	Ref
	NRCS	High	Physical WB	DASH (0-100)	1 y	Total Submuscular	45	29.2 (16.9)	NR	<0.001
Lee, 2021b, 33691448, South Korea	RCT	Moderate	Psychosocial WB	SF-36 (0–100): MCS	6 mo	Prepectoral	20	40.5 (10.5)	Ref	Ref
	RCT	Moderate	Psychosocial WB	SF-36 (0–100): MCS	6 mo	Partial Submuscular	14	40.5 (10.5)	NR	0.904
	RCT	Moderate	Psychosocial WB	HADS: Anxiety (0-21)	6 mo	Prepectoral	20	6.3 (3.3)	Ref	Ref
	RCT	Moderate	Psychosocial WB	HADS: Anxiety (0-21)	6 mo	Partial Submuscular	14	5.0 (2.9)	NR	0.959
	RCT	Moderate	Psychosocial WB	HADS: Depression (0-21)	6 mo	Prepectoral	20	7.5 (7.4)	Ref	Ref
	RCT	Moderate	Psychosocial WB	HADS: Depression (0-21)	6 mo	Partial Submuscular	14	6.3 (3.8)	NR	0.924
Cattelani, 2018, 29275104, Italy	NRCS	High	Psychosocial WB	Return to usual work	NR	Prepectoral	39	34.6 d (21)	Ref	Ref
	NRCS	High	Psychosocial WB	Return to usual work	NR	Total Submuscular	45	57.3 d (37.8)	NR	<0.001
Cattelani, 2018, 29275104, Italy	NRCS	High	Satisfaction with breasts	BREAST-Q (0-100): Satisfaction with breast	1 y	Prepectoral	39	92.2 (9.0)	Ref	Ref
	NRCS	High	Satisfaction with breasts	BREAST-Q (0-100): Satisfaction with breast	1 y	Total Submuscular	45	76.1 (14.6)	NR	<0.001
Avila, 2020, 33234947, US	NRCS	High	Pain	VAS (0-10)	NR	Prepectoral	73	3.94 (0.83)	Ref	Ref
	NRCS	High	Pain	VAS (0-10)	NR	Total Submuscular	73	5.25 (0.81)	NR	<0.001
Cattelani, 2018, 29275104, Italy	NRCS	High	Pain	BPI-SF (0-100)	1 d	Prepectoral	39	17.6 (15.5)	Ref	Ref
	NRCS	High	Pain	BPI-SF (0-100)	1 d	Total Submuscular	45	44.1 (15.8)	NR	<0.001
	NRCS	High	Pain	BPI-SF (0-100)	7 d	Prepectoral	39	8.2 (15.4)	Ref	Ref
	NRCS	High	Pain	BPI-SF (0-100)	7 d	Total Submuscular	45	22.0 (18.6)	NR	<0.001

Study, Year, PMID, Country	Design	RoB	Outcome	Outcome Measurement	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Kim, 2020, 33066236, South Korea	NRCS	Moderate	Pain	VAS (0-10)	1 d	Prepectoral	53	2.66 (1.82)	Ref	Ref
	NRCS	Moderate	Pain	VAS (0-10)	1 d	Partial Submuscular	114	2.26 (1.38)	adjMD -0.08	0.33
	NRCS	Moderate	Pain	VAS (0-10)	7 d	Prepectoral	53	1.08 (1.19)	Ref	Ref
	NRCS	Moderate	Pain	VAS (0-10)	7 d	Partial Submuscular	114	0.80 (1.07)	-0.12	0.12
Avila, 2020, 33234947, US	NRCS	High	Analgesic use	Oral morphine equivalents	NR	Prepectoral	73	17.4 mg (45.1)	Ref	Ref
	NRCS	High	Analgesic use	Oral morphine equivalents	NR	Total Submuscular	73	63.0 mg (44.9)	NR	0.03

Abbreviations: adj = adjusted, BPI-SF = Brief Pain Inventory Short Form, CI = confidence interval, d = days, DASH = Disabilities of the Arm, Shoulder, and Hand, HADS = Hospital Anxiety and Depression Scale, IBR = implant-based reconstruction, MCS = Mental Component Summary, NR = not reported, NRCS = nonrandomized comparative study, PCS = Physical Component Summary, PMID = PubMed identifier, Ref = reference, RoB = risk of bias, SD = standard deviation, SF = Short Form, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-4.2. Summary Table – Key Question 4: Comparisons of anatomic planes of implant placement for IBR – categorical outcomes (various)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Avila, 2020, 33234947, US	NRCS	High	Unplanned repeat surgeries for revision	NR	1 mo	Prepectoral	8/203 (3.94)	Ref	Ref
	NRCS	High	Unplanned repeat surgeries for revision	NR	1 mo	Total submuscular	17/202 (8.42)	NR	NS
Nealon, 2020a, 32032345, US	NRCS	High	Necrosis	Skin necrosis	1.7-2.4 y	Prepectoral	5/114 (4.4)	Ref	Ref
	NRCS	High	Necrosis	Skin necrosis	1.7-2.4 y	Total submuscular	6/142 (4.2)	adjOR 1.01 (0.74, 5.95)	0.77
Kraenzlin, 2021, 32568752, US	NRCS	High	Infections (not explicitly implant-related)	NR	NR	Prepectoral	34/169 (11.0)	Ref	Ref
	NRCS	High	Infections (not explicitly implant-related)	NR	NR	Total submuscular	34/117 (17.4)	NR	0.21
Nealon, 2020a, 32032345, US	NRCS	High	Infections (not explicitly implant-related)	NR	1.7-2.4 y	Prepectoral	2/114 (1.8)	Ref	Ref
	NRCS	High	Infections (not explicitly implant-related)	NR	1.7-2.4 y	Total submuscular	6/142 (4.2)	adjOR 0.31 (<0.01, 8.65)	0.52
Nealon, 2020a, 32032345, US	NRCS	High	Need for explant surgery	NR	1.7-2.4 y	Prepectoral	4/114 (3.5)	Ref	Ref
	NRCS	High	Need for explant surgery	NR	1.7-2.4 y	Total submuscular	7/142 (4.9)	adjOR 1.01 (0.07, 14.1)	0.99
	RCT	Moderate	Capsular contracture	NR	6 mo	Prepectoral	1/20 (5.0)	Ref	Ref

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	RCT	Moderate	Capsular contracture	NR	6 mo	Partial submuscular	0/14 (0)	Not calculable	-
Nealon, 2020a, 32032345, US	NRCS	High	Capsular contracture	NR	1.7-2.4 y	Prepectoral	2/114 (1.8)	Ref	Ref
	NRCS	High	Capsular contracture	NR	1.7-2.4 y	Total submuscular	12/142 (8.5)	adjOR 0.30 (0.03, 1.55)	0.16
Lee, 2021b, 33691448, South Korea	RCT	Moderate	Seroma	NR	6 mo	Prepectoral	3/20 (15.0)	Ref	Ref
	RCT	Moderate	Seroma	NR	6 mo	Partial submuscular	2/14 (14.3)	OR 1.06 (0.15, 7.34)	0.95
Nealon, 2020a, 32032345, US	NRCS	High	Seroma	NR	1.7-2.4 y	Prepectoral	10/114 (8.8)	Ref	Ref
	NRCS	High	Seroma	NR	1.7-2.4 y	Total submuscular	11/142 (7.7)	adjOR 1.49 (0.37, 6.11)	0.57
Nealon, 2020a, 32032345, US	NRCS	High	Hematoma	NR	1.7-2.4 y	Prepectoral	6/114 (5.3)	Ref	Ref
	NRCS	High	Hematoma	NR	1.7-2.4 y	Total submuscular	7/142 (4.9)	adjOR 5.18 (0.39, 7.05)	0.23
Avila, 2020, 33234947, US	NRCS	High	Composite or unspecified harms	Necrosis/infection, wound dehiscence/ hematoma/seroma	1 mo	Prepectoral	12/203 (5.91)	Ref	Ref
	NRCS	High	Composite or unspecified harms	Necrosis/infection, wound dehiscence/ hematoma/seroma	1 mo	Total submuscular	19/202 (9.41)	NR	NS
Gabriel, 2020, 32195862, US	NRCS	High	Composite or unspecified harms	Any complication	2 y	Prepectoral	19/129 breasts (14.7)	Ref	Ref
	NRCS	High	Composite or unspecified harms	Any complication	2 y	Partial submuscular	33/128 breasts (25.8)	adjOR 3.04 (1.34, 7.61)	0.013
Ozgur, 2020, 33223365, Turkey	NRCS	High	Composite or unspecified harms	Capsular contracture, inframammary fold problems, bottoming out, rippling, mechanical shift, animation deformity	5.3-6.1 y	Partial submuscular	8/91 breasts (8.8)	Ref	Ref

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
	NRCS	High	Composite or unspecified harms	Capsular contracture, inframammary fold problems, bottoming out, rippling, mechanical shift, animation deformity	5.3-6.1 y	Total submuscular	29/117 breasts (24.8)	adjOR 3.28 (1.39, 7.76)	0.007

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, HR = hazard ratio, mo = months, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, OR = odds ratio, PMID = PubMed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-5.1. Summary Table – Key Question 5: Use versus nonuse of human ADMs during IBR – continuous outcomes (physical well-being, psychosocial well-being, sexual well-being, and satisfaction with breasts)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	Physical WB	BREAST-Q (0-100): Chest and upper body	RCT	Moderate	Expansion	36	68.6 (10.6)	33	69.3 (7.9)	NMD 0.60 (−4.87, 6.07)*	0.83
	Physical WB	BREAST-Q (0-100): Chest and upper body	RCT	Moderate	After expansion	36	79.7 (15.1)	33	80.5 (13.3)	NMD 0.50 (−5.93, 6.93)*	0.88
Cattelani, 2018, 29275104, Italy	Physical WB	Constant Murley Score	NRCS	High	1 d	39	71.62 (8.87)	45	60.36 (10.54)	NR	<0.001
	Physical WB	Constant Murley Score	NRCS	High	7 d	39	65.67 (9.31)	45	52.36 (12.23)	NR	<0.001
	Physical WB	DASH score	NRCS	High	1 y	39	9.92 (17.87)	45	29.18 (16.91)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	Physical WB	BREAST-Q (0-100): Physical well-being	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −0.82 (−3.01, 1.37)	NR
Cattelani, 2018, 29275104, Italy	Psychosocial WB	Return to usual work	NRCS	High	NR	39	34.56 d (21)	45	57.31 d (37.77)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	Psychosocial WB	BREAST-Q (0-100): Psychosocial WB	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −0.26 (−2.97, 2.45)	NR
Ganesh Kumar, 2021, 33172826, US & Canada	Sexual WB	BREAST-Q (0-100): Sexual WB	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −2.28 (−5.63, 1.06)	NR
Cattelani, 2018, 29275104, Italy	Satisfaction with breasts	BREAST-Q: Satisfaction with breast	NRCS	High	1 y	39	92.2 (9.03)	45	76.1 (14.6)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	Satisfaction with breasts	BREAST-Q: Satisfaction with breast	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −1.95 (−4.96, 1.06)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, d = days, DASH = Disabilities of the Arm, Shoulder, and Hand, h = hours, IBR = implant-based reconstruction, MD = mean difference, N/A = not applicable, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

*calculated

Table E-5.2. Summary Table – Key Question 5: Use versus nonuse of human ADMs during IBR – categorical outcomes not meta-analyzed (various)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Wendel, 2013, None, US	RCT	High	Mortality	Death	1 mo	All patients	0/20 (0)	0/16 (0)	No events	N/A
Ibrahim, 2013, 24165587, US	NRCS	Moderate	Unplanned repeat surgeries for revision	NR	6 mo	All patients	237/3283 (0.5)	990/15714 (0.6)	NR	0.14
Nealon, 2020b, 31605310, US	NRCS	High	Unplanned repeat surgeries for revision	NR	5.3 y	All patients	NR	NR	adjOR 0.86 (0.69, 1.08)	0.19
Sobti, 2018, 29481386, US	NRCS	High	Unplanned repeat surgeries for revision	Revision for malposition or size	5 y	All patients	47/465 breasts (10.11)	24/217 breasts (11.06)	adjOR 1.10 (0.63, 1.92)	NR
Peled, 2012, 22634688, US	NRCS	High	Unplanned repeat surgeries for complications	For wound-healing/infectious complication	2.6-3.3 y	All patients	11/100 breasts (11)	21/90 breasts (23.3)	NR	<0.05
Ibrahim, 2013, 24165587, US	NRCS	Moderate	Thromboembolic events	Deep vein thrombosis	NR	All patients	9/3283 (0.3)	35/15714 (0.2)	NR	0.47
	NRCS	Moderate	Thromboembolic events	Pulmonary embolism	NR	All patients	2/3283 (0.06)	29/15714 (0.2)	NR	0.11
Craig, 2019, 29800083, US	NRCS	Low	Wound dehiscence	NR	7 mo	All patients	35/574 breasts (6.1)	20/796 breasts (2.5)	NR	NR
	NRCS	Low	Wound dehiscence	NR	7 mo	Postop radiation	42/88 breasts (47.7)	27/113 breasts (23.9)	NR	NR
	NRCS	Low	Wound dehiscence	NR	7 mo	No postop radiation	30/486 breasts (6.2)	17/683 breasts (2.5)	adjOR 2.46 (1.23, 4.93)	NR
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	Wound dehiscence	NR	2 y	All patients	24/738 (3.3)	5/713 (0.7)	NR	0.009
Ibrahim, 2013, 24165587, US	NRCS	Moderate	Wound dehiscence	NR	NR	All patients	15/3283 (0.5)	98/15714 (0.6)	NR	0.26
Qureshi, 2016, 27465177, US	NRCS	High	Wound dehiscence	Dehiscence without necrosis	2 y	All patients	NR/295 (NR)	NR/118 (NR)	adjOR 0.4 (NR, NR)	<0.05
Woo, 2017, 28509694, South Korea	NRCS	High	Delayed healing	Delayed wound healing or skin flap necrosis	NR	All patients	32/199 (16.1)	32/199 (16.1)	adjOR 1.41 (0.67, 2.96)	0.37

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Subgroup	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	Implant rupture	Implant rupture, leakage, or deflation	2 y	All patients	11/738 (1.5)	7/713 (1.0)	NR	0.58
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	Implant malposition	NR	2 y	All patients	9/738 (1.2)	4/713 (0.6)	NR	0.83
Vardanian, 2011, 22030500, US	NRCS	High	Implant malposition	NR	2.4 y	All patients	4/208 breasts (1.9)	12/129 breasts (9.3)	adjOR 0.23 (0.06, 0.78)	NR
Seth, 2012, 23018687, US	NRCS	High	Implant extrusion	NR	2 y	All patients	2/199 breasts (1)	9/293 breasts (2.3)	adjOR 0.43 (0.09, 2.02)	NR
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	Capsular contracture	NR	2 y	All patients	14/738 (1.9)	12/713 (1.7)	NR	0.24
Nealon, 2020b, 31605310, US	NRCS	High	Capsular contracture	NR	5.3 y	All patients	NR	NR	adjOR 0.78 (0.46, 1.36)	0.38
Sobti, 2018, 29481386, US	NRCS	High	Capsular contracture	NR	5 y	All patients	21/465 breasts (4.52)	7/217 breasts (3.23)	Nonuse vs use of ADM: adjOR 0.57 (0.23, 1.43)	NR
Vardanian, 2011, 22030500, US	NRCS	High	Capsular contracture	NR	2.4 y	All patients	8/208 breasts (3.8)	25/129 breasts (19.4)	adjOR 0.18 (0.08, 0.43)	NR
Vardanian, 2011, 22030500, US	NRCS	High	Harms to inframammary fold	Inframammary fold issues other than bottoming-out or shifting, but related to the integrity of the fold	2.4 y	All patients	17/208 breasts (8.2)	25/129 breasts (19.4)	adjOR 0.49 (0.23, 1.01)	NR

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, d = days, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-5.3. Summary Table – Key Question 5: Use versus nonuse of human ADMs during IBR – continuous outcomes (pain and analgesic use)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	RCT	Moderate	Pain	Visual analog scale (0-100)	24 h	36	54.6 (27.6)	33	42.8 (24.5)	NMD 6.2 (−4.9, 17.3)*	0.27
	RCT	Moderate	Pain	Visual analog scale (0-100)	Expansion phase	36	17 (15.9)	33	4.6 (8.9)	NMD 6.8 (1.1, 12.5)*	0.019
	RCT	Moderate	Pain	Visual analog scale (0-100)	After expansion	36	5.6 (11.6)	33	4.6 (8.9)	NMD −4.6 (−9.8, 0.6)*	0.081
Cattelani, 2018, 29275104, Italy	NRCS	High	Pain	BPI-SF (0-100)	1 d	39	17.56 (15.52)	45	44.11 (15.83)	NR	<0.001
	NRCS	High	Pain	BPI-SF (0-100)	7 d	39	8.23 (15.39)	45	21.96 (18.59)	NR	<0.001
McCarthy, 2012, 23096987, US	RCT	Moderate	Analgesic use	Oral codeine equivalents	0-6 h	33	228 (153)	30	256 (197)	MD −28 mg (−116, 60)*	0.77
	RCT	Moderate	Analgesic use	Oral codeine equivalents	6-24 h	33	619 (519)	30	715 (533)	MD −96 mg (−356, 164)*	0.38
	RCT	Moderate	Analgesic use	Oral codeine equivalents	0-24 h	36	776 (602)	32	910 (634)	MD −134 mg (−440, 172)*	0.38

Abbreviations: ADM = acellular dermal matrix, BPI-SF = Brief Pain Inventory-Short Form, CI = confidence interval, d = days, h = hours, IBR = implant-based reconstruction, MD = mean difference, mg = milligrams, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Calculated.

Table E-5.4. Summary Table – Key Question 5: Use versus nonuse of human ADMs during IBR – categorical outcomes (composite or unspecified harms)

Study, Year, PMID, Country	Design	Overall RoB	Outcome Measurement	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Wendel, 2013, None, US	RCT	High	Serious adverse events	1 mo	0/20 (0)	0/16 (0)	N/A	N/A
Brooke, 2012, 22868313, US	NRCS	High	Clinically significant complications, defined as cellulitis, abscess, seroma, expander leak or puncture, skin necrosis, wound dehiscence, or hematoma requiring readmission, reoperation, and/or expander explantation	NR	37/221 breasts (17)	7/64 breasts (11)	NR	0.48
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	Any complication	2 y	211/738 (28.6)	178/713 (25.0)	adjOR 1.21 (0.86, 1.70)	0.26
	NRCS	Moderate	Major complications	2 y	169/738 (22.9)	117/713 (16.4)	adjOR 1.43 (1.00, 2.05)	0.052
Hirsch, 2014, 25347643, US	NRCS	Low	Any complication	3.5 y	NR	NR	adjOR 0.90 (0.60, 1.34)	0.6
	NRCS	Low	Operative complication except explantation	3.5 y	NR	NR	adjOR 0.68 (0.46, 1.02)	0.46
	NRCS	Low	Nonoperative complication	3.5 y	NR	NR	adjOR 0.67 (0.26, 1.74)	0.43
Liu, 2011, 21228744, US	NRCS	High	Surgical complications	NR	52/266 (19.5)	25/204 (12.3)	adjOR 1.76 (1.03, 3.01)	0.036
Safran, 2020, 32221195, Canada	NRCS	High	Any complication, including hematoma, infection, seroma, implant displacement, NAC full-thickness necrosis, superficial cellulitis, red breast syndrome, incision necrosis, delayed healing, hypergranulation, and NAC superficial necrosis.	NR	NR/243 breasts (NR)	NR/70 breasts (NR)	adjOR 1.59 (0.56, 4.50)	NR
Stein, 2020, 32561384, Canada	NRCS	High	Any complication	10 mo – 5 y	16/41 (39.0)	37/89 (42.1)	adjOR 0.86 (0.26, 2.78)	NR
	NRCS	High	Major complications	10 mo – 5 y	10/41 (24.4)	22/89 (24.7)	adjOR 0.83 (0.22, 3.08)	NR
	NRCS	High	Minor complications	10 mo – 5 y	10/41 (24.4)	20/89 (22.5)	adjOR 0.83 (0.21, 3.29)	NR
Weichman, 2012, 22544088, US	NRCS	Moderate	Complications including mastectomy skin flap necrosis, mastectomy skin flap necrosis and associated infection, infection alone, seroma, and hematoma	3 y	NR/442 breasts (NR)	NR/186 breasts (NR)	NR	<0.05
Woo, 2017, 28509694, South Korea	NRCS	High	Major complication: Complications necessitating additional surgery or intervention	NR	26/199 (13.1)	38/199 (19.1)	adjOR 1.1 (0.5, 2.4)	0.81

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, RCT = randomized controlled trial, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table E-6.1. Summary Table – Key Question 6: Comparisons of flap types for AR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Design	Overall RoB	Outcome Measurement	Time Point	Flap Type	N	Mean (SD or 95% CI)	Effect Size (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	RCT	Moderate	CMSS: Total score (0-100)	1 y	LD	18	68.1 (58.2, 79.9)	Ref	Ref
	RCT	Moderate	CMSS: Total score (0-100)	1 y	TAP	22	78.7 (70.9, 86.4)	adjNMD 6.2 (0.5, 12.0)	0.033
	RCT	Moderate	CMSS: Pain (0-15)	1 y	LD	18	11.6 (9.8, 13.4)	Ref	Ref
	RCT	Moderate	CMSS: Pain (0-15)	1 y	TAP	22	14.0 (12.8, 15.2)	adjNMD 1.8 (0.2, 3.4)	0.023
	RCT	Moderate	CMSS: Activity in daily life (0-20)	1 y	LD	18	17.1 (14.9, 19.2)	Ref	Ref
	RCT	Moderate	CMSS: Activity in daily life (0-20)	1 y	TAP	22	18.7 (17.3, 20.0)	adjNMD 2.6 (1.1, 4.2)	<0.0001
	RCT	Moderate	CMSS: Range of motion (0-40)	1 y	LD	18	29.6 (24.6, 34.5)	Ref	Ref
	RCT	Moderate	CMSS: Range of motion (0-40)	1 y	TAP	22	34.8 (31.0, 38.6)	adjNMD 0.9 (−1.4, 3.2)	0.45
	RCT	Moderate	CMSS: Strength (0-25)	1 y	LD	18	9.9 (7.8, 12.0)	Ref	Ref
	RCT	Moderate	CMSS: Strength (0-25)	1 y	TAP	22	11.2 (9.3, 13.1)	adjNMD 1.2 (−1.0, 3.3)	0.29
Erdmann-Sager, 2018, 29019862, US & Canada	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −4.16 (−8.33, 0.02)	NR
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −4.01 (−8.48, 0.45)	NR
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD 4.72 (−0.07, 9.52)	NR
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −4.9 (−9.50, -0.31)	NR
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −7.22 (−12.30, −2.14)	NR
	NRCS	Moderate	BREAST-Q: Abdomen (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 0.58 (−4.79, 5.95)	NR
	NRCS	Moderate	BREAST-Q: Chest, upper body (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −1.55 (−5.35, 2.24)	NR

Study, Year, PMID, Country	Design	Overall RoB	Outcome Measurement	Time Point	Flap Type	N	Mean (SD or 95% CI)	Effect Size (95% CI)	P Value
Erdmann-Sager, continued	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.52 (−1.94, 4.99)	NR
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD 3.42 (−0.22, 7.05)	NR
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.22 (−5.89, 1.45)	NR
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −3.92 (−7.66, −0.18)	NR
	NRCS	Moderate	BREAST -Q: Chest, upper body (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 0.76 (−3.44, 4.95)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.03 (−2.36, 2.30)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.00 (−2.09, 2.10)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD 1.26 (−0.74, 3.26)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.42 (−1.52, 2.36)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.48 (−0.59, 3.55)	NR
	NRCS	Moderate	PROMIS: Physical functioning (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 1.20 (−1.09, 3.49)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	1 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	PROMIS: Pain interference (0−100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.34 (−1.91, 2.60)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −0.07 (−2.10, 1.97)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD −0.60 (−2.54, 1.34)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	2 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	PROMIS: Pain interference (0−100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.50 (−2.57, 1.57)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.44 (−2.25, 3.13)	NR
	NRCS	Moderate	PROMIS: Pain interference (0−100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 0.11 (−2.34, 2.57)	NR

Abbreviations: adj = adjusted, CI = confidence interval, CMSS = Constant Murley Shoulder Score, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, PROMIS = Patient-Reported Outcomes Measurement Information System, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, TAP = thoracodorsal artery perforator, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table E-6.2. Summary Table – Key Question 6: Comparisons of flap types for AR – NRCS, continuous outcomes (psychosocial and sexual well-being)

Study, Year, PMID, Country	Overall RoB	Outcome Measurement	Time Point	Flap Type	N	Mean (SD)	Effect Size (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	Moderate	BREAST-Q: Psychosocial WB (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	Moderate	BREAST-Q: Psychosocial WB (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −1.14 (−5.33, 3.05)	NR
	Moderate	BREAST-Q: Psychosocial WB (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.27 (−3.43, 5.97)	NR
	Moderate	BREAST-Q: Psychosocial WB (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD −0.67 (−5.66, 4.32)	NR
	Moderate	BREAST-Q: Psychosocial WB (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	Moderate	BREAST-Q: Psychosocial WB (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.08 (−5.33, 5.18)	NR
	Moderate	BREAST-Q: Psychosocial WB (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.62 (−3.95, 5.20)	NR
	Moderate	BREAST-Q: Psychosocial WB (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 1.64 (−3.64, 6.91)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	Moderate	BREAST-Q: Sexual WB (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.33 (−7.10, 2.44)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.81 (−4.31, 5.93)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD −2.66 (−8.63, 3.31)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	Moderate	BREAST-Q: Sexual WB (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD 2.35 (−3.40, 8.10)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −2.61 (−8.97, 3.75)	NR
	Moderate	BREAST-Q: Sexual WB (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 1.97 (−4.15, 8.09)	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, WB = well-being, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table E-6.3. Summary Table – Key Question 6: Comparisons of flap types for AR – continuous outcomes (patient satisfaction with breasts and duration of initial hospitalization)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	N	Mean (SD or Range)	Effect Size (95% CI)	P Value
Brandberg, 2000, 10626972, Sweden	RCT	High	Patient satisfaction with breasts	Cosmetic (1-6)	1 y	TRAM	26	5.6 (NR)	vs. LD: MD 0.36*	NR
	RCT	High	Patient satisfaction with breasts	Cosmetic (1-6)	1 y	LD	23	5.14 (NR)	vs. LTD: MD −0.05*	NR
	RCT	High	Patient satisfaction with breasts	Cosmetic (1-6)	1 y	LTD	12	5.19 (NR)	vs. TRAM: −0.46*	NR
	RCT	High	Patient satisfaction with breasts	Shape (1-6)	1 y	TRAM	26	5.3 (NR)	vs. LD: MD 0.36*	NR
	RCT	High	Patient satisfaction with breasts	Shape (1-6)	1 y	LD	23	4.94 (NR)	vs. LTD: MD 0.35*	NR
	RCT	High	Patient satisfaction with breasts	Shape (1-6)	1 y	LTD	12	4.59 (NR)	vs. TRAM: MD −0.71*	NR
	RCT	High	Patient satisfaction with breasts	Size (1-6)	1 y	TRAM	26	5.43 (NR)	vs. LD: MD 0.50*	NR
	RCT	High	Patient satisfaction with breasts	Size (1-6)	1 y	LD	23	4.93 (NR)	vs. LTD: MD −0.18*	NR
	RCT	High	Patient satisfaction with breasts	Size (1-6)	1 y	LTD	12	5.11 (NR)	vs. TRAM: MD −0.32*	NR
	RCT	High	Patient satisfaction with breasts	Scars on the breast (1-6)	1 y	TRAM	26	4.83 (NR)	vs. LD: MD 0.36*	NR
	RCT	High	Patient satisfaction with breasts	Scars on the breast (1-6)	1 y	LD	23	4.47 (NR)	vs. LTD: MD −0.65*	NR
	RCT	High	Patient satisfaction with breasts	Scars on the breast (1-6)	1 y	LTD	12	5.12 (NR)	vs. TRAM: MD 0.29*	NR
	RCT	High	Patient satisfaction with breasts	Donor site scars (1-6)	1 y	TRAM	26	4.76 (NR)	vs. LD: MD 0.07*	NR
	RCT	High	Patient satisfaction with breasts	Donor site scars (1-6)	1 y	LD	23	4.69 (NR)	vs. LTD: MD −0.26*	NR
	RCT	High	Patient satisfaction with breasts	Donor site scars (1-6)	1 y	LTD	12	4.95 (NR)	vs. TRAM: MD 0.19*	NR
	RCT	High	Patient satisfaction with breasts	Similarity with contralateral breast (1-6)	1 y	TRAM	26	4.76 (NR)	vs. LD: MD 0.10*	NR
	RCT	High	Patient satisfaction with breasts	Similarity with contralateral breast (1-6)	1 y	LD	23	4.66 (NR)	vs. LTD: MD 0.81*	NR
	RCT	High	Patient satisfaction with breasts	Similarity with contralateral breast (1-6)	1 y	LTD	12	3.85 (NR)	vs. TRAM: MD −0.91*	NR

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	N	Mean (SD or Range)	Effect Size (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	1 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.04 (−4.56, 4.63)	NR
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.36 (−3.45, 6.17)	NR
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	1 y	SIEA	NR	NR	vs. DIEP: adjMD −1.82 (−6.37, 2.72)	NR
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	DIEP	NR	NR	Ref	Ref
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.61 (−8.97, 3.75)	NR
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.36 (−3.45, 6.17)	NR
	NRCS	Moderate	Patient satisfaction with breasts	BREAST-Q: Satisfaction with breast (0-100)	2 y	SIEA	NR	NR	vs. DIEP: adjMD 0.42 (−5.56, 6.4)	NR
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Duration of initial hospitalization	Number of days	Post-op	LD	18	6.4 d (3-12)	Ref	Ref
	RCT	Moderate	Duration of initial hospitalization	Number of days	Post-op	TAP	22	6.5 d (4-14)	vs. TAP: 0.9 d (−1.4, 3.2)	0.45
Zoghbi, 2017, 28052051, US	NRCS	High	Duration of initial hospitalization	Number of days	Post-op	DIEP	9699	4.68 d (2.80)	Ref	Ref
	NRCS	High	Duration of initial hospitalization	Number of days	Post-op	TRAM	6137	4.79 d (2.69)	vs. DIEP: NR	<0.001

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* calculated.

Table E-6.4. Summary Table – Key Question 6: Comparisons of flap types for AR – categorical outcomes (patient satisfaction with breasts, patient satisfaction with outcome, recurrence of breast cancer, and duration of initial hospitalization)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Yueh, 2009, 19228537, US	NRCS	High	Patient satisfaction with breasts	Satisfied with breasts	NR	DIEP	NR/117 (NR)	vs. TRAM: 0.67 (0.37, 1.23) vs. LD: 0.90 (0.60, 1.34)*	NR
	NRCS	High	Patient satisfaction with breasts	Satisfied with breasts	NR	TRAM	102/143 (71.3)	Ref	Ref
	NRCS	High	Patient satisfaction with breasts	Satisfied with breasts	NR	LD	68/112 (60.7)	vs. TRAM: 0.78 (0.54, 1.14)	NR
	NRCS	High	Patient satisfaction with outcome	Generally satisfied with outcome	NR	DIEP	NR/117 (NR)	vs. TRAM: 0.82 (0.33, 2.01) vs. LD: 1.05 (0.70, 1.57)*	NS
	NRCS	High	Patient satisfaction with outcome	Generally satisfied with outcome	NR	TRAM	98/143 (68.5)	Ref	Ref
	NRCS	High	Patient satisfaction with outcome	Generally satisfied with outcome	NR	LD	63/112 (56.3)	vs. TRAM: 0.77 (0.53, 1.11)	NS
Brandberg, 2000, 10626972, Sweden	RCT	High	Recurrence of breast cancer	NR	1 y	TRAM	2/29 (6.9)	vs. LD: 2.15 (0.18, 25.07)*	0.54
	RCT	High	Recurrence of breast cancer	NR	1 y	LD	1/30 (3.33)	vs. LTD: 1.07 (0.03, 33.69)*	0.97
	RCT	High	Recurrence of breast cancer	NR	1 y	LTD	0/16 (0)	vs. TRAM: 0.44 (0.02, 10.28)*	0.61
Zoghbi, 2017, 28052051, US	NRCS	High	Duration of initial hospitalization	Increased length of stay	Postop	DIEP	NR/9699 (NR)	Ref	Ref
	NRCS	High	Duration of initial hospitalization	Increased length of stay	Postop	TRAM	NR/6137 (NR)	vs. DIEP: 1.59 (1.45, 1.72)	<0.001

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Calculated.

Table E-6.5. Summary Table – Key Question 6: Comparisons of flap types for AR – categorical outcomes (various)

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	n/N (%)	Effect Size (95% CI)	P Value
Brandberg, 2000, 10626972, Sweden	RCT	High	Mortality	NR	1 y	TRAM	1/29 (3.5)	vs. LD: OR 0.50 (0.040, 5.83)*	0.58
	RCT	High	Mortality	NR	1 y	LD	2/30 (6.7)	vs. LTD: OR 2.21 (0.09, 52.22)*	0.62
	RCT	High	Mortality	NR	1 y	LTD	0/16 (0)	vs. TRAM: OR 0.9 (0.03, 28.48)*	0.95
Massenburg, 2015, 26487657, US	NRCS	High	Unpanned repeat surgeries for revision	NR	1 mo	Pedicled TRAM	159/1608 (9.9)	vs. LD: adjOR 1.71 (1.25, 2.33)	NR
	NRCS	High	Unpanned repeat surgeries for revision	NR	1 mo	LD	62/1079 (5.7)	Ref	Ref
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Pain	Shoulder related pain (Yes/No)	1 y	LD	13/18 (72)	Ref	Ref
	RCT	Moderate	Pain	Shoulder related pain (Yes/No)	1 y	TAP	7/22 (32)	vs. LD: adjOR 0.05 (0.005, 0.51)	0.011
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Necrosis	Major necrosis requiring removal of the implant	1 y	LD	0/18 (0)	Ref	Ref
	RCT	Moderate	Necrosis	Major necrosis requiring removal of the implant	1 y	TAP	1/22 (4.54)	vs. LD: adjOR 1.67 (0.05, 52.7)*	0.77*
	RCT	Moderate	Necrosis	Minor necrosis: epidermolysis or small necrosis of most distal part of flap	1 y	LD	0/18 (0)	Ref	Ref
	RCT	Moderate	Necrosis	Minor necrosis: epidermolysis or small necrosis of most distal part of flap	1 y	TAP	2/22 (13.6)	vs. LD: adjOR 5.53 (0.26, 118.3)*	0.27*
Abedi, 2016, 25003437, Canada	NRCS	High	Necrosis	Mastectomy flap necrosis	1.6-1.9 y	DIEP	20/83 (24.1)	vs. TRAM: NR	0.61
	NRCS	High	Necrosis	Mastectomy flap necrosis	1.6-1.9 y	TRAM	40/312 (12.8)	Ref	Ref
Kroll, 2000, 10987463, US	NRCS	High	Necrosis	Fat necrosis	3 mo	DIEP	36/279 breasts (12.9)	vs. TRAM: adjOR 2.10 (0.87, 5.10)	0.10
	NRCS	High	Necrosis	Fat necrosis	3 mo	TRAM	9/31 breasts (29)	Ref	Ref

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	n/N (%)	Effect Size (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	NRCS	Moderate	Harms to area of flap harvest	Any donor site complication	2 y	DIEP	99/355 (27.9)	Ref	Ref
	NRCS	Moderate	Harms to area of flap harvest	Any donor site complication	2 y	Free TRAM	14/92 (15.2)	vs. DIEP: adjOR 0.52 (0.27, 1.02)	0.057
	NRCS	Moderate	Harms to area of flap harvest	Any donor site complication	2 y	Pedicled TRAM	14/78 (18.0)	vs. DIEP: adjOR 0.63 (0.32, 1.24)	0.18
	NRCS	Moderate	Harms to area of flap harvest	Any donor site complication	2 y	SIEA	33/62 (53.2)	vs. DIEP: adjOR 2.73 (1.51, 4.96)	0.001
Knox, 2016, 26267400, Canada	NRCS	High	Harms to area of flap harvest	Abdominal bulge or hernia	1.7-2.3 y	DIEP	4/130 (3.10)	Ref	Ref
	NRCS	High	Harms to area of flap harvest	Abdominal bulge or hernia	1.7-2.3 y	TRAM	80/377 (21.2)	vs. DIEP: adjOR 5.2 (1.3, 20.9)	0.002
Mennie, 2015, 25839173, UK	NRCS	High	Harms to area of flap harvest	Hernia repair	3 y	DIEP	63/5144 (1.22)	Ref	Ref
	NRCS	High	Harms to area of flap harvest	Hernia repair	3 y	Free TRAM	50/1963 (2.55)	vs. DIEP: adjOR 1.81 (1.24, 2.64)	NR
	NRCS	High	Harms to area of flap harvest	Hernia repair	3 y	Pedicled TRAM	36/822 (4.38)	vs. DIEP: adjOR 2.89 (1.91, 4.37)	NR
Zhong, 2014, 24675183, Canada	NRCS	High	Harms to area of flap harvest	Abdominal bulge or hernia	NR	DIEP	15/244 (6)	Ref	Ref
	NRCS	High	Harms to area of flap harvest	Abdominal bulge or hernia	NR	TRAM	8/48 (17)	vs. DIEP: adjOR 2.73 (1.01, 7.07)	0.04
Brorson 2020b, 32807615, Sweden	RCT	High	Thromboembolic events	DVT	1 mo	DIEP	0/24 (0)	No events	N/A
	RCT	High	Thromboembolic events	DVT	1 mo	LD	0/32 (0)	No events	N/A
	RCT	High	Thromboembolic events	PE	1 mo	DIEP	0/24 (0)	No events	N/A
	RCT	High	Thromboembolic events	PE	1 mo	LD	0/32 (0)	No events	N/A
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Infections	Any infection	1 y	LD	1/18 (5.6)	Ref	Ref
	RCT	Moderate	Infections	Any infection	1 y	TAP	1/22 (4.5)	vs. LD: OR 1.24 (0.07, 21.2)*	0.88*
Zoghbi, 2017, 28052051, US	NRCS	High	Infections	Wound infections	Postop	TRAM	NR/6137 (NR)	vs. DIEP: adjOR 1.67 (1.23, 2.27)	0.001
	NRCS	High	Infections	Wound infections	Postop	DIEP	NR/9699 (NR)	Ref	Ref
Zoghbi, 2017, 28052051, US	NRCS	High	Wound dehiscence	NR	NR	DIEP	NR/9699 (NR)	Ref	Ref
	NRCS	High	Wound dehiscence	NR	NR	TRAM	NR/6137 (NR)	vs. DIEP: adjOR 4.3 (NR)	<0.00001

Study, Year, PMID, Country	Design	Overall RoB	Outcome	Outcome Measurement	Time Point	Flap Type	n/N (%)	Effect Size (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Seroma	NR	1 y	LD	1/18 (5.6)	Ref	Ref
	RCT	Moderate	Seroma	NR	1 y	TAP	0/22 (0)	vs. LD: OR 2.53 (0.08, 80.0)*	0.59*
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Hematoma	NR	1 y	LD	0/18 (0)	Ref	Ref
	RCT	Moderate	Hematoma	NR	1 y	TAP	1/22 (4.5)	Not calculable (no events in Ref group)	Not calculable
Kroll, 2000, 10987463, US	NRCS	High	Flap failure/loss	Partial flap loss	3 mo	DIEP	5/31 breasts (16.1)	vs. TRAM: adjOR 6.74 (1.83, 24.7)	0.004
	NRCS	High	Flap failure/loss	Partial flap loss	3 mo	TRAM	6/279 breasts (2.20)	Ref	Ref
Massenburg, 2015, 26487657, US	NRCS	High	Flap failure/loss	NR	1 mo	Pedicled TRAM	67/2464 (2.7)	vs. LD: adjOR 2.28 (1.38, 3.77)	0.001
	NRCS	High	Flap failure/loss	NR	1 mo	LD	22/2085 (1.1)	Ref	Ref

Abbreviations: adj = adjusted AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, DVT = deep vein thrombosis, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, OR = odds ratio, PE = pulmonary embolism, RCT = randomized controlled trial, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

* Calculated.

Table E-6.6. Summary Table – Key Question 6: Comparisons of flap types for AR – categorical outcomes (composite or unspecified harms)

Study, Year, PMID, Country	Design	Overall RoB	Outcome Description	Time Point	Flap Type	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Brorson 2020b, 32807615, Sweden	RCT	High	Clavien-Dindo Grade I complications	1 mo	DIEP	16/34 (47)	Ref	Ref	Ref
	RCT	High	Clavien-Dindo Grade I complications	1 mo	LD	20/33 (63)	vs. DIEP	1.73 (0.66, 4.57)	0.27
	RCT	High	Clavien-Dindo Grade II complications	1 mo	DIEP	14/34 (41)	Ref	Ref	Ref
	RCT	High	Clavien-Dindo Grade II complications	1 mo	LD	16/32 (50)	vs. DIEP	1.29 (0.48, 3.44)	0.76
	RCT	High	Clavien-Dindo Grade IIIa complications	1 mo	DIEP	9/34 (26)	Ref	Ref	Ref
	RCT	High	Clavien-Dindo Grade IIIa complications	1 mo	LD	7/32 (22)	vs. DIEP	0.85 (0.27, 2.64)	0.77
	RCT	High	Clavien-Dindo Grade IIIb complications	1 mo	DIEP	11/34 (32)	Ref	Ref	Ref
	RCT	High	Clavien-Dindo Grade IIIb complications	1 mo	LD	3/32 (9)	vs. DIEP	0.22 (0.05, 0.87)	0.031
	RCT	High	Clavien-Dindo Grade IV complications	1 mo	DIEP	0/34 (0)	Ref	No events	N/A
	RCT	High	Clavien-Dindo Grade IV complications	1 mo	LD	0/32 (0)	vs. DIEP	No events	N/A
	RCT	High	Clavien-Dindo Grade V complications	1 mo	DIEP	0/34 (0)	Ref	No events	N/A
	RCT	High	Clavien-Dindo Grade V complications	1 mo	LD	0/32 (0)	vs. DIEP	No events	N/A
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Minor complications treated conservatively	1 y	LD	2/18 (11.1)	Ref	Ref	Ref
	RCT	Moderate	Minor complications treated conservatively	1 y	TAP	2/22 (9.09)	vs. LD	0.8 (0.1, 6.32)*	0.83*
	RCT	Moderate	Major complications requiring surgical intervention	1 y	LD	0/18 (0)	Ref	Ref	Ref
	RCT	Moderate	Major complications requiring surgical intervention	1 y	TAP	4/22 (18)	vs. LD	0.13 (0.01, 2.62)*	0.18*
Dauplat, 2021, 33622886, France	NRCS	Moderate	Major complications requiring surgical intervention or readmission	1 y	TRAM	10/30 (30)	Ref	Ref	Ref
	NRCS	Moderate	Major complications requiring surgical intervention or readmission	1 y	LD with implant	9/91 (9)	Ref	Ref	Ref
	NRCS	Moderate	Major complications requiring surgical intervention or readmission	1 y	LD without implant	7/78 (9)	vs. TRAM vs. LD with implant	1.69 (1.19, 2.41) 4.85 (1.67, 14.1)	NR NR
Erdmann-Sager, 2018, 29019862, US & Canada	NRCS	Moderate	Any breast complication	2 y	DIEP	NR	Ref	Ref	Ref
	NRCS	Moderate	Any breast complication	2 y	Free TRAM	NR	vs. DIEP	0.51 (0.25, 1.02)	0.58
	NRCS	Moderate	Any breast complication	2 y	Pedicled TRAM	NR	vs. DIEP	0.94 (0.46, 1.94)	0.87
	NRCS	Moderate	Any breast complication	2 y	SIEA	NR	vs. DIEP	1.15 (0.61, 2.17)	0.67

Study, Year, PMID, Country	Design	Overall RoB	Outcome Description	Time Point	Flap Type	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Massenburg, 2015, 26487657, US	NRCS	High	Any complication	1 mo	Pedicled TRAM	216/1608 (13.4)	vs. LD	1.92 (1.45, 2.55)	NR
	NRCS	High	Any complication	1 mo	LD	77/1079 (7.1)	Ref	Ref	Ref
	NRCS	High	Superficial SSI, deep SSI, organ space infection, or wound disruption/ dehiscence	1 mo	Pedicled TRAM	199/2464 (8.1)	vs. LD	1.80 (1.29, 2.51)	0.001
	NRCS	High	Superficial SSI, deep SSI, organ space infection, or wound disruption/ dehiscence	1 mo	LD	90/2085 (4.3)	Ref	Ref	Ref
Zhong, 2014, 24675183, Canada	NRCS	High	Major breast complications (total/partial flap loss, fat necrosis, or breast hematoma)	NR	DIEP	50/244 (20.5)	Ref	Ref	Ref
	NRCS	High	Major breast complications (total/partial flap loss, fat necrosis, or breast hematoma)	NR	TRAM	10/48 (20.8)	vs. DIEP	0.98 (0.4, 2.14)	0.95

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous, SIEA = superficial inferior epigastric artery, SSI = surgical site infection, TAP = thoracodorsal artery perforator, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Appendix F. Results: Full Evidence Tables for Outcomes

Table F-1.1. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (general quality of life)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Kouwenberg, 2019, 30270015, Netherlands	EQ-5D-5L utilities score (0-1)	NRCS	Moderate	NR	IBR	67	0.853 (0.18)	Ref	Ref
	EQ-5D-5L utilities score (0-1)	NRCS	Moderate	NR	AR	67	0.872 (0.14)	NR	0.7
Kouwenberg, 2020, 32590633, Netherlands	EQ-5D-5L utilities score (0-1)	NRCS	Moderate	>6 mo	IBR	296	0.85 (0.30)	Ref	Ref
	EQ-5D-5L utilities score (0-1)	NRCS	Moderate	>6 mo	AR	179	0.85 (0.20)	NR	NS
	EQ-5D-5L VAS (0-100)	NRCS	Moderate	>6 mo	IBR	296	77.6 (18.4)	Ref	Ref
	EQ-5D-5L VAS (0-100)	NRCS	Moderate	>6 mo	AR	179	79.2 (16.7)	NR	NS
	EORTC QLQC30: Global health status (0-100)	NRCS	Moderate	>6 mo	IBR	296	80.2 (18.4)	Ref	Ref
	EORTC QLQC30: Global health status (0-100)	NRCS	Moderate	>6 mo	AR	179	81.4 (14.7)	NR	NS
Roth, 2007, 17413877, US	SF-36: Role emotional (0-100)	NRCS	High	Pre-op	IBR	35	69.5 (NR)	Ref	Ref
	SF-36: Role emotional (0-100)	NRCS	High	Pre-op	AR	55	60.6 (NR)	NR	NR
	SF-36: Role emotional (0-100)	NRCS	High	2 y	IBR	35	86.7 (NR)	Ref	Ref
	SF-36: Role emotional (0-100)	NRCS	High	2 y	AR	55	86.1 (NR)	NR	≥0.05
	SF-36: Vitality (0-100)	NRCS	High	Pre-op	IBR	35	57.5 (NR)	Ref	Ref
	SF-36: Vitality (0-100)	NRCS	High	Pre-op	AR	55	55.8 (NR)	NR	NR
	SF-36: Vitality (0-100)	NRCS	High	2 y	IBR	35	65.7 (NR)	Ref	Ref
	SF-36: Vitality (0-100)	NRCS	High	2 y	AR	55	62.4 (NR)	NR	NR
	SF-36: General mental health (0-100)	NRCS	High	Pre-op	IBR	35	67.5 (NR)	Ref	Ref
	SF-36: General mental health (0-100)	NRCS	High	Pre-op	AR	55	65.9 (NR)	NR	NR
	SF-36: General mental health (0-100)	NRCS	High	2 y	IBR	35	77.6 (NR)	Ref	Ref
	SF-36: General mental health (0-100)	NRCS	High	2 y	AR	55	77 (NR)	NR	≥0.05
	FACT-B: Functional well-being (0-28)	NRCS	High	Pre-op	IBR	35	20.9 (NR)	Ref	Ref
	FACT-B: Functional well-being (0-28)	NRCS	High	Pre-op	AR	55	20.7 (NR)	NR	NR
	FACT-B: Functional well-being (0-28)	NRCS	High	2 y	IBR	35	23.3 (NR)	Ref	Ref
	FACT-B: Functional well-being (0-28)	NRCS	High	2 y	AR	55	24.1 (NR)	NR	≥0.05
	Body Image (9-45)	NRCS	High	Pre-op	IBR	35	34.2 (NR)	Ref	Ref
	Body Image (9-45)	NRCS	High	Pre-op	AR	55	34.7 (NR)	NR	NR
	Body Image (9-45)	NRCS	High	2 y	IBR	35	32.5 (NR)	Ref	Ref
	Body Image (9-45)	NRCS	High	2 y	AR	55	35.3 (NR)	NR	≥0.05

Abbreviations: adj = adjusted, CI = confidence interval, EQ-5D-5L = 5-level European Quality of Life-5D version, MD = mean difference, NR = not reported, NMD = net mean difference, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, Ref = reference group, RoB = risk of bias, SD = standard deviation, SF = Short Form.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.2. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	BREAST-Q: Chest (0-100)	RCT	Moderate	5.3 y	IBR	All	28	72.0 (21.5)	Ref	Ref
	BREAST-Q: Chest (0-100)	RCT	Moderate	5.3 y	AR	All	42	79.6 (21.1)	MD 7.6 (0.3, 14.9)	0.041
Eltahir, 2015, 25539295, Netherlands	BREAST-Q: Physical well-being (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	71.89 (15.06)	Ref	Ref
	BREAST-Q: Physical well-being (0-100)	NRCS	Moderate	2.2 y	AR	All	47	77.13 (17.11)	adjMD −2.6 (−9.77, 4.57)	0.473
	RAND R1: physical functioning (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	NR	Ref	Ref
	RAND R1: physical functioning (0-100)	NRCS	Moderate	2.2 y	AR	All	NR	NR	adjMD 2.13 (−4.2, 8.46)	0.506
Kouwenberg, 2020, 32590633, Netherlands	BREAST-Q: Chest (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	72.6 (17.8)	Ref	Ref
	BREAST-Q: Chest (0-100)	NRCS	Moderate	>6 mo	AR	All	179	75.8 (15.4)	NR	<0.05
	EORTC QLQC30 (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	88.0 (20.6)	Ref	Ref
	EORTC QLQC30 (0-100)	NRCS	Moderate	>6 mo	AR	All	179	85.6 (15.7)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1132	80 (14)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	IBR (all)	Unilateral	600	80.3 (13.9)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	IBR (all)	Bilateral	994	80.3 (14.6)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR (all)	All	493	76.5 (15.5)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR (all)	Unilateral	317	77.4 (15.8)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR (all)	Bilateral	224	77.1 (14.7)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	IBR (all)	All	791	76.7 (14.5)	Ref	Ref
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR (all)	All	386	74.9 (15.1)	vs IBR (all): adjMD 1.6 (−0.57, 3.68)	0.003
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	IBR (all)	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	IBR (all)	Unilateral	600	77.2 (13.8)	Ref	Ref
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	IBR (all)	Bilateral	994	77.3 (14.6)	Ref	Ref
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR (all)	Unilateral	317	76.3 (15.4)	Vs IBR (Unilateral): adjMD 1.77 (NR, NR)	0.238
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR (all)	Bilateral	224	74.5 (15.4)	Vs IBR (Bilateral): adjMD 0.57 (NR, NR)	0.57

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	IBR (all)	All	1846	NR	Ref	Ref
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR (all)	All	NR	NR	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR with DIEP	All	463	NR	vs IBR (all): adjMD 4.89 (NR, NR)	0.57
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR with free TRAM	All	111	NR	vs IBR (all): adjMD 2.51 (NR, NR)	0.06
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR with pedicled TRAM	All	94	NR	vs IBR (all): adjMD 6.71 (NR, NR)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR with LD	All	80	NR	vs IBR (all): adjMD −0.79 (NR, NR)	0.56
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 w	AR with SIEA	All	73	NR	vs IBR (all): adjMD 4.56 (NR, NR)	0.01
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	IBR (all)	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	IBR Direct	All	96	70.6 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	IBR TE	All	1329	67.5 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR (all)	All	NR	NR	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with DIEP	All	296	72.9 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with free TRAM	All	83	68.3 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with pedicled TRAM	All	91	70.9 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with LD	All	62	69.3 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with SIEA	All	56	73 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	IBR (all)	All	1490	NR	Ref	Ref
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	IBR Direct	All	93	NR	Ref	Ref
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	IBR TE	All	1263	NR	vs IBR (direct): adjMD 0.92 (NR, NR)	0.629
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR (all)	All	1523	75.6 (15.4)	vs IBR (all): adjMD 1.69 (0.13, 3.24)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	350	NR	vs IBR (TE): adjMD −1.44 (NR, NR)	0.289
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	87	NR	vs IBR (TE): adjMD −0.62 (NR, NR)	0.774

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	77	NR	vs IBR (TE): adjMD −3.93 (NR, NR)	0.068
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with LD	All	64	NR	vs IBR (TE): adjMD −0.22 (NR, NR)	0.93
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	62	NR	vs IBR (TE): adjMD 2.83 (NR, NR)	0.273
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	IBR (all)	All	1129	91.3 (12.4)		
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR (all)	All	491	87.6 (15)	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	IBR (all)	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR (all)	All	378	74.5 (19.1)	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	IBR (all)	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR (all)	All	763	76.3 (19.8)	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Abdomen	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	IBR (all)	All	1133	45.5 (7.1)	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR (all)	All	493	46.4 (7.7)	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	IBR (all)	All	773	46 (7.5)	Ref	Ref

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR (all)	All	384	48.4 (8.4)	vs IBR (all): adjMD 1.1 (0.01, 2.25)	0.048
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	.	.
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	.	.
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	.	.
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	.	.
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	.	.
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1135	53.3 (6.6)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	IBR (all)	Unilateral	600	53.1 (6.6)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	IBR (all)	Bilateral	994	53.5 (6.6)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR (all)	All	492	52.4 (7.1)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR (all)	Unilateral	317	52.5 (6.9)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR (all)	Bilateral	214	52.4 (7.1)	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	IBR (all)	All	777	52.2 (6.8)	Ref	Ref
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	IBR (all)	Unilateral	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	IBR (all)	Bilateral	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR (all)	All	385	50.1 (7.2)	vs IBR (all): adjMD −0.6 (−1.51, 0.39)	0.249
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR (all)	Unilateral	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR (all)	Bilateral	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	IBR (all)	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	IBR (all)	Unilateral	600	52.6 (6.5)	Ref	Ref
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	IBR (all)	Bilateral	994	52.8 (6.3)	Ref	Ref
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR (all)	Unilateral	317	51.3 (7.3)	vs IBR (unilateral): adjMD −0.14 (NR, NR)	0.830
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR (all)	Bilateral	214	49.8 (7.6)	vs IBR (bilateral): adjMD −1.21 (NR, NR)	0.06

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR
McCarthy, 2014, 24201740, US	BREAST-Q: Physical well-being (0-100)	NRCS	Moderate	1-5 y	IBR	All	141	76.5 (16)	Ref	Ref
	BREAST-Q: Physical well-being (0-100)	NRCS	Moderate	1-5 y	AR	.	74	82.5 (15.3)	NR	<0.05
Nelson, 2019, 31356276, US	BREAST-Q: Chest (0-100)	NRCS	High	1 y	IBR	.	1342	73.62 (15.95)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	1 y	AR	.	194	74.52 (17.28)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	3 y	IBR	.	1085	75.62 (16.09)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	3 y	AR	.	98	77.71 (14.81)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	5 y	IBR	.	743	76.98 (16.46)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High y	5 y	AR	.	41	84.12 (15.86)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	7 y	IBR	.	377	76.44 (17.23)	NR	NR
	BREAST-Q: Chest (0-100)	NRCS	High	7 y	AR	.	19	78.37 (14.47)	NR	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio (reported as odds of scoring higher), PMID = Pubmed identifier, PROMIS: Patient Reported Outcomes Measurement Information System, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.3. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (psychosocial well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	BREAST-Q: Psychosocial WB (0-100)	RCT	Moderate	5.3 y	IBR	All	28	78.8 (20.1)	Ref	Ref
	BREAST-Q: Psychosocial WB (0-100)	RCT	Moderate	5.3 y	AR	All	42	79.1 (21.5)	MD 0.3 (−6.7, 7.3)	0.93
Eltahir, 2015, 25539295, Netherlands	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	77.18 (18.1)	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2.2 y	AR	All	47	73.96 (17.8)	adjMD 4.61 (−2.8, 12.01)	0.22
	RAND R1: Social functioning (0-100)	NRCS	Moderate	2.2 y	IBR	All	NR	NR	Ref	Ref
	RAND R1: Social functioning (0-100)	NRCS	Moderate	2.2 y	AR	All	NR	NR	adjMD −1.21 (−8.44, 6.02)	0.741
Kouwenberg , 2020, 32590633, Netherlands	BREAST-Q: Psychosocial WB (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	71.6 (20.2)	Ref	Ref
	BREAST-Q: Psychosocial WB (0-100)	NRCS	Moderate	>6 mo	AR	All	179	75.8 (19.5)	NR	<0.05
	EORTC QLQC30: Social function (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	87.5 (27.2)	Ref	Ref
	EORTC QLQC30: Social function (0-100)	NRCS	Moderate	>6 mo	AR	All	179	88.0 (17.1)	NR	NS
	EORTC QLQC30: Emotional function (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	85.0 (23.3)	Ref	Ref
	EORTC QLQC30: Emotional function (0-100)	NRCS	Moderate	>6 mo	AR	All	179	87.0 (17.1)	NR	NS
	EORTC QLQC30: Cognitive function (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	85.0 (23.7)	Ref	Ref
	EORTC QLQC30: Cognitive function (0-100)	NRCS	Moderate	>6 mo	AR	All	179	83.7 (21.5)	NR	NS
	EORTC QLQC30: Role function (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	86.0 (28.1)	Ref	Ref
	EORTC QLQC30: Role function (0-100)	NRCS	Moderate	>6 mo	AR	All	179	84.0 (21.8)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1131	72.4 (17.5)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	IBR (all)	Unilateral	600	73 (17.5)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	IBR (all)	Bilateral	994	71.2 (17.5)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR (all)	All	492	68.4 (18.3)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR (all)	Unilateral	317	69 (18.3)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR (all)	Bilateral	224	66.5 (18.1)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	IBR (all)	All	791	71.8 (19)	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR (all)	All	386	74.7 (19.2)	vs IBR (all): adjMD 3.7 (0.73, 6.76)	0.015
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	IBR (all)	All	1490	74.5 (18.9)	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	IBR (all)	Unilateral	600	74.6 (18.7)	Ref	Ref

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	IBR (all)	Bilateral	994	74.5 (19)	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR (all)	All	523	75.8 (19)	vs IBR (all): adjMD 3.27 (1.25, 5.29)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR (all)	Unilateral	317	76.8 (18.9)	vs IBR (unilateral): adjMD 4.84 (NR, NR)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR (all)	Bilateral	224	73.4 (19)	vs IBR (bilateral): adjMD 0.91 (NR, NR)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1136	59.1 (8.8)	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR (all)	All	493	58.3 (8.8)	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	IBR (all)	All	775	49.7 (9.4)	Ref	Ref
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR (all)	All	383	50.4 (9.6)	vs IBR (all): adjMD 0.7 (−0.75, 2.08)	0.356
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	PROMIS: Anxiety (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1135	49.8 (8.3)	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR (all)	All	493	49.7 (8.5)	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	IBR (all)	All	776	47.3 (8)	Ref	Ref
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR (all)	All	385	47.9 (8.2)	vs IBR (all): adjMD 0.4 (−0.7, 1.45)	0.497
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	PROMIS: Depression (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Roth, 2007, 17413877, US	SF-36: Social functioning (0-100)	NRCS	High	Pre-op	IBR	All	35	74.3 (NR)	Ref	Ref
	SF-36: Social functioning (0-100)	NRCS	High	Pre-op	AR	All	55	78.2 (NR)	NR	NR
	SF-36: Social functioning (0-100)	NRCS	High	2 y	IBR	All	35	87.9 (NR)	Ref	Ref
	SF-36: Social functioning (0-100)	NRCS	High	2 y	AR	All	55	87.7 (NR)	NR	≥0.05
	FACT-B: Social/family well-being (0-28)	NRCS	High	Pre-op	IBR	All	35	20.8 (NR)	Ref	Ref
	FACT-B: Social/family well-being (0-28)	NRCS	High	Pre-op	AR	All	55	21.6 (NR)	NR	NR
	FACT-B: Social/family well-being (0-28)	NRCS	High	2 y	IBR	All	35	19.3 (NR)	Ref	Ref
	FACT-B: Social/family well-being (0-28)	NRCS	High	2 y	AR	All	55	20.3 (NR)	NR	0.24

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, FACT-B = Functional Assessment of Cancer Therapy – Breast, LD = latissimus dorsi, MD = mean difference, mo = months, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.4. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (sexual well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	BREAST-Q: Sexual well-being (0-100)	RCT	Moderate	5.3 y	IBR	All	28	58.4 (23.1)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	RCT	Moderate	5.3 y	AR	All	42	67.1 (28.1)	MD 8.7 (0.2, 17.2)	0.046
Eltahir, 2015, 25539295, Netherlands	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	61.14 (24.17)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2.2 y	AR	All	47	60.89 (20.82)	adjMD 6.44 (−3.56, 16.45)	0.204
Kouwenberg, 2020, 32590633, Netherlands	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	56.4 (30.7)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	>6 mo	AR	All	179	63.3 (30.4)	NR	<0.05
	EORTC QLQBR23: Sexual functioning (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	33.4 (29.4)	Ref	Ref

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	EORTC QLQBR23: Sexual functioning (0-100)	NRCS	Moderate	>6 mo	AR	All	179	32.0 (27.3)	NR	<0.05
	EORTC QLQBR23: Sexual enjoyment (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	63.8 (32.5)	Ref	Ref
	EORTC QLQBR23: Sexual enjoyment (0-100)	NRCS	Moderate	>6 mo	AR	All	179	64.2 (33.8)	NR	NS
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1104	59.1 (18.3)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	.	Unilateral	600	58.4 (19.7)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	.	Bilateral	994	59 (18.5)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR (all)	All	477	54 (20.9)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	.	Unilateral	317	54 (20.4)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	.	Bilateral	214	52.9 (21.5)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	IBR (all)	All	756	53 (21.1)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR (all)	All	370	55.4 (19.8)	vs IBR (all): adjMD 4.50 (1.52, 7.48)	0.003
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	IBR (all)	All	1490	53.9 (21.3)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	.	Unilateral	600	52.8 (20.5)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	.	Bilateral	994	54.7 (21.5)	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR (all)	All	523	57.1 (21.7)	vs IBR (all): adjMD 5.53 (2.95, 8.11)	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	.	Unilateral	317	58.9 (20.6)	vs IBR (unilateral): adjMD 11.42 (NR, NR)	<0.001
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	.	Bilateral	214	54.4 (23)	vs IBR (bilateral): adjMD 4.2 (NR, NR)	<0.001
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.5. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	BREAST-Q: Satisfaction with breast (0-100)	RCT	Moderate	5.3 y	IBR	All	28	63.4 (11.8)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	RCT	Moderate	5.3 y	AR	All	42	72.1 (17.7)	MD 8.7 (3.8, 13.6)	0.001
	BREAST-Q: Satisfaction with nipples (0-100)	RCT	Moderate	5.3 y	IBR	All	28	65.4 (21.8)	Ref	Ref
	BREAST-Q: Satisfaction with nipples (0-100)	RCT	Moderate	5.3 y	AR	All	42	67.7 (24.9)	MD 2.3 (−5.5, 10.1)	0.56
Brito, 2020, No PMID, Portugal	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	NR	IBR	All	68	56.3 (17.1)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	NR	AR	All	111	64.1 (17.1)	NR	0.004
Eltahir, 2015, 25539295, Netherlands	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	65.51 (17.55)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2.2 y	AR	All	47	75.19 (17.09)	adjMD −8.16 (−15.15, −1.18)	0.023
	BREAST-Q: Satisfaction with nipples (0-100)	NRCS	Moderate	2.2 y	IBR	All	45	63.62 (33.99)	Ref	Ref
	BREAST-Q: Satisfaction with nipples (0-100)	NRCS	Moderate	2.2 y	AR	All	47	65.31 (27.82)	adjMD −1.7 (−17.55, 14.15)	0.831
Kouwenberg, 2020, 32590633, Netherlands	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	59.4 (19.3)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	>6 mo	AR	All	179	71.3 (17.7)	NR	<0.05

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with nipples (0-100)	NRCS	Moderate	>6 mo	IBR	All	296	55.0 (48.7)	Ref	Ref
	BREAST-Q: Satisfaction with nipples (0-100)	NRCS	Moderate	>6 mo	AR	All	179	63.0 (29.0)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	IBR (all)	All	1132	64.9 (21.2)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	IBR (all)	Unilateral	600	65.8 (21.7)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	IBR (all)	Bilateral	994	62.8 (21)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR (all)	All	491	59 (20.7)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR (all)	Unilateral	317	59.6 (21.1)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR (all)	Bilateral	214	56.1 (18.5)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR with pedicled TRAM	All	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	Baseline	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	IBR (all)	All	795	64 (16.8)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR (all)	All	388	67.8 (17.2)	vs IBR (all): adjMD 6.3 (3.41, 9.09)	<0.001
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	IBR (all)	All	1490	64.2 (18)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	IBR (all)	Unilateral	600	61.2 (18)	Ref	Ref

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	IBR (all)	Bilateral	994	66.1 (17.7)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	IBR Direct	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	IBR TE	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR (all)	All	523	68.5 (18.3)	vs IBR (all): adjMD 7.94 (5.68, 10.2)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR (all)	Unilateral	317	68.3 (18.1)	vs IBR (unilateral): adjMD 9.85 (NR, NR)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR (all)	Bilateral	214	68.9 (18.6)	vs IBR (bilateral): adjMD 5.13 (NR, NR)	0.001
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with DIEP	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with free TRAM	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with LD	All	NR	NR	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR	NR
Nelson, 2019, 31356276, US	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	1 y	IBR		1342	64.17 (18.68)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	1 y	AR		194	68.25 (20.24)	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	Subgroup	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	3 y	IBR		1085	63.7 (17.66)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	3 y	AR		98	73.48 (17.07)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	5 y	IBR		743	63.06 (17.25)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	5 y	AR		41	79.65 (19.49)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	7 y	IBR		377	64.67 (19.19)	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	7 y	AR		19	76 (18.24)	NR	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.6. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (physical well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	IBR, n/N (%)	AR, n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Nelson, 2019, 31356276, US	Likely to have higher BREAST-Q: Chest scores	NRCS	High	1 y	NR/1342 (NR)	NR/194 (NR)	0.96 (0.67, 1.38)	NS
	Likely to have higher BREAST-Q: Chest scores	NRCS	High	3 y	NR/1085 (NR)	NR/98 (NR)	1.4 (0.83, 2.34)	NS
	Likely to have higher BREAST-Q: Chest scores	NRCS	High	5 y	NR/743 (NR)	NR/41 (NR)	4.52 (2.03, 10.1)	<0.001
	Likely to have higher BREAST-Q: Chest scores	NRCS	High	7 y	NR/377 (NR)	NR/19 (NR)	3.08 (1.03, 9.15)	0.043

Abbreviations: AR = autologous reconstruction, CI = confidence interval, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-1.7. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Odds Ratio (95% CI)	P Value
Lei, 2020, 32481367, China	Satisfied with breasts	NRCS	High	2 mo	IBR	NR	Ref	Ref	Ref
	Satisfied with breasts	NRCS	High	2 mo	AR	NR	vs. IBR	0.85 (0.36, 1.63)	0.40
Yueh, 2009, 19228537, US	Satisfied with breasts	NRCS	High	NR	IBR	42/87 (48.3)	Ref	Ref	Ref
	Satisfied with breasts	NRCS	High	NR	AR	NR/389 (NR)	vs. IBR	1.43 (1.18, 1.73)	NR
	Satisfied with breasts	NRCS	High	NR	AR with DIEP	NR/117 (NR)	vs. AR with TRAM	0.67 (0.37, 1.23)	NR
	Satisfied with breasts	NRCS	High	NR	AR with TRAM	102/143 (71.3)	vs. IBR	3.49 (1.91, 6.40)	NR
	Satisfied with breasts	NRCS	High	NR	AR with LD	68/112 (60.7)	vs. IBR vs. AR with TRAM	1.99 (1.09, 3.65) 0.78 (0.54, 1.14)	NR NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.8. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (patient satisfaction with outcome)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Tallroth, 2020, 33436336, Sweden	BREAST-Q: Satisfaction with outcome (0-100)	RCT	Moderate	5.3 y	IBR	28	79.4 (14.2)	Ref	Ref
	BREAST-Q: Satisfaction with outcome (0-100)	RCT	Moderate	5.3 y	AR	42	82.3 (21.4)	MD 2.9 (−3.1, 8.9)	0.34
Eltahir, 2015, 25539295, Netherlands	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	Moderate	2.2 y	IBR	45	74.53 (18.98)	Ref	Ref
	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	Moderate	2.2 y	AR	47	81.82 (18.69)	adjMD 4.9 (−3.09, 12.89)	0.226
Kouwenberg, 2020, 32590633, Netherlands	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	Moderate	>6 mo	IBR	296	66.4 (23.7)	Ref	Ref
	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	Moderate	>6 mo	AR	179	75.8 (22.2)	NR	<0.05
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	IBR Direct	79	73.4 (16.8)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	IBR TE	942	72.6 (18.1)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with DIEP	395	72.8 (13)	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with free TRAM	NR	72.8 (16.5)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with pedicled TRAM	65	76.2 (19.9)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with LD	53	69.3 (19.1)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	IBR Direct	79	87.5 (17.1)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	IBR TE	942	88.5 (17)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with DIEP	395	91.6 (14)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with free TRAM	NR	NR	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with pedicled TRAM	65	91 (15.9)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with LD	53	92.5 (14.4)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	IBR Direct	79	90.1 (18.4)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	IBR TE	942	93.2 (15.2)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with DIEP	395	90 (19)	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with free TRAM	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with pedicled TRAM	65	91 (13.8)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with LD	53	94.5 (12.7)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	IBR Direct	79	92.6 (15.8)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	IBR TE	942	96.6 (10.4)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with DIEP	395	93.8 (13.4)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with free TRAM	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with pedicled TRAM	65	93.5 (14.6)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with LD	53	94.7 (14.6)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR

Abbreviations: adj = adjusted, CI = confidence interval, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.9. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (patient satisfaction with outcome)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Satisfied with surgical outcome	NRCS	High	2 mo	IBR	NR	Ref	Ref	Ref

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Lei, 2020, 32481367, China	Satisfied with surgical outcome	NRCS	High	2 mo	AR	NR	vs. IBR	0.69 (0.45, 1.67)	0.33
Yueh, 2009, 19228537, US	Satisfied with surgical outcome	NRCS	High	NR	IBR	49/87 (56.3)	Ref	Ref	Ref
	Satisfied with surgical outcome	NRCS	High	NR	AR	NR/389 (NR)	vs. IBR	1.83 (1.11, 3.03)	NR
	Satisfied with surgical outcome	NRCS	High	NR	AR with DIEP	NR/117 (NR)	vs. AR with TRAM	0.82 (0.33, 2.01)	NR
	Satisfied with surgical outcome	NRCS	High	NR	AR with TRAM	98/143 (68.5)	vs. IBR	2.05 (1.13, 3.72)	NR
	Satisfied with surgical outcome	NRCS	High	NR	AR with LD	63/112 (56.3)	vs. IBR vs. AR with TRAM	1.12 (0.64, 2.12) 0.77 (0.53, 1.11)	NR NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.10. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (recurrence of breast cancer)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Ha, 2020, 32000718, South Korea	Locoregional recurrence detected by biopsy or imaging	NRCS	High	4.8 y	IBR	9/247 (3.6)	Ref	Ref
	Locoregional recurrence detected by biopsy or imaging	NRCS	High	4.8 y	AR	11/249 (4.4)	NR	0.704
	Any relapse	NRCS	High	4.8 y	IBR	14/247 (5.7)	Ref	Ref
	Any relapse	NRCS	High	4.8 y	AR	24/249 (9.6)	adjHR 3.39 (1.23, 9.32)	0.018
Kouwenberg, 2020, 32590633, Netherlands	Local recurrence	NRCS	Moderate	>6 mo	IBR	13/296 (4.5	Ref	Ref
	Local recurrence	NRCS	Moderate	>6 mo	AR	7/179 (4.0)	adjOR 0.89 (0.35, 2.26)	0.25
	Distant recurrence	NRCS	Moderate	>6 mo	IBR	13/296 (4.5)	Ref	Ref
	Distant recurrence	NRCS	Moderate	>6 mo	AR	8/179 (4.6)	adjOR 1.02 (0.41, 2.51)	0.97
Wu, 2021, 33740204, South Korea	NR	NRCS	High	5.8 y	IBR	29/138 (21.0)	Ref	Ref
	NR	NRCS	High	5.8 y	AR	64/276 (23.2)	NR	0.62

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, HR= hazard ratio, IBR = implant-based reconstruction, N/A = not applicable, OR = odds ratio, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, PMID = PubMed identifier.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.11. Full Evidence Table – Key Question 1: IBR versus AR – continuous outcomes (harms, pain, and analgesic use)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Eltahir, 2015, 25539295, Netherlands	Pain	RAND R7: Pain	NRCS	Moderate	2.2 y	IBR	NR	NR	Ref	Ref
	Pain	RAND R7: Pain	NRCS	Moderate	2.2 y	AR	NR	NR	adjMD 2.40 (−5.37, 10.17)	0.541
Kouwenberg, 2020, 32590633, Netherlands	Pain	EORTC QLQC30 Pain (0-100)	NRCS	Moderate	>6 mo	IBR	296	15.9 (26.3)	Ref	Ref
	Pain	EORTC QLQC30 Pain (0-100)	NRCS	Moderate	>6 mo	AR	179	17.2 (27.2)	NR	NS
Kulkarni, 2017, 28713853, US & Canada	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR (all)	463	NR	NR	NR
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR with DIEP	111	NR	vs. IBR (all): adjMD −1.2 (NR, NR)	0.01
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR with free TRAM	94	NR	vs. IBR (all): adjMD 0.26 (NR, NR)	0.72
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR with pedicled TRAM	NR	NR	vs. IBR (all): adjMD −1.04 (NR, NR)	0.17
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): adjMD 0.35 (NR, NR)	0.69
	Pain	MPQ-SF: Sensory	NRCS	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): adjMD 2.41 (NR, NR)	0.02
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	IBR Direct	96	4.2 (NR)	vs. IBR TE: adjMD 0 (NR, NR)	0.997
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	IBR TE	1329	5.7 (NR)	Ref	Ref
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR with DIEP	296	4.8 (NR)	vs. IBR TE: adjMD 1.1 (NR, NR)	0.004
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR with free TRAM	83	6.7 (NR)	vs. IBR TE: adjMD 2.48 (NR, NR)	<0.001
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR with pedicled TRAM	91	5 (NR)	vs. IBR TE: adjMD 1.19 (NR, NR)	0.08
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR with LD	62	5.4 (NR)	vs. IBR TE: adjMD 0.42 (NR, NR)	0.606
	Pain	MPQ-SF: Sensory	NRCS	Moderate	3 mo	AR with SIEA	56	NR	vs. IBR TE: adjMD 2.37 (NR, NR)	0.003
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR with DIEP	463	NR	vs. IBR (all): adjMD 0.24 (NR, NR)	0.16
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR with free TRAM	111	NR	vs. IBR (all): adjMD 0.37 (NR, NR)	0.16
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR with pedicled TRAM	94	NR	vs. IBR (all): adjMD −0.01 (NR, NR)	0.98
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): adjMD 0.47 (NR, NR)	0.15
	Pain	MPQ-SF: Affective	NRCS	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): adjMD −0.03 (NR, NR)	0.95
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	IBR (all)	1263	NR	NR	NR

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	IBR Direct	93	NR	vs. IBR TE: adjMD 0.02 (NR, NR)	0.919
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	IBR TE	1263	NR	Ref	Ref
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR (all)	NR	NR	NR	NR
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR with DIEP	350	NR	vs. IBR TE: adjMD 0.33 (NR, NR)	0.013
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR with free TRAM	87	NR	vs. IBR TE: adjMD 0.84 (NR, NR)	<0.001
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR with pedicled TRAM	77	NR	vs. IBR TE: adjMD 0.04 (NR, NR)	0.877
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR with LD	64	NR	vs. IBR TE: adjMD −0.13 (NR, NR)	0.63
	Pain	MPQ-SF: Affective	NRCS	Moderate	2 y	AR with SIEA	62	NR	vs. IBR TE: adjMD 1.24 (NR, NR)	<0.0001
	Pain	NPRS	NRCS	Moderate	1 w	IBR (all)	1846	NR	Ref	Ref
	Pain	NPRS	NRCS	Moderate	1 w	IBR Direct	NR	NR	NR	NR
	Pain	NPRS	NRCS	Moderate	1 w	IBR TE	NR	NR	NR	NR
	Pain	NPRS	NRCS	Moderate	1 w	AR (all)	NR	NR	NR	NR
	Pain	NPRS	NRCS	Moderate	1 w	AR with DIEP	463	NR	vs. IBR (all): adjMD −0.18 (NR, NR)	0.25
	Pain	NPRS	NRCS	Moderate	1 w	AR with free TRAM	111	NR	vs. IBR (all): adjMD −0.19 (NR, NR)	0.45
	Pain	NPRS	NRCS	Moderate	1 w	AR with pedicled TRAM	94	NR	vs. IBR (all): adjMD −0.72 (NR, NR)	0.01
	Pain	NPRS	NRCS	Moderate	1 w	AR with LD	80	NR	vs. IBR (all): adjMD 0.01 (NR, NR)	0.97
	Pain	NPRS	NRCS	Moderate	1 w	AR with SIEA	73	NR	vs. IBR (all): adjMD 0.21 (NR, NR)	0.51
	Pain	NPRS	NRCS	Moderate	3 mo	IBR (all)	NR	NR	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	IBR Direct	96	1.3 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	IBR TE	1329	2 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR (all)	NR	NR	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR with DIEP	296	1.5 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR with free TRAM	83	1.5 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR with pedicled TRAM	91	1.8 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR with LD	62	2 (NR)	NR	NR
	Pain	NPRS	NRCS	Moderate	3 mo	AR with SIEA	56	1.4 (NR)	NR	NR
Roth, 2007, 17413877, US	Pain	Bodily pain	NRCS	High	2 y	IBR	48	2.2 (1.2)	Ref	Ref
	Pain	Bodily pain	NRCS	High	2 y	AR	159	2.2 (1.2)	NR	NS
	Pain	Breast pain	NRCS	High	2 y	IBR	48	2.1 (1.3)	Ref	Ref
	Pain	Breast pain	NRCS	High	2 y	AR	159	1.8 (1.1)	NR	NS
	Pain	Abdominal pain	NRCS	High	2 y	IBR	48	4.8 (0.8)	Ref	Ref
	Pain	Abdominal pain	NRCS	High	2 y	AR	159	4 (1.2)	NR	<0.0001
	Pain	Back pain	NRCS	High	2 y	IBR	48	4 (1.3)	Ref	Ref
	Pain	Back pain	NRCS	High	2 y	AR	159	3.7 (1.5)	NR	NS
Shiraishi, 2020,	Pain	MPQ-SF: Total (0-10)	NRCS	High	1 y	IBR	56	NR	Ref	Ref

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
32589082, Japan	Pain	MPQ-SF: Total (0-10)	NRCS	High	1 y	AR	34	NR	1.08 (NR, NR)	NR
	Pain	MPQ-SF: Sensory (0-10)	NRCS	High	1 y	IBR	56	NR	Ref	Ref
	Pain	MPQ-SF: Sensory (0-10)	NRCS	High	1 y	AR	34	NR	0.80 (NR, NR)	NR
	Pain	MPQ-SF: Affective (0-10)	NRCS	High	1 y	IBR	56	NR	Ref	Ref
	Pain	MPQ-SF: Affective (0-10)	NRCS	High	1 y	AR	34	NR	0.28 (NR, NR)	NR
Shiraishi, 2020, 32589082, Japan	Analgesic use	Analgesic use score (0-5)	NRCS	High	1 y	IBR	56	NR	Ref	Ref
	Analgesic use	Analgesic use score (0-5)	NRCS	High	1 y	AR	34	NR	0.37 (NR, NR)	NR

Abbreviations: adj = adjusted, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MPQ-SF = McGill Pain Questionnaire-Short Form, MD = mean difference, NPRS = Numerical Pain Rating Scale, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery, TE = tissue expander, TRAM = transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table F-1.12. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes, mortality

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	IBR n/N (%)	AR n/N (%)	Effect Size (95% CI) for AR Versus IBR	P Value
Jiang, 2013, 24349366, US	Overall mortality	NRCS	High	8.9 y	241/1412 (17.1)	503/2649 (19.0)	adjOR 0.96 (0.89, 1.04)	NR
	Breast cancer-specific mortality	NRCS	High	8.9 y	209/1412 (14.8)	432/2649 (16.3)	adjOR 0.95 (0.87, 1.04)	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-1.13. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – unplanned repeat hospitalizations)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	IBR n/N (%)	AR n/N (%)	Effect Size (95% CI) for AR Versus IBR	P Value
Fischer, 2014, 24916480, US	Any unplanned readmission	NRCS	High	1 mo	7/155 (4.5)	10/155 (6.5)	NR	NR
Merchant, 2015, 26111325, US	Any unplanned readmission	NRCS	High	1 mo	338/10437 (3.24)	95/2329 (4.08)	adjOR 1.07 (0.95, 1.20)	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	IBR n/N (%)	AR n/N (%)	Effect Size (95% CI) for AR Versus IBR	P Value
Mioton, 2013, 23562485, US	Any unplanned readmission	NRCS	Moderate	1 mo	172/3960 (4.34)	56/1052 (5.32)	NR	NS
Nasser, 2018, 30204678	Unplanned ED visits	NRCS	High	1 mo	NR/28124 (NR)	NR/4773 (NR)	adjOR 1.11 (0.91, 1.25)	0.18
	Unplanned ED visits with pain-related diagnosis	NRCS	High	1 mo	NR/28124 (NR)	NR/4773 (NR)	adjOR 1.11 (0.83, 1.67)	0.41
Potter, 2019, 30639093, UK	Any unplanned readmission	Single group	Moderate	3 mo	372/2081 (18)	N/A	N/A	N/A
Sewart, 2021, 33609398, UK	Any unplanned readmission	Single group	Low	3 mo	147/891 (16.5)	N/A	N/A	N/A
Tran, 2018, 30665841	Any unplanned readmission	Single group	Low	NR	35/879 (2.8)	N/A	N/A	N/A
Polanco, 2021, 33745850, US	Any unplanned readmission	Single group	Low	1 mo	N/A	52/777 (6.7)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, RoB = risk of bias.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.14. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – unplanned repeat surgery for revision of reconstruction)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Fischer, 2014, 24916480, US	Unplanned reoperation	NRCS	High	<6 mo	IBR	8/155 (5.2)	Ref	Ref
	Unplanned reoperation	NRCS	High	<6 mo	AR	6/155 (3.9)	NR	0.562
	Unplanned reoperation	NRCS	High	<1 y	IBR	17/155 (11)	Ref	Ref
	Unplanned reoperation	NRCS	High	<1 y	AR	7/155 (4.5)	NR	0.017
	Unplanned reoperation	NRCS	High	<2 y	IBR	21/155 (13.5)	Ref	Ref
	Unplanned reoperation	NRCS	High	<2 y	AR	7/155 (4.5)	NR	0.003
Kulkarni, 2017, 28713853, US & Canada	Unplanned revision	NRCS	Moderate	2 y	IBR DTI	31/93 (33.3)	Vs. IBR with T/E: adjOR 0.58 (0.35, 0.96)	0.035
	Unplanned revision	NRCS	Moderate	2 y	IBR T/E	503/1263 (39.8)	Ref	Ref
	Unplanned revision	NRCS	Moderate	2 y	AR with DIEP	223/350 (63.7)	Vs. IBR with T/E: adjOR 2.66 (1.83, 3.86)	<0.001
	Unplanned revision	NRCS	Moderate	2 y	AR with free TRAM	56/87 (64.4)	Vs. IBR with T/E: adjOR 2.26 (1.35, 3.78)	0.002

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
	Unplanned revision	NRCS	Moderate	2 y	AR with pedicled TRAM	40/77 (57.1)	Vs. IBR with T/E: adjOR 1.34 (0.75, 2.4)	0.33
	Unplanned revision	NRCS	Moderate	2 y	AR with LD	41/64 (64.1)	Vs. IBR with T/E: adjOR 1.97 (1.07, 3.64)	0.031
	Unplanned revision	NRCS	Moderate	2 y	AR with SIEA	33/62 (53.2)	Vs. IBR with T/E: adjOR 1.83 (0.93, 3.6)	0.079
Zhang, 2019, 30675702, China	Reoperation	NRCS	High	4.9 y	IBR	230/394 (58.4)	adjOR 0.72 (0.5, 1.06)	0.093
	Reoperation	NRCS	High	4.9 y	AR	154/438 (35.2)	Ref	Ref
Coroneos, 2019, 30222598, US	Reoperation	Single group	Low	3 y	IBR	1026/5031 (20.4)	N/A	N/A
Park, 2019, 30863940, South Korea	Reoperation	Single group	Moderate	6 mo	IBR	87/999 (8.7)	N/A	N/A
Rogoff, 2020, 32243320, US	Reoperation	Single group	Low	NR	IBR	4/627 (0.6)	N/A	
Albornoz, 2013, 23897346, US	Flap revision	Single group	Low	NR	AR	210/21016 (1.0)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	Flap re-exploration	Single group	Low	9-10 mo	AR	67/910 flaps (7.4)	N/A	N/A
Fitzgerald, 2016, 27047776, UK	Reoperation	Single group	Low	NR	AR	135/1064 (12.7)	N/A	N/A
Gill, 2004, 15083015, US	Reoperation	Single group	Moderate	10 y	AR	45/758 (5.9)	N/A	N/A
Selber, 2009, 19935283, US	Revision	Single group	Low	5.6 mo	AR	197/1031 (19.1)	N/A	N/A
Tran, 2018, 29794694, US	Unplanned reoperation	Single group	Low	NR	AR	44/879 (5.0)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Secondary breast procedures: grouped into 4 broad categories: procedures for new or ongoing disease (mastectomy, lumpectomy, or biopsy); balancing procedures (mastopexy and reduction mammoplasty); planned secondary procedures (nipple-areolar reconstruction and exchange of tissue expander (TE) for permanent implant); and unplanned revisions (breast implant removal, revision, or exchange; TE removal without replacement; reconstruction with different modality; and revision of the reconstruction breast without further specification).

Table F-1.15. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – unplanned repeat surgery for complications)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Hangge, 2013, 31606126, US	NR	NRCS	High	NR	IBR DTI	81/193 (42)	vs. AR: adjOR 2.03 (1.03, 3.98)	0.042
	NR	NRCS	High	NR	IBR T/E	58/146 (40)	vs. AR: adjOR 1.81 (0.90, 3.64)	0.096

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
	NR	NRCS	High	NR	AR	17/60 (28)	Ref	Ref
Mioton, 2013, 23562485, US	NR	NRCS	Moderate	1 mo	IBR	662/9786 (6.76)	1.08 (0.88, 1.32)	NR
	NR	NRCS	Moderate	1 mo	AR	316/3296 (9.59)	Ref	Ref
Zhang, 2011, 30675702, China	Urgent surgery for a compromised implant/flap	NRCS	High	4.9 y	IBR	31/394 (7.9)	0.63 (0.29, 1.37)	NR
	Urgent surgery for a compromised implant/flap	NRCS	High	4.9 y	AR	33/438 (7.5)	Ref	Ref
Acosta, 2019, 21046538, Sweden	Wound revision	Single group	High	9 y	IBR	62/543 (11.4)	N/A	N/A
Hamdi, 2011, 20576480, Belgium	Reoperation with autologous tissue after failure of IBR	Single group	Low	2.6 y	IBR	54/688 (7.8)	N/A	N/A
Sewart, 2021, 33609398, UK	Any	Single group	Low	3 mo	IBR	150/891 (16.8)	N/A	N/A
Hamdi, 2010, 20679823, US	Reoperation after failure of free flap breast reconstruction	Single group	Low	3.1 y	AR	14/688 (2.0)	N/A	N/A
O'Neill, 2006, 31196805	Intraoperative complications requiring revision of/additional anastomoses	Single group	Low	3 mo	AR	56/912 (6.1)	N/A	N/A
Park, 2019, 30863940, South Korea	Any	Single group	Moderate	>6 mo	AR	62/999 (6.2)	N/A	N/A
Polanco, 2021, 33745850, US	Any	Single group	Low	1 mo	AR	79/777 (10.2)	N/A	N/A
Potter, 2019, 30639093, UK	NR	Single group	Moderate	3 mo	AR	370/2081 (18.0)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.16. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – pain, including chronic pain)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	NPRS: Moderate to severe	NRCS	Moderate	2 y	IBR DTI	All	NR	vs. IBR with T/E: adjOR 0.54 (NR, NR)	0.292
	NPRS: Moderate to severe	NRCS	Moderate	2 y	IBR T/E	All	NR	Ref	Ref
	NPRS: Moderate to severe	NRCS	Moderate	2 y	AR with DIEP	All	NR	vs. IBR with T/E: adjOR 1.22 (NR, NR)	0.454

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	NPRS: Moderate to severe	NRCS	Moderate	2 y	AR with free TRAM	All	NR	vs. IBR with T/E: adjOR 1.73 (NR, NR)	0.205
	NPRS: Moderate to severe	NRCS	Moderate	2 y	AR with pedicled TRAM	All	NR	vs. IBR with T/E: adjOR 1.64 (NR, NR)	0.266
	NPRS: Moderate to severe	NRCS	Moderate	2 y	AR with LD	All	NR	vs. IBR with T/E: adjOR 0.94 (NR, NR)	0.915
	NPRS: Moderate to severe	NRCS	Moderate	2 y	AR with SIEA	All	NR	vs. IBR with T/E: adjOR 1.43 (NR, NR)	0.445
Cordeiro, 2015b, 26090764, US	Breast pain	Single group	Low	2 y	IBR	All	88/4912 implants (1.79)	N/A	N/A
Huo, 2016, 27697676, US	Breast pain	Single group	Low	1 y	IBR	All	68/1332 (5.1)	N/A	N/A
	Breast pain	Single group	Low	1 y	IBR	Obese	22/383 (5.8)	N/A	N/A
	Breast pain	Single group	Low	1 y	IBR	Nonobese	46/949 (4.8)	N/A	N/A
Seth, 2015, 25180955, US	Breast pain or tightness	Single group	Low	NR	IBR	All	42/893 (4.7)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, N/A = not applicable, NPRS = Numerical Pain Rating Scale, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery perforator, T/E = tissue expander, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.17. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – necrosis)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Abedi, 2016, 25003437, Canada	Mastectomy flap necrosis	NRCS	High	1.6-1.9 y	IBR	All	70/606 (11.6)	adjOR 0.66 (0.38, 1.16)	0.15
	Mastectomy flap necrosis	NRCS	High	1.6-1.9 y	AR	All	60/395 (15.2)	Ref	Ref
Carramaschi, 1989, 2602589, France	More than local necrosis	NRCS	High	NR	IBR	All	5/166 (3)	NR	NR
	More than local necrosis	NRCS	High	NR	AR (all)	All	1/74 (1.4)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	More than local necrosis	NRCS	High	NR	AR with TRAM	All	0/40 (0)	NR	NR
	More than local necrosis	NRCS	High	NR	AR with LD	All	1/34 (2.9)	NR	NR
	Local necrosis	NRCS	High	NR	IBR	All	NR	NR	NR
	Local necrosis	NRCS	High	NR	AR (all)	All	7/74 (9.5)	NR	NR
	Local necrosis	NRCS	High	NR	AR with TRAM	All	5/40 (12.5)	NR	NR
	Local necrosis	NRCS	High	NR	AR with LD	All	2/34 (5.9)	NR	NR
de Araujo, 2016, 27673527, US	Major skin necrosis	NRCS	High	4.3 y	IBR	All	NR/38 (NR)	adjOR 17.894 (0.524, 610.484)	0.1092
	Major skin necrosis	NRCS	High	4.3 y	AR	All	NR/32 (NR)	Ref	Ref
Garvey, 2012, 23096600, US	Fat necrosis	NRCS	Moderate	1.5 y	IBR	All	NR	NR	NR
	Fat necrosis	NRCS	Moderate	1.5 y	AR	All	38/548 breasts (6.9)	NR	NR
	Partial flap necrosis	NRCS	Moderate	1.5 y	IBR	All	NR	NR	NR
	Partial flap necrosis	NRCS	Moderate	1.5 y	AR	All	21/548 breasts (3.8)	NR	NR
Naoum, 2020a, 31756414, US	Skin necrosis	NRCS	High	4-10 y	IBR	All	26/633 breasts (4.1)	Ref	Ref
	Skin necrosis	NRCS	High	4-10 y	AR	All	16/342 breasts (4.7)	adjOR 0.83 (0.19, 3.5)	0.8
	Fat necrosis	NRCS	High	4-10 y	IBR	All	1 breast/633 breasts (0.2)	Ref	Ref
	Fat necrosis	NRCS	High	4-10 y	AR	All	24/342 breasts (7)	adjOR 21.2 (2.5, 174.46)	0.004
Nelson, 2019, 31356276, US	Mastectomy flap necrosis	NRCS	High	<3 mo	IBR	All	65/1211 breasts (13.6)	NR	NR
	Mastectomy flap necrosis	NRCS	High	<3 mo	AR	All	NR	NR	NR
Woo, 2018, 30360958, South Korea	Skin flap necrosis	NRCS	High	NR	IBR	All	14/60 (23.3)	Ref	Ref
	Skin flap necrosis	NRCS	High	NR	AR	All	7/70 (10)	adjOR 0.66 (0.38, 1.16)	0.38
Banuelos, 2020, 31663932, US	Mastectomy flap necrosis	Single group	Low	≤1 mo	IBR	All	15/768 (1.8)	N/A	N/A
	Mastectomy flap necrosis	Single group	Low	>1 mo	IBR	All	4/768 (0.5)	N/A	N/A
Brooks, 2012, 22098451, US	NR	Single group	Low	3.4 mo	IBR	All	15/733 (2.0)	N/A	N/A
	NR	Single group	Low	3.4 mo	IBR	No radiation	14/636 (2.2)	N/A	N/A
	NR	Single group	Low	3.4 mo	IBR	Radiation	1/97 (1.0)	N/A	N/A
Cordeiro, 2006, 16980842, US	Native skin flap necrosis	Single group	Moderate	NR	IBR	All	45/2276 procedures (2.0)	N/A	N/A
	Native skin flap necrosis	Single group	Moderate	NR	IBR	T/E placement procedure	44/1221 procedures (3.6)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Native skin flap necrosis	Single group	Moderate	NR	IBR	Exchange procedure	1/1055 procedures (0.1)	N/A	N/A
	Native skin flap necrosis	Single group	Moderate	NR	IBR	Prior radiation	5/136 procedures (3.7)	N/A	N/A
	Native skin flap necrosis	Single group	Moderate	NR	IBR	No prior radiation	40/2140 procedures (1.9)	N/A	N/A
	Native skin flap necrosis	Single group	Moderate	NR	IBR	Immediate	44/1176 procedures (3.7)	N/A	N/A
	Native skin flap necrosis	Single group	Moderate	NR	IBR	Delayed	0/26 procedures (0)	N/A	N/A
Cordeiro, 2012, 22286416, US	Skin flap necrosis	Single group	Low	< 1 y	IBR	All	144/1699 (8.5)	N/A	N/A
	Skin flap necrosis	Single group	Low	< 1 y	IBR	Prior radiation	22/121 (18.2)	N/A	N/A
	Skin flap necrosis	Single group	Low	< 1 y	IBR	No prior radiation	122/1578 (7.7)	N/A	N/A
Gfrerer, 2015, 25626807, US	Skin necrosis	Single group	Low	7 y	IBR	All	97/3142 (3.1)	N/A	N/A
Hansen, 2018, 29778821, US	NR	Single group	Low	1 mo	IBR	All	14/930 (1.5)	N/A	N/A
	NR	Single group	Low	1 y	IBR	All	115/930 (12.4)	N/A	N/A
Hunsicker, 2017, 26849284, US	Skin necrosis/breakdown	Single group	Low	<1 y	IBR	All	94/1584 breasts (5.9)	N/A	N/A
Huo, 2016, 27697676, US	Fat necrosis	Single group	Low	1 y	IBR	All	66/1332 (5.0)	N/A	N/A
	Fat necrosis	Single group	Low	1 y	IBR	Non-obese	39/949 (4.1)	N/A	N/A
	Fat necrosis	Single group	Low	1 y	IBR	Obese	27/383 (7.1)	N/A	N/A
	Skin flap necrosis	Single group	Low	1 y	IBR	All	13/1332 (0.1)	N/A	N/A
	Skin flap necrosis	Single group	Low	1 y	IBR	Non-obese	9/949 (1.0)	N/A	N/A
	Skin flap necrosis	Single group	Low	1 y	IBR	Obese	4/383 (1.0)	N/A	N/A
Kanuri, 2014, 24675199, US	Mastectomy skin flap necrosis requiring excision and reclosure	Single group	Low	NR	IBR	All	79/710 breasts (11.1)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Lovecchio, 2015, 24691330, US	Necrosis or dehiscence	Single group	Low	2.3 y	IBR	All	159/1639 (9.7)	N/A	N/A
Parikh, 2018, 30204676, US	Mastectomy flap necrosis	Single group	Low	>2 y	IBR	All	20/1285 (1.6)	N/A	N/A
Park, 2019, 30863940, South Korea	Mastectomy flap necrosis	Single group	Moderate	>6 mo	IBR	All	94/999 (9.4)	N/A	N/A
Rogoff, 2020, 32243320, US	Mastectomy flap necrosis	Single group	Low	NR	IBR	All	77/627 (12.3)	N/A	
Seth, 2015, 25180955, US	Mastectomy flap necrosis: requiring surgical excision with or without closure in the office or in the operating room	Single group	Low	NR	IBR	All	96/893 (10.8)	N/A	N/A
Singh, 2012, 22342636, US	Breast necrosis	Single group	Low	6 mo	IBR	All	41/1316 (3.1)	N/A	N/A
	Breast necrosis	Single group	Low	6 mo	IBR	DTI	1/95 (1.1)	N/A	N/A
	Breast necrosis	Single group	Low	6 mo	IBR	T/E	40/1221 (3.3)	N/A	N/A
Singh, 2021, 33564597, US	NR	Single group	Low	3 mo	IBR	All	56/1740 (3.23)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	DTI	23/870 (2.67)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	T/E	33/870 (3.8)	N/A	N/A
Acosta, 2011, 21046538, Sweden	Partial necrosis	Single group	High	9 y	AR	All	11/543 (1.9)	N/A	N/A
	Complete necrosis	Single group	High	9 y	AR	All	14/543 (2.6)	N/A	N/A
Andree, 2012, 23197233, Germany	Margin necrosis	Single group	Low	1 y	AR	All	27/1068 flaps (2.5)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	Fat necrosis	Single group	Low	9-10 mo	AR	All	101/910 flaps (11.1)	N/A	N/A
Chang, 2000, 10809092, US	Flap fat necrosis	Single group	Low	NR	AR	All	55/936 flaps (5.9)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Mastectomy flap necrosis	Single group	Low	NR	AR	All	99/936 flaps (10.3)	N/A	N/A
Chang, 2011, 21407063, US	Fat necrosis	Single group	Low	NR	AR	All	135/818 (16.5)	N/A	N/A
	Fat necrosis	Single group	Low	NR	AR	Age <50	71/411 (17.3)	N/A	N/A
	Fat necrosis	Single group	Low	NR	AR	Age 50-59	43/285 (15.1)	N/A	N/A
	Fat necrosis	Single group	Low	NR	AR	Age 60-69	16/103 (15.5)	N/A	N/A
	Fat necrosis	Single group	Low	NR	AR	Age >70	5/19 (26.3)	N/A	N/A
Daly, 2020, 31994156, US	Fat necrosis ≥2 cm	Single group	Low	12 y	AR	All	172/1187 flaps (14.5)	N/A	N/A
	Umbilical necrosis	Single group	Low	12 y	AR	All	29/818 (3.5)	N/A	N/A
Enajat, 2010, 19790180, Sweden	Fat necrosis	Single group	Low	1-7 d	AR	All	56/564 flaps (10.0)	N/A	N/A
Gill, 2004, 15083015, US	Fat necrosis	Single group	Moderate	10 y	AR	All	98/758 (12.9)	N/A	N/A
Haddock, 2020, 33487570, US	Fat necrosis	Single group	Low	1.6 y	AR	All	66/506 (13)	N/A	N/A
Jo, 2020, 33386262, South Korea	Mastectomy flap necrosis	Single group	Low	11 mo – 1.5 y	AR	All	89/823 (14.3)	N/A	N/A
Langer, 2010, 20980954, Germany	Fat necrosis but intact skin island	Single group	Low	5 y	AR	All	2/670 flaps (0.3)	N/A	N/A
Lantieri, 2015, 26238173, France	Partial necrosis of flap with delayed healing	Single group	Moderate	NR	AR	All	52/952 (5.5)	N/A	N/A
Masoomi, 2019, 31331721, US	Fat necrosis	Single group	Low	NR	AR	All	490/55840 (0.9)	N/A	N/A
Mehrara, 2006, 17016173, US	Fat necrosis	Single group	Moderate	1 mo	AR	All	134/1195 (11.2)	N/A	N/A
Munder, 2020, 32565553, Germany	AR flap necrosis	Single group	Low	2 y	AR	All	32/1274 flaps (2.5)	N/A	N/A
	Fat necrosis	Single group	Low	2 y	AR	All	47/1274 flaps (3.6)	N/A	N/A
Nelson, 2014, 25046665, US	Breast fat necrosis	Single group	Moderate	NR	AR	All	71/1293 flaps (5.5)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Donor site fat necrosis	Single group	Moderate	NR	AR	All	3/1293 flaps (0.2)	N/A	N/A
	Breast skin flap necrosis	Single group	Moderate	NR	AR	All	194/1293 flaps (15.0)	N/A	N/A
	Donor site skin flap necrosis	Single group	Moderate	NR	AR	All	6/1293 flaps (0.5)	N/A	N/A
O'Neill, 2019, 31196805, Canada	Flap necrosis	Single group	Low	<3 mo	AR	All	50/912 (5.5)	N/A	N/A
	Fat necrosis	Single group	Low	<3 mo	AR	All	17/912 (1.3)	N/A	N/A
Rubio, 2019, 30665841, Belgium	Fat necrosis	Single group	Low	NR	AR	All	509/56522 (0.9)	N/A	N/A
Selber, 2009, 19935283, US	Fat necrosis	Single group	Low	5.6 mo	AR	All	35/1031 (3.4)	N/A	N/A
	Mastectomy flap necrosis	Single group	Low	5.6 mo	AR	All	4/1031 (0.4)	N/A	N/A
Shaikh, 2010, 22693373, India	Superficial skin necrosis	Single group	Low	NR	AR	All	20/546 (3.7)	N/A	N/A
Song, 2016, 26637165, US	Fat necrosis	Single group	Low	4.3-5.4 y	AR	All	353/1809 (19.5)	N/A	N/A
	Mastectomy flap necrosis requiring surgery	Single group	Low	4.3-5.4 y	AR	All	165/1809 (9.1)	N/A	N/A
Tran, 2018, 29794694, US	Fat necrosis	Single group	Low	NR	AR	All	174/1253 flaps (13.9)	N/A	N/A
	Umbilical necrosis	Single group	Low	NR	AR	All	29/879 (3.3)	N/A	N/A
Watterson, 1995, 7761505, Australia	Fat necrosis	Single group	Moderate	2.7 y	AR	All	59/556 (10.6)	N/A	N/A
Williams, 1995, 7794079, US	Fat necrosis	Single group	Moderate	2.4 y	AR	All	76/607 (12.5)	N/A	N/A
	Full thickness skin loss	Single group	Moderate	2.4 y	AR	All	8/607 (6.3)	N/A	N/A
Yoo, 2014, 24852813, South Korea	Breast skin necrosis	Single group	Moderate	NR	AR	All	75/500 (15)	N/A	N/A
	Donor site skin necrosis	Single group	Moderate	NR	AR	All	16/500 (3.2)	N/A	N/A
	Breast fat necrosis	Single group	Moderate	NR	AR	All	71/500 (14.2)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Donor site fat necrosis	Single group	Moderate	NR	AR	All	4/500 (0.8)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.18. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – thromboembolic events)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Brorson 2020a, 32807615, Sweden	DVT	RCT	High	1 mo	IBR	All	0/66 (0)	Ref	Ref
	DVT	RCT	High	1 mo	AR	All	0/51 (0)	No events	N/A
	PE	RCT	High	1 mo	IBR	All	1/66 (1.5)	Ref	Ref
	PE	RCT	High	1 mo	AR	All	0/51 (0)	Not calculable (no events in AR group)	Not calculable
Tallroth, 2020, 3346336, Sweden	DVT	RCT	Moderate	1 mo	IBR	All	1/28 (3.6)	Ref	Ref
	DVT	RCT	Moderate	1 mo	AR	All	0/42 (0)	Not calculable (no events in AR group)	Not calculable
	Arterial stop	RCT	Moderate	1 mo	IBR	All	0/28 (0)	Ref	Ref
	Arterial stop	RCT	Moderate	1 mo	AR	All	2/42 (4.8)	Not calculable (no events in IBR group)	Not calculable
	Venous stasis	RCT	Moderate	1 mo	IBR	All	0/28 (0)	Ref	Ref
	Venous stasis	RCT	Moderate	1 mo	AR	All	6/42 (14.3)	Not calculable (no events in IBR group)	Not calculable
Carramaschi, 1989, 2602589, France	PE	NRCS	High	NR	IBR	All	0/166 (0)	NR	NR
	PE	NRCS	High	NR	AR (all)	All	2/74 (2.7)	NR	NR
	PE	NRCS	High	NR	AR with TRAM	All	2/40 (5)	NR	NR
	PE	NRCS	High	NR	AR with LD	All	0/34 (0)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	DVT	NRCS	Moderate	1 y	IBR	All	5/1615 (0.3)	NR	NR
	DVT	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	DVT	NRCS	Moderate	1 y	AR with DIEP	All	1/365 (0.3)	NR	NR
	DVT	NRCS	Moderate	1 y	AR with free TRAM	All	1/97 (1)	NR	NR
	DVT	NRCS	Moderate	1 y	AR with pedicled TRAM	All	0/84 (0)	NR	NR
	DVT	NRCS	Moderate	1 y	AR with LD	All	1/73 (1.4)	NR	NR
	PE	NRCS	Moderate	1 y	IBR	All	4/1615 (0.3)	NR	NR
	PE	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	PE	NRCS	Moderate	1 y	AR with DIEP	All	4/365 (1.1)	NR	NR
	PE	NRCS	Moderate	1 y	AR with free TRAM	All	2/97 (2.1)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	PE	NRCS	Moderate	1 y	AR with pedicled TRAM	All	0/84 (0)	NR	NR
	PE	NRCS	Moderate	1 y	AR with LD	All	0/73 (0)	NR	NR
Mioton, 2013, 23562485, US	DVT	NRCS	Moderate	1 mo	IBR	All	27/9786 (0.28)	Ref	Ref
	DVT	NRCS	Moderate	1 mo	AR	All	20/3296 (0.61)	adjOR 0.992 (0.41, 2.41)	NR
	PE	NRCS	Moderate	1 mo	IBR	All	17/9786 (0.17)	Ref	Ref
	PE	NRCS	Moderate	1 mo	AR	All	17/3296 (0.52)	adjOR 1.84 (0.71, 4.77)	NR
Momeni, 2018, 29095189, US	DVT/PE	NRCS	High	3 mo	IBR	All	65/16851 (3.85)	adjOR 0.44 (0.35, 0.56)	.
	DVT/PE	NRCS	High	3 mo	AR	All	815/4622 (17.63)	Ref	Ref
Chen, 2018a, 29596085, US	DVT	Single group	Low	NR	IBR	All	9/23048 (0.04)	N/A	N/A
	DVT	Single group	Low	NR	IBR	All	20/23048 (0.09)	N/A	N/A
Albornoz, 2013, 23897346, US	DVT or PE	Single group	Low	NR	AR	All	231/21016 (1.1)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	Venous congestion	Single group	Low	9-10 mo	AR	All	40/910 flaps (4.4)	N/A	N/A
Chang, 2000, 10809092, US	Vessel thrombosis	Single group	Low	NR	AR	All	34/936 flaps (3.6)	N/A	N/A
Chang, 2011, 21407063, US	Thrombosis	Single group	Low	NR	AR	All	29/818 (3.5)	N/A	N/A
	Thrombosis	Single group	Low	NR	AR	Age <50	14/411 (3.4)	N/A	N/A
	Thrombosis	Single group	Low	NR	AR	Age 50-59	11/285 (3.9)	N/A	N/A
	Thrombosis	Single group	Low	NR	AR	Age 60-69	3/103 (2.9)	N/A	N/A
	Thrombosis	Single group	Low	NR	AR	Age >70	1/19 (5.3)	N/A	N/A
Chang, 2016, 25003429, US	Venous thrombosis	Single group	Low	NR	AR	All	69/1773 flaps (3.9)	N/A	N/A
	Arterial thrombosis	Single group	Low	NR	AR	All	68/1773 flaps (3.8)	N/A	N/A
	Venous or arterial thrombosis	Single group	Low	NR	AR	All	14/1773 flaps (0.8)	N/A	N/A
Chen, 2018b, 29596085, US	DVT	Single group	Low	NR	AR	All	24/19496 (0.1)	N/A	N/A
	PE	Single group	Low	NR	AR	All	44/19496 (0.2)	N/A	N/A
Daly, 2020, 31994156, US	PE	Single group	Low	12 y	AR	All	1/818 (0.1)	N/A	N/A
Enajat, 2010, 19790180, Sweden	Venous congestion	Single group	Low	1-7 d	AR	All	7/564 flaps (1.2)	N/A	N/A
	Arterial thrombosis	Single group	Low	1-7 d	AR	All	18/564 (implants) (3.2)	N/A	N/A
	Venous thrombosis	Single group	Low	1-7 d	AR	All	10/564 flaps (5.6)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Gill, 2004, 15083015, US	Venous occlusion	Single group	Moderate	10 y	AR	All	29/758 (3.8)	N/A	N/A
	Arterial occlusion	Single group	Moderate	10 y	AR	All	4/758 (0.5)	N/A	N/A
Haddock, 2019, 31461004, US	DVT	Single group	Moderate	NR	AR	All	5/509 (1.0)	N/A	N/A
Langer, 2010, 20980954, Germany	Venous congestion	Single group	Low	5 y	AR	All	4/670 flaps (0.6)	N/A	N/A
Liao, 2008, 18349626, US	DVT or PE	Single group	Low	NR	AR	All	7/679 (1.0)	N/A	N/A
Masoomi, 2019, 31331721, US	DVT	Single group	Low	NR	AR	All	203/7991 (2.5)	N/A	N/A
	VTE	Single group	Low	NR	AR	All	60/55840 (0.1)	N/A	N/A
Mehrara, 2006, 17016173, US	DVT	Single group	Moderate	1 mo	AR	All	9/1195 (0.1)	N/A	N/A
	Arterial thrombosis	Single group	Moderate	1 mo	AR	All	9/1195 (0.8)	N/A	N/A
	Arterial thrombosis	Single group	Moderate	1 mo	AR	TRAM	7/978 (0.7)	N/A	N/A
	Venous thrombosis	Single group	Moderate	1 mo	AR	All	15/1195 (1.3)	N/A	N/A
	Venous thrombosis	Single group	Moderate	1 mo	AR	TRAM	8/978 (0.8)	N/A	N/A
Mirzabeigi, 2015, 25811579, US	Intraoperative arterial thrombosis	Single group	Low	NR	AR	All	36/1347 flaps (2.7)	N/A	N/A
	Intraoperative venous thrombosis	Single group	Low	NR	AR	All	7/1347 flaps (0.5)	N/A	N/A
	Postoperative arterial thrombosis	Single group	Low	NR	AR	All	18/1347 flaps (1.3)	N/A	N/A
	Postoperative venous thrombosis	Single group	Low	NR	AR	All	16/1347 flaps (1.2)	N/A	N/A
Munder, 2020, 32565553, Germany	Insufficient arterial supply	Single group	Low	2 y	AR	All	1/1274 flaps (0.1)	N/A	N/A
	Insufficient venous supply	Single group	Low	2 y	AR	All	10/1274 flaps (0.8)	N/A	N/A
Nelson, 2014, 25046665, US	Arterial thrombosis	Single group	Moderate	Intra-op	AR	All	42/1293 flaps (3.3)	N/A	N/A
	Arterial thrombosis	Single group	Moderate	Delayed	AR	All	18/1293 flaps (1.4)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Venous thrombosis	Single group	Moderate	Intra-op	AR	All	7/1293 flaps (0.5)	N/A	N/A
	Venous thrombosis	Single group	Moderate	Delayed	AR	All	16/1293 flaps (1.2)	N/A	N/A
O'Neill, 2019, 31196805, Canada	DVT or PE	Single group	Low	1 day	AR	All	2/512 (0.4)	N/A	N/A
	DVT or PE	Single group	Low	<2 mo	AR	All	7/960 (0.5)	N/A	N/A
Prantl, 2020, 32895743, Germany	Arterial thrombosis	Single group	Low	3 mo	AR	All	74/4577 flaps (1.6)	N/A	N/A
	Venous thrombosis	Single group	Low	3 mo	AR	All	123/4577 flaps (2.7)	N/A	N/A
Rubio, 2019, 30665841, Belgium	PE	Single group	Low	NR	AR	All	113/56522 (0.2)	N/A	N/A
	DVT	Single group	Low	NR	AR	All	226/56522 (0.4)	N/A	N/A
	DVT or PE	Single group	Low	NR	AR	All	48/35883 (0.1)	N/A	N/A
Seidenstuecker, 2016, 27017243, Belgium	DVT, PE, or cardiac or pulmonary failure	Single group	Moderate	NR	AR	All	0/931 flaps (0)	N/A	N/A
Selber, 2009, 19935283, US	PE	Single group	Low	5.6 mo	AR	All	2/1031 (0.2)	N/A	N/A
	Vessel thrombosis	Single group	Low	5.6 mo	AR	All	1/1031 (0.1)	N/A	N/A
Song, 2016, 26637165, US	VTE	Single group	Low	4.3-5.4 y	AR	All	25/1809 (1.4)	N/A	N/A
Tran, 2018, 29794694, US	PE	Single group	Low	NR	AR	All	1/879 (0.08)	N/A	N/A
	DVT	Single group	Low	NR	AR	All	1/879 (0.08)	N/A	N/A
Yoo, 2014, 24852813, South Korea	PE	Single group	Moderate	NR	AR	All	17/504 (3.4)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.19. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – infections not explicitly implant related)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
de Araujo, 2016, 27673527, US	SSI	NRCS	High	4.3 y	IBR	All	NR/38 (NR)	adjOR 0.86 (0.18, 4.11)	0.847
	SSI	NRCS	High	4.3 y	AR	All	NR/32 (NR)	Ref	Ref
Garvey, 2012, 23096600, US	Infections	NRCS	Moderate	1.5 y	IBR	All	50/442 breasts (11.3)	Ref	Ref
	Infections	NRCS	Moderate	1.5 y	AR	All	21/548 breasts (3.8)	NR	<0.001
Kulkarni, 2017, 28713853, US & Canada	Breast WI	NRCS	Moderate	1 y	IBR (all)	All	162/1615 (10)	NR	NR
	Breast WI	NRCS	Moderate	1 y	IBR DTI	All	NR	NR	NR
	Breast WI	NRCS	Moderate	1 y	IBR T/E	All	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Breast WI	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Breast WI	NRCS	Moderate	1 y	AR with DIEP	All	14/365 (3.8)	NR	NR
	Breast WI	NRCS	Moderate	1 y	AR with free TRAM	All	4/97 (4.1)	NR	NR
	Breast WI	NRCS	Moderate	1 y	AR with pedicled TRAM	All	5/84 (6)	NR	NR
	Breast WI	NRCS	Moderate	1 y	AR with LD	All	6/73 (8.2)	NR	NR
	Breast WI	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
	Breast WI	NRCS	Moderate	2 y	IBR	All	NR	NR	NR
	Breast WI	NRCS	Moderate	2 y	IBR DTI	All	17/112 (15.2)	vs IBR T/E: adjOR 1.70 (0.91, 3.18)	0.1
	Breast WI	NRCS	Moderate	2 y	IBR T/E	All	159/1525 (10.4)	Ref	Ref
	Breast WI	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR
	Breast WI	NRCS	Moderate	2 y	AR with DIEP	All	27/390 (6.9)	vs IBR T/E: adjOR 0.44 (0.25, 0.78)	0.005
	Breast WI	NRCS	Moderate	2 y	AR with free TRAM	All	5/95 (5.3)	vs IBR T/E: adjOR 0.45 (0.17, 1.18)	0.10
	Breast WI	NRCS	Moderate	2 y	AR with pedicled TRAM	All	8/85 (9.4)	vs IBR T/E: adjOR 0.73 (0.31, 1.70)	0.46
	Breast WI	NRCS	Moderate	2 y	AR with LD	All	6/71 (8.5)	vs IBR T/E: adjOR 0.50 (0.15, 1.56)	0.23
	Breast WI	NRCS	Moderate	2 y	AR with SIEA	All	8/65 (12.3)	vs IBR T/E: adjOR 0.67 (0.25, 1.82)	0.43
Mioton, 2013, 23562485, US	WI	NRCS	Moderate	1 mo	IBR	All	338/9786 (3.45)	Ref	Ref
	WI	NRCS	Moderate	1 mo	AR	All	180/3296 (5.46)	adjOR 1.40 (1.01, 1.96)	NR
	Superficial SSI	NRCS	Moderate	1 mo	IBR	All	163/9786 (1.67)	Ref	Ref
	Superficial SSI	NRCS	Moderate	1 mo	AR	All	97/3296 (2.95)	adjOR 1.20 (0.81, 1.76)	NR
	Deep SSI	NRCS	Moderate	1 mo	IBR	All	195/9786 (1.07)	Ref	Ref
	Deep SSI	NRCS	Moderate	1 mo	AR	All	65/3296 (1.97)	adjOR 1.81 (1.12, 2.94)	NR
Naoum, 2020a, 31756414, US	NR	NRCS	High	4-10 y	IBR	All	23/633 breasts (3.6)	Ref	Ref
	NR	NRCS	High	4-10 y	AR	All	9/342 breasts (2.6)	adjOR 0.77 (0.20, 2.50)	0.67
Naoum, 2020b, 32607638, US	NR	NRCS	High	4.3-6.3 y	IBR DTI	All	7/127 (5.5)	Ref	Ref
	NR	NRCS	High	4.3-6.3 y	IBR with TE	All	2/88 (2.2)	Ref	Ref
	NR	NRCS	High	4.3-6.3 y	AR	All	11/85 (13.0)	vs. IBR DTI: 3.2 (0.6, 16) vs. IBR with TE: 8.1 (1.7, 39)	0.20 0.009
Nelson, 2019, 31356276, US	NR	NRCS	High	<3 mo	IBR	All	82/1211 breasts (6.7)	NR	NR
	NR	NRCS	High	<3 mo	AR	All	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Banuelos, 2020, 31663932, US	SSI	Single group	Low	≤1 mo	IBR	All	13/768 (1.7)	N/A	N/A
	SSI	Single group	Low	>1 mo	IBR	All	32/768 (4.2)	N/A	N/A
Brooks, 2012, 22098451, US	NR	Single group	Low	3.4 y	IBR	All	74/733 (10.1)	N/A	N/A
	NR	Single group	Low	3.4 y	IBR	Radiation	10/97 (9.7)	N/A	N/A
	NR	Single group	Low	3.4 y	IBR	No radiation	64/636 (10.1)	N/A	N/A
Chen, 2014, 25620484, China	NR	Single group	Low	NR	IBR	All	27/1860 (1.5)	N/A	N/A
Chen, 2016, 27930584, Taiwan	NR	Single group	Low	≥2 y	IBR	All	815/569 breasts (5.1)	N/A	N/A
Chen, 2018a, 29596085, US	NR	Single group	Low	NR	IBR	All	67/23048 (0.3)	N/A	N/A
Collier, 2019, 31461001, US	Readmitted for infection	Single group	Moderate	1 mo	IBR	All	374/18338 (2.0)	N/A	N/A
	Readmitted for infection	Single group	Moderate	3 mo	IBR	All	385/18338 (2.1)	N/A	N/A
Cordeiro, 2006, 16980842, US	NR	Single group	Moderate	NR	IBR	All	58/2276 procedures (2.5)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Expander placement procedure	38/1221 procedures (3.1)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Exchange procedure	20/1055 procedures (1.9)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Prior radiation	7/136 procedures (5.1)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	No prior radiation	51/2140 procedures (2.4)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Immediate	37/1176 procedures (3.1)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Delayed	1/26 procedures (3.8)	N/A	N/A
Cordeiro, 2012, 22286416, US	NR	Single group	Low	<1 y	IBR	All	85/1699 (5.0)	N/A	N/A
	NR	Single group	Low	<1 y	IBR	Prior radiation	10/121 (8.3)	N/A	N/A
	NR	Single group	Low	<1 y	IBR	No prior radiation	75/1578 (4.8)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Cordeiro, 2015b, 26090764, US	NR	Single group	Low	2 y	IBR	All	152/4912 implants (3.1)	N/A	N/A
Gfrerer, 2015, 25626807, US	NR	Single group	Low	7 y	IBR	All	92/3142 (2.9)	N/A	N/A
Hansen, 2018, 29778821, US	NR	Single group	Low	1 mo	IBR	All	28/930 (3.0)	N/A	N/A
	NR	Single group	Low	1 mo	IBR	All	64/930 (6.9)	N/A	N/A
Hunsicker, 2017, 26849284, US	NR	Single group	Low	<1 y	IBR	All	48/1584 breasts (3.0)	N/A	N/A
Huo, 2016, 27697676, US	NR	Single group	Low	1 y	IBR	All	257/1332 (19.3)	N/A	N/A
Kato, 2013, 24011080, Japan	Redness, pain, or fever, or positive bacterial culture	Single group	Low	<1 y	IBR	All	47/981 (4.8)	N/A	N/A
Law, 2018, 30463754, US	NR	Single group	Low	3 mo	IBR	All	2086/11039 (18.9)	N/A	N/A
	NR	Single group	Low	1 y	IBR	All	2661/11039 (24.1)	N/A	N/A
Lee, 2021a, 32974692, South Korea	NR	Single group	Low	5 y	IBR	All	10/605 breasts (1.7)	N/A	N/A
Lovecchio, 2015, 24691330, US	Infections requiring IV antibiotics	Single group	Low	2.3 y	IBR	All	67/1639 (4.1)	N/A	N/A
Parikh, 2018, 30204676, US	SSI	Single group	Low	>2 y	IBR	All	139/1285 (10.8)	N/A	N/A
Park, 2019, 30863940, South Korea	NR	Single group	Moderate	>6 mo	IBR	All	29/999 (2.9)	N/A	N/A
Rogoff, 2020, 32243320, US	NR	Single group	Low	NR	IBR	All	155/627 (24.7)	N/A	N/A
Seth, 2015, 25180955, US	Infections requiring IV antibiotics and/or readmission	Single group	Low	NR	IBR	All	59/893 (6.6)	N/A	N/A
Sewart, 2021, 33609398, UK	NR	Single group	Low	3 mo	IBR	All	229/691 (25.7)	N/A	N/A
Singh, 2012, 22342636, US	NR	Single group	Low	6 mo	IBR	All	161/1316 (12.2)	N/A	N/A
	NR	Single group	Low	6 mo	IBR	DTI	9/95 (9.5)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	NR	Single group	Low	6 mo	IBR	T/E	152/1221 (12.4)	N/A	N/A
Singh, 2021, 33564597, US	NR	Single group	Low	3 mo	IBR	All	95/1740 (5.47)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	DTI	41/870 (4.66)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	T/E	55/870 (6.27)	N/A	N/A
Warren, 2020, 33040748, US	Surgical site infection	Single group	Moderate	NR	IBR	All	82/1924 (4.3)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	NR	Single group	Low	9-10 mo	AR	All	63/910 flaps (6.9)	N/A	N/A
Chang, 2000, 10809092, US	Flap infection	Single group	Low	NR	AR	All	17/936 flaps (1.8)	N/A	N/A
Chang, 2011, 21407063, US	NR	Single group	Low	NR	AR	All	3/818 (0.4)	N/A	N/A
	NR	Single group	Low	NR	AR	Age <50	2/411 (0.5)	N/A	N/A
	NR	Single group	Low	NR	AR	Age 50-59	0/285 (0)	N/A	N/A
	NR	Single group	Low	NR	AR	Age 60-69	1/103 (1)	N/A	N/A
	NR	Single group	Low	NR	AR	Age >70	0/19 (0)	N/A	N/A
Chen, 2018b, 29596085, US	NR	Single group	Low	NR	AR	All	158/19496 (0.8)	N/A	N/A
Cleveland, 2013, 23945529, US	Cellulitis at donor site treated with antibiotics	Single group	Low	1 mo	AR	All	60/812 (7.4)	N/A	N/A
Daly, 2020, 31994156, US	NR	Single group	Low	12 y	AR	All	66/818 (8.1)	N/A	N/A
Enajat, 2010, 19790180, Sweden	NR	Single group	Low	1-7 d	AR	All	60/564 flaps (10.6)	N/A	N/A
Gill, 2004, 15083015, US	Any infection	Single group	Moderate	10 y	AR	All	21/758 (2.8)	N/A	N/A
Haddock, 2019, 31461004, US	NR	Single group	Moderate	NR	AR	All	40/509 (7.8)	N/A	N/A
Jo, 2020, 33386262, South Korea	NR	Single group	Low	11 mo – 1.5 y	AR	All	7/623 (1.12)	N/A	N/A
Masoomi, 2019, 31331721, US	WI	Single group	Low	NR	AR	All	750/55840 (1.3)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Nelson, 2014, 25046665, US	Breast WI	Single group	Moderate	NR	AR	All	60/1293 flaps (4.6)	N/A	N/A
	Donor site WI	Single group	Moderate	NR	AR	All	25/1293 flaps (1.9)	N/A	N/A
O'Neill, 2019, 31196805, Canada	NR	Single group	Low	1 d	AR	All	12/512 (2.3)	N/A	N/A
	NR	Single group	Low	<2 mo	AR	All	39/960 (4.0)	N/A	N/A
Prantl, 2020, 32895743, Germany	Breast WI	Single group	Low	3 mo	AR	All	20/4577 flaps (0.4)	N/A	N/A
	Donor site WI	Single group	Low	3 mo	AR	All	23/4577 flaps (0.5)	N/A	N/A
Rubio, 2019, 30665841, Belgium	WI	Single group	Low	NR	AR	All	735/56522 (1.3)	N/A	N/A
Seidenstuecker, 2016, 27017243, Belgium	Systemic infection	Single group	Moderate	NR	AR	All	0/931 flaps (0)	N/A	N/A
Selber, 2009, 19935283, US	WI	Single group	Low	5.6 mo	AR	All	37/1031 (3.6)	N/A	N/A
Song, 2016, 26637165, US	NR	Single group	Low	4.3-5.4 y	AR	All	186/1809 (10.3)	N/A	N/A
Tran, 2018, 29794694, US	NR	Single group	Low	NR	AR	All	67/879 (5.3)	N/A	N/A
Watterson, 1995, 7761505, Australia	WI	Single group	Moderate	2.7 y	AR	All	28/556 (5.0)	N/A	N/A
Williams, 1995, 7794079, US	Major infection	Single group	Moderate	2.4 y	AR	All	23/607 (3.8)	N/A	N/A
Yoo, 2014, 24852813, South Korea	Breast WI	Single group	Moderate	NR	AR	All	4/500 (0.8)	N/A	N/A
	Donor WI	Single group	Moderate	NR	AR	All	5/500 (1.0)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, d = days, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SSI = surgical site infection, T/E = tissue expander, WI = wound infection, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.20. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – wound dehiscence)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Garvey, 2012, 23096600, US	NR	NRCS	Moderate	1.5 y	IBR	All	28//442 breasts (6.3)	Ref	Ref
	NR	NRCS	Moderate	1.5 y	AR	All	25/548 breasts (4.6)	NR	0.25
	Breast WD	NRCS	Moderate	1 y	IBR	All	26/1615 (1.6)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	Breast WD	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Breast WD	NRCS	Moderate	1 y	AR with DIEP	All	13/365 (3.6)	NR	NR
	Breast WD	NRCS	Moderate	1 y	AR with free TRAM	All	1/97 (1)	NR	NR
	Breast WD	NRCS	Moderate	1 y	AR with pedicled TRAM	All	1/84 (1.2)	NR	NR
	Breast WD	NRCS	Moderate	1 y	AR with LD	All	1/73 (1.4)	NR	NR
	Breast WD	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
Mioton, 2013, 23562485, US	Wound disruption	NRCS	Moderate	1 mo	IBR	All	44*/9786 (0.44)	Ref	Ref
	Wound disruption	NRCS	Moderate	1 mo	AR	All	41*/3296 (1.24)	adjOR 1.79 (0.83, 3.84)	NR
Banuelos, 2020, 31663932, US	NR	Single group	Low	≤1 mo	IBR	All	15/768 (1.9)	N/A	N/A
	NR	Single group	Low	>1 mo	IBR	All	12/768 (1.6)	N/A	N/A
Brooks, 2012, 22098451, US	NR	Single group	Low	3.4 y	IBR	All	15/733 (2.1)	N/A	N/A
	NR	Single group	Low	3.4 y	IBR	Prior radiation	8/97 (11.9)	N/A	N/A
	NR	Single group	Low	3.4 y	IBR	No prior radiation	7/636 (1.1)	N/A	N/A
Chen, 2018a, 29596085, US	Wound disruption/complication	Single group	Low	NR	IBR	All	154/23048 (0.7)	N/A	N/A
Cordeiro, 2012, 22286416, US	WD or delayed healing	Single group	Low	<1 y	IBR	All	5/1699 (0.3)	N/A	N/A
	WD or delayed healing	Single group	Low	<1 y	IBR	Prior radiation	1/121 (0.8)	N/A	N/A
	WD or delayed healing	Single group	Low	<1 y	IBR	No prior radiation	4/1578 (0.3)	N/A	N/A
Huo, 2016, 27697676, US	NR	Single group	Low	1 y	IBR	All	41/1332 (3.1)	N/A	N/A
	NR	Single group	Low	1 y	IBR	Non-obese	27/949 (2.8)	N/A	N/A
	NR	Single group	Low	1 y	IBR	Obese	14/383 (3.6)	N/A	N/A
Lee, 2021a, 32974692, South Korea	NR		Low	5 y	IBR	All	13/605 breasts (2.1)	N/A	N/A
Parikh, 2018, 30204676, US	NR	Single group	Low	>2 y	IBR	All	21/1285 (1.6)	N/A	N/A
Park, 2019, 30863940, South Korea	NR	Single group	Moderate	>6 mo	IBR	All	49/999 (4.9)	N/A	N/A
Rogoff, 2020, 32243320, US	NR	Single group	Low	NR	IBR	All	69/627 (11)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	All	58/1740 (3.35)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Singh, 2021, 33564597, US	NR	Single group	Low	3 mo	IBR	DTI	22/870 (2.54)	N/A	N/A
	NR	Single group	Low	3 mo		T/E	36/870 (4.15)	N/A	N/A
Albornoz, 2013, 23897346, US	NR	Single group	Low	NR	AR	All	84/21016 (0.4)	N/A	N/A
Chang, 2011, 21407063, US	NR	Single group	Low	NR	AR	All	1/818 (0.1)	N/A	N/A
	NR	Single group	Low	NR	AR	Age <50	0/411 (0)	N/A	N/A
	NR	Single group	Low	NR	AR	Age 50-59	1/285 (0.4)	N/A	N/A
	NR	Single group	Low	NR	AR	Age 60-69	0/103 (0)	N/A	N/A
	NR	Single group	Low	NR	AR	Age >70	0/19 (0)	N/A	N/A
Chen, 2018b, 29596085, US	NR	Single group	Low	NR	AR	All	84/19496 (0.4)	N/A	N/A
Daly, 2020, 31994156, US	NR	Single group	Low	12 y	AR	All	93/818 (11.4)	N/A	N/A
Heo, 2018, 30039735, South Korea	Wound problems (i.e. wound dehiscence, wound infection, wound necrosis, delayed wound healing)	Single group	Low	1 y	AR	All	23/615 (3.7)	N/A	N/A
Masoomi, 2019, 31331721, US	NR	Single group	Low	NR	AR	All	436/55840 (0.8)	N/A	N/A
O'Neill, 2019, 31196805, Canada	NR	Single group	Low	1 d	AR	All	6/512 (1.2)	N/A	N/A
	NR	Single group	Low	<2 mo	AR	All	31/912 (3.4)	N/A	N/A
	NR	Single group	Low	<3 mo	AR	All	38/960 (3.9)	N/A	N/A
Prantl, 2020, 32895743, Germany	NR	Single group	Low	3 mo	AR	All	80/4577 flaps (1.7)	N/A	N/A
	NR	Single group	Low	3 mo	AR	All	70/4577 flaps (1.5)	N/A	N/A
Rubio, 2019, 30665841, Belgium	NR	Single group	Low	NR	AR	All	452/56522 (0.8)	N/A	N/A
Selber, 2009, 19935283, US	NR	Single group	Low	5.6 mo	AR	All	3/1031 (0.3)	N/A	N/A
Yoo, 2014, 24852813, South Korea	Breast WD	Single group	Moderate	NR	AR	All	5/500 (1.0)	N/A	N/A
	Donor site WD	Single group	Moderate	NR	AR	All	7/500 (1.4)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, d = days, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SSI = surgical site infection, T/E = tissue expander, WD = wound dehiscence, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.21. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – delayed healing)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Fischer, 2013, 23629074, US	Delayed wound healing (breast)	NRCS	High	4 y	IBR	All	9/60 (15)	Ref	Ref
	Delayed wound healing (breast)	NRCS	High	4 y	AR	All	52/142 (36.6)	adjOR 2.2 (1.0, 5.2)	0.06
Fischer, 2014, 24916480, US	Delayed mastectomy healing	NRCS	High	1.8-2.1 y	IBR	All	19/155 (12.5)	NR	NR
	Delayed mastectomy healing	NRCS	High	1.8-2.1 y	AR	All	27/155 (17.5)	NR	NR
Garvey, 2012, 23096600, US	NR	NRCS	Moderate	1.5 y	IBR	All	19/442 breasts (4.3)	Ref	Ref
	NR	NRCS	Moderate	1.5 y	AR	All	41/548 breasts (7.5)	NR	0.01
Cordeiro, 2006, 16980842, US	NR	Single group	Moderate	NR	IBR	All	8/2276 procedures (0.4)	N/A	N/A
	NR	Single group	Moderate	NR	NR	Expander placement procedure	6/1221 procedures (0.5)	N/A	N/A
	NR	Single group	Moderate	NR	NR	Exchange procedure	2/1055 procedures (0.2)	N/A	N/A
	NR	Single group	Moderate	NR	NR	Previous radiation	1/136 procedures (0.7)	N/A	N/A
	NR	Single group	Moderate	NR	NR	No previous radiation	7/2140 procedures (0.3)	N/A	N/A
	NR	Single group	Moderate	NR	NR	Immediate	6/1176 procedures (0.5)	N/A	N/A
	NR	Single group	Moderate	NR	NR	Delayed	0/26 procedures (0)	N/A	N/A
Huo, 2016, 27697676, US	Non-healing wound	Single group	Low	1 y	IBR	All	64/1332 (4.8)	N/A	N/A
	Non-healing wound	Single group	Low	1 y	IBR	Non-obese	35/949 (3.7)	N/A	N/A
	Non-healing wound	Single group	Low	1 y	IBR	Obese	29/383 (7.6)	N/A	N/A
Cleveland, 2013, 23945529, US	Skin necrosis or wound breakdown necessitating dressing changes and/or topical wound care for more than 3 weeks	Single group	Low	NR	AR	All	152/812 (18.7)	N/A	N/A
Jo, 2020, 33386262, South Korea	Delayed breast wound healing	Single group	Low	11 mo – 1.5 y	AR	All	17/623 (2.73)	N/A	N/A
Mehrara, 2006, 17016173, US	Wound healing or infection	Single group	Moderate	1 mo	AR	All	110/1195 (9.2)	N/A	N/A
Munder, 2020, 32565553, Germany	Delayed donor site wound healing	Single group	Low	2 y	AR	All	7/1274 flaps (0.5)	N/A	N/A
Nelson, 2014, 25046665, US	Delayed breast wound healing	Single group	Moderate	NR	AR	All	323/1293 flaps (25.0)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Delayed donor site wound healing	Single group	Moderate	NR	AR	All	149/1293 flaps (11.5)	N/A	N/A
Prantl, 2020, 32895743, Germany	Delayed breast wound healing	Single group	Low	3 mo	AR	All	70/4577 (1.5)	N/A	N/A
	Delayed donor site wound healing	Single group	Low	3 mo	AR	All	80/4577 (1.7)	N/A	N/A
Rubio, 2019, 30665841, Belgium	NR	Single group	Low	NR	AR	All	678/56522 (1.2)	N/A	N/A
Selber, 2009, 19935283, US	Delayed breast wound healing	Single group	Low	5.6 mo	AR	All	78/1031 (7.6)	N/A	N/A
	Delayed donor site wound healing	Single group	Low	5.6 mo	AR	All	35/1031 (3.4)	N/A	N/A
Song, 2016, 26637165, US	NR	Single group	Low	4.3-5.4 y	AR	All	357/1809 (19.7)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, d = days, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SSI = surgical site infection, T/E = tissue expander, WD = wound dehiscence, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.22. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – seroma)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Fischer, 2014, 24916480, US	Breast seroma	NRCS	High	1.8-2.1 y	IBR	All	13/155 (8.1)	Ref	Ref
	Breast seroma	NRCS	High	1.8-2.1 y	AR	All	4/155 (2.8)	NR	0.009
Garvey, 2012, 23096600, US	Seroma or hematoma	NRCS	Moderate	1.5 y	IBR	All	61/442 breasts (13.8)	Ref	Ref
	Seroma or hematoma	NRCS	Moderate	1.5 y	AR	All	27/548 breasts (4.9)	NR	<0.001
Kulkarni, 2017, 28713853, US & Canada	Breast seroma	NRCS	Moderate	1 y	IBR	All	47/1615 (2.9)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR with DIEP	All	3/365 (0.8)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR with free TRAM	All	0/97 (0)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR with pedicled TRAM	All	2/84 (2.4)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR with LD	All	2/73 (2.7)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	IBR	All	NR	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Donor site seroma	NRCS	Moderate	1 y	AR with DIEP	All	19/365 (5.2)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	AR with free TRAM	All	2/97 (2.1)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	AR with pedicled TRAM	All	0/84 (0)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	AR with LD	All	14/73 (19.2)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
Nelson, 2019, 31356276, US	NR	NRCS	High	<3 mo	IBR	All	49/1211 breasts (4.04)	NR	NR
	NR	NRCS	High	<3 mo	AR	All	NR	NR	NR
Chen, 2018a, 29596085, US	NR	Single group	Low	NR	IBR	All	139/23048 (0.6)	N/A	N/A
Cordeiro, 2006, 16980842, US	NR	Single group	Moderate	NR	IBR	All	5/2276 procedures (0.2)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Expander placement procedure	3/1221 procedures (0.2)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Exchange procedure	2/1055 procedures (0.2)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Previous radiation	1/136 procedures (0.7)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	No previous radiation	6/2140 procedures (0.3)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Immediate	3/1176 procedures (0.3)	N/A	N/A
	NR	Single group	Moderate	NR	IBR	Delayed	0/26 procedures (0)	N/A	N/A
Cordeiro, 2012, 22286416, US	NR	Single group	Low	<1 y	IBR	All	24/1699 (1.4)	N/A	N/A
	NR	Single group	Low	<1 y	IBR	Prior radiation	3/121 (2.5)	N/A	N/A
	NR	Single group	Low	<1 y	IBR	No Prior radiation	21/1578 (1.3)	N/A	N/A
Cordeiro, 2015b, 26090764, US	NR	Single group	Low	2 y	IBR	All	54/4912 implants (1.1)	N/A	N/A
Hansen, 2018, 29778821, US	NR	Single group	Low	1 mo	IBR	All	15/930 (1.6)	N/A	N/A
	NR	Single group	Low	1 y	IBR	All	28/930 (3.0)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Hunsicker, 2017, 26849284, US	NR	Single group	Low	<1 y	IBR	All	17/1584 breasts (1.1)	N/A	N/A
Huo, 2016, 27697676, US	NR	Single group	Low	1 y	IBR	All	89/1332 (6.7)	N/A	N/A
	NR	Single group	Low	1 y	IBR	Non-obese patients	45/949 (4.7)	N/A	N/A
	NR	Single group	Low	1 y	IBR	Obese patients	44/383 (11.4)	N/A	N/A
Lee, 2021a, 32974692, South Korea	Seroma or hematoma	Single group	Low	5 y	IBR	All	2/605 breasts (0.3)	N/A	N/A
Lovecchio, 2015, 24691330, US	NR	Single group	Low	6.4 y	IBR	All	46/1639 (2.8)	N/A	N/A
Parikh, 2018, 30204676, US	NR	Single group	Low	>2 y	IBR	All	72/1285 (5.6)	N/A	N/A
Park, 2019, 30863940, South Korea	NR	Single group	Moderate	>6 mo	IBR	All	38/999 (3.8)	N/A	N/A
Seth, 2015, 25180955, US	Seroma requiring drainage	Single group	Low	NR	IBR	All	40/893 (4.5)	N/A	N/A
Singh, 2012, 22342636, US	NR	Single group	Low	1 mo	IBR	All	61/1316 (4.6)		
	NR	Single group	Low	1 mo	IBR	DTI	6/95 (6.3)	N/A	N/A
	NR	Single group	Low	1 mo	IBR	T/E	55/1221 (4.5)	N/A	N/A
Albornoz, 2013, 23897346, US	Seroma or wound infection	Single group	Low	NR	AR	All	189/21016 (0.9)	N/A	N/A
Singh, 2021, 33564597, US	NR	Single group	Low	3 mo	IBR	All	219/1740 (12.59)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	DTI	98/870 (11.22)	N/A	N/A
	NR	Single group	Low	3 mo	IBR	T/E	122/870 (13.97)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	NR	Single group	Low	9-10 mo	AR	All	15/910 flaps (1.6)	N/A	N/A
Chang, 2000, 10809092, US	Flap seroma	Single group	Low	NR	AR	All	38/936 flaps (4.1)	N/A	N/A
Chang, 2011, 21407063, US	Donor site seroma	Single group	Low	NR	AR	All	4/818 (0.4)	N/A	N/A
	Donor site seroma	Single group	Low	NR	AR	Age <50	3/411 (0.7)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Donor site seroma	Single group	Low	NR	AR	Age 50-59	1/285 (0.4)	N/A	N/A
	Donor site seroma	Single group	Low	NR	AR	Age 60-69	0/103 (0)	N/A	N/A
	Donor site seroma	Single group	Low	NR	AR	Age >70	0/19 (0)	N/A	N/A
Chen, 2018b, 29596085, US	NR	Single group	Low	NR	AR	All	118/19496 (0.6)	N/A	N/A
Daly, 2020, 31994156, US	Breast seroma	Single group	Low	12 y	AR	All	25/818 (3.1)	N/A	N/A
	Donor site seroma	Single group	Low	12 y	AR	All	45/818 (5.5)	N/A	N/A
Enajat, 2010, 19790180, Sweden	NR	Single group	Low	1-7 d	AR	All	11/564 implants (1.9)	N/A	N/A
Gill, 2004, 15083015, US	NR	Single group	Moderate	10 y	AR	All	35/758 (4.6)	N/A	N/A
Heo, 2018, 30039735, South Korea	Seroma or hematoma	Single group	Low	1 y	AR	All	2/615 (0.3)	N/A	N/A
Jo, 2020, 33386262, South Korea	NR	Single group	Low	11 mo – 1.5 y	AR	All	24/623 (3.85)	N/A	N/A
Masoomi, 2019, 31331721, US	NR	Single group	Low	NR	AR	All	660/55840 (1.2)	N/A	N/A
Munder, 32565553, 2020, Germany	Donor site seroma	Single group	Low	2 y	AR	All	6/1274 flaps (0.5)	N/A	N/A
Nelson, 2014, 25046665, US	Breast seroma	Single group	Moderate	NR	AR	All	35/1293 flaps (2.7)	N/A	N/A
	Donor site seroma	Single group	Moderate	NR	AR	All	11/1293 flaps (0.9)	N/A	N/A
O'Neill, 2019, 31196805, Canada	NR	Single group	Low	<3 mo	AR	All	17/912 (1.9)	N/A	N/A
Rubio, 2019, 30665841, Belgium	NR	Single group	Low	NR	AR	All	622/56522 (1.1)	N/A	N/A
Selber, 2009, 19935283, US	NR	Single group	Low	5.6 mo	AR	All	30/1031 (2.9)	N/A	N/A
Song, 2016, 26637165, US	NR	Single group	Low	4.3-5.4 y	AR	All	151/1809 (8.3)	N/A	N/A
Tran, 2018, 29794694, US	NR	Single group	Low	NR	AR	All	26/1253 flaps (2.1)	N/A	N/A
Williams, 1995, 7794079, US	NR	Single group	Moderate	2.4 y	AR	All	8/607 (1.3)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, d = days, DIEP = deep inferior epigastric perforator, DTI = direct to implant, IBR = implant-based reconstruction, LD = latissimus dorsi, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SSI = surgical site infection, T/E = tissue expander, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.23. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – scarring)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Cordeiro, 2015b, 26090764, US	Hypertrophic or other scarring	Single group	Low	2 y	IBR	69/4912 implants (1.4)	N/A	N/A
Yoo, 2014, 24852813, South Korea	Breast hypertrophic scarring	Single group	Moderate	NR	AR	13/500 (2.6)	N/A	N/A
	Donor site hypertrophic scarring	Single group	Moderate	NR	AR	26/500 (5.2)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.24. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – reconstructive failure)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Chetta, 2017, 28002254, US	NR	NRCS	High	1.3 mo	IBR	All	1101/3746 (29.4)	0.09 (0.07, 0.13)	<0.001
	NR	NRCS	High	1.3 mo	AR	All	40/935 (4.3)	Ref	Ref
Fischer, 2013, 23629074, US	Flap loss in AR cohort or an unplanned, nonaesthetic TE/I removal related to a complication in TE/I cohort	NRCS	High	4 y	IBR	All	4/60 (7.3)	Ref	Ref
	Flap loss in AR cohort or an unplanned, nonaesthetic TE/I removal related to a complication in TE/I cohort	NRCS	High	4 y	AR	All	2/142 (1.3)	0.19 (0.04, 0.8)	0.03
Fischer, 2014, 24916480, US	Total flap loss or TE/I removal secondary to infection or exposure	NRCS	High	1.8-2.1 y	IBR	All	9/155 (5.6)	NR	NR
	Total flap loss or TE/I removal secondary to infection or exposure	NRCS	High	1.8-2.1 y	AR	All	2/155 (1.2)	NR	NR
	Implant/flap failure	NRCS	High	11 mo	IBR	All	14/155 (5.6)	NR	NR
	Implant/flap failure	NRCS	High	11 mo	AR	All	3/155 (1.2)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Garvey, 2012, 23096600, US	NR	NRCS	Moderate	1.5 y	IBR	All	70/442 breasts (15.8)	Ref	Ref
	NR	NRCS	Moderate	1.5 y	AR	All	8/548 breasts (1.5)	NR	<0.001
Kulkarni, 2017, 28713853, US & Canada	NR	NRCS	Moderate	2 y	IBR (all)	All	NR	NR	NR
	NR	NRCS	Moderate	2 y	IBR (all)	Unilateral	41/600 (6.83)	Ref	Ref
	NR	NRCS	Moderate	2 y	IBR (all)	Bilateral	74/994 (7.44)	Ref	Ref
	NR	NRCS	Moderate	2 y	IBR DTI	All	8/112 (7.1)	NR	NR
	NR	NRCS	Moderate	2 y	IBR T/E	All	108/1525 (7.1)	NR	NR
	NR	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR
	NR	NRCS	Moderate	2 y	AR (all)	Unilateral	4/317 (1.26)	vs. IBR (all): 0.12 (0.04, 0.36)	<0.001
	NR	NRCS	Moderate	2 y	AR (all)	Bilateral	4/224 (1.87)	vs. IBR (all): 0.14 (0.05, 0.45)	0.001
	NR	NRCS	Moderate	2 y	AR with DIEP	All	5/390 (1.3)	NR	NR
	NR	NRCS	Moderate	2 y	AR with free TRAM	All	2/95 (2.1)	NR	NR
	NR	NRCS	Moderate	2 y	AR with pedicled TRAM	All	1/85 (1.2)	NR	NR
	NR	NRCS	Moderate	2 y	AR with LD	All	2/71 (2.8)	NR	NR
	NR	NRCS	Moderate	2 y	AR with SIEA	All	0/65 (0)	NR	NR
Mioton, 2013, 23562485, US	Implant/flap failure	NRCS	Moderate	1 mo	IBR	All	83/9786 (0.85)	Ref	Ref
	Implant/flap failure	NRCS	Moderate	1 mo	AR	All	103/3296 (3.13)	1.69 (1.08, 2.62)	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.25. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (harms – hematoma or hemorrhage)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Fischer, 2014, 24916480, US	Breast hematoma	NRCS	High	1.8-2.1 mo	IBR	All	4/155 (2.4)	Ref	Ref
	Breast hematoma	NRCS	High	1.8-2.1 mo	AR	All	4/155 (2.8)	NR	1.0

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	Breast hematoma	NRCS	Moderate	1 y	IBR	All	56/1615 (3.5)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	AR with DIEP	All	22/365 (6)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	AR with free TRAM	All	4/97 (4.1)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	AR with pedicled TRAM	All	3/84 (3.6)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	AR with LD	All	3/73 (4.1)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	IBR	All	N/A	N/A	N/A
	Donor site hematoma	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	AR with DIEP	All	10/365 (2.7)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	AR with free TRAM	All	0/97 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	AR with pedicled TRAM	All	0/84 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	AR with LD	All	0/73 (0)	NR	NR
Nelson, 2019, 31356276, US	Hematoma	NRCS	High	<3 mo	IBR	All	15/1211 breasts (1.2)	NR	NR
	Hematoma	NRCS	High	<3 mo	AR	All	NR	NR	NR
Banuelos, 2020, 31663932, US .	Hematoma	Single group	Low	≤1 mo	IBR	All	21/768 (2.7)	N/A	N/A
	Hematoma	Single group	Low	>1 mo	IBR	All	0/768 (0)	N/A	N/A
Brooks, 2012, 22098451, US	Hematoma	Single group	Low	3.4 y	IBR	All	18/733 (2.5)		
	Hematoma	Single group	Low	3.4 y	IBR	Radiation	0/97 (0)	N/A	N/A
	Hematoma	Single group	Low	3.4 y	IBR	No radiation	18/636 (2.8)	N/A	N/A
Chen, 2018a, 29596085, US	Hematoma or hemorrhage	Single group	Low	NR	IBR	All	495/23048 (2.1)	N/A	N/A
Cordeiro, 2006, 16980842, US	Hematoma	Single group	Moderate	NR	IBR	All	10/2276 procedures (0.4)	N/A	N/A
	Hematoma	Single group	Moderate	NR	IBR	Expander placement procedure	7/1221 procedures (0.6)	N/A	N/A
	Hematoma	Single group	Moderate	NR	IBR	Exchange procedure	3/1055 procedures (0.3)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Hematoma	Single group	Moderate	NR	IBR	Previous radiation	0/136 procedures (0)	N/A	N/A
	Hematoma	Single group	Moderate	NR	IBR	No previous radiation	10/2140 procedures (0.5)	N/A	N/A
	Hematoma	Single group	Moderate	NR	IBR	Immediate	7/1176 procedures (0.6)	N/A	N/A
	Hematoma	Single group	Moderate	NR	IBR	Delayed	0/26 procedures (0)	N/A	N/A
Cordeiro, 2012, 22286416, US	Hematoma	Single group	Low	<1 y	IBR	All	29/1699 (1.7)	N/A	N/A
	Hematoma	Single group	Low	<1 y	IBR	Prior radiation	1/121 (0.8)	N/A	N/A
	Hematoma	Single group	Low	<1 y	IBR	No prior radiation	28/1578 (1.8)	N/A	N/A
Hunsicker, 2017, 26849284, US	Hematoma	Single group	Low	<1 y	IBR	All	15/1584 breasts (0.9)	N/A	N/A
Huo, 2016, 27697676, US	Hematoma	Single group	Low	1 y	IBR	All	35/1332 (2.6)	N/A	N/A
	Hematoma	Single group	Low	1 y	IBR	Non-obese	26/949 (2.7)	N/A	N/A
	Hematoma	Single group	Low	1 y	IBR	Obese	9/383 (2.3)	N/A	N/A
Lovecchio, 2015, 24691330, US	Hematoma	Single group	Low	2.3 y	IBR	All	33/1639 (2.0)	N/A	N/A
Park, 2019, 30863940, South Korea	Hematoma	Single group	Moderate	>6 mo	IBR	All	11/999 (1.1)	N/A	N/A
Rogoff, 2020, 32243320, US	Hematoma	Single group	Low	NR	IBR	All	26/627 (4.1)	N/A	N/A
Seth, 2015, 25180955, US	Hematoma requiring reoperation	Single group	Low	NR	IBR	All	29/893 (3.2)	N/A	N/A
Singh, 2012, 22342636, US	Hematoma	Single group	Low	1 mo	IBR	DTI	6/95 (6.3)	N/A	N/A
	Hematoma	Single group	Low	1 mo	IBR	T/E	36/1221 (2.9)	N/A	N/A
Singh, 2021, 33564597, US	Hematoma	Single group	Low	3 mo	IBR	All	219/1740 (12.6)	N/A	N/A
	Hematoma	Single group	Low	3 mo	IBR	DTI	97/870 (11.2)	N/A	N/A
	Hematoma	Single group	Low	3 mo	IBR	T/E	122/870 (14.0)	N/A	N/A
Albornoz, 2013, 23897346, US	Hematoma or hemorrhage	Single group	Low	NR	AR	All	651/21016 (3.1)	N/A	N/A
	Transfusion	Single group	Low	NR	.	All	1681/21016 (8.0)	N/A	N/A
Andree, 2012, 23197233, Germany	Breast hematoma	Single group	Low	1 mo	AR	All	26/1068 flaps (2.4)	N/A	N/A
	Donor site hematoma	Single group	Low	1 y	AR	All	9/1068 flaps (0.8)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Beugels, 2018, 29399731, Netherlands	Breast hematoma	Single group	Low	9-10 mo	AR	All	53/910 flaps (5.8)	N/A	N/A
Chang, 2000, 10809092, US	Flap hematoma	Single group	Low	NR	AR	All	16/936 flaps (1.7)	N/A	N/A
Chang, 2011, 21407063, US	Hematoma	Single group	Low	NR	AR	All	7/818 (0.9)	N/A	N/A
	Hematoma	Single group	Low	NR	AR	Age <50	2/411 (0.5)	N/A	N/A
	Hematoma	Single group	Low	NR	AR	Age 50-59	4/285 (1.4)	N/A	N/A
	Hematoma	Single group	Low	NR	AR	Age 60-69	0/103 (0)	N/A	N/A
	Hematoma	Single group	Low	NR	AR	Age >70	1/19 (5.3)	N/A	N/A
Chen, 2018b, 29596085, US	Bleeding (hematoma/ hemorrhage)	Single group	Low	NR	AR	All	688/19496 (3.5)	N/A	N/A
Cleveland, 2013, 23945529, US	Postop transfusion	Single group	Low	NR	AR	All	65/812 (8.0)	N/A	N/A
Enajat, 2010, 19790180, Sweden	Hematoma	Single group	Low	1-7 d	AR	All	44/564 flaps (7.8)	N/A	N/A
Gill, 2004, 15083015, US	Hematoma	Single group	Moderate	10 y	AR	All	14/758 (1.8)	N/A	N/A
Haddock, 2019, 31461004, US	Hematoma	Single group	Moderate	NR	AR	All	15/509 (2.9)	N/A	N/A
Jo, 2020, 33386262, South Korea	Breast hematoma	Single group	Low	11 mo – 1.5 y	AR	All	36/623 (5.78)	N/A	N/A
Liao, 2008, 18349626, US	Hematoma	Single group	Low	NR	AR	All	5/679 (0.7)	N/A	N/A
Masoomi, 2019, 31331721, US	Hematoma	Single group	Low	NR	AR	All	1465/55840 (2.6)	N/A	N/A
	Blood transfusion	Single group	Low	NR	AR	All	687/7991 (8.6)	N/A	N/A
Munder, 2020, 32565553, Germany	Breast hematoma	Single group	Low	2 y	AR	All	17/1274 flaps (1.3)	N/A	N/A
	Donor site hematoma	Single group	Low	2 y	AR	All	5/1274 flaps (0.4)	N/A	N/A
Mehrara, 2006, 17016173, US	Hematoma	Single group	Moderate	1 mo	AR	All	19/1195 (1.6)	N/A	N/A
Nelson, 2014, 25046665, US	Breast hematoma	Single group	Moderate	NR	AR	All	29/1293 flaps (2.2)	N/A	N/A
	Donor site hematoma	Single group	Moderate	NR	AR	All	1 flap/1293 flaps (0.1)	N/A	N/A
O'Neill, 2019, 31196805, Canada	Hematoma	Single group	Low	1 d	AR	All	24/512 (4.7)	N/A	N/A
	Hematoma	Single group	Low	<2 mo	AR	All	42/960 (4.4)	N/A	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Hematoma	Single group	Low	3 mo	AR	All	62/912 (6.8)	N/A	N/A
Phan, 2020, 31124177, UK	Hematoma	Single group	Low	NR	AR	All	69/1070 (6.4)	N/A	N/A
	Hematoma requiring postop blood transfusion	Single group	Low	NR	AR	All	10/1070 (0.9)	N/A	N/A
Prantl, 2020, 32895743, Germany	Breast hematoma	Single group	Low	3 mo	AR	All	148 flaps/4577 flaps (3.2)	N/A	N/A
	Donor site hematoma	Single group	Low	3 mo	AR	All	37 flaps/4577 flaps (0.8)	N/A	N/A
Rubio, 2019, 30665841, Belgium	Hematoma	Single group	Low	NR	AR	All	1357/56522 (2.4)	N/A	N/A
Selber, 2009, 19935283, US	Hematoma	Single group	Low	5.6 mo	AR	All	13/1031 (1.3)	N/A	N/A
Song, 2016, 26637165, US	Hematoma requiring reoperation	Single group	Low	4.3-5.4 y	AR	All	103/1809 (5.7)	N/A	N/A
Tran, 2018, 29794694, US	Hematoma	Single group	Low	NR	AR	All	50/1253 flaps (4.0)	N/A	N/A
Watterson, 1995, 7761505, Australia	Hematoma	Single group	Moderate	2.7 mo	AR	All	7/556 (1.3)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-1.26. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (composite/unspecified harms)

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Brorson 2020a, 32807615, Sweden	Clavien-Dindo Grade I complications	RCT	High	1 mo	IBR	All	29/70 (41)	Ref	Ref
	Clavien-Dindo Grade I complications	RCT	High	1 mo	AR	All	23/55 (42)	OR 1.26 (0.63, 2.55)	0.65
	Clavien-Dindo Grade II complications	RCT	High	1 mo	IBR	All	18/70 (26)	Ref	Ref
	Clavien-Dindo Grade II complications	RCT	High	1 mo	AR	All	14/55 (25)	OR 0.99 (0.44, 2.22)	0.53
	Clavien-Dindo Grade IIIa complications	RCT	High	1 mo	IBR	All	1/70 (1.4)	Ref	Ref
	Clavien-Dindo Grade IIIa complications	RCT	High	1 mo	AR	All	1/55 (1.8)	OR 1.28 (0.08, 20.9)	0.86
	Clavien-Dindo Grade IIIb complications	RCT	High	1 mo	IBR	All	4/70 (5.7)	Ref	Ref
	Clavien-Dindo Grade IIIb complications	RCT	High	1 mo	AR	All	1/55 (1.8)	OR 0.31 (0.03, 2.82)	0.30
	Clavien-Dindo Grade IV complications	RCT	High	1 mo	IBR	All	0/70 (0)	Ref	Ref
	Clavien-Dindo Grade IV complications	RCT	High	1 mo	AR	All	0/54 (0)	No events	N/A
	Clavien-Dindo Grade V complications	RCT	High	1 mo	IBR	All	0/70 (0)	Ref	Ref
	Clavien-Dindo Grade V complications	RCT	High	1 mo	AR	All	0/54 (0)	No events	N/A

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Chetta, 2017, 28002254, US	Any complication: infection, wound complications, hematoma, mechanical implant complications (rupture), capsular contractures of implant, fat necrosis and flap venous congestion	NRCS	High	1.3 y	IBR	All	1742/3846 (45.3)	adjOR 0.48 (0.4, 0.57)	NR
	Any complication: infection, wound complications, hematoma, mechanical implant complications (rupture), capsular contractures of implant, fat necrosis and flap venous congestion	NRCS	High	1.3 y	AR	All	189/935 (30.8)	Ref	Ref
Dauplat, 2021, 33622886, France	Major complications (rehospitalization or reoperation)	NRCS	Moderate	1 y	IBR	All	37/205 (18)	Ref	Ref
	Major complications (rehospitalization or reoperation)	NRCS	Moderate	1 y	AR with LD without implant	All	7/78 (9)	adjOR 2.86 (1.41, 5.83)	NR
Fischer, 2014, 24916480, US	Major surgical complication	NRCS	High	1.8-2.1 y	IBR	All	31/155 (20)	Ref	Ref
	Major surgical complication	NRCS	High	1.8-2.1 y	AR	All	17/155 (11)	NR	0.08
Fischer, 2015, 26366550, US	Complications requiring hospitalization	NRCS	High	3 mo	IBR DTI	All	113/1717 (6.6)	Ref	Ref
	Complications requiring hospitalization	NRCS	High	3 mo	IBR with T/E	All	695/10690 (6.5)	Ref	Ref
	Complications requiring hospitalization	NRCS	High	3 mo	AR	All	360/2747 (13.1)	vs. IBR DTI: adjOR 1.36 (1.22, 1.52) vs. IBR with T/E: adjOR 2.09 (1.82, 2.41)	NR
Kouwenberg, 2020, 32590633, Netherlands	Any complication	NRCS	NRCS	>6 mo	IBR	All	94/296 (31.6)	Ref	Ref
	Any complication	NRCS	NRCS	>6 mo	AR	All	83/179 (46.6)	adjOR 1.86 (1.27, 2.72)	0.002
Kulkarni, 2017, 28713853, US & Canada	Any complication	NRCS	Moderate	1 y	IBR (all)	All	NR	Ref	Ref
	Any complication	NRCS	Moderate	1 y	IBR (all)	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR (all)	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR DTI	All	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR DTI	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR DTI	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR with T/E	All	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	IBR with T/E	Unilateral	NR	NR	NR

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Any complication	NRCS	Moderate	1 y	IBR with T/E	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR (all)	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR (all)	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with DIEP	All	NR/365 (NR)	vs. IBR (all): adjOR 2.22 (1.57, 3.13)	<0.001
	Any complication	NRCS	Moderate	1 y	AR with DIEP	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with DIEP	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with free TRAM	All	NR	vs. IBR (all): adjOR 1.94 (1.17, 3.23)	0.011
	Any complication	NRCS	Moderate	1 y	AR with free TRAM	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with free TRAM	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	vs. IBR (all): adjOR 1.89 (1.08, 3.30)	0.025
	Any complication	NRCS	Moderate	1 y	AR with pedicled TRAM	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with pedicled TRAM	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with LD	All	NR	vs. IBR (all): adjOR 1.95 (1.08, 3.51)	0.026
	Any complication	NRCS	Moderate	1 y	AR with LD	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with LD	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with SIEA	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR	All	NR	NR	NR

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Any complication	NRCS	Moderate	2 y	IBR	Unilateral	145/600 (24.2)	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR	Bilateral	287/994 (28.9)	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR DTI	All	35/112 (31.3)	vs. IBR with T/E: adjOR 1.08 (0.65, 1.77)	0.78
	Any complication	NRCS	Moderate	2 y	IBR DTI	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR DTI	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR with T/E	All	406/1525 (26.6)	Ref	Ref
	Any complication	NRCS	Moderate	2 y	IBR with T/E	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	IBR with T/E	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR (all)	Unilateral	147/317 (46.4)	NR	NR
	Any complication	NRCS	Moderate	2 y	AR (all)	Bilateral	123/214 (57.5)	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with DIEP	All	185/390 (47.4)	vs. IBR with T/E: adjOR 1.97 (1.41, 2.76)	<0.001
	Any complication	NRCS	Moderate	2 y	AR with DIEP	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with DIEP	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with free TRAM	All	34/95 (35.8)	vs. IBR with T/E: adjOR 2.48 (1.33, 4.64)	0.005
	Any complication	NRCS	Moderate	2 y	AR with free TRAM	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with free TRAM	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with pedicled TRAM	All	35/85 (41.2)	vs. IBR with T/E: adjOR 1.91 (1.01, 1.31)	0.005
	Any complication	NRCS	Moderate	2 y	AR with pedicled TRAM	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with pedicled TRAM	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with LD	All	28/71 (39.4)	vs. IBR with T/E: adjOR 1.87 (1.03, 3.4)	0.04

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Any complication	NRCS	Moderate	2 y	AR with LD	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with LD	Bilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with SIEA	All	48/65 (73.9)	vs. IBR with T/E: adjOR 4.71 (2.32, 9.54)	<0.001
	Any complication	NRCS	Moderate	2 y	AR with SIEA	Unilateral	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with SIEA	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR (all)	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR (all)	Unilateral	105/600 (17.5)	Ref	Ref
	Major complications	NRCS	Moderate	1 y	IBR (all)	Bilateral	215/994 (21.6)	Ref	Ref
	Major complications	NRCS	Moderate	1 y	IBR DTI	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR DTI	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR DTI	Bilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR with T/E	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR with T/E	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	IBR with T/E	Bilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR (all)	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR (all)	Unilateral	87/317 (27.4)	vs. IBR (all): adjOR 2.19 (1.39, 3.47)	0.001
	Major complications	NRCS	Moderate	1 y	AR (all)	Bilateral	81/224 (37.9)	vs. IBR (all): adjOR 1.69 (1.11, 2.56)	0.014
	Major complications	NRCS	Moderate	1 y	AR with DIEP	All	NR	vs. IBR (all): adjOR 1.75 (1.19, 2.58)	0.004
	Major complications	NRCS	Moderate	1 y	AR with DIEP	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with DIEP	Bilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with free TRAM	All	NR	vs. IBR (all): adjOR 1.75 (1.19, 2.58)	0.12
	Major complications	NRCS	Moderate	1 y	AR with free TRAM	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with free TRAM	Bilateral	NR	NR	NR

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	Major complications	NRCS	Moderate	1 y	AR with pedicled TRAM	All	NR	vs. IBR (all): adjOR 1.86 (1.02, 3.4)	0.044
	Major complications	NRCS	Moderate	1 y	AR with pedicled TRAM	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with pedicled TRAM	Bilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with LD	All	NR	vs. IBR (all): adjOR 0.98 (0.47, 2)	0.953
	Major complications	NRCS	Moderate	1 y	AR with LD	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with LD	Bilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with SIEA	All	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with SIEA	Unilateral	NR	NR	NR
	Major complications	NRCS	Moderate	1 y	AR with SIEA	Bilateral	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	IBR	All	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	IBR DTI	All	21/112 (18..8)	vs. IBR with T/E: adjOR 1.06 (0.56, 1.99)	0.87
	Reoperative complications	NRCS	Moderate	2 y	IBR with T/E	All	237/1525 (15.5)	Ref	Ref
	Reoperative complications	NRCS	Moderate	2 y	AR (all)	All	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	AR with DIEP	All	114/390 (29.2)	vs. IBR with T/E: adjOR 2.76 (1.87, 4.07)	<0.001
	Reoperative complications	NRCS	Moderate	2 y	AR with free TRAM	All	26/95 (27.4)	vs. IBR with T/E: adjOR 3.02 (1.73, 5.29)	<0.01
	Reoperative complications	NRCS	Moderate	2 y	AR with pedicled TRAM	All	25/85 (19.4)	vs. IBR with T/E: adjOR 2.48 (1.33, 4.64)	0.005
	Reoperative complications	NRCS	Moderate	2 y	AR with LD	All	10/71 (14.1)	vs. IBR with T/E: adjOR 1.03 (0.46, 2.29)	0.94
	Reoperative complications	NRCS	Moderate	2 y	AR with SIEA	All	20/65 (30.8)	vs. IBR with T/E: adjOR 2.62 (1.24, 5.52)	0.01

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Laporta, 2017, 28061518, Italy	Overall surgical complication: including mastectomy skin flap and NAC necrosis, vascular thrombosis, flap loss, partial flap loss, infection, hematoma, donor site seroma, and wound dehiscence, whereas late surgical complications consisted of fat necrosis, an abdominal bulge or hernia, capsular contracture or implant leak, implant loss; number of take backs to the theater for secondary surgery.	NRCS	High	>6 mo	IBR	All	NR/356 breasts (NR)	adjOR 1.6 (0.6, 4.1)	0.034
	Overall surgical complication: including mastectomy skin flap and NAC necrosis, vascular thrombosis, flap loss, partial flap loss, infection, hematoma, donor site seroma, and wound dehiscence, whereas late surgical complications consisted of fat necrosis, an abdominal bulge or hernia, capsular contracture or implant leak, implant loss; number of take backs to the theater for secondary surgery.	NRCS	High	>6 mo	AR	All	NR/895 breasts (NR)	Ref	Ref
Liu, 2014, 24558063, US	Major complications: defined as requiring subsequent unanticipated surgical interventions	NRCS	High	>6 mo	IBR	All	67/179 (37.4)	Ref	Ref
	Major complications: defined as requiring subsequent unanticipated surgical interventions	NRCS	High	>6 mo	AR	All	16/75 (21.3)	adjOR 5.363 (1.128, 25.507)	0.035
Mak, 2020, 32665188, China	Any complication	NRCS	Moderate	1 mo	IBR	All	15/30 (50.0)	Ref	Ref
	Any complication	NRCS	Moderate	1 mo	AR	All	52/213 (24.4)	2.24 (1.09, 5.39)	0.030
	Any complication requiring reoperation	NRCS	Moderate	1 mo	IBR	All	2/30 (6.7)	Ref	Ref
	Any complication requiring reoperation	NRCS	Moderate	1 mo	AR	All	14/213 (6.6)	NR	0.99
Palve, 2020, 32468337, Finland	Any complication	NRCS	Moderate	3 mo	IBR	All	NR/51 (NR)	Ref	Ref
	Any complication	NRCS	Moderate	3 mo	AR	All	NR/283 (NR)	adjOR 4.05 (2.10, 7.81)	<0.001
Qin, 2018, 29384865, China	postoperative complications(infection, any of these: marginal necrosis of incision, dehiscence of incisions, upper limb lymphedema, bleeding, nipple necrosis, seroma, capsular contracture	NRCS	High	3.7 y	IBR DTI	All	15/54 (27.8)	vs. IBR with T/E and AR: adjOR 1.13 (0.84, 1.36)	NR

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
	postoperative complications(infection, any of these: marginal necrosis of incision, dehiscence of incisions, upper limb lymphedema, bleeding, nipple necrosis, seroma, capsular contracture	NRCS	High	3.7 y	IBR with T/E	All	5/38 (13.2)	vs. IBR DTI and AR: adjOR 1.07 (0.92, 1.16)	NR
	postoperative complications(infection, any of these: marginal necrosis of incision, dehiscence of incisions, upper limb lymphedema, bleeding, nipple necrosis, seroma, capsular contracture	NRCS	High	3.7 y	AR	All	20/59 (33.9)	vs. IBR DTI and IBR with T/E: adjOR 1.58 (1.32, 2.75)	NR
Simon, 2020, 33363007, Italy	Any complication	Ref	Moderate	3.3 y	IBR	All	NR/68 (NR)	Ref	Ref
	All complication	Ref	Moderate	3.3 y	AR	All	NR/139 (NR)	adjOR 8.28 (1.71, 4.01)	0.009
Xu, 2018, 30261115, China	Overall complications, including capsular contracture, hematoma, wound infection, wound dehiscence, seroma, fat liquefaction/necrosis, implant rupture, flap/nipple areola necrosis, abdominal bulge/hernia, and implant/flap failure	NRCS	Moderate	1.2 y	IBR	All	57/326 (17.5)	adjOR 0.747 (0.366, 1.525)	0.424
	Overall complications, including capsular contracture, hematoma, wound infection, wound dehiscence, seroma, fat liquefaction/necrosis, implant rupture, flap/nipple areola necrosis, abdominal bulge/hernia, and implant/flap failure	NRCS	Moderate	1.2 y	AR	All	27/100 (27.0)	Ref	Ref
Salibian, 2019, 31333984, US	Major ischemic complications	Single group	Low	3.3 y	IBR	All	70/1045 (6.7)	N/A	N/A
Acosta, 2011, 21046538, Sweden	Overall complications	Single group	High	9 y	AR	All	105/543 (19.3)	N/A	N/A
Beugels, 2018, 29399731, Netherlands	Wound problems: included wound dehiscence and superficial skin necrosis related to the breast reconstruction, but not necrosis of mastectomy skin	Single group	Low	9-10 mo	AR	All	115/910 flaps (12.6)	N/A	N/A

Study, Year, PMID, Country	Outcome	Design	Overall RoB	Time Point	Arm	Subgroup	n/N (%)	Effect Size (95% CI)	P Value
Langer, 2010, 20980954, Germany	Breast seroma, hematoma, or wound infection	Single group	Low	5 y	AR	All	23/670 flaps (3.4)	N/A	N/A
Prantl, 2020, 32895743, Germany	Deep vein thrombosis, pulmonary embolism, myocardial infarct and others	Single group	Low	3 mo	AR	All	294/4577 flaps (6.4)	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-2.1. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (physical well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015, 30270015, US	EORTC QLQC30: Global health status	NRCS	High	3.3 y	84	72.5 (2.6)	22	73.4 (1.9)	NR	NS
Yoon, 2020, 32332528, US & Canada	BREAST-Q: Physical WB (0-100)	NRCS	Moderate	2 y	80	NR	237	NR	−0.64 (−7.19, 5.90)	0.84
	PROMIS: Physical function (0-100)	NRCS	Moderate	2 y	80	NR	237	NR	−0.04 (−2.40, 2.32)	0.97

Abbreviations: CI = confidence interval, EORTC = European Organization for Research and Treatment of Cancer, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, PROMIS = Patient-Reported Outcomes Measurement Information System, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-2.2. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (psychosocial well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015, 30270015, US	BREAST-Q: Psychosocial WB (0-100)	NRCS	High	3.3 y	84	71.1 (1.4)	22	72.3 (1.2)	NR	<0.01
Yoon, 2020, 32332528, US & Canada	BREAST-Q: Psychosocial WB (0-100)	NRCS	Moderate	2 y	80	NR	237	NR	0.48 (−7.72, 8.68)	0.91

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-2.3. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (sexual well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015, 30270015, US	BREAST-Q: Sexual WB (0-100)	NRCS	High	3.3 y	84	54.0 (0.9)	22	55.4 (0.7)	NR	<0.01
Yoon, 2020, 32332528, US & Canada	BREAST-Q: Sexual WB (0-100)	NRCS	Moderate	2 y	80	NR	237	NR	−1.00 (−8.41, 6.40)	0.78
	EORTC: Sexual function	NRCS	Moderate	2 y	80	NR	237	NR	−1.40 (−8.58, 5.77)	0.70

Abbreviations: CI = confidence interval, EORTC = European Organization for Research and Treatment of Cancer, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, WB = well-being, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-2.4. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015, 30270015, US	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	3.3 y	84	56.2 (3.3)	22	57.2 (3.1)	NR	NS
Yoon, 2020, 32332528, US & Canada	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	80	NR	237	NR	−3.89 (−11.0, 3.23)	0.28

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.5. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (patient satisfaction with outcome)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015, 30270015, US	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	High	3.3 y	84	68.4 (3.8)	22	70.2 (3.0)	NR	0.02

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.6. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – continuous outcomes (pain)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR Before Radiation, N	IBR Before Radiation, Mean (SD)	IBR After Radiation, N	IBR After Radiation, Mean (SD)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Yoon, 2020, 32332528, US & Canada	PROMIS: Pain interference (0−100)	NRCS	Moderate	3.3 y	80	NR	237	NR	2.86 (−1.05, 6.77)	0.14

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = PubMed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.7. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (unplanned repeat surgeries for revision of reconstruction)

Study, Year, PMID	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Eriksson, 2013, 24258257	NRCS	High	3.6 y	NR	NR	adjHR 0.94 (0.63, 1.40)*	NR

Abbreviations: adj = adjusted, CI = confidence interval, HR = hazard ratio, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.
* Calculated

Table F-2.8. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (necrosis)

Study, Year, PMID	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR After Versus Before Radiation, Effect Size (95% CI)	P Value
Hirsch, 2014, 25347643	NRCS	High	3.1 y	NR	NR	adjOR 0.96 (0.68, 1.35)	0.94

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.9. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (infections not explicitly implant related)

Study, Year, PMID	Outcome Description	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR After Versus Before Radiation, Effect Size (95% CI)	P Value
Yoon, 2020, 32332528, US & Canada	Major (IV antibiotics with or without return to surgery)	NRCS	Moderate	2 y	5/46 (10.9)	7/104 (6.7)	NR	0.40
	Minor (oral antibiotics)	NRCS	Moderate	2 y	3/46 (6.5)	7/104 (6.7)	NR	0.96

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, IV = intravenous, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.10. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (wound dehiscence)

Study, Year, PMID	Outcome	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR After Versus Before Radiation, Effect Size (95% CI)	P Value
Yoon, 2020, 32332528, US & Canada	Wound dehiscence	NRCS	Moderate	2 y	0/46 (0)	5/104 (4.8)	NR	0.32

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.11. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (seroma)

Study, Year, PMID	Outcome	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR After Versus Before Radiation, Effect Size (95% CI)	P Value
Yoon, 2020, 32332528, US & Canada	Seroma	NRCS	Moderate	2 y	2/46 (4.4)	8/104 (7.7)	NR	0.47

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.12. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (implant failure/loss)

Study, Year, PMID	Outcome Description	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Cordeiro, 2015a, 25742523	Implant loss	NRCS	High	3.3 y	26/210 (12.4)	17/94 (18.1)	adjOR 0.96 (0.64, 1.43)*	NR
Eriksson, 2013, 24258257	IBR failure	NRCS	High	3.6 y	NR	NR	adjHR 0.62 (0.41, 0.93)*	NR
Hirsch, 2014, 25347643	Explantation	NRCS	High	3.5 y	NR	NR	adjOR 1.12 (0.75, 1.68)*	0.09

Abbreviations: adj = adjusted, CI = confidence interval, HR = Hazard ratio, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = year.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* Calculated.

Table F-2.13. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (capsular contracture)

Study, Year, PMID	Outcome	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Yoon, 2020, 32332528, US & Canada	Capsular contracture	NRCS	Moderate	2 y	1/46 (2.2)	3/104 (2.9)	NR	0.80

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-2.14. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (hematoma)

Study, Year, PMID	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR After Versus Before Radiation, Effect Size (95% CI)	P Value
Hirsch, 2014, 25347643	NRCS	High	3.1 y	NR	NR	adjOR 0.56 (0.22, 1.45)	0.39
Yoon, 2020, 32332528, US & Canada	NRCS	Moderate	2 y	1/46 (2.2)	4/104 (3.9)	NR	0.63

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-2.15. Full Evidence Table – Key Question 2: Timing of radiation therapy relative to IBR – categorical outcomes (combined/unspecified harms)

Study, Year, PMID	Outcome Description	Design	Overall RoB	Time Point	IBR Before Radiation, n/N (%)	IBR After Radiation, n/N (%)	IBR Before Versus After Radiation, Effect Size (95% CI)	P Value
Hirsch, 2014, 25347643	Any complication	NRCS	High	3.5 y	NR	NR	adjOR 0.81 (0.56, 1.17)	NR
	Operative complications	NRCS	High	3.5 y	NR	NR	adjOR 0.92 (0.59, 1.45)	NR
	Nonoperative complications	NRCS	High	3.5 y	NR	NR	adjOR 0.90 (0.60, 1.34)	NR
Stein, 2020, 32561384, Canada	Any complication	NRCS	High	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 0.82 (0.03, 2.19)	0.69
	Major complications	NRCS	High	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 0.62 (0.21, 1.86)	0.40
	Minor complications	NRCS	High	10 mo – 5 y	NR/76 (NR)	NR/54 (NR)	adjOR 1.29 (0.41, 4.03)	0.65
Yoon, 2020, 32332528, US & Canada	Any complication	NRCS	Moderate	2 y	33/80 (41.3)	95/237 (40.1)	NR	0.85
	Major complications	NRCS	Moderate	2 y	26/80 (32.5)	82/237 (34.6)	NR	0.73

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-3.1. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (general quality of life)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	EORTC QLQC30: Global health status	NRCS	High	2.6-4.5 y	72	79.9 (18.1)	67	74.9 (20.9)	NR	0.13

Abbreviations: CI = confidence interval, EORTC QLQC3 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.2. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (physical well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Silicone Versus Saline, Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	BREAST-Q: Physical well-being	NRCS	High	2.6-4.5 y	74	76.2 (14.9)	68	73.4 (16.3)	NR	0.29

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.3. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (psychosocial well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	BREAST-Q: Psychosocial well-being	NRCS	High	2.6-4.5 y	75	77.6 (18.6)	67	70.8 (18.8)	NR	0.004

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.4. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (sexual well-being)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	BREAST-Q: Sexual well-being	NRCS	High	2.6-4.5 y	71	54.4 (19.8)	65	47.6 (20.9)	NR	0.0562

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.5. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Silicone Versus Saline, Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	BREAST-Q: Satisfaction with breast	NRCS	High	2.6-4.5 y	75	63.8 (15.2)	67	56.9 (15.1)	NR	0.0083
McCarthy, 2010, 21136577	BREAST-Q: Satisfaction with breast	NRCS	High	2.4-3.3 y	176	58 (20.3)	306	52.5 (20.4)	adjMD 4.1 (1.31*, 6.89*)	0.032

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* Calculated.

Table F-3.6. Full Evidence Table – Key Question 3: Comparison of materials for IBR – continuous outcomes (patient satisfaction with outcome)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, N	IBR With Silicone, Mean (SD)	IBR With Saline, N	IBR With Saline, Mean (SD)	Effect Size (95% CI)	P Value
Macadam, 2010, 20009795	BREAST-Q: Satisfaction with outcome	NRCS	High	2.6-4.5 y	75	75.4 (17.6)	68	69.5 (22.6)	NR	0.0815

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.7. Full Evidence Table – Key Question 3: Comparison of materials for IBR – categorical outcomes (mortality)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Le, 2005, 15743498	Breast cancer mortality	NRCS	High	12.4 y	IBR with silicone	NR	Ref	Ref
	Breast cancer mortality	NRCS	High	12.4 y	IBR with saline	NR	vs. Silicone: adjHR 1.01 (0.44, 2.34)	NR
	Breast cancer mortality	NRCS	High	12.4 y	IBR with double lumen	NR	vs. Silicone: adjHR 1.49 (0.83, 2.7)	NR
	Non-breast cancer mortality	NRCS	High	12.4 y	IBR with silicone	NR	Ref	Ref
	Non-breast cancer mortality	NRCS	High	12.4 y	IBR with saline	NR	vs. Silicone: adjHR 1.75 (0.29, 10.39)	NR
	Non-breast cancer mortality	NRCS	High	12.4 y	IBR with double lumen	NR	vs. Silicone: adjHR 3.13 (0.91, 10.78)	NR

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, HR = hazard ratio, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, Ref = reference group, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.8. Full Evidence Table – Key Question 3: Comparison of materials for IBR – categorical outcomes (capsular contracture)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, n/N (%)	IBR With Saline, n/N (%)	Effect Size (95% CI)	P Value
Antony, 2014, 24135689	Baker Grade III or IV	NRCS	High	3-5 y	NR/179 (NR)	NR/166 (NR)	NR	NS

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, NS = not significant, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-3.9. Full Evidence Table – Key Question 3: Comparison of materials for IBR – categorical outcomes (implant failure/loss)

Study, Year, PMID	Outcome Measurement	Design	Overall RoB	Time Point	IBR With Silicone, n/N (%)	IBR With Saline, n/N (%)	Silicone Versus Saline, Effect Size (95% CI)	P Value
Cordeiro, 2015a, 25742523, US	TE and implant loss	NRCS	High	3.3 y	NR/159 (NR)	NR/129 (NR)	adjOR 0.61 (0.36, 1.07)	NS

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , NS = not significant, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, TE = tissue expander, y = years.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.1. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	SF-36 (0–100): PCS	RCT	Moderate	6 mo	Prepectoral	20	45.2 (7.1)	Ref	Ref
	SF-36 (0–100): PCS	RCT	Moderate	6 mo	Partial Submuscular	14	45.2 (7.1)	NR	0.689
Cattelani, 2018, 29275104, Italy	Constant Murley (0–100): Upper limb	NRCS	High	1 d	Prepectoral	39	71.6 (8.9)	Ref	Ref
	Constant Murley (0–100): Upper limb	NRCS	High	1 d	Total submuscular	45	60.4 (10.5)	NR	<0.001
	Constant Murley (0–100): Upper limb	NRCS	High	7 d	Prepectoral	39	65.7 (9.3)	Ref	Ref
	Constant Murley (0–100): Upper limb	NRCS	High	7 d	Total submuscular	45	52.4 (12.2)	NR	<0.001
	DASH score	NRCS	High	1 y	Prepectoral	39	9.9 (17.9)	Ref	Ref
	DASH score	NRCS	High	1 y	Total submuscular	45	29.2 (16.9)	NR	<0.001

Abbreviations: CI = confidence interval, d = days, DASH = Disabilities of the Arm, Shoulder, and Hand, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PCS = Physical Component Summary, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-4.2. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – continuous outcomes (psychosocial well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	SF-36 (0–100): MCS	RCT	Moderate	6 mo	Prepectoral	20	40.5 (10.5)	Ref	Ref
	SF-36 (0–100): MCS	RCT	Moderate	6 mo	Partial Submuscular	14	40.5 (10.5)	NR	0.904
	HADS: Anxiety (0-21)	RCT	Moderate	6 mo	Prepectoral	20	6.3 (3.3)	Ref	Ref
	HADS: Anxiety (0-21)	RCT	Moderate	6 mo	Partial Submuscular	14	5.0 (2.9)	NR	0.959

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	HADS: Depression (0-21)	RCT	Moderate	6 mo	Prepectoral	20	7.5 (7.4)	Ref	Ref
	HADS: Depression (0-21)	RCT	Moderate	6 mo	Partial Submuscular	14	6.3 (3.8)	NR	0.924
Cattelani, 2018, 29275104, Italy	Return to usual work	NRCS	High	NR	Prepectoral	39	34.6 (21)	Ref	Ref
	Return to usual work	NRCS	High	NR	Total submuscular	45	57.3 (37.8)	NR	<0.001

Abbreviations: CI = confidence interval, d = days, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-4.3. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Cattelani, 2018, 29275104, Italy	BREAST-Q	NRCS	High	1 y	Prepectoral	39	92.2 (9.0)	Ref	Ref
	BREAST-Q	NRCS	High	1 y	Total submuscular	45	76.1 (14.6)	NR	<0.001

Abbreviations: CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.4. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – continuous outcomes (pain, including chronic pain and analgesic use)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Avila, 2020, 33234947, US	Pain	VAS (0-10)	NRCS	High	NR	Prepectoral	73	3.94 (0.83)	Ref	Ref
	Pain	VAS (0-10)	NRCS	High	NR	Total Submuscular	73	5.25 (0.81)	NR	<0.001
Cattelani, 2018, 29275104, Italy	Pain	BPI-SF	NRCS	High	1 d	Prepectoral	39	17.6 (15.5)	Ref	Ref
	Pain	BPI-SF	NRCS	High	1 d	Total submuscular	45	44.1 (15.8)	NR	<0.001
	Pain	BPI-SF	NRCS	High	7 d	Prepectoral	39	8.2 (15.4)	Ref	Ref
	Pain	BPI-SF	NRCS	High	7 d	Total submuscular	45	22 (18.6)	NR	<0.001
Kim, 2020, 33066236, South Korea	Pain	VAS (0-10)	NRCS	Moderate	1 d	Prepectoral	53	2.66 (1.82)	Ref	Ref
	Pain	VAS (0-10)	NRCS	Moderate	1 d	Partial Submuscular	114	2.26 (1.38)	adjMD -0.08	0.33
	Pain	VAS (0-10)	NRCS	Moderate	7 d	Prepectoral	53	1.08 (1.19)	Ref	Ref
	Pain	VAS (0-10)	NRCS	Moderate	7 d	Partial Submuscular	114	0.80 (1.07)	-0.12	0.12
Avila, 2020, 33234947, US	Analgesic use	Oral morphine equivalents	NRCS	High	NR	Prepectoral	73	17.4 mg (45.1)	Ref	Ref
	Analgesic use	Oral morphine equivalents	NRCS	High	NR	Total Submuscular	73	63.0 mg (44.9)	NR	0.03

Abbreviations: BPI-SF = Brief Pain Inventory-Short Form, CI = confidence interval, d = days, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, VAS = visual analog scale.
Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table F-4.5. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (analgesic use)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Cattelani, 2018, 29275104, Italy	Paracetamol, ketoprofen, or opioid use	NRCS	High	1 d	Prepectoral	39/39 (100)	Ref	Ref
	Paracetamol, ketoprofen, or opioid use	NRCS	High	1 d	Total Submuscular	45/45 (100)	NR	NR
	Paracetamol, ketoprofen, or opioid use	NRCS	High	7 d	Prepectoral	9/39 (23.1)	Ref	Ref
	Paracetamol, ketoprofen, or opioid use	NRCS	High	7 d	Total Submuscular	33/45 (73.3)	NR	NR
	Opioid use	NRCS	High	1 d	Prepectoral	3/39 (7.7)	Ref	Ref
	Opioid use	NRCS	High	1 d	Total Submuscular	11/45 (24.4)	NR	NR
	Opioid use	NRCS	High	7 d	Prepectoral	0/39 (0)	Ref	Ref
	Opioid use	NRCS	High	7 d	Total Submuscular	0/45 (0)	NR	NR

Abbreviations: d = days, CI = confidence interval, d = days, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , PMID = Pubmed identifier, RoB = risk of bias.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.6. Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (unplanned repeat surgeries for revision)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Avila, 2020, 33234947, US	NR	NRCS	High	1 mo	Prepectoral	8/203 (3.94)	Ref	Ref
	NR	NRCS	High	1 mo	Total submuscular	17/202 (8.42)	NR	NS

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.7. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (necrosis)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Nealon, 2020, 32032345, US	Skin necrosis	NRCS	High	1.7-2.4 y	Prepectoral	5/114 (4.4)	Ref	Ref
	Skin necrosis	NRCS	High	1.7-2.4 y	Total Submuscular	6/142 (4.2)	adjOR 1.01 (0.74, 5.95)	0.77

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.8. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (infections)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Kraenzlin, 2021, 32568752, US	Infections (not explicitly implant-related)	NR	NRCS	High	NR	Prepectoral	34/169 (11.0)	Ref	Ref
	Infections (not explicitly implant-related)	NR	NRCS	High	NR	Total submuscular	34/117 (17.4)	NR	0.21
Nealon, 2020, 32032345, US	Infections (not explicitly implant-related)	NR	NRCS	High	1.7-2.4 y	Prepectoral	2/114 (1.8)	Ref	Ref
	Infections (not explicitly implant-related)	NR	NRCS	High	1.7-2.4 y	Total Submuscular	6/142 (4.2)	adjOR 0.31 (0, 8.65)	0.52

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-4.9. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (seroma)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	NR	RCT	Moderate	6 mo	Prepectoral	3/20 (15.0)	Ref	Ref
	NR	RCT	Moderate	6 mo	Partial submuscular	2/14 (14.3)	OR 1.06 (0.15, 7.34)	0.95
Nealon, 2020, 32032345, US	NR	NRCS	High	1.7-2.4 y	Prepectoral	10/114 (8.8)	Ref	Ref
	NR	NRCS	High	1.7-2.4 y	Total Submuscular	11/142 (7.7)	adjOR 1.49 (0.37, 6.11)	0.57

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-4.10. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (need for explant surgery)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Nealon, 2020, 32032345, US	NR	NRCS	High	1.7-2.4 y	Prepectoral	4/114 (3.5)	Ref	Ref
	NR	NRCS	High	1.7-2.4 y	Total Submuscular	7/142 (4.9)	adjOR 1.01 (0.07, 14.11)	0.99

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.11. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (capsular contracture)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Lee, 2021b, 33691448, South Korea	NR	RCT	Moderate	6 mo	Prepectoral	1/20 (5.0)	Ref	Ref
	NR	RCT	Moderate	6 mo	Partial submuscular	0/14 (0)	Not calculable	-
Nealon, 2020, 32032345, US	NR	NRCS	High	1.7-2.4 y	Prepectoral	2/114 (1.8)	Ref	Ref
	NR	NRCS	High	1.7-2.4 y	Total Submuscular	12/142 (8.5)	adjOR 0.30 (0.03, 1.55)	0.16

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-4.12. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (hematoma)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Nealon, 2020, 32032345, US	NR	NRCS	High	1.7-2.4 y	Prepectoral	6/114 (5.3)	Ref	Ref
	NR	NRCS	High	1.7-2.4 y	Total Submuscular	7/142 (4.9)	adjOR 5.18 (0.39, 7.05)	0.23

Abbreviations: adj = adjusted, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study , OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-4.13. Full Evidence Table – Key Question 4: Comparison of anatomic planes for IBR – categorical outcomes (combined/unspecified harms)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Avila, 2020, 33234947, US	Necrosis/infection, wound dehiscence/ hematoma/seroma	NRCS	High	1 mo	Prepectoral	12/203 (5.91)	Ref	Ref
	Necrosis/infection, wound dehiscence/ hematoma/seroma	NRCS	High	1 mo	Total submuscular	19/202 (9.41)	NR	NS
Gabriel, 2020, 32195862, US	Any complication	NRCS	High	2 y	Prepectoral	19/129 breasts (14.7)	Ref	Ref
	Any complication	NRCS	High	2 y	Partial submuscular	33/128 breasts (25.8)	adjOR 3.04 (1.34, 7.61)	0.013
Ozgur, 2020, 33223365, Turkey	Capsular contracture, inframammary fold problems, bottoming out, rippling, mechanical shift, animation deformity	NRCS	High	5.3-6.1 y	Partial submuscular	8/91 breasts (8.8)	Ref	Ref
	Capsular contracture, inframammary fold problems, bottoming out, rippling, mechanical shift, animation deformity	NRCS	High	5.3-6.1 y	Total submuscular	29/117 breasts (24.8)	adjOR 3.28 (1.39, 7.76)	0.007

Abbreviations: BPI-SF = Brief Pain Inventory-Short Form, CI = confidence interval, d = days, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, VAS = visual analog scale.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.1. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	BREAST-Q: Chest and Upper Body	RCT	Moderate	Baseline	36	85.6 (13.5)	33	86.9 (12.4)	N/A	N/A
	BREAST-Q: Chest and Upper Body	RCT	Moderate	24 h	36	65.8 (12.7)	33	68.2 (13.7)	NMD −1.1 (−7.3, 5.1)*	0.73*
	BREAST-Q: Chest and Upper Body	RCT	Moderate	Expansion phase	36	68.6 (10.6)	33	69.3 (7.9)	NMD 0.6 (−4.9, 6.1)*	0.83*
	BREAST-Q: Chest and Upper Body	RCT	Moderate	After expansion	36	79.7 (15.1)	33	80.5 (13.3)	NMD 0.5 (−5.9, 6.9)*	0.88*
Cattelani, 2018, 29275104, Italy	Constant Murley Score	NRCS	High	1 d	39	71.62 (8.87)	45	60.36 (10.54)	NR	<0.001
	Constant Murley Score	NRCS	High	7 d	39	65.67 (9.31)	45	52.36 (12.23)	NR	<0.001
	DASH score	NRCS	High	1 y	39	9.92 (17.87)	45	29.18 (16.91)	NR	<0.001
	Return to usual work	NRCS	High	NR (d)	39	34.56 (21)	45	57.31 (37.77)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	BREAST-Q (0-100): Physical well-being	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −0.82 (−3.01, 1.37)	NR

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, d = days, DASH = Disabilities of the Arm, Shoulder, and Hand, h = hours, IBR = implant-based reconstruction, N/A = not applicable, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Table F-5.2. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (psychosocial well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
Cattelani, 2018, 29275104, Italy	Return to usual work	NRCS	High	NR	39	34.56 d (21)	45	57.31 d (37.77)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	BREAST-Q (0-100): Psychosocial WB	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −0.26 (−2.97, 2.45)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, MD = mean difference, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.3. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (sexual well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
Ganesh Kumar, 2021, 33172826, US & Canada	BREAST-Q: Sexual well-being	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −2.28 (−5.63, 1.06)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, N/A = not applicable, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, MD = mean difference, y = years.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-5.4. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
Cattelani, 2018, 29275104, Italy	BREAST-Q: Satisfaction with breast	NRCS	High	1 y	39	92.2 (9.03)	45	76.1 (14.6)	NR	<0.001
Ganesh Kumar, 2021, 33172826, US & Canada	BREAST-Q: Satisfaction with breast	NRCS	Moderate	2 y	738	NR	713	NR	adjMD −1.95 (−4.96, 1.06)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, MD = mean difference, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.5. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (analgesic use)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	Oral codeine equivalents	RCT	Moderate	0-6 h	33	228 (153)	30	256 (197)	MD −28 mg (−116, 60)*	0.77
	Oral codeine equivalents	RCT	Moderate	6-24 h	33	619 (519)	30	715 (533)	MD −96 mg (−356, 164)*	0.38
	Oral codeine equivalents	RCT	Moderate	0-24 h	36	776 (602)	32	910 (634)	MD −134 mg (−440, 172)*	0.38

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, h = hours, IBR = implant-based reconstruction, MD = mean difference, mg = milligrams, MD = mean difference, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation.

Colors: Header rows are shaded orange. The color does not add unique information.

* Calculated.

Table F-5.6. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (analgesic use)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Cattelani, 2018, 29275104, Italy	Use of paracetamol, ketoprofen, or opioids	NRCS	High	1 d	39/39 (100)	45/45 (100)	NR	NR
	Use of paracetamol, ketoprofen, or opioids	NRCS	High	7 d	9/39 (23.1)	33/45 (73.3)	NR	NR
	Opioid use	NRCS	High	1 d	3/39 (7.7)	11/45 (24.4)	NR	NR
	Opioid use	NRCS	High	7 d	0/39 (0)	0/39 (0)	NR	NR

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, d = days, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-5.7. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (mortality)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Wendel, 2013, None, US	RCT	High	1 mo	0/20 (0)	0/16 (0)	N/A (No events)	N/A

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, N/A = not applicable, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-5.8. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (unplanned repeat surgeries)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Ibrahim, 2013, 24165587, US	For revision of reconstruction (e.g., for asymmetry)	NRCS	Moderate	6 mo	237/3283 (0.5)	990/15714 (0.6)	NR	0.14
Nealon, 2020b, 31605310, US	Revision of reconstruction	NRCS	High	5.3 y	NR	NR	adjOR 0.86 (0.69, 1.08)	0.19
Sobti, 2018, 29481386, US	Revision of reconstruction for malposition or size	NRCS	High	5 y	47/465 breasts (10.11)	24/217 breasts (11.06)	adjOR 1.10 (0.63, 1.92)	NR
Peled, 2012, 22634688, US	For wound-healing or infectious complication, but not other indications, such as hematoma, oncologic indications, or revision procedures	NRCS	High	2.6-3.3 y	11/100 breasts (11)	21/90 breasts (23.3)	NR	<0.05

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant−based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.9. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – continuous outcomes (pain, including chronic pain)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, N	Use of ADM, Mean (SD)	Nonuse of ADM, N	Nonuse of ADM, Mean (SD)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	VAS	RCT	Moderate	Baseline	36	7 (14.9)	33	1.4 (3.2)	NR	NR
	VAS	RCT	Moderate	24 h	36	54.6 (27.6)	33	42.8 (24.5)	NMD 6.2 (−4.9, 17.3)*	0.27*
	VAS	RCT	Moderate	Expansion phase	36	17 (15.9)	33	4.6 (8.9)	NMD 6.8 (1.1, 12.5)*	0.019
	VAS	RCT	Moderate	After expansion	36	5.6 (11.6)	33	4.6 (8.9)	NMD −4.6 (−9.8, 0.6)*	0.081
Cattelani, 2018, 29275104, Italy	BPI-SF	NRCS	High	1 d	39	17.56 (15.52)	45	44.11 (15.83)	NR	<0.001
	BPI-SF	NRCS	High	7 d	39	8.23 (15.39)	45	21.96 (18.59)	NR	<0.001

Abbreviations: ADM = acellular dermal matrix, BPI-SF = Brief Pain Inventory-Short Form, CI = confidence interval, d = days, h = hours, IBR = implant-based reconstruction, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, SD = standard deviation, VAS = Visual Analog Scale.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Table F-5.10. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (necrosis)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Subgroup	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Craig, 2019, 29800083, US	NR	NRCS	Low	7 mo	All patients	145/574 breasts (25.3)	60/796 breasts (7.5)	NR	NR
	NR	NRCS	Low	7 mo	Post-op radiation	21/88 breasts (23.9)	15/113 breasts (13.3)	NR	0.37
	NR	NRCS	Low	7 mo	No post-op radiation	124/486 breasts (25.5)	45/683 breasts (6.6)	adjOR 4.99 (3.28, 8.03)	NR
Hirsch, 2014, 25347643, US	Major flap necrosis	NRCS	Low	3.1 y	All patients	NR	NR	adjOR 0.98 (0.58, 1.66)	0.94
Nealon, 2020b, 31605310, US	Skin necrosis	NRCS	High	5.3 y	All patients	NR	NR	adjOR 0.87 (0.51, 1.52)	0.62
Qureshi, 2016, 27465177, US	Mastectomy flap necrosis	NRCS	High	2 y	All patients	NR/295 (NR)	NR/118 (NR)	adjOR 3.1 (1.00, 9.61)*	<0.05
Seth, 2012, 23018687, US	Major flap necrosis	NRCS	High	2 y	All patients	17/199 breasts (8.5)	26/393 breasts (6.6)	adjOR 1.32 (0.70, 2.49)	NR
Sobti, 2018, 29481386, US	Tissue necrosis	NRCS	High	5 y	All patients	14/338 (2.4)	30/376 (5.1)	adjOR 0.53 (0.27, 1.02)	NR
Sorkin, 2017, 28806288, US & Canada	Mastectomy skin flap necrosis	NRCS	Moderate	2 y	All patients	44/655 (6.7)	34/642 (5.3)	NR	0.23

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Table F-5.11. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (thromboembolic events)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Ibrahim, 2013, 24165587, US	Deep vein thrombosis	NRCS	Moderate	NR	9/3283 (0.3)	35/15714 (0.2)	NR	0.47
	Pulmonary embolism	NRCS	Moderate	NR	2/3283 (0.06)	29/15714 (0.2)	NR	0.11

Abbreviations: ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-5.12. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (wound dehiscence)

Study, Year, PMID, Country	Outcome Measurement	Subgroup	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Craig, 2019, 29800083, US	NR	All patients	NRCS	Low	7 mo	35/574 breasts (6.1)	20/796 breasts (2.5)	NR	NR
	NR	Post-op radiation	NRCS	Low	7 mo	42/88 breasts (47.7)	27/113 breasts (23.9)	NR	NR
	NR	No post-op radiation	NRCS	Low	7 mo	30/486 breasts (6.2)	17/683 breasts (2.5)	adjOR 2.46 (1.23, 4.93)	NR
Ganesh Kumar, 2021, 33172826, US & Canada	NR	All patients	NRCS	Moderate	2 y	24/738 (3.3)	5/713 (0.7)	NR	0.009
Ibrahim, 2013, 24165587, US	NR	All patients	NRCS	Moderate	NR	15/3283 (0.5)	98/15714 (0.6)	NR	0.26
Qureshi, 2016, 27465177, US	Dehiscence without necrosis	All patients	NRCS	High	2 y	NR/295 (NR)	NR/118 (NR)	adjOR 0.4 (NR. NR)	<0.05

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.13. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (delayed healing)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Woo, 2017, 28509694, South Korea	Delayed wound healing or skin flap necrosis	NRCS	High	NR	32/199 (16.1)	32/199 (16.1)	adjOR 1.41 (0.67, 2.96)	0.37

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-5.14. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (seroma)

Study, Year, PMID, Country	Subgroup	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	All patients	RCT	Moderate	NR	1/36 (2.78)	3/33 (9.09)	OR 0.29 (0.03, 2.89)*	0.29*
Chun, 2010, 20124828, US	All patients	NRCS	High	NR	38/269 breasts (14.1)	4/146 breasts (2.7)	adjOR 4.24 (1.28, 14)	0.018
Craig, 2019, 29800083, US	All patients	NRCS	Low	7 mo	65/574 breasts (11.3)	32/796 breasts (4)	NR	NR
	Post-op radiation	NRCS	Low	7 mo	12/88 breasts (13.6)	6/113 breasts (5.3)	NR	NR
	No post-op radiation	NRCS	Low	7 mo	53/486 breasts (10.9)	26/683 breasts (3.8)	adjOR 3.19 (1.85, 5.52)	NR
Seth, 2012, 23018687, US	All patients	NRCS	High	2 y	8/199 breasts (4)	8/393 breasts (2)	adjOR 2.02 (0.75, 5.45)	NR
Sorkin, 2017, 28806288, US & Canada	All patients	NRCS	Moderate	2 y	21/655 (3.2)	20/642 (3.1)	NR	0.97
Woo, 2017, 28509694, South Korea	All patients	NRCS	High	NR	8/199 (4)	17/199 (8.5)	adjOR 0.89 (0.33, 2.39)	0.81

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Table F-5.15. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (infections not explicitly implant related)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Subgroup	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
McCarthy, 2012, 23096987, US	NR	RCT	Moderate	NR	All patients	3/36 (8.3)	1/33 (3.0)	OR 2.91 (0.29, 29.45)*	0.37*
Wendel, 2013, None, US	NR	RCT	High	1 mo	All patients	6/20 (30)	2/16 (12.5)	OR 3.00 (0.51, 17.50)*	0.22*
Brooke, 2012, 22868313, US	NR	NRCS	High	NR	All patients	22/221 breasts (10)	1 breast/64 breasts (2)	NR	0.09
Chun, 2010, 20124828, US	Overall infection	NRCS	High	NR	All patients	24/269 breasts (8.9)	3/146 breasts (2.1)	adjOR 5.37 (1.63, 17.6)	0.006
	Major infection requiring admission for IV antibiotics and/or surgery	NRCS	High	NR	All patients	22/269 breasts (8.2)	1/146 breasts (0.68)	NR	0.0016
Craig, 2019, 29800083, US	NR	NRCS	Low	7 mo	All patients	70/574 breasts (12.2)	38/796 breasts (4.8)	NR	NR
	NR	NRCS	Low	7 mo	Post-op radiation	14/88 breasts (15.9)	13/113 breasts (11.5)	NR	0.77
	NR	NRCS	Low	7 mo	No post-op radiation	56/486 breasts (11.5)	25/683 breasts (3.7)	adjOR 2.68 (1.54, 5.06)	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Subgroup	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Ibrahim, 2013, 24165587, US	Superficial surgical-site infection	NRCS	Moderate	NR	All patients	70/3283 (2.1)	246/15714 (1.6)	NR	0.021
	Deep incisional surgical-site infection	NRCS	Moderate	NR	All patients	39/3283 (1.2)	159/15714 (1)	NR	0.37
	Organ space infection	NRCS	Moderate	NR	All patients	17/1717 (1)	55/7442 (0.7)	NR	0.29
	Sepsis	NRCS	Moderate	NR	All patients	17/3283 (0.5)	61/15714 (0.4)	NR	0.52
Liu, 2011, 21228744, US	Wound infection: including major infection and minor infection	NRCS	High	NR	All patients	18/266 (6.8)	5/204 (2.5)	adjOR 3.25 (0.8, 13.12)	0.097
Nealon, 2020b, 31605310, US	NR	NRCS	High	5.3 y	All patients	NR	NR	adjOR 0.96 (0.57, 1.65)	0.57
Peled, 2012, 22634688, US	Localized or systemic infection treated with oral antibiotics or admission for IV antibiotics.	NRCS	High	2.6-3.3 y	All patients	20/100 breasts (20)	25/90 breasts (27.8)	NR	<0.05
Seth, 2012, 23018687, US	NR	NRCS	High	2 y	All patients	14/199 breasts (7)	17/393 breasts (4.3)	adjOR 1.67 (0.81, 3.47)	0.81
Sobti, 2018, 29481386, US	NR	NRCS	High	5 y	All patients	56/338 (4.6)	29/376 (4.9)	adjOR 0.88 (0.51, 1.53)	0.51
Sorkin, 2017, 28806288, US & Canada	Wound infection – Any	NRCS	Moderate	2 y	All patients	74/655 (11.3)	61/642 (9.5)	NR	0.11
	Wound infection requiring IV antibiotics or reoperation	NRCS	Moderate	2 y	All patients	46/655 (7)	29/642 (4.5)	NR	0.045
	Wound infection requiring oral antibiotics	NRCS	Moderate	2 y	All patients	32/655 (4.9)	34/642 (5.3)	adjOR 1.49 (0.9, 2.44)	0.12
Woo, 2017, 28509694, South Korea	NR	NRCS	High	NR	All patients	6/199 (3)	7/199 (3.5)	adjOR 2.33 (0.61, 8.91)	0.22

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, IV = intravenous, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* Calculated.

Table F-5.16. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (implant failure/loss or need for explant surgery)

Study, Year, PMID, Country	Outcome Measurement	Subgroup	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Craig, 2019, 29800083, US	Need for explant surgery	All patients	NRCS	Low	7 mo	56/574 breasts (9.8)	63/796 breasts (7.9)	NR	NR
	Need for explant surgery	Post-op radiation	NRCS	Low	7 mo	10/88 breasts (11.4)	23/113 breasts (20.4)	adjOR 0.38 (0.11, 0.96)	0.04
	Need for explant surgery	No post-op radiation	NRCS	Low	7 mo	46/486 breasts (9.5)	40/683 breasts (5.9)	adjOR 1.90 (1.03, 3.51)	NR
Hirsch, 2014, 25347643, US	Explantation with/without conversion to AR	All patients	NRCS	Low	3.5 y	NR	NR	adjOR 0.41 (0.15, 1.17)	0.09
Ibrahim, 2013, 24165587, US	Graft/prosthesis failure	All patients	NRCS	Moderate	NR	25/3283 (0.8)	121/15714 (0.8)	NR	0.9
Nealon, 2020b, 31605310, US	Need for explant surgery	All patients	NRCS	High	5.3 y	NR	NR	adjOR 1.92 (0.41, 8.33)	0.39
Pannucci, 2013, 23508050, US	Expander/Implant loss	All patients	NRCS	Moderate	NR	89/3450 (2.6)	NR/10799 (NR)	adjOR 1.42 (1.04, 1.94)	0.026
Peled, 2012, 22634688, US	Expander-implant loss	All patients	NRCS	High	2.6-3.3 y	7/100 breasts (7)	16/90 breasts (17.8)	NR	<0.05
Qureshi, 2016, 27465177, US	Explantation	All patients	NRCS	High	2 y	NR/296 (NR)	NR/118 (NR)	adjOR 1.2 (NR, NR)	NR
Seth, 2012, 23018687, US	ECF, explantation or conversion to flap	All patients	NRCS	High	2 y	17/199 breasts (8.5)	29/293 breasts (7.4)	adjOR 1.17 (0.63, 2.19)	NR
Sorkin, 2017, 28806288, US & Canada	Reconstructive/implant failure	All patients	NRCS	Moderate	2 y	60/655 (9.2)	37/642 (5.8)	adjOR 1.55 (0.93, 2.58)	0.089
Woo, 2017, 28509694, South Korea	Implant loss	All patients	NRCS	High	NR	4/199 (2)	4/199 (2)	adjOR 1 (0.3, 3.35)	1.0

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.17. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (implant complications except for implant failure)

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Seth, 2012, 23018687, US	Implant extrusion/exposure	Extrusion	NRCS	High	2 y	2/199 breasts (1)	9/293 breasts (2.3)	adjOR 0.43 (0.09, 2.02)	NR
Ganesh Kumar, 2021, 33172826, US & Canada	Implant rupture	Implant rupture, leakage, or deflation	NRCS	Moderate	2 y	11/738 (1.5)	7/713 (1.0)	NR	0.58

Study, Year, PMID, Country	Outcome	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Ganesh Kumar, 2021, 33172826, US & Canada	Implant malposition	NR	NRCS	Moderate	2 y	9/738 (1.2)	4/713 (0.6)	NR	0.83
Vardanian, 2011, 22030500, US	Implant malposition	NR	NRCS	High	2.4 y	4/208 breasts (1.9)	12/129 breasts (9.3)	adjOR 0.23 (0.06, 0.78)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate outcome are shaded blue. The colors do not add unique information.

Table F-5.18. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (capsular contracture)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Nealon, 2020b, 31605310, US	NRCS	High	5.3 y	NR	NR	adjOR 0.78 (0.46, 1.36)	0.38
Ganesh Kumar, 2021, 33172826, US & Canada	NRCS	Moderate	2 y	14/738 (1.9)	12/713 (1.7)	NR	0.24
Sobti, 2018, 29481386, US	NRCS	High	5 y	21/465 breasts (4.52)	7/217 breasts (3.23)	Nonuse vs use of ADM: adjOR 0.57 (0.23, 1.43)	NR
Vardanian, 2011, 22030500, US	NRCS	High	2.4 y	8/208 breasts (3.8)	25/129 breasts (19.4)	adjOR 0.18 (0.08, 0.43)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.19. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (hematoma)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Hirsch, 2014, 25347643, US	NRCS	Low	3.1 y	NR	NR	adjOR 1.47 (0.62, 3.49)	0.39
Nealon, 2020b, 31605310, US	NRCS	High	5.3 y	NR	NR	adjOR 0.84 (0.40, 1.84)	0.64
Seth, 2012, 23018687, US	NRCS	High	2 y	6/199 breasts (3)	6/393 breasts (1.5)	adjOR 0.78 (0.12, 7.09)	NR
Sobti, 2018, 29481386, US	NRCS	High	5 y	2/338 (0.3)	3/376 (0.8)	adjOR 0.50 (0.0, 1.28)	NR
Sorkin, 2017, 28806288, US & Canada	NRCS	Moderate	2 y	17/655 (2.6)	26/642 (4)	NR	0.15

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.20. Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (combined/unspecified harms)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Wendel, 2013, None, US	Serious adverse events	RCT	High	1 mo	0/20 (0)	0/16 (0)	N/A (No events)	N/A
Brooke, 2012, 22868313, US	Clinically significant complications, defined as cellulitis, abscess, seroma, expander leak or puncture, skin necrosis, wound dehiscence, or hematoma requiring readmission, reoperation, and/or expander explantation	NRCS	High	NR	37/221 breasts (17)	7/64 breasts (11)	NR	0.48
Ganesh Kumar, 2021, 33172826, US & Canada	Any complication	NRCS	Moderate	2 y	211/738 (28.6)	178/713 (25.0)	adjOR 1.21 (0.86, 1.70)	0.26
	Major complications	NRCS	Moderate	2 y	169/738 (22.9)	117/713 (16.4)	adjOR 1.43 (1.00, 2.05)	0.052
Hirsch, 2014, 25347643, US	Any complication	NRCS	Low	3.5 y	NR	NR	adjOR 0.9 (0.6, 1.34)	0.60
	Operative complication except explantation	NRCS	Low	3.5 y	NR	NR	adjOR 0.68 (0.46, 1.02)	0.46
	Nonoperative complication	NRCS	Low	3.5 y	NR	NR	adjOR 0.67 (0.26, 1.74)	0.43
Liu, 2011, 21228744, US	Surgical complications	NRCS	High	NR	52/266 (19.5)	25/204 (12.3)	adjOR 1.76 (1.03, 3.01)	0.036
Safran, 2020, 32221195, Canada	Any complication, including hematoma, infection, seroma, implant displacement, NAC full-thickness necrosis, superficial cellulitis, red breast syndrome, incision necrosis, delayed healing, hypergranulation, and NAC superficial necrosis.	NRCS	High	NR	NR/243 breasts (NR)	NR/70 breasts (NR)	adjOR 1.59 (0.56, 4.50)	NR
Stein, 2020, 32561384, Canada	Any complication	NRCS	High	10 mo – 5 y	16/41 (39.0)	37/89 (42.1)	adjOR 0.86 (0.26, 2.78)	NR
	Major complications	NRCS	High	10 mo – 5 y	10/41 (24.4)	22/89 (24.7)	adjOR 0.83 (0.22, 3.08)	NR
	Minor complications	NRCS	High	10 mo – 5 y	10/41 (24.4)	20/89 (22.5)	adjOR 0.83 (0.21, 3.29)	NR
Weichman, 2012, 22544088, US	Complications including mastectomy skin flap necrosis, mastectomy skin flap necrosis and associated infection, infection alone, seroma, and hematoma	NRCS	Moderate	3 y	NR/442 breasts (NR)	NR/186 breasts (NR)	NR	<0.05
Woo, 2017, 28509694, South Korea	Major complication: defined as complications that necessitated additional surgery or intervention	NRCS	High	NR	26/199 (13.1)	38/199 (19.1)	adjOR 1.1 (0.5, 2.4)	0.81

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, mo = months, N/A = not applicable, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RCT = randomized controlled trial, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-5.21: Full Evidence Table – Key Question 5: Use versus nonuse of human ADM during IBR – categorical outcomes (harms to the inframammary fold)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Use of ADM, n/N (%)	Nonuse of ADM, n/N (%)	Effect Size (95% CI)	P Value
Vardanian, 2011, 22030500, US	Problems of the inframammary fold: defined as inframammary fold issues other than bottoming-out or shifting, but related to the integrity of the fold	NRCS	High	2.4 y	17/208 breasts (8.2)	25/129 breasts (19.4)	adjOR 0.49 (0.23, 1.01)	NR

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, IBR = implant-based reconstruction, NR = not reported, NRCS = nonrandomized comparative study, OR = odds ratio, PMID = Pubmed identifier, RoB = risk of bias, y = years.

Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.1. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (physical well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Flap	N	Mean (SD or 95% CI)	Effect Size (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Constant Murley Shoulder Score: Total (0-100)	RCT	Moderate	1 y	LD	18	68.1 (58.2, 79.9)	Ref	Ref
	Constant Murley Shoulder Score: Total (0-100)	RCT	Moderate	1 y	TAP	22	78.7 (70.9, 86.4)	adjNMD 6.2 (0.5, 12.0)	0.033
	Constant Murley Shoulder Score: Pain (0-15)	RCT	Moderate	1 y	LD	18	11.6 (9.8, 13.4)	Ref	Ref
	Constant Murley Shoulder Score: Pain (0-15)	RCT	Moderate	1 y	TAP	22	14.0 (12.8, 15.2)	adjNMD 1.8 (0.2, 3.4)	0.023
	Constant Murley Shoulder Score: Activity in daily life (0-20)	RCT	Moderate	1 y	LD	18	17.1 (14.9, 19.2)	Ref	Ref
	Constant Murley Shoulder Score: Activity in daily life (0-20)	RCT	Moderate	1 y	TAP	22	18.7 (17.3, 20.0)	adjNMD 2.6 (1.1, 4.2)	<0.0001
	Constant Murley Shoulder Score: Range of motion (0-40)	RCT	Moderate	1 y	LD	18	29.6 (24.6, 34.5)	Ref	Ref
	Constant Murley Shoulder Score: Range of motion (0-40)	RCT	Moderate	1 y	TAP	22	34.8 (31.0, 38.6)	adjNMD 0.9 (−1.4, 3.2)	0.45
	Constant Murley Score: Strength (0-25)	RCT	Moderate	1 y	LD	18	9.9 (7.8, 12.0)	Ref	Ref
	Constant Murley Score: Strength (0-25)	RCT	Moderate	1 y	TAP	22	11.2 (9.3, 13.1)	adjNMD 1.2 (−1.0, 3.3)	0.29
Erdmann-Sager, 2018, 29019862, US & Canada	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −4.16 (−8.33, 0.02)	NR
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −4.01 (−8.48, 0.45)	NR
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 4.72 (−0.07, 9.52)	NR
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −4.9 (−9.50, −0.31)	NR
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −7.22 (−12.30, −2.14)	NR
	BREAST-Q: Abdomen (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 0.58 (−4.79, 5.95)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −1.55 (−5.35, 2.24)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.52 (−1.94, 4.99)	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Flap	N	Mean (SD or 95% CI)	Effect Size (95% CI)	P Value
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 3.42 (−0.22, 7.05)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.22 (−5.89, 1.45)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −3.92 (−7.66, −0.18)	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 0.76 (−3.44, 4.95)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.03 (−2.36, 2.30)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.00 (−2.09, 2.10)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 1.26 (−0.74, 3.26)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.42 (−1.52, 2.36)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.48 (−0.59, 3.55)	NR
	PROMIS: Physical functioning (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 1.20 (−1.09, 3.49)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.34 (−1.91, 2.60)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −0.07 (−2.10, 1.97)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD −0.6 (−2.54, 1.34)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.5 (−2.57, 1.57)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.44 (−2.25, 3.13)	NR
	PROMIS: Pain interference (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 0.11 (−2.34, 2.57)	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Flap	N	Mean (SD or 95% CI)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	DIEP	296	72.9 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	Free TRAM	83	68.3 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	Pedicled TRAM	91	70.9 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	LD	62	69.3 (NR)	NR	NR
	BREAST-Q: Chest and upper body (0-100)	NRCS	Moderate	3 mo	AR with SIEA	56	73 (NR)	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	BREAST-Q: Abdomen (0-100)	NRCS	High	4.5-7.3 y	DIEP	387	83.5 (17.4)	NR	NR
	BREAST-Q: Abdomen (0-100)	NRCS	High	4.5-7.3 y	Free TRAM	74	78.6 (23.4)	NR	NR
	BREAST-Q: Abdomen (0-100)	NRCS	High	4.5-7.3 y	Pedicled TRAM	359	76.2 (21.8)	NR	NR
	BREAST-Q: Abdomen (0-100)	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	123	78.1 (22.8)	NR	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, mo = months, NMD = net mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, PROMIS = Patient-Reported Outcomes Measurement Information System, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.2. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (psychosocial well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −1.14 (−5.33, 3.05)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.27 (−3.43, 5.97)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD −0.67 (−5.66, 4.32)	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −0.08 (−5.33, 5.18)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.62 (−3.95, 5.20)	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 1.64 (−3.64, 6.91)	NR
Macadam, 2016, 26910656, US, Canada, & Japan	BREAST-Q: Psychosocial well-being (0-100)	NRCS	High	4.5-7.3 y	DIEP	387	79.9 (18.4)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	High	4.5-7.3 y	Free TRAM	74	79.1 (21.7)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	High	4.5-7.3 y	Pedicled TRAM	359	79.6 (20.4)	NR	NR
	BREAST-Q: Psychosocial well-being (0-100)	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	123	75.9 (22.7)	NR	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.3. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (sexual well-being)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.33 (−7.10, 2.44)	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 0.81 (−4.31, 5.93)	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD −2.66 (−8.63, 3.31)	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD 2.35 (−3.40, 8.10)	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD −2.61 (−8.97, 3.75)	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 1.97 (−4.15, 8.09)	NR
Macadam, 2016, 26910656, US, Canada, & Japan	BREAST-Q: Sexual well-being (0-100)	NRCS	High	4.5-7.3 y	DIEP	387	59.0 (21.5)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	High	4.5-7.3 y	Free TRAM	74	59.4 (25)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	High	4.5-7.3 y	Pedicled TRAM	359	57.3 (24)	NR	NR
	BREAST-Q: Sexual well-being (0-100)	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	123	56.0 (23.8)	NR	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.4. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Brandberg, 2000, 10626972, Sweden	Cosmetic (1-6)	RCT	High	1 y	AR with TRAM	26	5.6 (NR)	vs. LD: MD 0.36*	NR
	Cosmetic (1-6)	RCT	High	1 y	LD	23	5.14 (NR)	vs. LTD: MD −0.05*	NR
	Cosmetic (1-6)	RCT	High	1 y	AR with LTD	12	5.19 (NR)	vs. TRAM: −0.46*	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	Shape (1-6)	RCT	High	1 y	AR with TRAM	26	5.3 (NR)	vs. LD: MD 0.36*	NR
	Shape (1-6)	RCT	High	1 y	LD	23	4.94 (NR)	vs. LTD: MD 0.35*	NR
	Shape (1-6)	RCT	High	1 y	AR with LTD	12	4.59 (NR)	vs. TRAM: MD −0.71*	NR
	Size (1-6)	RCT	High	1 y	AR with TRAM	26	5.43 (NR)	vs. LD: MD 0.50*	NR
	Size (1-6)	RCT	High	1 y	LD	23	4.93 (NR)	vs. LTD: MD −0.18*	NR
	Size (1-6)	RCT	High	1 y	AR with LTD	12	5.11 (NR)	vs. TRAM: MD −0.32 *	NR
	Scars on the breast (1-6)	RCT	High	1 y	AR with TRAM	26	4.83 (NR)	vs. LD: MD 0.36*	NR
	Scars on the breast (1-6)	RCT	High	1 y	LD	23	4.47 (NR)	vs. LTD: MD −0.65*	NR
	Scars on the breast (1-6)	RCT	High	1 y	AR with LTD	12	5.12 (NR)	vs. TRAM: MD 0.29*	NR
	Donor site scars (1-6)	RCT	High	1 y	AR with TRAM	26	4.76 (NR)	vs. LD: MD 0.07*	NR
	Donor site scars (1-6)	RCT	High	1 y	LD	23	4.69 (NR)	vs. LTD: MD −0.26*	NR
	Donor site scars (1-6)	RCT	High	1 y	AR with LTD	12	4.95 (NR)	vs. TRAM: MD 0.19*	NR
	Similarity with contralateral breast (1−6)	RCT	High	1 y	AR with TRAM	26	4.76 (NR)	vs. LD: MD 0.10*	NR
	Similarity with contralateral breast (1−6)	RCT	High	1 y	LD	23	4.66 (NR)	vs. LTD: MD 0.81*	NR
	Similarity with contralateral breast (1−6)	RCT	High	1 y	AR with LTD	12	3.85 (NR)	vs. TRAM: MD −0.91*	NR
Erdmann−Sager, 2018, 29019862, US & Canada	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	Free TRAM	NR	NR	vs. DIEP: adjMD 0.04 (−4.56, 4.63)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.36 (−3.45, 6.17)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	1 y	AR with SIEA	NR	NR	vs. DIEP: adjMD −1.82 (−6.37, 2.72)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	DIEP	NR	NR	Ref	Ref
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	Free TRAM	NR	NR	vs. DIEP: adjMD −2.61 (−8.97, 3.75)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	Pedicled TRAM	NR	NR	vs. DIEP: adjMD 1.36 (−3.45, 6.17)	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	Moderate	2 y	AR with SIEA	NR	NR	vs. DIEP: adjMD 0.42 (−5.56, 6.4)	NR
Macadam, 2016, 26910656, US, Canada, & Japan	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	4.5-7.3 y	DIEP	387	71.9 (17.3)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	4.5-7.3 y	Free TRAM	74	71.7 (21)	NR	NR
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	4.5-7.3 y	Pedicled TRAM	359	69.8 (20.7)	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with breast (0-100)	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	123	68.7 (18.7)	NR	NR

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, MD = mean difference, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* calculated

Table F-6.5. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (patient satisfaction with breast)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Yueh, 2009, 19228537, US	Satisfied with breasts (Yes/No)	NRCS	High	NR	DIEP	NR/117 (NR)	vs. TRAM	0.67 (0.37, 1.23)	NR
	Satisfied with breasts (Yes/No)	NRCS	High	NR	AR with TRAM	102/143 (71.3)	Ref	Ref	Ref
	Satisfied with breasts (Yes/No)	NRCS	High	NR	LD	68/112 (60.7)	vs. TRAM	0.78 (0.54, 1.14)	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.6. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (patient satisfaction with outcome)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	DIEP	395	72.8 (13)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	Free TRAM	NR	72.8 (16.5)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	Pedicled TRAM	65	76.2 (19.9)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	LD	53	69.3 (19.1)	NR	NR
	BREAST-Q: Satisfaction with information (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	DIEP	395	91.6 (14)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	Free TRAM	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	Pedicled TRAM	65	91 (15.9)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	LD	53	92.5 (14.4)	NR	NR
	BREAST-Q: Satisfaction with surgeon (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	DIEP	395	90 (19)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	Free TRAM	NR	NR	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	Pedicled TRAM	65	91 (13.8)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	LD	53	94.5 (12.7)	NR	NR
	BREAST-Q: Satisfaction with medical team (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	DIEP	395	93.8 (13.4)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	Free TRAM	NR	NR	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	Pedicled TRAM	65	93.5 (14.6)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	LD	53	94.7 (14.6)	NR	NR
	BREAST-Q: Satisfaction with office staff (0-100)	NRCS	Moderate	3 mo	AR with SIEA	NR	NR	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	High	4.5-7.3 y	DIEP	387	78.6 (19.3)	NR	NR
	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	High	4.5-7.3 y	Free TRAM	74	76.4 (22.2)	NR	NR
	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	High	4.5-7.3 y	Pedicled TRAM	359	73.9 (24.2)	NR	NR
	BREAST-Q: Satisfaction with outcome (0-100)	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	123	72.9 (23.3)	NR	NR

Abbreviations: Adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, MD = mean difference, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized

controlled trial, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.7. Full Evidence Table – Key Question 1: IBR versus AR – categorical outcomes (patient satisfaction with outcome)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Yueh, 2009, 19228537, US	Generally satisfied with outcome (Yes/No)	NRCS	High	NR	DIEP	NR/117 (NR)	vs. TRAM	0.82 (0.33, 2.01)	NS
	Generally satisfied with outcome (Yes/No)	NRCS	High	NR	TRAM	98/143 (68.5)	Ref	Ref	Ref
	Generally satisfied with outcome (Yes/No)	NRCS	High	NR	LD	63/112 (56.3)	vs. TRAM	0.77 (0.53, 1.11)	NS

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NRCS = nonrandomized comparative study, NR = not reported, NS = not significant, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.8. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (recurrence of breast cancer)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Odds Ratio (95% CI)	P Value
Brandberg, 2000, 10626972, Sweden	RCT	High	1 y	AR with TRAM	2/29 (6.9%)	vs. LD	2.15 (0.18, 25.07)*	0.54
	RCT	High	1 y	LD	1/30 (3.33%)	vs. LTD	1.07 (0.03, 33.69)*	0.97
	RCT	High	1 y	AR with LTD	0/16 (0%)	vs. TRAM	0.44 (0.02, 10.28)*	0.61

Abbreviations: AR = autologous reconstruction, CI = confidence interval, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, RCT = randomized controlled trial, PMID = PubMed identifier, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
* calculated
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.9. Full Evidence Table – Key Question 6: Comparison of flap types for AR – continuous outcomes (duration of initial hospitalization)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Arm	N	Mean (SD or Range)	Adjusted Mean Difference (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	RCT	Moderate	Post-op	LD	18	6.4 d (range 3-12 d)	Ref	Ref
	RCT	Moderate	Post-op	TAP	22	6.5 d (range 4-14 d)	0.9 d (−1.4, 3.2)	0.45
Zoghbi, 2017, 28052051, US	NRCS	High	Post-op	DIEP	9699	4.68 d (2.80 d)	Ref	Ref
	NRCS	High	Post-op	AR with TRAM	6137	4.79 d (2.69 d)	NR	<0.001

Abbreviations: CI = confidence interval, d = days, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SD = standard deviation, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.10. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (duration of initial hospitalization)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Zoghbi, 2017, 28052051, US	Increased length of stay	NRCS	High	Post-surgery	DIEP	NR/9699 (NR)	Ref	Ref
	Increased length of stay	NRCS	High	Post-surgery	AR with TRAM	NR/6137 (NR)	1.59 (1.45, 1.72)	<0.001

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.11. Full Evidence Table – Question 6: Comparison of flap types for AR – categorical outcomes (mortality)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Odds Ratio (95% CI)	P Value
Brandberg, 2000, 10626972, Sweden	RCT	High	1 y	AR with TRAM	1/29 (3.5)	vs. LD	0.50 (0.04, 5.83)*	0.58
	RCT	High	1 y	LD	2/30 (6.7)	vs. LTD	2.21 (0.09, 52.2)*	0.62
	RCT	High	1 y	AR with LTD	0/16 (0)	vs. TRAM	0.9 (0.03, 28.5)*	0.95

Abbreviations: AR = autologous reconstruction, CI = confidence interval, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, RCT = randomized controlled trial, PMID = PubMed identifier, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

* calculated

Table F-6.12. Full Evidence Table – Question 6: Comparison of flap types for AR – categorical outcomes (unplanned repeat surgeries for revision of reconstruction)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	NRCS	Moderate	2 y	DIEP	223/350 (63.7)	NR	NR	NR
	NRCS	Moderate	2 y	Free TRAM	56/87 (64.4)	NR	NR	NR
	NRCS	Moderate	2 y	Pedicled TRAM	40/77 (57.1)	NR	NR	NR
	NRCS	Moderate	2 y	LD	41/64 (64.1)	NR	NR	NR
	NRCS	Moderate	2 y	AR with SIEA	33/62 (53.2)	NR	NR	NR
Massenburg, 2015, 26487657, US	NRCS	High	2 y	Free TRAM	95/609 (15.6)	vs. LD	2.03 (1.39, 2.96)	NR
	NRCS	High	2 y	Pedicled TRAM	159/1608 (9.9)	vs. LD	1.71 (1.25, 2.33)	NR
	NRCS	High	2 y	LD	62/1079 (5.7)	Ref	Ref	Ref

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.13. Full Evidence Table – Key Question 6: IBR versus AR – comparison of flap types for AR – continuous outcomes (pain, including chronic pain)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	N	Mean (SD)	Effect Size (95% CI)	P Value
Kulkarni, 2017, 28713853, US & Canada	MPQ-SF: Sensory (0-10)	NRCS	Moderate	3 mo	DIEP	296	4.8 (NR)	NR	NR
	MPQ-SF: Sensory (0-10)	NRCS	Moderate	3 mo	Free TRAM	83	6.7 (NR)	NR	NR
	MPQ-SF: Sensory (0-10)	NRCS	Moderate	3 mo	Pedicled TRAM	91	5 (NR)	NR	NR
	MPQ-SF: Sensory (0-10)	NRCS	Moderate	3 mo	LD	62	5.4 (NR)	NR	NR
	MPQ-SF: Sensory (0-10)	NRCS	Moderate	3 mo	AR with SIEA	56	NR	NR	NR
	NPRS (0-10)	NRCS	Moderate	3 mo	DIEP	296	1.5 (NR)	NR	NR
	NPRS (0-10)	NRCS	Moderate	3 mo	Free TRAM	83	1.5 (NR)	NR	NR
	NPRS (0-10)	NRCS	Moderate	3 mo	Pedicled TRAM	91	1.8 (NR)	NR	NR
	NPRS (0-10)	NRCS	Moderate	3 mo	LD	62	2 (NR)	NR	NR
	NPRS (0-10)	NRCS	Moderate	3 mo	AR with SIEA	56	1.4 (NR)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, mo = months, MPQ-SF = McGill Pain Questionnaire-Short Form, NPRS = Numerical Pain Rating Scale, NR = not reported, NRCS = nonrandomized comparative study, PMID = Pubmed identifier, RoB = risk of bias, SD = standard deviation, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.14. Full Evidence Table – Key Question 6: IBR versus AR – comparison of flap types for AR – categorical outcomes (pain, including chronic pain)

Study, Year, PMID, Country	Outcome Measurement	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Odds Ratio (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Shoulder related pain (Yes/No)	RCT	Moderate	1 y	LD	13/18 (72%)	Ref	Ref	Ref
	Shoulder related pain (Yes/No)	RCT	Moderate	1 y	TAP	7/22 (32%)	vs. LD	0.05 (0.005, 0.51)	0.011

Abbreviations: AR = autologous reconstruction, CI = confidence interval, LD = latissimus dorsi, PMID = Pubmed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, TAP = thoracodorsal artery perforator, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.15. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (necrosis)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Major necrosis requiring removal of the implant	RCT	Moderate	1 y	LD	0/18 (0)	Ref	Ref	Ref
	Major necrosis requiring removal of the implant	RCT	Moderate	1 y	TAP	1/22 (4.54)	vs. LD	1.67 (0.05, 52.7)*	0.77*
	Minor necrosis: epidermolysis or small necrosis of most distal part of flap	RCT	Moderate	1 y	LD	0/18 (0)	Ref	Ref	Ref

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Minor necrosis: epidermolysis or small necrosis of most distal part of flap	RCT	Moderate	1 y	TAP	2/22 (13.6)	vs. LD	5.53 (0.26, 118.3)*	0.27*
Abedi, 2016, 25003437, Canada	Mastectomy flap necrosis	NRCS	High	1.6-1.9 y	DIEP	20/83 (24.1)	vs. TRAM	NR	0.61
	Mastectomy flap necrosis	NRCS	High	1.6-1.9 y	AR with TRAM	40/312 (12.8)	Ref	Ref	Ref
Baumann, 2010, 20440154, US	Fat necrosis	NRCS	High	Mean 1.2 y	DIEP	14/71 (20)	NR	NR	NR
	Fat necrosis	NRCS	High	Mean 1.2 y	AR with TRAM	13/120 (11)	NR	NR	NR
	Fat necrosis	NRCS	High	Mean 1.2 y	AR with SIEA	5/37 (14)	NR	NR	NR
Carramaschi, 1989, 2602589, France	Local necrosis	NRCS	High	NR	AR with TRAM	0/40 (0)	NR	NR	NR
	Local necrosis	NRCS	High	NR	LD	1/34 (2.9)	NR	NR	NR
	More than local necrosis	NRCS	High	NR	AR with TRAM	5/40 (12.5)	NR	NR	NR
	More than local necrosis	NRCS	High	NR	LD	2/34 (5.9)	NR	NR	NR
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site necrosis	NRCS	Moderate	2 y	DIEP	25/355 (7)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	2 y	Free TRAM	2/92 (2.2)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	2 y	Pedicled TRAM	2/78 (2.6)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	2 y	AR with SIEA	5/62 (8.1)	NR	NR	NR
	Donor site chronic fat necrosis	NRCS	Moderate	2 y	DIEP	12/355 (3.4)	NR	NR	NR
	Donor site chronic fat necrosis	NRCS	Moderate	2 y	Free TRAM	1/92 (1.1)	NR	NR	NR
	Donor site chronic fat necrosis	NRCS	Moderate	2 y	Pedicled TRAM	1/78 (1.3)	NR	NR	NR
	Donor site chronic fat necrosis	NRCS	Moderate	2 y	AR with SIEA	2/62 (3.2)	NR	NR	NR
	Breast chronic fat necrosis	NRCS	Moderate	2 y	DIEP	34/355 (9.6)	NR	NR	NR
	Breast chronic fat necrosis	NRCS	Moderate	2 y	Free TRAM	6/92 (6.5)	NR	NR	NR
	Breast chronic fat necrosis	NRCS	Moderate	2 y	Pedicled TRAM	8/78 (10.3)	NR	NR	NR
	Breast chronic fat necrosis	NRCS	Moderate	2 y	AR with SIEA	7/62 (11.3)	NR	NR	NR
	Mastectomy skin flap necrosis	NRCS	Moderate	2 y	DIEP	31/355 (8.7)	NR	NR	NR
	Mastectomy skin flap necrosis	NRCS	Moderate	2 y	Free TRAM	6/92 (6.5)	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Mastectomy skin flap necrosis	NRCS	Moderate	2 y	Pedicled TRAM	6/78 (7.7)	NR	NR	NR
	Mastectomy skin flap necrosis	NRCS	Moderate	2 y	AR with SIEA	6/62 (9.7)	NR	NR	NR
Israeli, 2014, 24572840, US	Skin or fat necrosis	NRCS	High	1.5 y	AR with TRAM	16/252 (6.4)	NR	NR	NR
	.	.	.	.	LD	5/302 (1.7)	NR	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Chronic fat necrosis: Breast	NRCS	Moderate	1 y	DIEP	33/365 (9)	NR	NR	NR
	Chronic fat necrosis: Breast	NRCS	Moderate	1 y	Free TRAM	5/97 (5.2)	NR	NR	NR
	Chronic fat necrosis: Breast	NRCS	Moderate	1 y	Pedicled TRAM	6/84 (7.1)	NR	NR	NR
	Chronic fat necrosis: Breast	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR	NR
	Chronic fat necrosis: Donor site	NRCS	Moderate	1 y	DIEP	7/365 (1.9)	NR	NR	NR
	Chronic fat necrosis: Donor site	NRCS	Moderate	1 y	Free TRAM	0/97 (0)	NR	NR	NR
	Chronic fat necrosis: Donor site	NRCS	Moderate	1 y	Pedicled TRAM	2/84 (2.4)	NR	NR	NR
	Chronic fat necrosis: Donor site	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	1 y	DIEP	19/365 (5.2)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	1 y	Free TRAM	2/97 (2.1)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	1 y	Pedicled TRAM	1/84 (1.2)	NR	NR	NR
	Donor site necrosis	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR	NR
	Acute partial flap necrosis	NRCS	Moderate	1 y	DIEP	9/365 (2.5)	NR	NR	NR
	Acute partial flap necrosis	NRCS	Moderate	1 y	Free TRAM	5/97 (5.2)	NR	NR	NR
	Acute partial flap necrosis	NRCS	Moderate	1 y	Pedicled TRAM	10/84 (11.9)	NR	NR	NR
	Acute partial flap necrosis	NRCS	Moderate	1 y	LD	1/73 (1.4)	NR	NR	NR
Kroll, 2000, 10987463, US	Fat necrosis	NRCS	High	3 mo	DIEP	36/279 breasts (12.9)	vs. TRAM	2.10 (0.87, 5.10)	0.101
	Fat necrosis	NRCS	High	3 mo	AR with TRAM	9/31 breasts (29)	Ref	Ref	Ref
Macadam, 2016, 26910656, US, Canada, & Japan	Fat necrosis	NRCS	High	4.5-7.3 y	DIEP	109/670 (16.3)	NR	NR	NR
	Fat necrosis	NRCS	High	4.5-7.3 y	Free TRAM	24/144 (16.7)	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Fat necrosis	NRCS	High	4.5-7.3 y	Pedicled TRAM	171/683 (25.3)	NR	NR	NR
	Fat necrosis	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	44/293 (15)	NR	NR	NR
	Membranous fat necrosis of breast requiring dressing	NRCS	High	4.5-7.3 y	DIEP	79/670 (11.8)	NR	NR	NR
	Membranous fat necrosis of breast requiring dressing	NRCS	High	4.5-7.3 y	Free TRAM	12/144 (8.3)	NR	NR	NR
	Membranous fat necrosis of breast requiring dressing	NRCS	High	4.5-7.3 y	Pedicled TRAM	72/683 (10.7)	NR	NR	NR
	Membranous fat necrosis of breast requiring dressing	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	35/293 (11.9)	NR	NR	NR
	Membranous fat necrosis of breast requiring surgery	NRCS	High	4.5-7.3 y	DIEP	55/670 (8.2)	NR	NR	NR
	Membranous fat necrosis of breast requiring surgery	NRCS	High	4.5-7.3 y	Free TRAM	6/144 (4.2)	NR	NR	NR
	Membranous fat necrosis of breast requiring surgery	NRCS	High	4.5-7.3 y	Pedicled TRAM	82/683 (12.1)	NR	NR	NR
	Membranous fat necrosis of breast requiring surgery	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	21/293 (7.2)	NR	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

* calculated

Table F-6.16. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (thromboembolic events)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Brorson 2020b, 32807615, Sweden	Thromboembolic events	RCT	High	1 mo	DIEP	0/24 (0)	No events	N/A
	Thromboembolic events	RCT	High	1 mo	LD	0/32 (0)	No events	N/A

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
	Thromboembolic events	RCT	High	1 mo	DIEP	0/24 (0)	No events	N/A
	Thromboembolic events	RCT	High	1 mo	LD	0/32 (0)	No events	N/A
Carramaschi, 1989, 2602589, France	Deep vein thrombosis or pulmonary embolism	NRCS	High	NR	AR with TRAM	2/40 (5)	NR	NR
	Deep vein thrombosis or pulmonary embolism	NRCS	High	NR	LD	0/34 (0)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Deep venous thrombosis	NRCS	Moderate	1 y	DIEP	1/365 (0.3)	NR	NR
	Deep venous thrombosis	NRCS	Moderate	1 y	Free TRAM	0/97 (0)	NR	NR
	Deep venous thrombosis	NRCS	Moderate	1 y	Pedicled TRAM	0/84 (0)	NR	NR
	Deep venous thrombosis	NRCS	Moderate	1 y	LD	1/73 (1.4)	NR	NR
	Pulmonary embolism	NRCS	Moderate	1 y	DIEP	4/365 (1.1)	NR	NR
	Pulmonary embolism	NRCS	Moderate	1 y	Free TRAM	1/97 (1)	NR	NR
	Pulmonary embolism	NRCS	Moderate	1 y	Pedicled TRAM	0/84 (0)	NR	NR
	Pulmonary embolism	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Deep vein thrombosis or pulmonary embolism	NRCS	High	4.5-7.3 y	DIEP	8/670 (1.2)	NR	NR
	Deep vein thrombosis or pulmonary embolism	NRCS	High	4.5-7.3 y	Free TRAM	2/97 (2.1)	NR	NR
	Deep vein thrombosis or pulmonary embolism	NRCS	High	4.5-7.3 y	Pedicled TRAM	11/683 (1.6)	NR	NR
	Deep vein thrombosis or pulmonary embolism	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	4/293 (1.4)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous, y = years.

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.17. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (infections not explicitly implant related)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Any infection	RCT	Moderate	1 y	LD	1/18 (5.6)	Ref	Ref
	Any infection	RCT	Moderate	1 y	TAP	1/22 (4.5)	1.24 (0.07, 21.2)*	0.88*
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site wound infection	NRCS	Moderate	2 y	DIEP	10/355 (2.8)	NR	NR
	Donor site wound infection	NRCS	Moderate	2 y	Free TRAM	3/92 (3.3)	NR	NR
	Donor site wound infection	NRCS	Moderate	2 y	Pedicled TRAM	6/78 (7.7)	NR	NR
	Donor site wound infection	NRCS	Moderate	2 y	AR with SIEA	9/62 (14.5)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
	Breast wound infection	NRCS	Moderate	2 y	DIEP	22/355 (6.2)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	Free TRAM	4/92 (4.4)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	Pedicled TRAM	7/78 (9)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	AR with SIEA	1/62 (1.6)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Breast wound infection	NRCS	Moderate	1 y	DIEP	14/365 (3.8)	NR	NR
	Breast wound infection	NRCS	Moderate	1 y	Free TRAM	4/97 (4.1)	NR	NR
	Breast wound infection	NRCS	Moderate	1 y	Pedicled TRAM	5/84 (6)	NR	NR
	Breast wound infection	NRCS	Moderate	1 y	LD	6/73 (8.2)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	DIEP	27/390 (6.9)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	Free TRAM	5/95 (5.3)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	Pedicled TRAM	8/85 (9.4)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	LD	6/71 (8.5)	NR	NR
	Breast wound infection	NRCS	Moderate	2 y	AR with SIEA	8/65 (12.3)	NR	NR
	Donor site wound infection	NRCS	Moderate	1 y	DIEP	12/365 (3.3)	NR	NR
	Donor site wound infection	NRCS	Moderate	1 y	Free TRAM	2/97 (2.1)	NR	NR
	Donor site wound infection	NRCS	Moderate	1 y	Pedicled TRAM	5/84 (6)	NR	NR
	Donor site wound infection	NRCS	Moderate	1 y	LD	2/73 (2.7)	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Any infection	NRCS	High	4.5-7.3 y	DIEP	42/670 (6.3)	NR	NR
	Any infection	NRCS	High	4.5-7.3 y	Free TRAM	14/144 (9.7)	NR	NR
	Any infection	NRCS	High	4.5-7.3 y	Pedicled TRAM	106/683 (15.7)	NR	NR
	Any infection	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	21/293 (7.2)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Zoghbi, 2017, 28052051, US	Wound infections	NRCS	High	Post-surgery	AR with TRAM	NR/6137 (NR)	1.67 (1.23, 2.27)	0.001
	Wound infections	NRCS	High	Post-surgery	DIEP	NR/9699 (NR)	Ref	Ref

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TAP = thoracodorsal artery perforator TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* calculated

Table F-6.18. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (wound dehiscence)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site wound dehiscence	NRCS	Moderate	2 y	DIEP	37/355 (10.4)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	2 y	Free TRAM	3/92 (3.3)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	2 y	Pedicled TRAM	2/78 (2.6)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	2 y	AR with SIEA	17/62 (27.4)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	2 y	DIEP	23/355 (6.5)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	2 y	Free TRAM	3/92 (3.3)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	2 y	Pedicled TRAM	2/78 (2.6)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	2 y	AR with SIEA	4/62 (6.5)	NR	NR
Israeli, 2014, 24572840, US	Wound problems/need for negative pressure wound therapy	NRCS	High	1.5 y	AR with TRAM	14/252 (5.6)	NR	NR
	Wound problems/need for negative pressure wound therapy	NRCS	High	1.5 y	LD	2/302 (1)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Breast wound dehiscence	NRCS	Moderate	1 y	DIEP	13/365 (3.6)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	1 y	Free TRAM	1/97 (1)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	1 y	Pedicled TRAM	1/84 (1.2)	NR	NR
	Breast wound dehiscence	NRCS	Moderate	1 y	LD	1/73 (1.4)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	1 y	DIEP	31/365 (8.5)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	1 y	Free TRAM	3/97 (3.1)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	1 y	Pedicled TRAM	1/84 (1.2)	NR	NR
	Donor site wound dehiscence	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR
Zoghbi, 2017, 28052051, US	Wound dehiscence	NRCS	High	NR	DIEP	NR/9699 (NR)	Ref	Ref
	Wound dehiscence	NRCS	High	NR	AR with TRAM	NR/6137 (NR)	4.3 (NR)	<0.00001

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.19. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (delayed healing)

Study, Year, PMID, Country	Design	Overall RoB	Time Point	Arm	n/N (%)	Effect Size (95% CI)	P Value
Macadam, 2016, 26910656, US, Canada, & Japan	NRCS	High	4.5-7.3 y	DIEP	103/670 (18.5)	NR	NR
	NRCS	High	4.5-7.3 y	Free TRAM	26/144 (22.4)	NR	NR
	NRCS	High	4.5-7.3 y	Pedicled TRAM	174/683 (28.2)	NR	NR
	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	51/293 (26.7)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. The color does not add unique information.

Table F-6.20. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (seroma)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Seroma	RCT	Moderate	1 y	LD	1/18 (5.6)	Ref	Ref
	Seroma	RCT	Moderate	1 y	TAP	0/22 (0)	2.53 (0.08, 80.0)*	0.60*
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site seroma	NRCS	Moderate	2 y	DIEP	25/355 (7)	NR	NR
	Donor site seroma	NRCS	Moderate	2 y	Free TRAM	3/92 (3.3)	NR	NR
	Donor site seroma	NRCS	Moderate	2 y	Pedicled TRAM	2/78 (2.6)	NR	NR
	Donor site seroma	NRCS	Moderate	2 y	AR with SIEA	19/62 (30.7)	NR	NR
	Breast seroma	NRCS	Moderate	2 y	DIEP	4/355 (1.1)	NR	NR
	Breast seroma	NRCS	Moderate	2 y	Free TRAM	0/92 (0)	NR	NR
	Breast seroma	NRCS	Moderate	2 y	Pedicled TRAM	2/78 (2.6)	NR	NR
	Breast seroma	NRCS	Moderate	2 y	AR with SIEA	1/62 (1.6)	NR	NR
Israeli, 2014, 24572840, US	Seroma/hematoma	NRCS	High	1.5 y	AR with TRAM	13/252 (5.2)	NR	NR
	Seroma/hematoma	NRCS	High	1.5 y	LD	19/302 (6.3)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Breast seroma	NRCS	Moderate	1 y	DIEP	3/365 (0.8)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	Free TRAM	0/97 (0)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	Pedicled TRAM	2/84 (2.4)	NR	NR
	Breast seroma	NRCS	Moderate	1 y	LD	2/73 (2.7)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	DIEP	19/365 (5.2)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	Free TRAM	2/97 (2.1)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	Pedicled TRAM	0/84 (0)	NR	NR
	Donor site seroma	NRCS	Moderate	1 y	LD	14/73 (19.2)	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Seroma	NRCS	High	4.5-7.3 y	DIEP	34/670 (5.1)	NR	NR
	Seroma	NRCS	High	4.5-7.3 y	Free TRAM	15/144 (10.4)	NR	NR
	Seroma	NRCS	High	4.5-7.3 y	Pedicled TRAM	78/683 (11.5)	NR	NR
	Seroma	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	20/293 (6.8)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior

epigastric artery, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* Calculated.

Table F-6.21. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (scarring)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Garbay, 1992, 1624727, France	Very visible or cheloid donor site scarring	NRCS	High	1.9 y	AR with TRAM	3/63 (5)	NR	NR
	Very visible or cheloid donor site scarring	NRCS	High	1.9 y	LD	NR/NR (24)	NR	NR
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site hypertrophic or keloid scarring	NRCS	Moderate	2 y	DIEP	5/355 (1.4)	NR	NR
	Donor site hypertrophic or keloid scarring	NRCS	Moderate	2 y	Free TRAM	1/92 (1.1)	NR	NR
	Donor site hypertrophic or keloid scarring	NRCS	Moderate	2 y	Pedicled TRAM	1/78 (1.3)	NR	NR
	Donor site hypertrophic or keloid scarring	NRCS	Moderate	2 y	AR with SIEA	0/62 (0)	NR	NR
	Breast hypertrophic or keloid scarring	NRCS	Moderate	2 y	DIEP	8/355 (2.3)	NR	NR
	Breast hypertrophic or keloid scarring	NRCS	Moderate	2 y	Free TRAM	0/92 (0)	NR	NR
	Breast hypertrophic or keloid scarring	NRCS	Moderate	2 y	Pedicled TRAM	0/78 (0)	NR	NR
	Breast hypertrophic or keloid scarring	NRCS	Moderate	2 y	AR with SIEA	1/62 (1.6)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.22. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (harms to area of flap harvest)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Carramaschi, 1989, 2602589, France	Abdominal hernia	NRCS	High	NR	AR with TRAM	1/40 (2.5)	NR	NR	NR
	Abdominal hernia	NRCS	High	NR	LD	NR	NR	NR	NR
	Surgical abdominal asymmetry	NRCS	High	NR	AR with TRAM	7/40 (17.5)	NR	NR	NR
	Surgical abdominal asymmetry	NRCS	High	NR	LD	NR	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	2 y	DIEP	6/355 (1.7)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	2 y	Free TRAM	5/92 (5.4)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	2 y	Pedicled TRAM	7/78 (9)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	2 y	AR with SIEA	0/62 (0)	NR	NR	NR
	Any donor site complication	NRCS	Moderate	2 y	DIEP	99/355 (27.9)	Ref	Ref	Ref
	Any donor site complication	NRCS	Moderate	2 y	Free TRAM	14/92 (15.2)	vs. DIEP	0.52 (0.27, 1.02)	0.057
	Any donor site complication	NRCS	Moderate	2 y	Pedicled TRAM	14/78 (18)	vs. DIEP	0.63 (0.32, 1.24)	0.178
	Any donor site complication	NRCS	Moderate	2 y	AR with SIEA	33/62 (53.2)	vs. DIEP	2.73 (1.51, 4.96)	0.001
Knox, 2016, 26267400, Canada	Abdominal bulge or hernia	NRCS	High	1.7-2.3 y	DIEP	4/130 (3.1)	Ref	Ref	Ref
	Abdominal bulge or hernia	NRCS	High	1.7-2.3 y	AR with TRAM	80/377 (21.2)	vs. DIEP	5.2 (1.3, 20.9)	0.002
Kulkarni, 2017, 28713853, US & Canada	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	1 y	DIEP	6/365 (1.6)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	1 y	Free TRAM	3/97 (3.1)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	1 y	Pedicled TRAM	4/84 (4.8)	NR	NR	NR
	Abdominal wall bulge, laxity, or hernia	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Abdominal hernia	NRCS	High	4.5-7.3 y	DIEP	13/670 (1.9)	NR	NR	NR
	Abdominal hernia	NRCS	High	4.5-7.3 y	Free TRAM	4/144 (2.8)	NR	NR	NR
	Abdominal hernia	NRCS	High	4.5-7.3 y	Pedicled TRAM	46/683 (6.7)	NR	NR	NR
	Abdominal hernia	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	4/293 (4.8)	NR	NR	NR
	Abdominal bulge	NRCS	High	4.5-7.3 y	DIEP	18/670 (2.7)	NR	NR	NR
	Abdominal bulge	NRCS	High	4.5-7.3 y	Free TRAM	5/144 (3.5)	NR	NR	NR
	Abdominal bulge	NRCS	High	4.5-7.3 y	Pedicled TRAM	74/683 (10.9)	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Abdominal bulge	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	15/293 (5.1)	NR	NR	NR
Mennie, 2015, 25839173, UK	Hernia repair	NRCS	High	3 y	DIEP	63/5144 (1.2)	Ref	Ref	Ref
	Hernia repair	NRCS	High	3 y	Free TRAM	50/1963 (2.6)	vs. DIEP	1.81 (1.24, 2.64)	NR
	Hernia repair	NRCS	High	3 y	Pedicled TRAM	36/822 (4.4)	vs. DIEP	2.89 (1.91, 4.37)	NR
Zhong, 2014, 24675183, Canada	Abdominal bulge or hernia	NRCS	High	NR	DIEP	15/244 (6)	Ref	Ref	Ref
	Abdominal bulge or hernia	NRCS	High	NR	AR with TRAM	8/48 (17)	vs. DIEP	2.73 (1.01, 7.07)	0.04

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.23. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (flap failure/loss)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	Flap failure/loss	NRCS	Moderate	2 y	DIEP	4/355 (1.1)	NR	NR	NR
	Flap failure/loss	NRCS	Moderate	2 y	Free TRAM	2/92 (2.17)	NR	NR	NR
	Flap failure/loss	NRCS	Moderate	2 y	Pedicled TRAM	1/78 (1.2)	NR	NR	NR
	Flap failure/loss	NRCS	Moderate	2 y	AR with SIEA	0/62 (0)	NR	NR	NR
Kroll, 2000, 10987463, US	Partial flap loss	NRCS	High	3 mo	DIEP	5/31 breasts (16.1)	vs. TRAM	6.74 (1.83, 24.7)	0.004
	Partial flap loss	NRCS	High	3 mo	AR with TRAM	6/279 breasts (2.2)	Ref	Ref	Ref
Kulkarni, 2017, 28713853, US & Canada	Total flap loss	NRCS	Moderate	1 y	DIEP	5/365 (1.4)	NR	NR	NR
	Total flap loss	NRCS	Moderate	1 y	Free TRAM	2/97 (2.1)	NR	NR	NR
	Total flap loss	NRCS	Moderate	1 y	Pedicled TRAM	1/84 (1.2)	NR	NR	NR
	Total flap loss	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR	NR
	Reconstructive failure	NRCS	Moderate	1 y	DIEP	5/390 (1.3)	NR	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Reconstructive failure	NRCS	Moderate	1 y	Free TRAM	2/95 (2.1)	NR	NR	NR
	Reconstructive failure	NRCS	Moderate	1 y	Pedicled TRAM	1/85 (1.2)	NR	NR	NR
	Reconstructive failure	NRCS	Moderate	1 y	LD	2/71 (2.8)	NR	NR	NR
	Reconstructive failure	NRCS	Moderate	1 y	AR with SIEA	0/65 (0)	NR	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Partial flap loss	NRCS	High	4.5-7.3 y	DIEP	47/670 (4)	NR	NR	NR
	Partial flap loss	NRCS	High	4.5-7.3 y	Free TRAM	11/144 (7.6)	NR	NR	NR
	Partial flap loss	NRCS	High	4.5-7.3 y	Pedicled TRAM	60/683 (8.9)	NR	NR	NR
	Partial flap loss	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	14/293 (4.8)	NR	NR	NR
	Total flap loss	NRCS	High	4.5-7.3 y	DIEP	11/670 (1.6)	NR	NR	NR
	Total flap loss	NRCS	High	4.5-7.3 y	Free TRAM	3/144 (2.1)	NR	NR	NR
	Total flap loss	NRCS	High	4.5-7.3 y	Pedicled TRAM	8/683 (1.2)	NR	NR	NR
	Total flap loss	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	4/293 (1.4)	NR	NR	NR
Massenburg, 2015, 26487657, US	Flap failure/loss	NRCS	High	2 y	Free TRAM	56/2306 (2.4)	vs. LD	3.17 (1.90, 5.30)	<0.001
	Flap failure/loss	NRCS	High	2 y	Pedicled TRAM	67/2464 (2.7)	vs. LD	2.28 (1.38, 3.77)	0.001
	Flap failure/loss	NRCS	High	2 y	LD	22/2085 (1.1)	Ref	Ref	Ref

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, mo = months, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Table F-6.24. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (hematoma/hemorrhage)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Rindom, 2019, 31515191, Denmark	Hematoma	RCT	Moderate	1 y	LD	0/18 (0)	Ref	Ref
	Hematoma	RCT	Moderate	1 y	TAP	1/22 (4.5)	0.6 (0.02, 19.0)*	0.77*
	Donor site hematoma	NRCS	Moderate	2 y	DIEP	8/355 (2.3)	NR	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Adjusted Odds Ratio (95% CI)	P Value
Erdmann-Sager, 2018, 29019862, US & Canada	Donor site hematoma	NRCS	Moderate	2 y	Free TRAM	0/92 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	2 y	Pedicled TRAM	0/78 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	2 y	AR with SIEA	4/62 (6.5)	NR	NR
	Breast hematoma	NRCS	Moderate	2 y	DIEP	25/355 (7)	NR	NR
	Breast hematoma	NRCS	Moderate	2 y	Free TRAM	5/92 (5.4)	NR	NR
	Breast hematoma	NRCS	Moderate	2 y	Pedicled TRAM	3/78 (3.9)	NR	NR
	Breast hematoma	NRCS	Moderate	2 y	AR with SIEA	7/62 (11.3)	NR	NR
Kulkarni, 2017, 28713853, US & Canada	Breast hematoma	NRCS	Moderate	1 y	DIEP	22/365 (6)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	Free TRAM	4/97 (4.1)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	Pedicled TRAM	3/84 (3.6)	NR	NR
	Breast hematoma	NRCS	Moderate	1 y	LD	3/73 (4.1)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	DIEP	10/365 (2.7)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	Free TRAM	0/97 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	Pedicled TRAM	0/84 (0)	NR	NR
	Donor site hematoma	NRCS	Moderate	1 y	LD	0/73 (0)	NR	NR
Macadam, 2016, 26910656, US, Canada, & Japan	Hematoma requiring surgery	NRCS	High	4.5-7.3 y	DIEP	56/670 (8.4)	NR	NR
	Hematoma requiring surgery	NRCS	High	4.5-7.3 y	Free TRAM	5/144 (3.5)	NR	NR
	Hematoma requiring surgery	NRCS	High	4.5-7.3 y	Pedicled TRAM	26/683 (3.8)	NR	NR
	Hematoma requiring surgery	NRCS	High	4.5-7.3 y	Muscle-sparing TRAM	14/293 (4.4)	NR	NR

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.
* calculated

Table F-6.25. Full Evidence Table – Key Question 6: Comparison of flap types for AR – categorical outcomes (composite/unspecified harms)

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
Brorson 2020b, 32807615, Sweden	Clavien-Dindo Grade I complications	RCT	High	1 mo	DIEP	16/34 (47)	Ref	Ref	Ref
	Clavien-Dindo Grade I complications	RCT	High	1 mo	LD	20/33 (63)	vs. DIEP	1.73 (0.66, 4.57)	0.27
	Clavien-Dindo Grade II complications	RCT	High	1 mo	DIEP	14/34 (41)	Ref	Ref	Ref
	Clavien-Dindo Grade II complications	RCT	High	1 mo	LD	16/32 (50)	vs. DIEP	1.29 (0.48, 3.44)	0.76
	Clavien-Dindo Grade IIIa complications	RCT	High	1 mo	DIEP	9/34 (26)	Ref	Ref	Ref
	Clavien-Dindo Grade IIIa complications	RCT	High	1 mo	LD	7/32 (22)	vs. DIEP	0.85 (0.27, 2.64)	0.77
	Clavien-Dindo Grade IIIb complications	RCT	High	1 mo	DIEP	11/34 (32)	Ref	Ref	Ref

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Clavien-Dindo Grade IIIb complications	RCT	High	1 mo	LD	3/32 (9)	vs. DIEP	0.22 (0.05, 0.87)	0.031
	Clavien-Dindo Grade IV complications	RCT	High	1 mo	DIEP	0/34 (0)	Ref	No events	N/A
	Clavien-Dindo Grade IV complications	RCT	High	1 mo	LD	0/32 (0)	vs. DIEP	No events	N/A
	Clavien-Dindo Grade V complications	RCT	High	1 mo	DIEP	0/34 (0)	Ref	No events	N/A
	Clavien-Dindo Grade V complications	RCT	High	1 mo	LD	0/32 (0)	vs. DIEP	No events	N/A
Rindom, 2019, 31515191, Denmark	Minor complications treated conservatively	RCT	Moderate	1 y	LD	2/18 (11.1)	Ref	Ref	Ref
	Minor complications treated conservatively	RCT	Moderate	1 y	TAP	2/22 (9.09)	vs. LD	0.8 (0.1, 6.32)*	0.83*
	Major complications requiring surgical intervention	RCT	Moderate	1 y	LD	0/18 (0)	Ref	Ref	Ref
	Major complications requiring surgical intervention	RCT	Moderate	1 y	TAP	4/22 (18)	vs. LD	0.13 (0.01, 2.62)*	0.18*
Dauplat, 2021, 33622886, France	Major complications requiring surgical intervention or readmission	NRCS	Moderate	1 y	TRAM	10/30 (30)	Ref	Ref	Ref
	Major complications requiring surgical intervention or readmission	NRCS	Moderate	1 y	LD with implant	9/91 (9)	Ref	Ref	Ref
	Major complications requiring surgical intervention or readmission	NRCS	Moderate	1 y	LD without implant	7/78 (9)	vs. TRAM vs. LD with implant	1.69 (1.19, 2.41) 4.85 (1.67, 14.1)	NR NR
Erdmann-Sager, 2018, 29019862, US & Canada	Any breast complication	NRCS	Moderate	2 y	DIEP	NR	Ref	Ref	Ref
	Any breast complication	NRCS	Moderate	2 y	Free TRAM	NR	vs. DIEP	0.51 (0.25, 1.02)	0.58
	Any breast complication	NRCS	Moderate	2 y	Pedicled TRAM	NR	vs. DIEP	0.94 (0.46, 1.94)	0.87
	Any breast complication	NRCS	Moderate	2 y	AR with SIEA	NR	vs. DIEP	1.15 (0.61, 2.17)	0.67
Kulkarni, 2017, 28713853, US & Canada	Any complication	NRCS	Moderate	2 y	DIEP	185/390 (47.4)	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	Free TRAM	34/95 (35.8)	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	Pedicled TRAM	35/85 (41.2)	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	LD	28/71 (39.4)	NR	NR	NR
	Any complication	NRCS	Moderate	2 y	AR with SIEA	48/65 (73.9)	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	DIEP	114/390 (29.2)	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	Free TRAM	26/95 (27.4)	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	Pedicled TRAM	25/85 (19.4)	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	LD	10/71 (14.1)	NR	NR	NR
	Reoperative complications	NRCS	Moderate	2 y	AR with SIEA	20/65 (30.8)	NR	NR	NR
Massenburg, 2015, 26487657, US	Any complication	NRCS	High	2 y	Free TRAM	118/609 (19.4)	vs. LD	1.91 (1.35, 2.70)	NR
	Any complication	NRCS	High	2 y	Pedicled TRAM	216/1608 (13.4)	vs. LD	1.92 (1.45, 2.55)	NR

Study, Year, PMID, Country	Outcome Description	Design	Overall RoB	Time Point	Arm	n/N (%)	Comparison	Adjusted Odds Ratio (95% CI)	P Value
	Any complication	NRCS	High	2 y	LD	77/1079 (7.1)	Ref	Ref	Ref
	Superficial SSI, deep SSI, organ space infection, or wound disruption/ dehiscence	NRCS	High	2 y	Free TRAM	143/2306 (6.2)	vs. LD	1.46 (1.00, 2.12)	0.046
	Superficial SSI, deep SSI, organ space infection, or wound disruption/ dehiscence	NRCS	High	2 y	Pedicled TRAM	199/2464 (8.1)	vs. LD	1.80 (1.29, 2.51)	0.001
	Superficial SSI, deep SSI, organ space infection, or wound disruption/ dehiscence	NRCS	High	2 y	LD	90/2085 (4.3)	Ref	Ref	Ref
Woo, 2018, 30360958, South Korea	Lymphedema	NRCS	High	NR	DIEP	23/163 (14.1)	NR	NR	NR
	Lymphedema	NRCS	High	NR	LD	19/44 (43.2)	NR	NR	NR
Zhong, 2014, 24675183, Canada	Major breast complications included total or partial flap loss, fat necrosis, and breast hematoma	NRCS	High	NR	DIEP	50/244 (20.5)	Ref	Ref	Ref
	Major breast complications included total or partial flap loss, fat necrosis, and breast hematoma	NRCS	High	NR	AR with TRAM	10/48 (20.8)	vs. DIEP	0.98 (0.40, 2.14)	0.95

Abbreviations: AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, NR = not reported, NRCS = nonrandomized comparative study, PMID = PubMed identifier, RCT = randomized controlled trial, Ref = reference group, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SSI = surgical site infection, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous, y = years.
* calculated

Colors: Header rows are shaded orange. Rows for every alternate study are shaded blue. The colors do not add unique information.

Appendix G. Results: Evidence Profiles

Table G-1. Key Question 1: IBR versus AR – full evidence profile

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Clinical	General quality of life	3 (709)	Moderate	Consistent	Precise	Direct	None	Moderate	Comparable in both groups
	Physical well-being	6 (5717)	Moderate	Consistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Psychosocial well-being	5 (2760)	Moderate	Consistent	Precise	Direct	None	Moderate	Clinically comparable in both groups: summary adjMD 3.14 (95% CI 1.26, 5.02); 3 studies
	Sexual well-being	4 (3307)	Moderate	Inconsistent	Precise	Direct	None	Moderate	Clinically significant better with AR: summary adjMD 5.83 (95% CI 3.44, 8.23); 3 studies
	Patient satisfaction with breast	7 (4557)	Moderate	Consistent	Precise	Direct	None	Moderate	Clinically significant better satisfaction with breast with AR: summary adjMD 8.08 (95% CI 6.11, 10.1); 3 studies. Inconsistent results regarding satisfaction with nipples.
	Patient satisfaction with surgical outcome	5 (1432)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Mortality	1 (4061)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Unplanned repeat hospitalization	3 (50675)	High	Consistent	Precise	Direct	None	Moderate	Comparable in both groups
	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Unplanned repeat surgeries for revision	3 (3138)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Unplanned repeat surgeries for complications	3 (14313)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Pain	5 (3173)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Analgesic use	1 (90)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Necrosis	4 (34742)	High	Inconsistent	Imprecise	Direct	None	Insufficient	None (Inconsistent results)
	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Thromboembolic events	2 (34555)	High	Consistent	Precise	Direct	None	Moderate	Increased risk of deep vein thrombosis or pulmonary embolism in AR group
	Infections (not explicitly implant-related)	4 (17246)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
	Seroma	2 (1300)	Moderate	Consistent	Unclear	Direct	None	Low	Increased risk of breast seroma in IBR group

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Reconstructive Failure	5 (21090)	Moderate	Consistent	Precise	Direct	None	Moderate	Increased risk with IBR in the long-term (1.5 to 4 years of followup)

Abbreviations: adj = adjusted, AR = autologous reconstruction, DIEP = deep inferior epigastric perforator, IBR = implant-based reconstruction, MD = mean difference, N/A = not applicable, NR = not reported, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SoE = strength of evidence, TRAM = transverse rectus abdominis myocutaneous.

For continuous outcomes, clinical significance is based on published estimates of minimal clinically important differences (MCIDs), where available.

Colors: Header rows are shaded orange. The color does not add unique information.

Table G-2. Key Question 2: Timing of chemotherapy and radiation therapy relative to IBR and AR – full evidence profile

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
IBR before vs. after chemotherapy	Clinical	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IBR before vs. after radiation	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical	Psychosocial well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical	Sexual well-being	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical	Patient satisfaction with breast	2 (423)	High	Consistent	Precise	Direct	Sparse	Low	Comparable in both groups
	Clinical	Patient satisfaction with outcome	1 (106)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	1 (368)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	1 (317)	Moderate	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	1 (876)	High	Unclear	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Implant failure/loss or need for explant surgery	4 (2537)	High	Consistent	Precise	Direct	None	Moderate	Comparable in both groups: summary adjOR 0.87 (95% CI 0.65, 1.17)
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	1 (150)	Moderate	Unclear	Unclear	Direct	.	Insufficient	None (Sparse evidence)
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
AR before vs. after chemotherapy	Clinical	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IBR before vs. after radiation	Clinical	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	All	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, IBR = implant-based reconstruction, OR = odds ratio, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Table G-3. Key Question 3: Comparison of materials for IBR – full evidence profile

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Silicone vs. saline	Clinical	General quality of life	1 (139)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Physical well-being	1 (142)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	1 (142)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Sexual well-being	1 (137)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with breast	2 (624)	High	Consistent	Unclear	Direct	None	Low	Comparable in both groups
	Clinical	Patient satisfaction with outcome	1 (143)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	1 (NR)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Implant failure/loss or need for explant surgery	1 (288)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Capsular contracture	1 (345)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Silicone vs. double lumen	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	1 (NR)	High	Unclear	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant failure/loss/need for explant surgery	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Capsular contracture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Saline vs. double lumen	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant failure/loss/need for explant surgery	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Capsular contracture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: N/A = not applicable, NR = not reported, RoB = risk of bias, SoE = strength of evidence.

For continuous outcomes, clinical significance is based on published estimates of minimal clinically important differences (MCIDs), where available.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Table G-4. Key Question 4: Comparison of anatomic planes of implant placement for IBR – full evidence profile

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Prepectoral versus total submuscular	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	1 (84)	High	Unclear	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	1 (84)	High	Unclear	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	1 (405)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	2 (230)	High	Inconsistent	Precise	Direct	N/A	Insufficient	None (Inconsistent results)
	Surgical complications	Analgesic use	1 (146)	High	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Necrosis	1 (256)	High	Unclear	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant failure/loss or need for explant surgery	1 (256)	High	Unclear	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Capsular contracture	1 (256)	High	Unclear	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections (not explicitly implant-related)	2 (542)	High	Direct	Precise	Direct	N/A	Low	Comparable risk
	Surgical complications	Seroma	1 (256)	High	Unclear	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Prepectoral versus partial submuscular	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	1 (34)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	1 (34)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	1 (167)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant failure/loss or need for explant surgery	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Capsular contracture	1 (34)	Moderate	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections (not explicitly implant-related)	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	1 (34)	Moderate	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total versus partial submuscular	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant-rupture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant malposition	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Implant failure/loss or need for explant surgery	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Capsular contracture	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections (not explicitly implant-related)	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Chronic conditions	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: N/A = not applicable, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Table G-5. Key Question 5: Use versus nonuse of human ADMs during IBR – full evidence profile

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clinical	Physical well-being	3 (1604)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
Clinical	Psychosocial well-being	2 (1535)	Moderate	Inconsistent	Precise	Direct	Low	Insufficient	None (Inconsistent results)
Clinical	Sexual well-being	1 (1451)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
Clinical	Patient satisfaction with breast	2 (1535)	Moderate	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clinical	Mortality	1 (36)	High	N/A	N/A	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Unplanned repeat surgeries for revision	3 (20808)	High	Consistent	Precise	Direct	Moderate	None	Comparable risks in both groups
Surgical complications	Unplanned repeat surgeries for complications	1 (128)	High	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Pain	2 (153)	Moderate	Inconsistent	Unclear	Direct	None	Insufficient	None (Inconsistent results)
Surgical complications	Analgesic use	1 (68)	Moderate	N/A	Precise	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Necrosis	7 (2101)	High	Consistent	Precise	Direct	None	Low	Comparable risks in both groups: summary adjOR 0.89 (95% CI 0.63, 1.25); 4 studies
Surgical complications	Animation deformity	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Implant-related infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Implant-rupture	1 (1451)	Moderate	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Implant deflation	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Implant malposition	2 (1654)	Moderate	Inconsistent	Unclear	Direct	Sparse	Insufficient	None (Inconsistent results)

Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	Other	SoE	Conclusions (Reason, if None)
Surgical complications	Implant failure/loss/need for explant surgery	10 (38983)	Moderate	Consistent	Precise	Direct	None	Moderate	Higher risk with ADM: summary adjOR 1.28 (95% CI 0.97, 1.70); 6 studies
Surgical complications	Capsular contracture	4 (3485)	High	Inconsistent	Precise	Direct	None	Insufficient	None (Inconsistent results)
Surgical complications	New neoplasms	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surgical complications	Thromboembolic events	1 (18997)	Moderate	N/A	Unclear	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Infections (not explicitly implant-related)	13 (25228)	Moderate	Inconsistent	Precise	Direct	None	Low	Higher risk with ADM: summary adjOR 1.56 (95% CI 0.96, 2.53); 7 studies
Surgical complications	Wound dehiscence	4 (21798)	Moderate	Inconsistent	Unclear	Direct	None	Insufficient	None (Inconsistent results)
Surgical complications	Delayed healing	1 (398)	High	N/A	Imprecise	Direct	Sparse	Insufficient	None (Sparse evidence)
Surgical complications	Seroma	6 (3575)	Moderate	Consistent	Precise	Direct	None	Moderate	Comparable risks in both groups: summary adjOR 1.52 (95% CI 0.62, 3.71); 4 studies

Abbreviations: adj = adjusted, ADM = acellular dermal matrix, CI = confidence interval, N/A = not applicable, OR = odds ratio, RoB = risk of bias, SoE = strength of evidence.

Colors: Header rows are shaded orange. The color does not add unique information.

Table G-6. Key Question 6: Comparison of flap types for AR – full evidence profile

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
TRAM vs. DIEP	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Sexual well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with breast	2 (NR)	Moderate	Consistent	Precise	Direct	Low	Comparable in both groups
	Clinical	Patient satisfaction with outcome	1 (260)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	2 (959)	High	Consistent	Unclear	Direct	Low	Comparable in both groups
	Surgical complications	Harms to area of flap harvest	4 (9253)	High	Consistent	Precise	Direct	Moderate	Increased risk of abdominal bulge/hernia and abdominal hernia repair
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
	Surgical complications	Wound dehiscence	1 (15836)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
SIEA vs. DIEP	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Sexual well-being	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with breast	1 (NR)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Harms to area of flap harvest	1 (417)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
TAP vs. LD	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	1 (40)	Moderate	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Harms to area of flap harvest	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	1 (40)	Moderate	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
TRAM vs. LD	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	1 (49)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	1 (255)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	1 (59)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	1 (3296)	High	N/A	Precise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Harms to area of flap harvest	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
DIEP vs. LD	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	1 (229)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	1 (229)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Harms to area of flap harvest	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	1 (56)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
TRAM vs. LTD	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	1 (38)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	1 (45)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Harms to area of flap harvest	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Comparison	Outcome Category	Outcome	N Studies (Patients)	RoB	Consistency	Precision	Directness	SoE	Conclusions (Reason, if None)
LD vs. LTD	Clinical	General quality of life	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Physical well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Psychosocial well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Sexual well-being	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Patient satisfaction with breast	1 (35)	High	N/A	Unclear	Direct	Insufficient	None (Sparse evidence)
	Clinical	Patient satisfaction with outcome	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Planned surgeries for reconstruction	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Duration of initial hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Clinical	Mortality	1 (46)	High	N/A	Imprecise	Direct	Insufficient	None (Sparse evidence)
	Surgical complications	Unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Duration of unplanned repeat hospitalization	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for revision	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Unplanned repeat surgeries for complications	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Pain	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Analgesic use	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Necrosis	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Harms to area of flap harvest	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Complications delaying other cancer treatments	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Thromboembolic events	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Infections	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Wound dehiscence	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Delayed healing	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A
	Surgical complications	Seroma	0 (0)	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: adj = adjusted, AR = autologous reconstruction, CI = confidence interval, DIEP = deep inferior epigastric perforator, LD = latissimus dorsi, LTD = lateral thoracodorsal flap, OR = odds ratio, N/A = not applicable, RoB = risk of bias, SIEA = superficial inferior epigastric artery, SoE = strength of evidence, TAP = thoracodorsal artery perforator, TRAM = transverse rectus abdominis myocutaneous.

Colors: Header rows are shaded orange. Rows for every alternate comparison are shaded blue. The colors do not add unique information.

Appendix H. Appendix References

1. Abedi N, Ho AL, Knox A, et al. Predictors of Mastectomy Flap Necrosis in Patients Undergoing Immediate Breast Reconstruction: A Review of 718 Patients. Ann Plast Surg. 2016 Jun;76(6):629-34. doi: 10.1097/sap.0000000000000262. PMID: 25003437.
2. Acosta R, Smit JM, Audolfsson T, et al. A clinical review of 9 years of free perforator flap breast reconstructions: an analysis of 675 flaps and the influence of new techniques on clinical practice. J Reconstr Microsurg. 2011 Feb;27(2):91-8. doi: 10.1055/s-0030-1267835. PMID: 21046538.
3. Albornoz CR, Cordeiro PG, Hishon L, et al. A nationwide analysis of the relationship between hospital volume and outcome for autologous breast reconstruction. Plast Reconstr Surg. 2013 Aug;132(2):192e-200e. doi: 10.1097/PRS.0b013e31829586c1. PMID: 23897346.
4. Andree C, Munder BI, Seidenstuecker K, et al. Skin-sparing mastectomy and immediate reconstruction with DIEP flap after breast-conserving therapy. Med Sci Monit. 2012 Dec;18(12):Cr716-20. doi: 10.12659/msm.883598. PMID: 23197233.
5. Antony AK, McCarthy C, Disa JJ, et al. Bilateral implant breast reconstruction: outcomes, predictors, and matched cohort analysis in 730 2-stage breast reconstructions over 10 years. Ann Plast Surg. 2014;72(6):625-30. doi: 10.1097/SAP.0b013e31826af03e. PMID: 24135689.
6. Atisha D, Alderman AK, Lowery JC, et al. Prospective analysis of long-term psychosocial outcomes in breast reconstruction: two-year postoperative results from the Michigan Breast Reconstruction Outcomes Study. Ann Surg. 2008 Jun;247(6):1019-28. doi: 10.1097/SLA.0b013e3181728a5c. PMID: 18520230.
7. Avila A, Bartholomew AJ, Sosin M, et al. Acute Postoperative Complications in Prepectoral versus Subpectoral Reconstruction following Nipple-Sparing Mastectomy. Plast Reconstr Surg. 2020 Dec;146(6):715e-20e. doi: 10.1097/prs.0000000000007326. PMID: 33234947.
8. Banuelos J, Taslakian EN, Nguyen MT, et al. The American College of Surgeons National Quality Improvement Program Incompletely Captures Implant-Based Breast Reconstruction Complications. Ann Plast Surg. 2020 Mar;84(3):271-5. doi: 10.1097/sap.0000000000002051. PMID: 31663932.
9. Baumann DP, Lin HY, Chevray PM. Perforator number predicts fat necrosis in a prospective analysis of breast reconstruction with free TRAM, DIEP, and SIEA flaps. Plast Reconstr Surg. 2010 May;125(5):1335-41. doi: 10.1097/PRS.0b013e3181d4fb4a. PMID: 20440154.
10. Bennett KG, Qi J, Kim HM, et al. Comparison of 2-Year Complication Rates Among Common Techniques for Postmastectomy Breast Reconstruction. JAMA Surg. 2018 Oct 1;153(10):901-8. doi: 10.1001/jamasurg.2018.1687. PMID: 29926077.
11. Beugels J, Bod L, van Kuijk SMJ, et al. Complications following immediate compared to delayed deep inferior epigastric artery perforator flap breast reconstructions. Breast Cancer Res Treat. 2018 Jun;169(2):349-57. doi: 10.1007/s10549-018-4695-0. PMID: 29399731.

12. Beugels J, Kool M, Hoekstra LT, et al. Quality of Life of Patients After Immediate or Delayed Autologous Breast Reconstruction: A Multicenter Study. Ann Plast Surg. 2018 Nov;81(5):523-7. doi: 10.1097/sap.0000000000001618. PMID: 30247195.
13. Bozzuto LM, Bartholomew AJ, Tung S, et al. Decreased postoperative pain and opioid use following prepectoral versus subpectoral breast reconstruction after mastectomy: A retrospective cohort study: Pain after pre- versus subpectoral reconstruction. J Plast Reconstr Aesthet Surg. 2020 Dec 13. doi: 10.1016/j.bjps.2020.12.009. PMID: 33451949.
14. Brandberg Y, Malm M, Blomqvist L. A prospective and randomized study, "SVEA," comparing effects of three methods for delayed breast reconstruction on quality of life, patient-defined problem areas of life, and cosmetic result. Plast Reconstr Surg. 2000 Jan;105(1):66-74; discussion 5-6. doi: 10.1097/00006534-200001000-00011. PMID: 10626972.
15. Brandberg Y, Malm M, Rutqvist LE, et al. A prospective randomised study (named SVEA) of three methods of delayed breast reconstruction. Study design, patients' preoperative problems and expectations. Scand J Plast Reconstr Surg Hand Surg. 1999 Jun;33(2):209-16. doi: 10.1080/02844319950159479. PMID: 10450579.
16. Brooke S, Mesa J, Uluer M, et al. Complications in tissue expander breast reconstruction: a comparison of AlloDerm, DermaMatrix, and FlexHD acellular inferior pole dermal slings. Ann Plast Surg. 2012 Oct;69(4):347-9. doi: 10.1097/SAP.0b013e31824b3d97. PMID: 22868313.
17. Brooks S, Djohan R, Tendulkar R, et al. Risk factors for complications of radiation therapy on tissue expander breast reconstructions. Breast J. 2012 Jan-Feb;18(1):28-34. doi: 10.1111/j.1524-4741.2011.01182.x. PMID: 22098451.
18. Brorson F, Thorarinsson A, Kölby L, et al. Early complications in delayed breast reconstruction: A prospective, randomized study comparing different reconstructive methods in radiated and non-radiated patients. Eur J Surg Oncol. 2020 Dec;46(12):2208-17. doi: 10.1016/j.ejso.2020.07.010. PMID: 32807615.
19. Carramaschi F, Bricout N, Servant JM, et al. [Breast reconstruction after mastectomy. Critical analysis of 240 cases]. AMB Rev Assoc Med Bras. 1989 Jan-Feb;35(1):15-9. PMID: 2602589.
20. Cattelani L, Polotto S, Arcuri MF, et al. One-Step Prepectoral Breast Reconstruction With Dermal Matrix-Covered Implant Compared to Submuscular Implantation: Functional and Cost Evaluation. Clin Breast Cancer. 2018 Aug;18(4):e703-e11. doi: 10.1016/j.clbc.2017.11.015. PMID: 29275104.
21. Chang DW, Wang B, Robb GL, et al. Effect of obesity on flap and donor-site complications in free transverse rectus abdominis myocutaneous flap breast reconstruction. Plast Reconstr Surg. 2000 Apr;105(5):1640-8. doi: 10.1097/00006534-200004050-00007. PMID: 10809092.
22. Chang EI, Chang EI, Soto-Miranda MA, et al. Demystifying the use of internal mammary vessels as recipient vessels in free flap breast reconstruction. Plast Reconstr Surg. 2013 Oct;132(4):763-8. doi:

10.1097/PRS.0b013e31829fe321. PMID: 24076668.
23. Chang EI, Chang EI, Soto-Miranda MA, et al. Comprehensive Evaluation of Risk Factors and Management of Impending Flap Loss in 2138 Breast Free Flaps. Ann Plast Surg. 2016 Jan;77(1):67-71. doi: 10.1097/sap.0000000000000263. PMID: 25003429.
24. Chang EI, Chang EI, Soto-Miranda MA, et al. Comprehensive analysis of donor-site morbidity in abdominally based free flap breast reconstruction. Plast Reconstr Surg. 2013 Dec;132(6):1383-91. doi: 10.1097/PRS.0b013e3182a805a3. PMID: 24005365.
25. Chang EI, Vaca L, DaLio AL, et al. Assessment of advanced age as a risk factor in microvascular breast reconstruction. Ann Plast Surg. 2011 Sep;67(3):255-9. doi: 10.1097/SAP.0b013e3181f9b20c. PMID: 21407063.
26. Chen AD, Chi D, Wu WW, et al. The Influence of Connective Tissue Disease in Breast Reconstruction: A National Database Analysis. Ann Plast Surg. 2018 Apr;80(4 Suppl 4):S182-s8. doi: 10.1097/sap.0000000000001387. PMID: 29596085.
27. Chen CF, Lin SF, Hung CF, et al. Risk of infection is associated more with drain duration than daily drainage volume in prosthesis-based breast reconstruction: A cohort study. Medicine (Baltimore). 2016 Dec;95(49):e5605. doi: 10.1097/md.0000000000005605. PMID: 27930584.
28. Chen Y, Chen J, Chen J, et al. [Current trends of breast reconstruction after mastectomy for breast cancer patients in China: a survey report]. Zhonghua Zhong Liu Za Zhi. 2014 Nov;36(11):851-7. PMID: 25620484.
29. Chetta MD, Aliu O, Zhong L, et al. Reconstruction of the Irradiated Breast: A National Claims-Based Assessment of Postoperative Morbidity. Plast Reconstr Surg. 2017 Apr;139(4):783-92. doi: 10.1097/prs.0000000000003168. PMID: 28002254.
30. Chun YS, Verma K, Rosen H, et al. Implant-based breast reconstruction using acellular dermal matrix and the risk of postoperative complications. Plast Reconstr Surg. 2010 Feb;125(2):429-36. doi: 10.1097/PRS.0b013e3181c82d90. PMID: 20124828.
31. Clarke-Pearson EM, Lin AM, Hertl C, et al. Revisions in Implant-Based Breast Reconstruction: How Does Direct-to-Implant Measure Up? Plast Reconstr Surg. 2016 Jun;137(6):1690-9. doi: 10.1097/prs.0000000000002173. PMID: 27219225.
32. Cleveland EC, Fischer JP, Nelson JA, et al. Optimizing the fascial closure: an analysis of 1261 abdominally based free flap reconstructions. Ann Plast Surg. 2013 Sep;71(3):255-60. doi: 10.1097/SAP.0b013e318286380e. PMID: 23945529.
33. Cohen WA, Ballard TN, Hamill JB, et al. Understanding and Optimizing the Patient Experience in Breast Reconstruction. Ann Plast Surg. 2016 Aug;77(2):237-41. doi: 10.1097/sap.0000000000000550. PMID: 26101986.
34. Collier W, Scheefer Van Boerum M, Kim J, et al. Are 30-Day Outcomes Enough? Late Infectious Readmissions following Prosthetic-Based Breast Reconstruction. Plast Reconstr Surg. 2019 Sep;144(3):360e-8e. doi:

10.1097/prs.0000000000005903. PMID: 31461001.
35. Cordeiro PG, Albornoz CR, McCormick B, et al. The impact of postmastectomy radiotherapy on two-stage implant breast reconstruction: an analysis of long-term surgical outcomes, aesthetic results, and satisfaction over 13 years. Plast Reconstr Surg. 2014 Oct;134(4):588-95. doi: 10.1097/prs.0000000000000523. PMID: 25357021.
36. Cordeiro PG, Albornoz CR, McCormick B, et al. What Is the Optimum Timing of Postmastectomy Radiotherapy in Two-Stage Prosthetic Reconstruction: Radiation to the Tissue Expander or Permanent Implant? Plast Reconstr Surg. 2015 Jun;135(6):1509-17. doi: 10.1097/prs.0000000000001278. PMID: 25742523.
37. Cordeiro PG, McCarthy CM. A single surgeon's 12-year experience with tissue expander/implant breast reconstruction: part I. A prospective analysis of early complications. Plast Reconstr Surg. 2006 Sep 15;118(4):825-31. doi: 10.1097/01.prs.0000232362.82402.e8. PMID: 16980842.
38. Cordeiro PG, McGuire P, Murphy DK. Natrelle 410 Extra-Full Projection Silicone Breast Implants: 2-Year Results from Two Prospective Studies. Plast Reconstr Surg. 2015 Oct;136(4):638-46. doi: 10.1097/prs.0000000000001636. PMID: 26090764.
39. Cordeiro PG, Snell L, Heerdt A, et al. Immediate tissue expander/implast breast reconstruction after salvage mastectomy for cancer recurrence following lumpectomy/irradiation. Plast Reconstr Surg. 2012 Feb;129(2):341-50. doi: 10.1097/PRS.0b013e318205f203. PMID: 22286416.
40. Coroneos CJ, Selber JC, Offodile AC, 2nd, et al. US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients. Ann Surg. 2019 Jan;269(1):30-6. doi: 10.1097/sla.0000000000002990. PMID: 30222598.
41. Craig ES, Clemens MW, Koshy JC, et al. Outcomes of Acellular Dermal Matrix for Immediate Tissue Expander Reconstruction with Radiotherapy: A Retrospective Cohort Study. Aesthet Surg J. 2019 Feb 15;39(3):279-88. doi: 10.1093/asj/sjy127. PMID: 29800083.
42. Daly LT, Doval AF, Lin SJ, et al. Role of CTA in Women with Abdominal Scars Undergoing DIEP Breast Reconstruction: Review of 1,187 Flaps. J Reconstr Microsurg. 2020 May;36(4):294-300. doi: 10.1055/s-0039-1701040. PMID: 31994156.
43. Dauplat J, Thivat E, Rouanet P, et al. Risk Factors Associated With Complications After Unilateral Immediate Breast Reconstruction: A French Prospective Multicenter Study. In Vivo. 2021 Mar-Apr;35(2):937-45. doi: 10.21873/invivo.12334. PMID: 33622886.
44. Davila AA, Seth AK, Wang E, et al. Human Acellular Dermis versus Submuscular Tissue Expander Breast Reconstruction: A Multivariate Analysis of Short-Term Complications. Arch Plast Surg. 2013 Jan;40(1):19-27. doi: 10.5999/aps.2013.40.1.19. PMID: 23362476.
45. de Araujo TB, Jue Xu M, Susarla SM, et al. Impact of Prior Unilateral Chest Wall Radiotherapy on Outcomes in Bilateral Breast Reconstruction. Plast Reconstr Surg. 2016 Oct;138(4):575e-80e. doi:

10.1097/prs.0000000000002532. PMID: 27673527.
46. Eltahir Y, Werners LL, Dreise MM, et al. Which breast is the best? Successful autologous or alloplastic breast reconstruction: patient-reported quality-of-life outcomes. Plast Reconstr Surg. 2015 Jan;135(1):43-50. doi: 10.1097/prs.0000000000000804. PMID: 25539295.
47. Enajat M, Rozen WM, Whitaker IS, et al. A single center comparison of one versus two venous anastomoses in 564 consecutive DIEP flaps: investigating the effect on venous congestion and flap survival. Microsurgery. 2010;30(3):185-91. doi: 10.1002/micr.20712. PMID: 19790180.
48. Erdmann-Sager J, Wilkins EG, Pusic AL, et al. Complications and Patient-Reported Outcomes after Abdominally Based Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium Study. Plast Reconstr Surg. 2018 Feb;141(2):271-81. doi: 10.1097/prs.0000000000004016. PMID: 29019862.
49. Eriksson M, Anveden L, Celebioglu F, et al. Radiotherapy in implant-based immediate breast reconstruction: risk factors, surgical outcomes, and patient-reported outcome measures in a large Swedish multicenter cohort. Breast Cancer Res Treat. 2013 Dec;142(3):591-601. doi: 10.1007/s10549-013-2770-0. PMID: 24258257.
50. Fischer JP, Fox JP, Nelson JA, et al. A Longitudinal Assessment of Outcomes and Healthcare Resource Utilization After Immediate Breast Reconstruction-Comparing Implant- and Autologous-based Breast Reconstruction. Ann Surg. 2015 Oct;262(4):692-9. doi: 10.1097/sla.0000000000001457. PMID: 26366550.
51. Fischer JP, Nelson JA, Cleveland E, et al. Breast reconstruction modality outcome study: a comparison of expander/implants and free flaps in select patients. Plast Reconstr Surg. 2013 May;131(5):928-34. doi: 10.1097/PRS.0b013e3182865977. PMID: 23629074.
52. Fischer JP, Wes AM, Nelson JA, et al. Propensity-matched, longitudinal outcomes analysis of complications and cost: comparing abdominal free flaps and implant-based breast reconstruction. J Am Coll Surg. 2014 Aug;219(2):303-12. doi: 10.1016/j.jamcollsurg.2014.02.028. PMID: 24916480.
53. Fitzgerald O'Connor E, Rozen WM, Chowdhry M, et al. The microvascular anastomotic coupler for venous anastomoses in free flap breast reconstruction improves outcomes. Gland Surg. 2016 Apr;5(2):88-92. doi: 10.3978/j.issn.2227-684X.2015.05.14. PMID: 27047776.
54. Gabriel A, Sigalove S, Storm-Dickerson TL, et al. Dual-Plane versus Prepectoral Breast Reconstruction in High-Body Mass Index Patients. Plast Reconstr Surg. 2020 Jun;145(6):1357-65. doi: 10.1097/prs.0000000000006840. PMID: 32195862.
55. Ganesh Kumar N, Berlin NL, Kim HM, et al. Development of an evidence-based approach to the use of acellular dermal matrix in immediate expander-implant-based breast reconstruction. J Plast Reconstr Aesthet Surg. 2021 Jan;74(1):30-40. doi: 10.1016/j.bjps.2020.10.005. PMID: 33172826.
56. Garbay JR, Rietjens M, Petit JY. [Esthetic results of breast reconstruction after amputation for cancer. 323 cases].

J Gynecol Obstet Biol Reprod (Paris). 1992;21(4):405-12. PMID: 1624727.
57. Gart MS, Smetona JT, Hanwright PJ, et al. Autologous options for postmastectomy breast reconstruction: a comparison of outcomes based on the American College of Surgeons National Surgical Quality Improvement Program. J Am Coll Surg. 2013 Feb;216(2):229-38. doi: 10.1016/j.jamcollsurg.2012.11.003. PMID: 23211118.
58. Garvey PB, Villa MT, Rozanski AT, et al. The advantages of free abdominal-based flaps over implants for breast reconstruction in obese patients. Plast Reconstr Surg. 2012 Nov;130(5):991-1000. doi: 10.1097/PRS.0b013e318267efc5. PMID: 23096600.
59. Gfrerer L, Mattos D, Mastroianni M, et al. Assessment of patient factors, surgeons, and surgeon teams in immediate implant-based breast reconstruction outcomes. Plast Reconstr Surg. 2015 Feb;135(2):245e-52e. doi: 10.1097/prs.0000000000000912. PMID: 25626807.
60. Gill PS, Hunt JP, Guerra AB, et al. A 10-year retrospective review of 758 DIEP flaps for breast reconstruction. Plast Reconstr Surg. 2004 Apr 1;113(4):1153-60. doi: 10.1097/01.prs.0000110328.47206.50. PMID: 15083015.
61. Goodwin SJ, McCarthy CM, Pusic AL, et al. Complications in smokers after postmastectomy tissue expander/implant breast reconstruction. Ann Plast Surg. 2005 Jul;55(1):16-9; discussion 9-20. doi: 10.1097/01.sap.0000168282.81348.b3. PMID: 15985785.
62. Ha JH, Hong KY, Lee HB, et al. Oncologic outcomes after immediate breast reconstruction following mastectomy: comparison of implant and flap using propensity score matching. BMC Cancer. 2020 Jan 30;20(1):78. doi: 10.1186/s12885-020-6568-2. PMID: 32000718.
63. Haddock NT, Cho MJ, Teotia SS. Comparative Analysis of Single versus Stacked Free Flap Breast Reconstruction: A Single-Center Experience. Plast Reconstr Surg. 2019 Sep;144(3):369e-77e. doi: 10.1097/prs.0000000000005906. PMID: 31461004.
64. Haddock NT, Culver AJ, Teotia SS. Abdominal weakness, bulge, or hernia after DIEP flaps: An algorithm of management, prevention, and surgical repair with classification. J Plast Reconstr Aesthet Surg. 2020 Dec 26. doi: 10.1016/j.bjps.2020.12.044. PMID: 33487570.
65. Hamdi M, Andrades P, Thiessen F, et al. Is a second free flap still an option in a failed free flap breast reconstruction? Plast Reconstr Surg. 2010 Aug;126(2):375-84. doi: 10.1097/PRS.0b013e3181de22f3. PMID: 20679823.
66. Hamdi M, Casaer B, Andrades P, et al. Salvage (tertiary) breast reconstruction after implant failure. J Plast Reconstr Aesthet Surg. 2011 Mar;64(3):353-9. doi: 10.1016/j.bjps.2010.05.019. PMID: 20576480.
67. Hangge PT, Jogerst K, Mohsen A, et al. Making an informed choice: Which breast reconstruction type has the lowest complication rate? Am J Surg. 2019 Dec;218(6):1040-5. doi: 10.1016/j.amjsurg.2019.09.033. PMID: 31606126.
68. Hansen N, Espino S, Blough JT, et al. Evaluating Mastectomy Skin Flap Necrosis in the Extended Breast Reconstruction Risk Assessment Score for 1-Year Prediction of Prosthetic

Reconstruction Outcomes. J Am Coll Surg. 2018 Jul;227(1):96-104. doi: 10.1016/j.jamcollsurg.2018.05.003. PMID: 29778821.
69. Hembd AS, Yan J, Zhu H, et al. Intraoperative Assessment of DIEP Flap Breast Reconstruction Using Indocyanine Green Angiography: Reduction of Fat Necrosis, Resection Volumes, and Postoperative Surveillance. Plast Reconstr Surg. 2020 Jul;146(1):1e-10e. doi: 10.1097/prs.0000000000006888. PMID: 32590635.
70. Heo JW, Park SO, Jin US. Donor-site morbidities in 615 patients after breast reconstruction using a free muscle-sparing type I transverse rectus abdominis myocutaneous flap: a single surgeon experience. J Plast Surg Hand Surg. 2018 Dec;52(6):325-32. doi: 10.1080/2000656x.2018.1493389. PMID: 30039735.
71. Hirsch EM, Seth AK, Kim JY, et al. Analysis of risk factors for complications in expander/implant breast reconstruction by stage of reconstruction. Plast Reconstr Surg. 2014 Nov;134(5):692e-9e. doi: 10.1097/prs.0000000000000607. PMID: 25347643.
72. Hunsicker LM, Ashikari AY, Berry C, et al. Short-Term Complications Associated With Acellular Dermal Matrix-Assisted Direct-to-Implant Breast Reconstruction. Ann Plast Surg. 2017 Jan;78(1):35-40. doi: 10.1097/sap.0000000000000742. PMID: 26849284.
73. Huo J, Smith BD, Giordano SH, et al. A comparison of patient-centered economic and clinical outcomes of post-mastectomy breast reconstruction between obese and non-obese patients. Breast. 2016 Dec;30:118-24. doi: 10.1016/j.breast.2016.09.004. PMID: 27697676.
74. Ibrahim AM, Shuster M, Koolen PG, et al. Analysis of the National Surgical Quality Improvement Program database in 19,100 patients undergoing implant-based breast reconstruction: complication rates with acellular dermal matrix. Plast Reconstr Surg. 2013 Nov;132(5):1057-66. doi: 10.1097/PRS.0b013e3182a3beec. PMID: 24165587.
75. Israeli R, Funk S, Reaven NL. Comparative analysis of 18-month outcomes and costs of breast reconstruction flap procedures. Plast Reconstr Surg. 2014 Mar;133(3):471-9. doi: 10.1097/prs.0000000000000064. PMID: 24572840.
76. Jiang YZ, Liu YR, Yu KD, et al. Immediate postmastectomy breast reconstruction showed limited advantage in patient survival after stratifying by family income. PLoS One. 2013;8(12):e82807. doi: 10.1371/journal.pone.0082807. PMID: 24349366.
77. Jo T, Hur J, Min K, et al. Immediate breast reconstruction after salvage mastectomy: Case control outcome comparisons of DIEP flap and DTI reconstruction. J Plast Reconstr Aesthet Surg. 2020 Dec 9. doi: 10.1016/j.bjps.2020.11.034. PMID: 33386262.
78. Kanuri A, Liu AS, Guo L. Whom should we SPY? A cost analysis of laser-assisted indocyanine green angiography in prevention of mastectomy skin flap necrosis during prosthesis-based breast reconstruction. Plast Reconstr Surg. 2014 Apr;133(4):448e-54e. doi: 10.1097/prs.0000000000000025. PMID: 24675199.

79. Kato H, Nakagami G, Iwahira Y, et al. Risk factors and risk scoring tool for infection during tissue expansion in tissue expander and implant breast reconstruction. Breast J. 2013 Nov-Dec;19(6):618-26. doi: 10.1111/tbj.12175. PMID: 24011080.
80. Kim EK, Eom JS, Ahn SH, et al. Evolution of the pedicled TRAM flap: a prospective study of 500 consecutive cases by a single surgeon in Asian patients. Ann Plast Surg. 2009 Oct;63(4):378-82. doi: 10.1097/SAP.0b013e3181951708. PMID: 19745709.
81. Kim EK, Eom JS, Ahn SH, et al. The efficacy of prophylactic low-molecular-weight heparin to prevent pulmonary thromboembolism in immediate breast reconstruction using the TRAM flap. Plast Reconstr Surg. 2009 Jan;123(1):9-12. doi: 10.1097/PRS.0b013e3181904be7. PMID: 19116509.
82. Kim HJ, Park EH, Lim WS, et al. Nipple areola skin-sparing mastectomy with immediate transverse rectus abdominis musculocutaneous flap reconstruction is an oncologically safe procedure: a single center study. Ann Surg. 2010 Mar;251(3):493-8. doi: 10.1097/SLA.0b013e3181c5dc4e. PMID: 20134317.
83. Kim JH, Hong SE. A Comparative Analysis between Subpectoral versus Prepectoral Single Stage Direct-to-Implant Breast Reconstruction. Medicina (Kaunas). 2020 Oct 13;56(10). doi: 10.3390/medicina56100537. PMID: 33066236.
84. Knox AD, Ho AL, Leung L, et al. Comparison of Outcomes following Autologous Breast Reconstruction Using the DIEP and Pedicled TRAM Flaps: A 12-Year Clinical Retrospective Study and Literature Review. Plast Reconstr Surg. 2016 Jul;138(1):16-28. doi: 10.1097/prs.0000000000001747. PMID: 26267400.
85. Kouwenberg CAE, de Ligt KM, Kranenburg LW, et al. Long-Term Health-Related Quality of Life after Four Common Surgical Treatment Options for Breast Cancer and the Effect of Complications: A Retrospective Patient-Reported Survey among 1871 Patients. Plast Reconstr Surg. 2020 Jul;146(1):1-13. doi: 10.1097/prs.0000000000006887. PMID: 32590633.
86. Kouwenberg CAE, Kranenburg LW, Visser MS, et al. "The validity of the EQ-5D-5L in measuring quality of life benefits of breast reconstruction". J Plast Reconstr Aesthet Surg. 2019 Jan;72(1):52-61. doi: 10.1016/j.bjps.2018.08.023. PMID: 30270015.
87. Kraenzlin F, Darrach H, Khavanin N, et al. Tissue Expander-Based Breast Reconstruction in the Prepectoral Versus Subpectoral Plane: An Analysis of Short-Term Outcomes. Ann Plast Surg. 2021 Jan;86(1):19-23. doi: 10.1097/sap.0000000000002415. PMID: 32568752.
88. Kroll SS. Fat necrosis in free transverse rectus abdominis myocutaneous and deep inferior epigastric perforator flaps. Plast Reconstr Surg. 2000 Sep;106(3):576-83. doi: 10.1097/00006534-200009030-00008. PMID: 10987463.
89. Kulkarni AR, Pusic AL, Hamill JB, et al. Factors Associated with Acute Postoperative Pain Following Breast Reconstruction. JPRAS Open. 2017 Mar;11:1-13. doi: 10.1016/j.jpra.2016.08.005. PMID: 28713853.

90. Langer S, Munder B, Seidenstuecker K, et al. Development of a surgical algorithm and optimized management of complications - based on a review of 706 abdominal free flaps for breast reconstruction. Med Sci Monit. 2010 Nov;16(11):Cr518-22. PMID: 20980954.
91. Lantieri L, Hivelin M, Benjoar MD, et al. [Setting of a breast autologous microsurgical reconstructive surgery evolution in 20 years and review of 1138 cases]. Ann Chir Plast Esthet. 2015 Dec;60(6):484-9. doi: 10.1016/j.anplas.2015.06.009. PMID: 26238173.
92. Laporta R, Sorotos M, Longo B, et al. Breast Reconstruction in Elderly Patients: Risk Factors, Clinical Outcomes, and Aesthetic Results. J Reconstr Microsurg. 2017 May;33(4):257-67. doi: 10.1055/s-0036-1597822. PMID: 28061518.
93. Law TY, Moeller E, Hubbard ZS, et al. Preoperative Hypoglycemia and Hyperglycemia Are Related to Postoperative Infection Rates in Implant-Based Breast Reconstruction. J Surg Res. 2018 Dec;232:437-41. doi: 10.1016/j.jss.2018.06.068. PMID: 30463754.
94. Le GM, O'Malley CD, Glaser SL, et al. Breast implants following mastectomy in women with early-stage breast cancer: prevalence and impact on survival. Breast Cancer Res. 2005;7(2):R184-93. doi: 10.1186/bcr974. PMID: 15743498.
95. Lee JS, Park E, Lee JH, et al. A prospective comparison study of early functional outcomes after implant-based breast reconstruction: subpectoral versus prepectoral technique. Ann Palliat Med. 2021 Mar;10(3):2520-9. doi: 10.21037/apm-20-1550. PMID: 33691448.
96. Lee KT, Bae J, Jeon BJ, et al. Adjuvant Chemotherapy in Two-Stage Tissue Expander/Implant Breast Reconstruction: Does it Affect Final Outcomes? Ann Surg Oncol. 2021 Apr;28(4):2191-8. doi: 10.1245/s10434-020-09177-z. PMID: 32974692.
97. Lee KT, Bang SI, Pyon JK, et al. Method of breast reconstruction and the development of lymphoedema. Br J Surg. 2017 Feb;104(3):230-7. doi: 10.1002/bjs.10397. PMID: 27861758.
98. Lee KT, Kim S, Jeon BJ, et al. Association of the Implant Surface Texture Used in Reconstruction With Breast Cancer Recurrence. JAMA Surg. 2020 Dec 1;155(12):1132-40. doi: 10.1001/jamasurg.2020.4124. PMID: 33026424.
99. Lee KT, Lee H, Jeon BJ, et al. Impact of overweight/obesity on the development of hematoma following tissue expander-based breast reconstruction. J Plast Reconstr Aesthet Surg. 2020;74(2):307-15.
100. Lee KT, Pyon JK, Bang SI, et al. Does the reconstruction method influence development of mastectomy flap complications in nipple-sparing mastectomy? J Plast Reconstr Aesthet Surg. 2013 Nov;66(11):1543-50. doi: 10.1016/j.bjps.2013.06.032. PMID: 23834909.
101. Lei C, Xu L, Xu F, et al. Patient satisfaction in one-stage immediate breast reconstruction after mastectomy: A multi-center comparative patient evaluation of prosthesis, LDMF, and TRAM techniques. Medicine (Baltimore). 2020 May 29;99(22):e19991. doi: 10.1097/md.0000000000019991. PMID: 32481367.
102. Liao EC, Taghinia AH, Nguyen LP, et al. Incidence of hematoma complication

with heparin venous thrombosis prophylaxis after TRAM flap breast reconstruction. Plast Reconstr Surg. 2008 Apr;121(4):1101-7. doi: 10.1097/01.prs.0000302454.43201.83. PMID: 18349626.
103. Liu AS, Kao HK, Reish RG, et al. Postoperative complications in prosthesis-based breast reconstruction using acellular dermal matrix. Plast Reconstr Surg. 2011 May;127(5):1755-62. doi: 10.1097/PRS.0b013e31820cf233. PMID: 21228744.
104. Liu C, Momeni A, Zhuang Y, et al. Outcome analysis of expander/implant versus microsurgical abdominal flap breast reconstruction: a critical study of 254 cases. Ann Surg Oncol. 2014 Jun;21(6):2074-82. doi: 10.1245/s10434-014-3521-0. PMID: 24558063.
105. Lovecchio F, Jordan SW, Lim S, et al. Risk Factors for Complications Differ Between Stages of Tissue-Expander Breast Reconstruction. Ann Plast Surg. 2015 Sep;75(3):275-80. doi: 10.1097/sap.0000000000000109. PMID: 24691330.
106. Macadam SA, Ho AL, Cook EF, Jr., et al. Patient satisfaction and health-related quality of life following breast reconstruction: patient-reported outcomes among saline and silicone implant recipients. Plast Reconstr Surg. 2010 Mar;125(3):761-71. doi: 10.1097/PRS.0b013e3181cb5cf8. PMID: 20009795.
107. Macadam SA, Zhong T, Weichman K, et al. Quality of Life and Patient-Reported Outcomes in Breast Cancer Survivors: A Multicenter Comparison of Four Abdominally Based Autologous Reconstruction Methods. Plast Reconstr Surg. 2016 Mar;137(3):758-71. doi: 10.1097/01.prs.0000479932.11170.8f. PMID: 26910656.
108. Mak JC, Kwong A. Complications in Post-mastectomy Immediate Breast Reconstruction: A Ten-year Analysis of Outcomes. Clin Breast Cancer. 2020 Oct;20(5):402-7. doi: 10.1016/j.clbc.2019.12.002. PMID: 32665188.
109. Masoomi H, Blumenauer BJ, Blakkolb CL, et al. Predictors of blood transfusion in autologous breast reconstruction surgery: A retrospective study using the nationwide inpatient sample database. J Plast Reconstr Aesthet Surg. 2019 Oct;72(10):1616-22. doi: 10.1016/j.bjps.2019.06.012. PMID: 31331721.
110. Masoomi H, Paydar KZ, Wirth GA, et al. Predictive risk factors of venous thromboembolism in autologous breast reconstruction surgery. Ann Plast Surg. 2014 Jan;72(1):30-3. doi: 10.1097/sap.0000000000000003. PMID: 24317244.
111. Massenburg BB, Sanati-Mehrizy P, Ingargiola MJ, et al. Flap Failure and Wound Complications in Autologous Breast Reconstruction: A National Perspective. Aesthetic Plast Surg. 2015 Dec;39(6):902-9. doi: 10.1007/s00266-015-0575-8. PMID: 26487657.
112. McCarthy CM, Klassen AF, Cano SJ, et al. Patient satisfaction with postmastectomy breast reconstruction: a comparison of saline and silicone implants. Cancer. 2010 Dec 15;116(24):5584-91. doi: 10.1002/cncr.25552. PMID: 21136577.
113. McCarthy CM, Lee CN, Halvorson EG, et al. The use of acellular dermal matrices in two-stage expander/implant reconstruction: a multicenter, blinded, randomized controlled trial. Plast Reconstr Surg. 2012 Nov;130(5 Suppl 2):57s-66s. doi:

10.1097/PRS.0b013e31825f05b4. PMID: 23096987.
114. McCarthy CM, Mehrara BJ, Long T, et al. Chest and upper body morbidity following immediate postmastectomy breast reconstruction. Ann Surg Oncol. 2014 Jan;21(1):107-12. doi: 10.1245/s10434-013-3231-z. PMID: 24201740.
115. McCarthy CM, Mehrara BJ, Riedel E, et al. Predicting complications following expander/implant breast reconstruction: an outcomes analysis based on preoperative clinical risk. Plast Reconstr Surg. 2008 Jun;121(6):1886-92. doi: 10.1097/PRS.0b013e31817151c4. PMID: 18520873.
116. Mehrara BJ, Santoro TD, Arcilla E, et al. Complications after microvascular breast reconstruction: experience with 1195 flaps. Plast Reconstr Surg. 2006 Oct;118(5):1100-9; discussion 10-1. doi: 10.1097/01.prs.0000236898.87398.d6. PMID: 17016173.
117. Mennie JC, Mohanna PN, O'Donoghue JM, et al. Donor-Site Hernia Repair in Abdominal Flap Breast Reconstruction: A Population-Based Cohort Study of 7929 Patients. Plast Reconstr Surg. 2015 Jul;136(1):1-9. doi: 10.1097/prs.0000000000001398. PMID: 25839173.
118. Merchant SJ, Goldstein L, Kruper LL. Patterns and Trends in Immediate Postmastectomy Reconstruction in California: Complications and Unscheduled Readmissions. Plast Reconstr Surg. 2015 Jul;136(1):10e-9e. doi: 10.1097/prs.0000000000001326. PMID: 26111325.
119. Mioton LM, Smetona JT, Hanwright PJ, et al. Comparing thirty-day outcomes in prosthetic and autologous breast reconstruction: a multivariate analysis of 13,082 patients? J Plast Reconstr Aesthet Surg. 2013 Jul;66(7):917-25. doi: 10.1016/j.bjps.2013.03.009. PMID: 23562485.
120. Mirzabeigi MN, Nelson JA, Fischer JP, et al. Tamoxifen (selective estrogen-receptor modulators) and aromatase inhibitors as potential perioperative thrombotic risk factors in free flap breast reconstruction. Plast Reconstr Surg. 2015 Apr;135(4):670e-9e. doi: 10.1097/prs.0000000000001127. PMID: 25811579.
121. Mlodinow AS, Ver Halen JP, Lim S, et al. Predictors of readmission after breast reconstruction: a multi-institutional analysis of 5012 patients. Ann Plast Surg. 2013 Oct;71(4):335-41. doi: 10.1097/SAP.0b013e3182a0df25. PMID: 24025652.
122. Momeni A, Fox JP. Venous Thromboembolism After Surgical Treatment of Breast Cancer. Ann Plast Surg. 2018 Feb;80(2):188-92. doi: 10.1097/sap.0000000000001249. PMID: 29095189.
123. Munder B, Andree C, Witzel C, et al. The DIEP Flap as Well-established Method of Choice for Autologous Breast Reconstruction with a Low Complication Rate - Retrospective Single-centre 10-Year Experience. Geburtshilfe Frauenheilkd. 2020 Jun;80(6):628-38. doi: 10.1055/a-1116-2102. PMID: 32565553.
124. Naoum GE, Oladeru OT, Niemierko A, et al. Optimal breast reconstruction type for patients treated with neoadjuvant chemotherapy, mastectomy followed by radiation therapy. Breast Cancer Res Treat. 2020 Aug;183(1):127-36. doi: 10.1007/s10549-020-05747-7. PMID: 32607638.

125. Naoum GE, Salama L, Niemierko A, et al. Single Stage Direct-to-Implant Breast Reconstruction Has Lower Complication Rates Than Tissue Expander and Implant and Comparable Rates to Autologous Reconstruction in Patients Receiving Postmastectomy Radiation. Int J Radiat Oncol Biol Phys. 2020 Mar 1;106(3):514-24. doi: 10.1016/j.ijrobp.2019.11.008. PMID: 31756414.
126. Nasser JS, Huetteman HE, Chung TT, et al. Unplanned Emergency Department Visits within 30 Days of Mastectomy and Breast Reconstruction. Plast Reconstr Surg. 2018 Dec;142(6):1411-20. doi: 10.1097/prs.0000000000004970. PMID: 30204678.
127. Nealon KP, Sobti N, Gadd M, et al. Assessing the additional surgical risk of contralateral prophylactic mastectomy and immediate breast implant reconstruction. Breast Cancer Res Treat. 2020 Jan;179(2):255-65. doi: 10.1007/s10549-019-05460-0. PMID: 31605310.
128. Nealon KP, Weitzman RE, Sobti N, et al. Prepectoral Direct-to-Implant Breast Reconstruction: Safety Outcome Endpoints and Delineation of Risk Factors. Plast Reconstr Surg. 2020 Feb 5. doi: 10.1097/prs.0000000000006721. PMID: 32032345.
129. Nelson JA, Allen RJ, Jr., Polanco T, et al. Long-term Patient-reported Outcomes Following Postmastectomy Breast Reconstruction: An 8-year Examination of 3268 Patients. Ann Surg. 2019 Sep;270(3):473-83. doi: 10.1097/sla.0000000000003467. PMID: 31356276.
130. Nelson JA, Fischer JP, Grover R, et al. The impact of anemia on microsurgical breast reconstruction complications and outcomes. Microsurgery. 2014 May;34(4):261-70. doi: 10.1002/micr.22202. PMID: 24436188.
131. Nelson JA, Stransky CA, Fischer JP, et al. Reexamining free flap breast reconstruction in the community and university setting: is there a difference? Ann Plast Surg. 2014 Dec;73 Suppl 2:S171-4. doi: 10.1097/sap.0000000000000204. PMID: 25046665.
132. Nelson JA, Voineskos SH, Qi J, et al. Elective Revisions after Breast Reconstruction: Results from the Mastectomy Reconstruction Outcomes Consortium. Plast Reconstr Surg. 2019 Dec;144(6):1280-90. doi: 10.1097/prs.0000000000006225. PMID: 31764633.
133. O'Neill AC, Barandun M, Cha J, et al. Restrictive use of perioperative blood transfusion does not increase complication rates in microvascular breast reconstruction. J Plast Reconstr Aesthet Surg. 2016 Aug;69(8):1092-6. doi: 10.1016/j.bjps.2016.04.021. PMID: 27236504.
134. O'Neill AC, Sebastiampillai S, Zhong T, et al. Increasing body mass index increases complications but not failure rates in microvascular breast reconstruction: A retrospective cohort study. J Plast Reconstr Aesthet Surg. 2019 Sep;72(9):1518-24. doi: 10.1016/j.bjps.2019.05.013. PMID: 31196805.
135. Ozgur I, Kurul S, Bademler S, et al. Comparison of subpectoral versus dual-plane implant based immediate breast reconstruction after nipple-areola sparing mastectomy. Ann Chir Plast Esthet. 2020 Nov 19. doi: 10.1016/j.anplas.2020.10.002. PMID: 33223365.
136. Palve JS, Luukkaala TH, Kääriäinen MT. Predictive risk factors of complications in different breast

reconstruction methods. Breast Cancer Res Treat. 2020 Jul;182(2):345-54. doi: 10.1007/s10549-020-05705-3. PMID: 32468337.
137. Pannucci CJ, Antony AK, Wilkins EG. The impact of acellular dermal matrix on tissue expander/implant loss in breast reconstruction: an analysis of the tracking outcomes and operations in plastic surgery database. Plast Reconstr Surg. 2013 Jul;132(1):1-10. doi: 10.1097/PRS.0b013e318290f917. PMID: 23508050.
138. Parikh RP, Brown GM, Sharma K, et al. Immediate Implant-Based Breast Reconstruction with Acellular Dermal Matrix: A Comparison of Sterile and Aseptic AlloDerm in 2039 Consecutive Cases. Plast Reconstr Surg. 2018 Dec;142(6):1401-9. doi: 10.1097/prs.0000000000004968. PMID: 30204676.
139. Park JW, Lee KT, Jeon BJ, et al. Effects of Antihypertensive Drugs on Outcomes of Breast Reconstruction. Ann Surg Oncol. 2019 Jun;26(6):1712-9. doi: 10.1245/s10434-019-07293-z. PMID: 30863940.
140. Peled AW, Foster RD, Garwood ER, et al. The effects of acellular dermal matrix in expander-implant breast reconstruction after total skin-sparing mastectomy: results of a prospective practice improvement study. Plast Reconstr Surg. 2012 Jun;129(6):901e-8e. doi: 10.1097/PRS.0b013e31824ec447. PMID: 22634688.
141. Phan R, Rozen WM, Chowdhry M, et al. Risk factors and timing of postoperative hematomas following microvascular breast reconstruction: A prospective cohort study. Microsurgery. 2020 Feb;40(2):99-103. doi: 10.1002/micr.30473. PMID: 31124177.
142. Polanco TO, Shamsunder MG, Hicks MEV, et al. Goal-directed fluid therapy in autologous breast reconstruction results in less fluid and more vasopressor administration without outcome compromise. J Plast Reconstr Aesthet Surg. 2021 Feb 4. doi: 10.1016/j.bjps.2021.01.017. PMID: 33745850.
143. Potter S, Conroy EJ, Cutress RI, et al. Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study. Lancet Oncol. 2019 Feb;20(2):254-66. doi: 10.1016/s1470-2045(18)30781-2. PMID: 30639093.
144. Prantl L, Moellhoff N, von Fritschen U, et al. Immediate versus secondary DIEP flap breast reconstruction: a multicenter outcome study. Arch Gynecol Obstet. 2020 Dec;302(6):1451-9. doi: 10.1007/s00404-020-05779-w. PMID: 32895743.
145. Pusic AL, Matros E, Fine N, et al. Patient-Reported Outcomes 1 Year After Immediate Breast Reconstruction: Results of the Mastectomy Reconstruction Outcomes Consortium Study. J Clin Oncol. 2017 Aug 1;35(22):2499-506. doi: 10.1200/jco.2016.69.9561. PMID: 28346808.
146. Qin Q, Tan Q, Lian B, et al. Postoperative outcomes of breast reconstruction after mastectomy: A retrospective study. Medicine (Baltimore). 2018 Feb;97(5):e9766. doi: 10.1097/md.0000000000009766. PMID: 29384865.
147. Qureshi AA, Broderick KP, Belz J, et al. Uneventful versus Successful Reconstruction and Outcome Pathways in Implant-Based Breast Reconstruction

with Acellular Dermal Matrices. Plast Reconstr Surg. 2016 Aug;138(2):173e-83e. doi: 10.1097/prs.0000000000002402. PMID: 27465177.
148. Ricci JA, Kamali P, Becherer BE, et al. Umbilical necrosis rates after abdominal-based microsurgical breast reconstruction. J Surg Res. 2017 Jul;215:257-63. doi: 10.1016/j.jss.2017.04.010. PMID: 28688657.
149. Rindom MB, Gunnarsson GL, Lautrup MD, et al. Shoulder-related donor site morbidity after delayed breast reconstruction with pedicled flaps from the back: An open label randomized controlled clinical trial. J Plast Reconstr Aesthet Surg. 2019 Dec;72(12):1942-9. doi: 10.1016/j.bjps.2019.07.027. PMID: 31515191.
150. Rogoff H, Marquez JE, Ghosh K, et al. Clinical Outcomes After Hematoma Development: A Study of 627 Tissue Expander Breast Reconstructions. Ann Plast Surg. 2020 Jul;85(S1 Suppl 1):S63-s7. doi: 10.1097/sap.0000000000002343. PMID: 32243320.
151. Roth RS, Lowery JC, Davis J, et al. Persistent pain following postmastectomy breast reconstruction: long-term effects of type and timing of surgery. Ann Plast Surg. 2007 Apr;58(4):371-6. doi: 10.1097/01.sap.0000239810.38137.84. PMID: 17413877.
152. Roth RS, Qi J, Hamill JB, et al. Is chronic postsurgical pain surgery-induced? A study of persistent postoperative pain following breast reconstruction. Breast. 2018 Feb;37:119-25. doi: 10.1016/j.breast.2017.11.001. PMID: 29145033.
153. Roy M, Sebastiampillai S, Zhong T, et al. Synergistic Interaction Increases Complication Rates following Microvascular Breast Reconstruction. Plast Reconstr Surg. 2019 Jul;144(1):1e-8e. doi: 10.1097/prs.0000000000005695. PMID: 31246793.
154. Rubio GA, McGee CS, Thaller SR. Autologous breast reconstruction surgery outcomes in patients with autoimmune connective tissue disease. J Plast Reconstr Aesthet Surg. 2019 May;72(5):848-62. doi: 10.1016/j.bjps.2018.12.038. PMID: 30665841.
155. Safran T, Al-Halabi B, Viezel-Mathieu A, et al. Direct-to-Implant, Prepectoral Breast Reconstruction: A Single-Surgeon Experience with 201 Consecutive Patients. Plast Reconstr Surg. 2020 Apr;145(4):686e-96e. doi: 10.1097/prs.0000000000006654. PMID: 32221195.
156. Salibian AA, Frey JD, Bekisz JM, et al. Ischemic Complications after Nipple-sparing Mastectomy: Predictors of Reconstructive Failure in Implant-based Reconstruction and Implications for Decision-making. Plast Reconstr Surg Glob Open. 2019 May;7(5):e2280. doi: 10.1097/gox.0000000000002280. PMID: 31333984.
157. Santosa KB, Chen X, Qi J, et al. Postmastectomy Radiation Therapy and Two-Stage Implant-Based Breast Reconstruction: Is There a Better Time to Irradiate? Plast Reconstr Surg. 2016 Oct;138(4):761-9. doi: 10.1097/prs.0000000000002534. PMID: 27673513.
158. Santosa KB, Qi J, Kim HM, et al. Long-term Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. JAMA Surg. 2018 Oct 1;153(10):891-9. doi:

10.1001/jamasurg.2018.1677. PMID: 29926096.
159. Seidenstuecker K, van Waes C, Munder BI, et al. DIEAP flap for safe definitive autologous breast reconstruction. Breast. 2016 Apr;26:59-66. doi: 10.1016/j.breast.2015.12.005. PMID: 27017243.
160. Selber JC, Bergey M, Sonnad SS, et al. Free flap breast reconstruction in advanced age: is it safe? Plast Reconstr Surg. 2009 Oct;124(4):1015-22. doi: 10.1097/PRS.0b013e3181b453fd. PMID: 19935283.
161. Seth AK, Hirsch EM, Fine NA, et al. Additive risk of tumescent technique in patients undergoing mastectomy with immediate reconstruction. Ann Surg Oncol. 2011 Oct;18(11):3041-6. doi: 10.1245/s10434-011-1913-y. PMID: 21947584.
162. Seth AK, Hirsch EM, Fine NA, et al. Utility of acellular dermis-assisted breast reconstruction in the setting of radiation: a comparative analysis. Plast Reconstr Surg. 2012 Oct;130(4):750-8. doi: 10.1097/PRS.0b013e318262f009. PMID: 23018687.
163. Seth AK, Hirsch EM, Kim JY, et al. Two surgeons, one patient: the impact of surgeon-surgeon familiarity on patient outcomes following mastectomy with immediate reconstruction. Breast. 2013 Oct;22(5):914-8. doi: 10.1016/j.breast.2013.04.013. PMID: 23673077.
164. Seth AK, Hirsch EM, Kim JY, et al. Hematoma after mastectomy with immediate reconstruction: an analysis of risk factors in 883 patients. Ann Plast Surg. 2013 Jul;71(1):20-3. doi: 10.1097/SAP.0b013e318243355f. PMID: 22791066.
165. Seth AK, Hirsch EM, Kim JY, et al. Long-term outcomes following fat grafting in prosthetic breast reconstruction: a comparative analysis. Plast Reconstr Surg. 2012 Nov;130(5):984-90. doi: 10.1097/PRS.0b013e318267d34d. PMID: 22777039.
166. Seth AK, Silver HR, Hirsch EM, et al. Comparison of Delayed and Immediate Tissue Expander Breast Reconstruction in the Setting of Postmastectomy Radiation Therapy. Ann Plast Surg. 2015 Nov;75(5):503-7. doi: 10.1097/sap.0000000000000191. PMID: 25180955.
167. Sewart E, Turner NL, Conroy EJ, et al. Patient-reported outcomes of immediate implant-based breast reconstruction with and without biological or synthetic mesh. BJS Open. 2021 Jan 8;5(1). doi: 10.1093/bjsopen/zraa063. PMID: 33609398.
168. Shaikh IA, Thomas H, Vidyadharan R, et al. Post mastectomy immediate breast reconstruction 13 years experience in a single centre. Indian J Surg Oncol. 2010 Sep;1(3):250-5. doi: 10.1007/s13193-011-0051-0. PMID: 22693373.
169. Shammas RL, Ren Y, Thomas SM, et al. The Association of Overall Annual Hospital Volume and Perioperative Outcomes following Free Flap Breast Reconstruction. Plast Reconstr Surg. 2021 Feb 1;147(2):196e-206e. doi: 10.1097/prs.0000000000007549. PMID: 33565821.
170. Shiraishi M, Sowa Y, Fujikawa K, et al. Factors associated with chronic pain following breast reconstruction in Japanese women. J Plast Surg Hand Surg. 2020 Oct;54(5):317-22. doi: 10.1080/2000656x.2020.1780246. PMID: 32589082.
171. Simon P, Barrou J, Cohen M, et al. Types of Mastectomies and Immediate Reconstructions for Ipsilateral Breast Local Recurrences. Front Oncol. 2020;10:567298. doi:

10.3389/fonc.2020.567298. PMID: 33363007.
172. Singh D, Slavin BR, Holton T. Comparing Surgical Site Occurrences in 1 versus 2-stage Breast Reconstruction via Federated EMR Network. Plast Reconstr Surg Glob Open. 2021 Jan;9(1):e3385. doi: 10.1097/gox.0000000000003385. PMID: 33564597.
173. Singh N, Reaven NL, Funk SE. Immediate 1-stage vs. tissue expander postmastectomy implant breast reconstructions: a retrospective real-world comparison over 18 months. J Plast Reconstr Aesthet Surg. 2012 Jul;65(7):917-23. doi: 10.1016/j.bjps.2011.12.040. PMID: 22342636.
174. Sobti N, Ji E, Brown RL, et al. Evaluation of Acellular Dermal Matrix Efficacy in Prosthesis-Based Breast Reconstruction. Plast Reconstr Surg. 2018 Mar;141(3):541-9. doi: 10.1097/prs.0000000000004109. PMID: 29481386.
175. Song D, Slater K, Papsdorf M, et al. Autologous Breast Reconstruction in Women Older Than 65 Years Versus Women Younger Than 65 Years: A Multi-Center Analysis. Ann Plast Surg. 2016 Feb;76(2):155-63. doi: 10.1097/sap.0000000000000527. PMID: 26637165.
176. Sorkin M, Qi J, Kim HM, et al. Acellular Dermal Matrix in Immediate Expander/Implant Breast Reconstruction: A Multicenter Assessment of Risks and Benefits. Plast Reconstr Surg. 2017 Dec;140(6):1091-100. doi: 10.1097/prs.0000000000003842. PMID: 28806288.
177. Stein MJ, Chung A, Arnaout A, et al. Complication rates of acellular dermal matrix in immediate breast reconstruction with radiation: A single-institution retrospective comparison study. J Plast Reconstr Aesthet Surg. 2020 Dec;73(12):2156-63. doi: 10.1016/j.bjps.2020.05.065. PMID: 32561384.
178. Tallroth L, Velander P, Klasson S. A short-term comparison of expander prosthesis and DIEP flap in breast reconstructions: A prospective randomized study. J Plast Reconstr Aesthet Surg. 2020 Nov 12. doi: 10.1016/j.bjps.2020.10.104. PMID: 33436336.
179. Taylor EM, Wilkins EG, Pusic AL, et al. Impact of Unilateral versus Bilateral Breast Reconstruction on Procedure Choices and Outcomes. Plast Reconstr Surg. 2019 Jun;143(6):1159e-68e. doi: 10.1097/prs.0000000000005602. PMID: 31136472.
180. Tong WM, Baumann DP, Villa MT, et al. Obese Women Experience Fewer Complications after Oncoplastic Breast Repair following Partial Mastectomy Than after Immediate Total Breast Reconstruction. Plast Reconstr Surg. 2016 Mar;137(3):777-91. doi: 10.1097/01.prs.0000479939.69211.19. PMID: 26910658.
181. Tran BNN, Ruan QZ, Cohen JB, et al. Does Hormone Therapy Use Increase Perioperative Complications in Abdominally Based Microsurgical Breast Reconstruction? Plast Reconstr Surg. 2018 Jun;141(6):805e-13e. doi: 10.1097/prs.0000000000004359. PMID: 29794694.
182. Vardanian AJ, Clayton JL, Roostaeian J, et al. Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. Plast Reconstr Surg. 2011 Nov;128(5):403e-10e. doi: 10.1097/PRS.0b013e31822b6637. PMID: 22030500.

183. Vargas CR, Koolen PG, Ho OA, et al. Preoperative CT-angiography in autologous breast reconstruction. Microsurgery. 2016 Nov;36(8):623-7. doi: 10.1002/micr.30065. PMID: 27159778.
184. Warren DK, Nickel KB, Hostler CJ, et al. Surgeon choice in the use of postdischarge antibiotics for prophylaxis following mastectomy with and without breast reconstruction. Infect Control Hosp Epidemiol. 2021 Apr;42(4):467-70. doi: 10.1017/ice.2020.462. PMID: 33040748.
185. Watterson PA, Bostwick J, 3rd, Hester TR, Jr., et al. TRAM flap anatomy correlated with a 10-year clinical experience with 556 patients. Plast Reconstr Surg. 1995 Jun;95(7):1185-94. doi: 10.1097/00006534-199506000-00007. PMID: 7761505.
186. Weichman KE, Clavin NW, Miller HC, et al. Does the use of biopatch devices at drain sites reduce perioperative infectious complications in patients undergoing immediate tissue expander breast reconstruction? Plast Reconstr Surg. 2015 Jan;135(1):9e-17e. doi: 10.1097/prs.0000000000000810. PMID: 25539357.
187. Weichman KE, Hamill JB, Kim HM, et al. Understanding the recovery phase of breast reconstructions: Patient-reported outcomes correlated to the type and timing of reconstruction. J Plast Reconstr Aesthet Surg. 2015 Oct;68(10):1370-8. doi: 10.1016/j.bjps.2015.05.039. PMID: 26165633.
188. Weichman KE, Wilson SC, Weinstein AL, et al. The use of acellular dermal matrix in immediate two-stage tissue expander breast reconstruction. Plast Reconstr Surg. 2012 May;129(5):1049-58. doi: 10.1097/PRS.0b013e31824a2acb. PMID: 22544088.
189. Wendel J. Use of Dermal Matrix in Breast Reconstruction. ClinicalTrials.gov; 2013.
190. Wilkins EG, Hamill JB, Kim HM, et al. Complications in Postmastectomy Breast Reconstruction: One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study. Ann Surg. 2018 Jan;267(1):164-70. doi: 10.1097/sla.0000000000002033. PMID: 27906762.
191. Williams JK, Bostwick J, 3rd, Bried JT, et al. TRAM flap breast reconstruction after radiation treatment. Ann Surg. 1995 Jun;221(6):756-64; discussion 64-6. doi: 10.1097/00000658-199506000-00014. PMID: 7794079.
192. Woo KJ, Lee KT, Mun GH, et al. Effect of breast reconstruction modality on the development of postmastectomy shoulder morbidity. J Plast Reconstr Aesthet Surg. 2018 Dec;71(12):1761-7. doi: 10.1016/j.bjps.2018.07.033. PMID: 30360958.
193. Woo KJ, Park JW, Mun GH, et al. Does the Use of Acellular Dermal Matrix Increase Postoperative Complications of the First-Stage Reconstruction of Immediate Expander-Implant Breast Reconstruction: A Matched Cohort Study. Ann Plast Surg. 2017 Oct;79(4):341-5. doi: 10.1097/sap.0000000000001067. PMID: 28509694.
194. Wu ZY, Han HH, Kim HJ, et al. A propensity score-matched comparison of recurrence outcomes after immediate implant vs autologous flap reconstruction in patients receiving neoadjuvant chemotherapy for breast cancer. Breast Cancer Res Treat. 2021

Mar 19. doi: 10.1007/s10549-021-06114-w. PMID: 33740204.
195. Xu F, Sun H, Zhang C, et al. Comparison of surgical complication between immediate implant and autologous breast reconstruction after mastectomy: A multicenter study of 426 cases. J Surg Oncol. 2018 Nov;118(6):953-8. doi: 10.1002/jso.25238. PMID: 30261115.
196. Yoo H, Kim BH, Kim HH, et al. Local recurrence of breast cancer in reconstructed breasts using TRAM flap after skin-sparing mastectomy: clinical and imaging features. Eur Radiol. 2014 Sep;24(9):2220-6. doi: 10.1007/s00330-014-3214-x. PMID: 24852813.
197. Yoon AP, Qi J, Kim HM, et al. Patient-Reported Outcomes after Irradiation of Tissue Expander versus Permanent Implant in Breast Reconstruction: A Multicenter Prospective Study. Plast Reconstr Surg. 2020 May;145(5):917e-26e. doi: 10.1097/prs.0000000000006724. PMID: 32332528.
198. Yueh JH, Slavin SA, Adesiyun T, et al. Patient satisfaction in postmastectomy breast reconstruction: a comparative evaluation of DIEP, TRAM, latissimus flap, and implant techniques. Plast Reconstr Surg. 2010 Jun;125(6):1585-95. doi: 10.1097/PRS.0b013e3181cb6351. PMID: 20517080.
199. Yueh JH, Slavin SA, Bar-Meir ED, et al. Impact of regional referral centers for microsurgical breast reconstruction: the New England perforator flap program experience. J Am Coll Surg. 2009 Feb;208(2):246-54. doi: 10.1016/j.jamcollsurg.2008.10.033. PMID: 19228537.
200. Zhang L, Jin K, Wang X, et al. The Impact of Radiotherapy on Reoperation Rates in Patients Undergoing Mastectomy and Breast Reconstruction. Ann Surg Oncol. 2019 Apr;26(4):961-8. doi: 10.1245/s10434-018-07135-4. PMID: 30675702.
201. Zhong T, Novak CB, Bagher S, et al. Using propensity score analysis to compare major complications between DIEP and free muscle-sparing TRAM flap breast reconstructions. Plast Reconstr Surg. 2014 Apr;133(4):774-82. doi: 10.1097/prs.0000000000000024. PMID: 24675183.
202. Zoghbi Y, Gerth DJ, Tashiro J, et al. Deep Inferior Epigastric Perforator Versus Free Transverse Rectus Abdominis Myocutaneous Flap: Complications and Resource Utilization. Ann Plast Surg. 2017 May;78(5):516-20. doi: 10.1097/sap.0000000000000936. PMID: 28052051.