Effective Health Care Program

Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

Comparative Effectiveness Review
Number 22

Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

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 are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see http://effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an e-mail list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

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Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Ms. Annabritt Chisholm (article retrieval and data entry), Ms. Liza Bialy (extraction of graphical data, formatting of evidence tables), Dr. Donna M. Dryden (presentation of results), Mr. David Jones (study screening and selection), Ms. Nicola Hooten (study selection) and Mr. Kai Wong (data extraction of prognostic factors). We also thank Ms. Rose Campbell of the Scientific Resource Center, AHRQ Effective Health Care Program, for her assistance with searching the grey literature.

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Contents

Tables

Figures

Appendixes

Executive Summary

Introduction

The rotator cuff (RC) is comprised of four muscle-tendon units, which stabilize the humeral head within the shoulder joint and aid in powering the movement of the upper extremity.[1] RC tears refer to a partial or full discontinuation of one or more of the muscles or tendons and may occur as a result of traumatic injury or degeneration over a period of years. The incidence of RC tears is related to increasing age; 54 percent of patients over the age of 60 years have a partial or complete RC tear compared with only 4 percent of adults under 40 years of age.[2] Although not a life-threatening condition, RC tears may cause significant pain, weakness, and limitation of motion.[1]

Both nonoperative and operative treatments are used in an attempt to relieve pain and restore movement and function of the shoulder.[3] The majority of patients first undergo 6 weeks to 3 months of nonoperative treatment, which may consist of any combination of pain management (medications and injections), rest from activity, passive and active exercise, and treatments with heat, cold or ultrasound. Failing nonoperative treatment, the cuff may be surgically repaired using an open, mini-open, or all-arthroscopic approach. A variety of postoperative rehabilitation programs are used to restore range of motion, muscle strength, and function following operative treatment.

Earlier operative treatment has been proposed to improve patient outcomes and result in an earlier return to work, and decreased costs;[4,5] therefore, patients and clinicians face the difficult decision of when to forgo attempts at nonoperative treatment in favor of operative treatment. Moreover, the comparative effectiveness of the various nonoperative and operative treatment options for patients with RC tears remains uncertain.

Key Questions

The following key questions (KQ) were investigated for a population of adult patients with partial- and full-thickness RC tears:

1. Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

2. What is the comparative effectiveness of operative approaches (e.g., open surgery, mini-open surgery, and arthroscopy) and postoperative rehabilitation on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

   i. Which operative approach should be used for different types of tears (e.g., partial-thickness or full-thickness; small, medium, large, or massive; with or without fatty infiltration of muscle tissue)?

3. What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual

therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.

   i. Which nonoperative treatment approach should be used for different types of tears (e.g., partial-thickness, full-thickness; small, medium, large, or massive; with or without fatty infiltration of muscle tissue)?

4. Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?
6. Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment?

   i. Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?

Methods

Literature Search

The following bibliographic databases were searched systematically for studies published between 1990 and 2009: Medline[®], Embase, Evidence-Based Medicine Reviews – The Cochrane Library, AMED, Cumulative Index to Nursing and Allied Health Literature (CINAHL), SPORTDiscus with Full Text, Academic Search Elite, Health Source, Science Citation Index Expanded (via Web of Science[®]), Scopus[®], BIOSIS Previews[®], and PubMed. Additional searches of the Grey Literature were conducted in Conference Papers Index, Computer Retrieval of Information on Scientific Projects (CRISP), Scopus[®], as well as government Web sites by the U.S. Food and Drug Administration and Health Canada. Databases that yielded included studies (Medline[®], Embase, Central, and CINAHL[®]) were searched again in September 2009 to identify recently published studies. Hand searches were conducted to identify literature from symposia proceedings from the following scientific meetings: Arthroscopy Association of North America (2007-2009), American Academy of Orthopaedic Surgeons (2007-2009), American Physical Therapy Association (2006-2008), American Shoulder and Elbow Surgeons (2005-2008), American Society of Shoulder and Elbow Therapists (2004-2008), European Congress of Physical and Rehabilitation Medicine 2008, Congress of the European Society for Surgery of the Shoulder and the Elbow (2009), and the Mid-America Orthopaedic Association (2006-2008). Ongoing studies were identified by searching clinical trials registers and by contacting experts in the field. Reference lists of relevant reviews were searched to identify additional studies. No language restrictions were applied.

Study Selection

Two reviewers independently screened titles and abstracts using general inclusion criteria. The full text publication of all articles identified as "include" or "unclear" were retrieved

for formal review. Each full-text article was assessed independently by two reviewers using detailed a priori inclusion criteria and a standardized form. Disagreements were resolved by consensus or by third-party adjudication.

Controlled and prospective uncontrolled studies were included in the review if they were published in 1990 or later, included a minimum of 11 participants, focused on adults with a partial or full-thickness tear that was confirmed by imaging or intraoperative findings, and examined any operative or nonoperative intervention or postoperative rehabilitation. In addition, studies were required to report on at least one outcome of interest (quality of life, function, time to return to work, cuff integrity, pain, range of motion, and/or strength) and have a minimum followup duration of 12 months for operative studies. For the review update, only controlled studies were included.

Quality Assessment and Rating of the Body of Evidence

Two reviewers independently assessed the methodological quality of included studies. The Cochrane Collaboration's "risk of bias" tool was used to assess randomized controlled trials and controlled clinical trials. Observational analytic studies were assessed using modified cohort and case-control Newcastle-Ottawa Quality Assessment Scales. The methodological quality of uncontrolled studies was assessed using a quality checklist developed by the University of Alberta Evidence-based Practice Center; the checklist consisted of three items: consecutive enrollment, incomplete outcome data, and standardized/independent approach to outcome assessment. In addition, the source of funding was recorded for all studies.

The body of evidence was rated by one reviewer using the EPC GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. The strength of evidence was assessed for four key outcomes considered by the clinical investigators to be most clinically relevant: health-related quality of life, functional outcomes, time to return to work, and cuff integrity. The following four major domains were assessed: risk of bias (low, medium, high), consistency (no inconsistency, inconsistency present, unknown, or not applicable), directness (direct, indirect), and precision (precise, imprecise).

Data Extraction

Data were extracted by one reviewer using a standardized form and verified for accuracy and completeness by a second reviewer. Extracted data included study characteristics, inclusion/exclusion criteria, participant characteristics, interventions, and outcomes. Reviewers resolved discrepancies by consensus or in consultation with a third party.

Data Analysis

Evidence tables and qualitative descriptions of results were presented for all included studies. Comparative studies were considered appropriate to combine in a meta-analysis if the study design, study population, interventions being compared, and outcomes were deemed sufficiently similar. Results were combined using random effects models. Statistical heterogeneity was quantified using the I-squared (I^2) statistic. Graphs were created to display the preoperative and postoperative scores of uncontrolled studies, cohort studies, and trials over the duration of the study followup period.

Results

Description of Included Studies

The search strategy identified 5,677 citations; 137 unique studies met the eligibility criteria and were included in the review. The studies included 27 trials, 39 cohort studies, and 71 uncontrolled studies. The number of participants in the studies ranged from 12 to 224 (median=55 [IQR: 33 to 93]). The mean age of study participants ranged from 41.2 to 80 years.

Methodological Quality of Included Studies

All the randomized controlled trials and controlled clinical trials were considered to have a high risk of bias. The most common sources of potential bias were inadequate blinding, inadequate allocation concealment, and incomplete outcome data. The methodological quality of the cohort studies was moderate, with a median score of 5 stars on a possible score of 8 stars (IQR: 4 to 6). Common weaknesses in the design of the studies included lack of independent blind outcome assessment and failure to control adequately for potential confounding factors. Uncontrolled studies generally had moderate quality, with consecutive enrollment, adequate followup, and standardized outcome assessment being reported in 63 percent, 77 percent, and 44 percent of studies, respectively. Across all studies, a source of funding was rarely reported (n=49, 36 percent).

Results of Included Studies

The results of the included studies are presented by the key question(s) they address. A table with the summary of findings for nonoperative and operative interventions is presented below.

Key Question 1: Early versus late surgical repair. One study compared early surgical repair versus late surgical repair after failed nonoperative treatment. Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.

Key Question 2: Comparative effectiveness of operative interventions and postoperative rehabilitation. A total of 113 studies examined the effectiveness of operative interventions, while 11 studies evaluated postoperative rehabilitation protocols following surgery. A median of 55 patients (IQR: 34 to 95) with a median age of 58.6 years (IQR: 55.5 to 61.7) were included in the operative studies. Males comprised an average of 64.6 percent of study participants. For postoperative rehabilitation, studies included a median of 61 participants (IQR: 36 to 79.5) with a median age of 58.0 years (IQR: 56.3 to 60.8). Males comprised an average of 58.9 percent of study participants.

Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, and debridement), technique (i.e., suture or anchor type or configuration) or augmentation for RC repair. The majority of surgical studies (32 comparative studies and 58 uncontrolled studies) evaluated operative approaches. The comparative studies provided moderate evidence indicating no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. Similarly, there was moderate evidence demonstrating no difference in function between mini-open and

arthroscopic repair and arthroscopic repair with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared with arthroscopic debridement. The strength of evidence was low for the remaining comparisons and outcomes examined in the studies, precluding any conclusions regarding their comparative effectiveness. The uncontrolled studies consistently reported functional improvement from preoperative to postoperative scores, regardless of the type of approach used (open, mini-open, or arthroscopic), the study design, the sample size of the study, or the type of outcome measure used.

Operative techniques were examined in 15 comparative studies. Six studies compared single-row versus double-row fixation of repairs, providing moderate evidence of no clinically significant difference in function and no difference in cuff integrity. There was moderate evidence for no difference in cuff integrity between mattress locking and simple stitch. The evidence was too limited to make conclusions about the other techniques.

Eight studies, including three comparative and five uncontrolled studies, assessed augmentations for operative repair. The three comparative studies were relatively small and no overall conclusions were possible. Although the five uncontrolled studies evaluated different types of augmentation, they all indicated improvement in functional score from baseline to final followup.

Of the 11 postoperative rehabilitation studies (10 comparative, 1 uncontrolled), 3 compared continuous passive motion with physical therapy versus physical therapy alone. These three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with continuous passive motion. Each of the remaining studies examined different rehabilitation protocols; therefore, the evidence was too limited to make any conclusions regarding their comparative effectiveness.

Key Question 3: Comparative effectiveness of nonoperative interventions. Nonoperative interventions were examined in three comparative and seven uncontrolled studies. The studies included a median of 42 patients (IQR: 25.3 to 73.3), with a median age of 61 years (IQR: 60.4 to 61.5). Males comprised an average of 50 percent of participants. Each of the comparative studies assessed different interventions, including: sodium hyaluraonate versus dexamethasone; rehabilitation versus no rehabilitation (not otherwise specified); and physical therapy, oral medications, and steroid injection versus physical therapy, oral medications, and no steroid injection. The limited evidence precludes conclusions of comparative effectiveness. The degree of improvement in functional outcome scores varied considerably across the uncontrolled studies.

Key Question 4: Comparative effectiveness of nonoperative versus operative interventions. Five studies compared nonoperative to operative treatments, with a median sample size of 103 (IQR: 40 to 108). The mean ages in the studies ranged from 46.8 to 64.8 years. Males represented 55 percent of study participants. The interventions varied across studies, but generally the nonoperative arms included components such as steroid injection, stretching, and strengthening and were compared with open repair or debridement. The evidence was too limited to make conclusions regarding the comparative effectiveness of the interventions.

Key Question 5: Complications. A total of 85 studies provided data on 34 different complications of nonoperative, operative, and postoperative rehabilitation interventions. Complications were poorly reported, with studies providing limited information on how

complications were defined and assessed. In 21 studies, it was reported that no complications occurred during the course of the study. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.

Key Question 6: Prognostic factors. Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions are limited, due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, workers' compensation board (WCB) status, sex, and duration of symptoms generally showed no significant impact.

The following table summarizes the findings of the studies and indicates the overall strength of the evidence on each topic examined.

Summary of strength of evidence for nonoperative and operative interventions for RC tears

Comparison (number of studies)	Strength of evidence	Summary
Early vs. late repair		
Early RCR vs. late RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Operative approaches		
Open RCR vs. mini-open RCR (n=3)	Moderate	No statistically significant or clinically important difference for function. Some evidence for earlier return to work or sports (by approximately 1 month) with mini-open repairs.
	Low	The evidence was too limited to make a conclusion for health-related quality of life.
Mini-open RCR vs. arthroscopic RCR (n=10)	Moderate	No difference in function or cuff integrity.
Open RCR vs. arthroscopic RCR (n=3)	Low	The evidence was too limited to make a conclusion.
Open or mini-open RCR vs. arthroscopic RCR (n=2)	Moderate	No difference in function.
	Low	The evidence was too limited to make a conclusion for cuff integrity.
Open RCR vs. open or arthroscopic debridement (n=4)	Moderate	Some evidence for greater improvement in function for open RCR.
Arthroscopic RCR with acromioplasty vs. without acromioplasty (n=3)	Moderate	No difference in function.
Arthroscopic RCR vs. acromioplasty alone	Low	The evidence was too limited to make a conclusion.
Biceps tenotomy vs. tenodesis (n=1)	Low	The evidence was too limited to make a conclusion.
RCR vs. palliative treatment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Mini-open RCR plus tenodesis with detachment vs. without detachment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic debridement with biceps tenotomy vs. without tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Complete open RCR vs. partial open RCR vs. debridement (n=1)	Low	The evidence was too limited to make a conclusion.

Summary of strength of evidence for nonoperative and operative interventions for RC tears (continued)

Comparison (number of studies)	Strength of evidence	Summary
Operative approaches (continued)		
Open RCR with classic open acromioplasty vs. open RCR with modified open acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.
Operative techniques		
Single-row vs. double-row suture anchor fixation (n=6)	Moderate	No clinically important difference for function and no difference for cuff integrity.
Bioabsorbable tacs vs. suture tying (n=1)	Low	The evidence was too limited to make a conclusion.
Side-to-side vs. tendon-to-bone fixation (n=1)	Low	The evidence was too limited to make a conclusion.
Nonabsorbable vs. absorbable sutures (n=1)	Low	The evidence was too limited to make a conclusion.
Bioabsorbable corkscrews vs. metal suture anchor (n=1)	Low	The evidence was too limited to make a conclusion.
Mattress locking vs. simple stitch (n=2)	Moderate	No difference in cuff integrity.
	Low	The evidence was too limited to make a conclusion for function.
Mattress vs. transosseous suture (n=1)	Low	The evidence was too limited to make a conclusion.
Ultrasonic welding vs. hand-tied knots (n=1)	Low	The evidence was too limited to make a conclusion.
Staple fixation vs. side-to-side suture (n=1)	Low	The evidence was too limited to make a conclusion.
Operative augmentation		
Porcine small intestine submucosa vs. no augmentation (n=2)	Low	The evidence was too limited to make a conclusion.
Patch graft vs. no augmentation (n=1)	Low	The evidence was too limited to make a conclusion.
Postoperative rehabilitation		
Continuous passive motion with PT treatment vs. PT treatment (n=3)	Moderate	No clinical or statistical difference in function. Some evidence for earlier return to work with continuous passive motion.
Aquatic therapy with land-based therapy vs. land-based therapy (n=1)	Low	The evidence was too limited to make a conclusion.
Inpatient vs. day patient rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Individualized PT program with home exercise vs. home exercise (n=1)	Low	The evidence was too limited to make a conclusion.
Progressive vs. traditional loading (n=1)	Low	The evidence was too limited to make a conclusion.
Inpatient rehabilitation vs. outpatient CGE (n=1)	Low	The evidence was too limited to make a conclusion.
Standardized vs. non-standardized PT program (n=1)	Low	The evidence was too limited to make a conclusion.
Videotape vs. PT home exercise instruction (n=1)	Low	The evidence was too limited to make a conclusion.

Summary of strength of evidence for nonoperative and operative interventions for RC tears (continued)

Comparison (number of studies)	Strength of evidence	Summary
Nonoperative interventions		
Sodium hyaluraonate vs. dexamethasone (n=1)	Low	The evidence was too limited to make a conclusion.
Rehabilitation vs. no rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy, oral medications and steroid injection vs. physical therapy, oral medications and no steroid injection (n=1)	Low	The evidence was too limited to make a conclusion.
Nonoperative vs. operative treatment		
Shock-wave therapy vs. mini-open RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Steroid injection, physical therapy, and activity modification vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy vs. open or mini-open RCR	Low	The evidence was too limited to make a conclusion.
Physical therapy treatment, oral medication, and steroid injection vs. arthroscopic debridement vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.
Passive stretching, strengthening, and corticosteroid injection vs. open repair with acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.

CGE = Concept Global d'Epaule; RCR = rotator cuff repair; SLAP = superior labral from anterior to posterior

Future Research

Recommendations for further research:

- Primary evidence is needed, comparing the effectiveness of early versus delayed surgery, nonoperative versus operative interventions, and among the nonoperative treatment options. Future research examining the comparative effectiveness of open, mini-open, or arthroscopic approaches is also a priority, as arthroscopic procedures are more costly and technically difficult.
- All future studies should employ a comparison or control group and should ensure comparability of treatment groups, optimally through the use of randomization.
- Future research should seek to minimize bias by blinding outcome assessors, using validated and standardized outcome assessment instruments, and ensuring adequate allocation concealment (where applicable) and the appropriate handling and reporting of missing data.
- Studies examining the long-term effectiveness of treatments over the course of several years are needed; at the very least, studies should follow patients for a minimum of 12 months.
- To avoid numerous studies on disparate interventions, the interventions and comparisons chosen for study should be guided by consensus regarding the most promising and/or controversial interventions.

- To ensure consistency and comparability across future studies, consensus is needed on outcomes that are important to both clinicians and patients. Moreover, consensus on minimal clinically important differences is needed to guide study design and interpretation of results.
- To permit the appropriate interpretation of results, future research needs to be reported in a consistent and comprehensive manner.

Conclusions

For the majority of interventions, only sparse data are available, precluding firm conclusions for any single approach or for the optimal overall management of this condition. The paucity of evidence related to early versus delayed surgery is of particular concern, as patients and providers must decide whether to attempt initial nonoperative management or proceed immediately with surgical repair. The majority of the data is derived from studies of low methodological quality or from study designs associated with higher risk of bias (e.g., observational and before-and-after studies). Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. Complication rates were generally low and the majority of complications were not deemed to be clinically important; therefore, the benefit of receiving treatment for rotator cuff tears appears to outweigh the risk of associated harms. Future research is needed to determine the relative effectiveness of rotator cuff treatment options.

Chapter 1. Introduction

Condition and Prevalence

The rotator cuff (RC) is comprised of four muscle-tendon units (supraspinatus, infraspinatus, subscapularis, and teres minor) that originate on the scapula and combine to form a covering or "cuff" around the top of the humeral head.[1] The RC helps to stabilize the humeral head within the shoulder joint and aids in powering the upper extremity through the movements of flexion, extension, abduction, adduction and external and internal rotation.

A "tear" is the term given to a discontinuation in either one or more of the tendons or muscles that make up the RC; tears are classified as either partial or full thickness. Partial-thickness tears involve only a portion of the tendon thickness and do not lead to retraction of the muscle-tendon unit.[6] In contrast, full-thickness tears refer to a complete discontinuity of RC fibers, resulting in contact between the articular and bursal spaces. RC tears are rated as small (<1 cm), medium (1-3 cm), large (3-5 cm), and massive (>5 cm). Tears that involve two or more tendons may also be classified as massive and may require more complex reconstruction.[7] The degree of functional impairment of the muscle depends in part on the size of the tear.[8]

The RC can be torn from a single traumatic injury or, more commonly, a tear may result from overuse of the muscles and tendons over a period of years, leading to degeneration of the tendon that progresses to a tear.[9] A cuff tear may also occur concurrently with another injury to the shoulder, such as a fracture or dislocation, or be the result of poor vascular supply, impingement, glenohumeral instability, scapulothoracic dysfunction or congenital abnormalities, such as os acromiale.[10] RC tears also occur in the shoulders of overhead or throwing athletes, whose throwing motion involves maximum abduction and external rotation making the shoulder vulnerable to injury from repetitive high energy forces.[11] Once a tear occurs, it is unlikely to heal without treatment.[6] Left untreated, large tears may result in chronically retracted muscle-tendon units that undergo fatty degeneration resulting in weakness, a potentially irreversible process.[9]

The incidence of RC tears is expected to increase with the growth of an aging population that is more active and less willing to accept functional limitations.[12] Magnetic resonance imaging (MRI) studies have shown partial or complete tears in only 4 percent of patients under 40 years of age compared with 54 percent of patients over 60 years of age.[2] Larger tear size and occurrence of bilateral RC tears also increase with age.[13] Although large proportion of patients with RC tears are asymptomatic, research has shown that over 50 percent of individuals with asymptomatic RC tears will develop pain over an average of 2.8 years.[10]

Although not a life-threatening condition, RC tears may cause significant pain, weakness, and limitation of motion.[1] A shoulder disorder can increase functional dependency in the elderly due to difficulties in completing activities of daily living.[13] In younger adults, this morbidity may also lead to significant disability, including absenteeism from work and lost productivity. The impact of RC disease on lost productivity is reflected in the high costs associated with shoulder injuries in the workers' compensation system, and has been found to be the second most common cause after back pain for time away from work in manual laborers.[14-16] According to data from the United States Department of Labor, 253,670 occupational shoulder injuries were reported in 2007. The average time off of work due to occupational shoulder injuries ranged from 4.3 to 7.5 days; however, 41.5 percent of occupational shoulder injuries required more than 31 days away from work in 2007.[17] In addition, severe pain may affect sleep. The impact of RC disease on health-related quality of life, as measured by the SF-36, is comparable to the effects of

hypertension, myocardial infarction, congestive heart failure, diabetes mellitus, and clinical depression.[18]

Diagnosis and Treatment

Diagnosis of an RC tear involves a complete history, appropriate clinical examination, and a comparison of the involved shoulder to the uninjured side. The shoulder is palpated to identify areas of tenderness and range of motion of the shoulder is assessed both actively and passively.[19] RC strength is evaluated and a number of provocative maneuvers are completed to assist in the development of a differential diagnosis. Since most clinical tests for rotator cuff pathology have been shown to have poor diagnostic accuracy[20] and give poor estimates of cuff tear size,[21] diagnostic imaging should be employed as part of the preliminary work-up for chronic shoulder pain. Radiographs may be used initially followed by MRI, arthrography, computed tomography (CT) or ultrasound for further evaluation and clarification of possible pathology.[19]

Two treatment modalities, nonoperative and operative, are used in an attempt to relieve pain and restore movement and function of the shoulder.[3] Most patients initially undergo 6 weeks to 3 months of nonoperative treatment; however, surgical repair may be indicated early on in the appropriate patient with a traumatic RC injury and a significant functional deficit.[22] The most common nonoperative interventions include pain management (medications and injections), rest from activity, and a variety of treatments, both passive and active, delivered by physical therapists. Success rates with nonoperative treatments vary from less than 50 percent to greater than 90 percent; however, studies have used a variety of interventions and evaluation tools.[22]

Modalities used to decrease pain include heat or cold, ultrasound, and iontophoresis,[13,23] as well as medications such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections. When pain is controlled the patient can participate in physical therapy exercises designed to increase shoulder flexibility and strength. These exercises are designed to return the shoulder to optimal functioning through improvements in range of motion, proprioception and strength.[23] When other nonoperative modalities have failed to reduce pain (e.g., relative rest, activity modification, physical therapy, and NSAIDs), corticosteroid injections combined with a local anesthetic may be used.[24] Controversy exists regarding the benefit of corticosteroid injections in the treatment of RC tears. Study results investigating the efficacy of injections vary, and it is unclear if corticosteroid injections provide significant benefit to the patient over treatment with NSAIDs.[13,23]

Failing nonoperative treatment, there are three surgical approaches to rotator cuff repair (RCR): open, mini-open, and arthroscopic, the last two of which have evolved throughout the last decade.[25] The first surgical repair of a torn RC was performed in 1909 by Ernest Codman.[26] In 1972, Charles Neer developed an open surgical technique, which uses a large (9-centimetre) incision over the shoulder from the anterior edge of the acromion to a point just lateral to the coracoid. The deltoid is split (5 centimetres) and dissected from the anterolateral acromion and the distal clavicle. This allows for adequate visualization of the RC tear. A small wedge-shaped piece of bone is removed from underneath the acromion, as is the coracoacomial ligament. In the case of acromioclavicular osteophytes and acromioclavicular arthritis, up to 2 centimetres of the distal clavical may be excised along with any prominences on the acromial side. Careful reattachment of the deltoid to the acromion and clavicle is required following the repair.[27]

A mini-open repair combines an open technique with arthroscopy to reduce the size of the incision required to perform the repair. Initially, portals are created to allow the insertion of

the arthroscope and arthroscopic tools. To perform the repair, an additional incision is created to visualize the RC. The surgeon reaches the RC tear by splitting the deltoid muscle in line with its fibers rather than releasing it from the acromion. A temporary suture is placed in the deltoid to prevent further tearing of the muscle and damage to the axillary nerve while the RCR is completed. Mini-open repair is currently considered best suited for small and medium tears, but may be used for larger tears.[26] The mini-open approach reduces the chance of deltoid injury and failure of the deltoid repair that may occur with a traditional open technique.[27]

Arthroscopic surgery uses specially designed instruments (a camera, a fiberoptic light source, and the instruments required for the repair) that are inserted into the joint through a series of small incisions or portals. Modern arthroscopic techniques now allow for not only the evaluation of both the bursal and articular surfaces of the RC, as well as other structures within the shoulder joint, but also allow for definitive treatment of the injured RC.[11] Most authors agree that indications for arthroscopic repair are similar to those for open repair.[27] Arthroscopic repair has a number of benefits over open repair including: shorter hospital stays, lower levels of pain, better cosmetic outcomes, preservation of the deltoid muscle, and direct inspection of the glenohumeral joint.[27]

Regardless of whether surgery is open, mini-open, or arthrocopic, treatment may involve any combination of RCR, debridement, and acriomplasty. The repair itself involves suturing the torn edges of the involved tendon(s) together and repair of the tendon back to the humeral head. A full or partial repair may be performed, depending on the severity of the tear. As its name implies, full repair is the complete repair of the tear. When a complete repair is not feasible, such as when the tear is extremely large, a partial repair may be performed in order to restore adequate function and delay the progression of the tear.[8] Debridement involves removing loose fragments of tendon, bursa, and other debris from the space in the shoulder where the RC moves.[11] Acromioplasty involves the removal of bone from the underside of the anterolateral acromion (the tip of the shoulder blade), thus creating more room in the subacromial space, and decreasing mechanical impingement of the acromion on the RC. Subacromial decompression combines an acromioplasty with the removal of the subacromial bursa and, in some cases, removal of the coracoacromial ligament. Though performed on their own, debridement, acromioplasty and/or subacromial decompression are often performed in combination with an RCR.

Other procedures that may accompany RCR include labral repair, biceps tenotomy or tenodesis, and acromioclavicular joint arthroplasty. A labral repair involves the surgical repair of the labrum, a cuff of cartilage that circles the glenoid or socket of the shoulder and helps to stabilize the shoulder. A labral tear may occur as a result of trauma to the shoulder or fray and tear as part of the aging process. A biceps tenodesis detaches the tendon from its insertion at the top of the labrum and reattaches the tendon in the bicipital groove at the anterolateral aspect of the proximal humerus. Biceps tenotomy involves the release of the biceps tendon from its attachment without reattachment to the proximal humerus, thus allowing the tendon to retract distally in the upper arm outside of the shoulder joint. These procedures are performed for partial tears of the biceps tendon that cannot be repaired, bicep tendons that are subluxed or dislocated, or in situations when tears of the superior glenoid labrum cannot be repaired.

The final step in the surgical treatment of RC tears is a program of rehabilitation, the development of which is based on the type of surgery, size of tear, tissue quality, fixation methods, and patient characteristics.[3] Following surgery, the shoulder is generally immobilized using a sling, both as a comfort measure and as a reminder to the patient to avoid use of the shoulder. Passive motion, continuous passive motion (the continuous movement of the repaired

shoulder by a machine), and unassisted exercises are then used to restore range of motion and muscle strength, and to re-establish shoulder stability and function. Strengthening exercises are generally added gradually with progressive levels of resistance as sudden increases in exercise demands may lead to a failure of the repair. The primary goal of rehabilitation should be to protect the cuff repair, promote healing, restore passive and active motion, and increase muscular strength.[3]

It has been proposed that earlier surgical intervention may result in better outcomes, earlier return to work and decreased costs;[4,5] thus, clinicians face the difficult decision of when to forego attempts at nonoperative management in favour of surgical treatment. Despite the significant morbidity and cost associated with RC tears, there remains much uncertainty regarding the comparative effectiveness of the many nonoperative and operative treatment options.

Outcome Assessment Scales

A wide variety of outcome measures have been used to evaluate the efficacy of RC treatments by assessing changes in patient function over the study period. A list of the frequently reported outcome measures is provided in Table 1. The majority of scales used in the RC literature are disease-specific questionnaires developed for the assessment of the shoulder; however, generic scales (e.g., SF-36) have also been used. The scales can broadly be classified into health-related quality of life and functional outcome measures. Health-related quality scales are developed with the intent of assessing patients' perception of the impact of their condition on their physical, social, psychological/emotional, and cognitive state. Functional outcome measures evaluate a patient's ability to perform activities of daily living and frequently incorporate clinically assessed components, such as range-of-motion or strength.

Three health-related quality of life measures were used in the studies reviewed in this report: the Rotator Cuff Quality of Life (RC-QOL) scale, the Short-Form-36 (SF-36) and the Western Ontario Rotator Cuff (WORC) index. These self-reported scales assess similar domains, such as pain, physical symptoms, social and emotional functioning. The RC-QOL and SF-36 are scored on a scale of 0 to 100 points, where higher scores indicate better quality of life, while the WORC Index provides a score of up to 2,100 points with higher scores indicating poorer outcomes. There is evidence to support the reliability and convergent validity of each of the scales.

Nine scales assessing functional outcomes were frequently used in the included studies. Of these, four scales were entirely patient self-reported, while the remaining five included both self-reported and health professional-assessed components. The majority of the measures assessed pain, activities of daily living, range of motion and strength. Less commonly evaluated domains included patient satisfaction, joint stability, and recreation activities. Most scoring systems calculated an overall score out of 100 points, however the distribution of the points by domain varied across the tools. Psychometric properties also varied across the scales. The majority of the scales have evidence to support their reliability. In addition, some scales demonstrated strong correlations with other commonly used shoulder assessment scales.

Table 1. Summary of most frequently reported outcome measures

Health-related quality of life scales			
Outcome measure	**Domains**	**Scaling**	**Psychometric properties (validity; reliability; responsiveness)**
Rotator Cuff Quality of Life (RC-QOL)[28] *Patient self-reported*	Symptoms & physical complaints (16 items) Work-related concerns (4 items) Sports & recreation (4 items) Lifestyle issues (5 items) Social & emotional issues (5 items)	34 items, each rated on a 100-point VAS. Total score ranges from 0 (worst) to 100 (best).	Correlation with SF-36 (r_p=0.778), ASES (r_p=0.842),[28] Correlation with WORC (r_s≥0.70);[29] ICC 0.97* (test-retest reliability presented as avg error difference of 5.05%);[28] SRM 1.43,[29] MCID NR
Short Form-36 (SF-36)[30] *Patient self-reported*	Physical function (10 items) Role-physical (4 items) Bodily pain (2 items) General health (5 items) Vitality (4 items) Social function (2 items) Role-emotional (3 items) Mental health (5 items)	Items are scored using 5-level response options. Domains are summed & translated to two aggregate summary measures (physical health & mental health), with scores ranging from 0 (worst health) to 100 (best health)	Moderate correlation with shoulder instruments (SPADI, SST, ASES) 0.58≤r_p≤0.72;[31] Cronback's α≥0.85; ICC≥0.80 for all dimensions except social functioning (0.76);[30] Low responsiveness: SRM: PCSS 1.0, MCSS 0, subscales on bodily pain: 1.1[32]
Western Ontario Rotator Cuff Index (WORC)[33] *Patient self-reported*	Physical Symptoms (6 items) Sports/Recreation (4 items) Work (4 items) Lifestyle (4 items) Emotions (3 items)	21 items, each rated on a 100-point VAS. Scores presented in raw form or converted to a percentage. Best score (no decrease in shoulder-related QOL) is 100% (raw score=0). Worst score (extreme decrease in shoulder-related QOL) is 0% (raw score=2100).	As a discriminative instrument, correlated most strongly with ASES (r=0.68) & DASH (r=0.63); as a evaluative instrument, correlated with ASES (r=0.75) & UCLA (r=0.65);[33] ICC 0.96;[33] SRM 1.44,[29] MID change in total score of 245.26 (11.7%), moderate difference change in total score of 371.3 (17.68%), and large difference change in total score of 773.4 (36.82%)[33]

Functional outcome scales: self-reported			
Outcome measure	**Domains**	**Scaling**	**Psychometric properties (validity; reliability; responsiveness)**
Disabilities of the Arm, Shoulder and Hand (DASH)[34,35] *Patient self-reported*	Items related to activities of daily living, pain, weakness & function. *Optional modules to assess: high performance sport/ music or work.	30 items, rated on a 5-point Likert scale. Total score ranges from 0 points (best) to 100 points (worst).	Strong correlation (r≥0.70) with commonly used scales, except SF-36 and clinical variables (r=0.30–0.70);[36] ICC 0.82–0.98, weighted avg 0.90, SEM 2.84–5.22, weighted avg 4.5, MDC (90% CI) 6.6–12.2, weighted avg 10.5;[36] Responsiveness similar to other joint-specific measures. ES 0.4–1.4, weighted avg 1.1, SRM 1.1–1.7, weighted avg 1.3, MCID 10.2[36]

ASES = American Shoulder and Elbow Surgeons scale; avg = average; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; ES = effect size; ICC = interclass correlation coefficient; JOA = Japanese Orthopaedic Association scale; MCID = minimal clinically important difference; MCSS = mental component summary score; MDC = minimal detectable change; MID = minimal important difference; PCSS = physical component summary score; PENN = University of Pennsylvania Shoulder Score; RC-QOL = Rotator Cuff Quality of Life questionnaire; ROM = range of motion; SEM = standard error of the measure; SF-36 = Short Form-36; SST = Simple Shoulder Test; SPADI = Shoulder Pain and Disability Index; SRM = standardized response mean (mean change score/SD change score); SRQ = Shoulder Rating Scale; UCLA = University of California Los Angeles scale; UEFI = upper extremity functional index; VAS = visual analogue scale; WORC = Western Ontario Rotator Cuff Index
*Calculated by UAEPC using raw data from Hollinshead et al.

Table 1. Summary of most frequently reported outcomes measures (continued)

Functional outcome scales: self-reported			
Outcome measure	**Domains**	**Scaling**	**Psychometric properties (validity; reliability; responsiveness)**
Insalata Shoulder Rating Questionnaire (SRQ)[37] *Patient self-reported*	Global Assessment Domain (10-point VAS) Pain (4 items) Activities of Daily Living (6 items) Recreation & Athletic Activities (3 items) Work (4 items) Satisfaction (1 item) Importance (patients ranks the 2 areas most important for improvement)	18 items rated using 5-level response options; one item rated on a 10-point VAS. Total scores range from 17 (worst) to 100 (best) points & are calculated using a weighting system.	High correlation with the Arthritis Impact Measurement Scales 2 (0.56–0.89);[37] Cronbach's α 0.86, Kappa 0.73–0.97;[37] SRM 1.9,[37] MCID 13[38]
Simple Shoulder Test (SST)[39] *Patient self-reported*	Items related to activities of daily living.	12 functional task questions answered yes=1 or no=0. Total score is the number of "yes" responses; Best score 12/12, represents no disability; Total score range is 0-12 (transformed to a percentage).	Strong correlation (r≥0.70) with commonly used scales, except SF-36 and clinical variables (r=0.30–0.70);[36] Cronbach's α 0.85, SEM (95% CI) 11.65 (22.8),[40] ICC 0.97–0.99, weighted avg 0.98, MDC not defined;[36] ES 0.8, SRM 0.8–1.8, weighted avg 0.9, MCID not defined[36]
Shoulder Pain and Disability Index (SPADI)[41,42] *Patient self-reported*	Pain (5 items) Disability (8 items)	13 items each scored on a scale from 0 to 10. Total score ranges from 0 points (best) to 100 points (worst)	Strong correlation (r≥0.70) with commonly used scales, except SF-36 and clinical variables (r=0.30–0.70);[36] Cronbach's α 0.95,0.96, ICC>0.85, 0.85–0.95, weighted avg 0.89, SEM 6.2–7.8, MDC (90% CI) 18.1;[36] ES 1.2–2.1, weighted avg 1.6, SRM 1.1–1.7, weighted avg 1.3, MCID 8, 13.2[36,38]
Functional outcome scales: self-reported and clinician-assessed			
Outcome measure	**Domains**	**Scaling**	**Psychometric properties (validity; reliability; responsiveness)**
American Shoulder and Elbow Surgeons (ASES)[43,44] *Patient self-reported & clinician-assessed*	Pain (1 item, 10-point VAS) Activities of daily living (10 items, rated on 4-point scale) ROM – active & passive Physical signs (0 to 3) Strength (0 to 5 grade) Instability (0 to 3)	Shoulder score derived from self-reported components (pain & cumulative activities of daily living score), ranging from 0 points (worst) to 100 points (best).	Strong correlation (r≥0.70) with commonly used scales, except SF-36 and clinical variables (r=0.30–0.70);[36] Cronbach's α 0.86, ICC>0.84, ICC 0.84–0.96, weighted avg 0.91,[36] MDC (90% CI) 9.4, SEM 6.7;[45] ES 0.9–3.5, weighted avg 1.4, SRM 0.5–1.6, weighted avg 1.1, MCID 6.4[36,45]
Japanese Orthopaedic Association (JOA) *Patient self-reported & clinician-assessed*	Pain (30 points) Function (strength in abduction, endurance, activities of daily living) (20 points) ROM (30 points) Radiographic evaluation (5 points) Joint stability (15 points)	Total score ranges from 0 points (worst) to 100 points (best).	Spearman's rank correlation coefficient between observers: r>0.78

6

Table 1. Summary of most frequently reported outcome measures (continued)

Functional outcome scales: self-reported and clinician-assessed			
Outcome measure	**Domains**	**Scaling**	**Psychometric properties (validity; reliability; responsiveness)**
University of California Los Angeles (UCLA)[46,47] *Patient self-reported & clinician-assessed*	Pain (10 points) Function (10 points) ROM (5 points) Strength (5 points) Patient satisfaction (5 points)	Maximum 35 points (best).	Fair correlation with CMS (r_s=0.66) & SST(r_s=0.76);[47] ICC: pain (0.59–0.78), function (0.51–0.89), satisfaction (0.79)[48]
University of Pennsylvania Shoulder Score (PENN)[49] *Patient self-reported & clinician-assessed*	Pain (30 points) Satisfaction Function (20 items, 4-category Likert scale) ROM Strength	Maximum 100 points for both the self-reported and clinician-assessed measures; higher scores indicate greater (best) function	Strong correlation with CMS (r=0.85) & ASES (r=0.87); Cronbach's α 0.93, ICC (95% CI) 0.94 (0.89-0.97), MDC (90% CI) 8.5, SEM (90% CI) 12.1 ES 1.01, SRM 1.27, MCID 11.4[49]

Objectives

The objective of this review is to provide a comprehensive synthesis of the evidence examining the effectiveness of nonoperative and operative interventions for the treatment of RC tears. The report is intended for a broad audience, including professional societies developing clinical practice guidelines, patients and their care providers, as well as researchers conducting studies on treatments of this condition. Outcomes of interest include health-related quality of life, shoulder function, time to return to work, cuff integrity, pain, range of motion and strength of the shoulder. The key questions investigated in this report are presented below, alongside an analytic framework (Figure 1).

Key Questions

The following key questions were investigated for a population of adult patients with partial- and full-thickness RC tears:

1. Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

2. What is the comparative effectiveness of operative approaches (e.g., open surgery, mini-open surgery, arthroscopy) and postoperative rehabilitation on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

    a. Which operative approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?

3. What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, other treatments and modalities typically delivered by physical therapists, osteopaths and chiropractors.

    b. Which nonoperative treatment approach should be used for different types of tears (e.g., partial-thickness, full-thickness, small, medium, large or massive, with or without fatty infiltration of muscle tissue)?

4. Does operative repair compared to nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?

5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?

6. Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size / severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment?

      c. Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early vs. delayed surgical treatment?

Figure 1. Analytic framework corresponding to the key questions
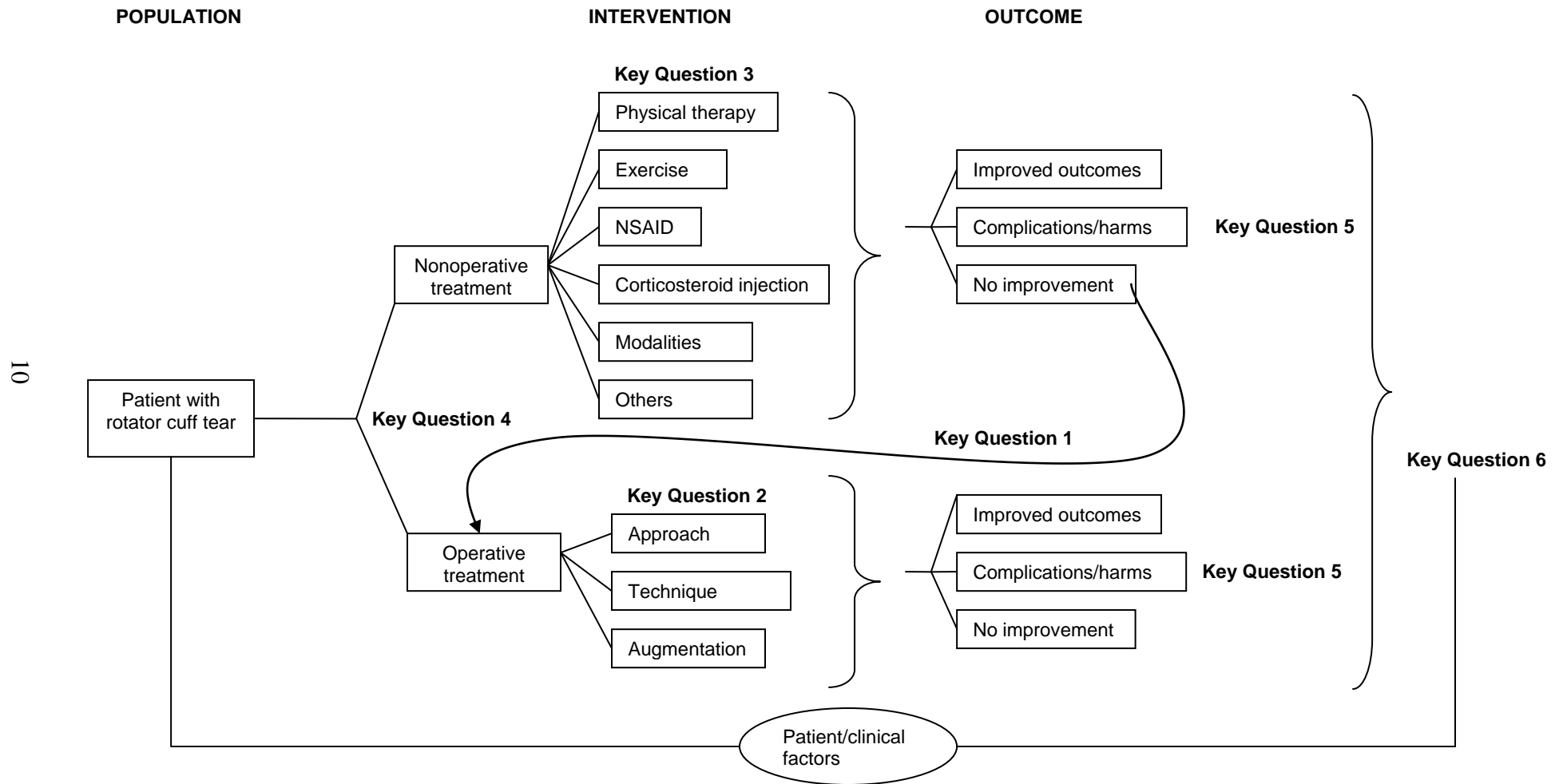
Chapter 2. Methods

This chapter describes the prospectively designed protocol that the University of Alberta Evidence-based Practice Center (UAEPC) used to synthesize the evidence on nonoperative and operative interventions for RC tears. The topic refinement process for developing the key questions is described. We outline the literature search strategy, the selection process for identifying relevant articles, the process for extracting data from eligible studies, the methods for assessing the methodological quality of individual studies and for rating the overall body of evidence, and our approach to data analysis and synthesis.

Topic Refinement and Technical Expert Panel

The UAEPC was commissioned to conduct a preliminary literature review to gauge the availability of evidence and to draft the key research questions for a full comparative effectiveness review. In consultation with AHRQ and the Scientific Resource Center, a Technical Expert Panel (TEP) was invited to provide input in the development of the key questions and scope of the evidence report. The public was invited to comment on these questions over a period of 3 months. After reviewing the public commentary, the key questions were finalized and submitted to AHRQ for approval.

The TEP was subsequently invited to provide high-level content and methodological expertise throughout the development of the comparative effectiveness report. The names of technical experts are available in Appendix A.

Literature Search Strategy

Search strategies were designed and implemented to identify evidence relevant to the report. The following bibliographic databases were searched systematically for studies published from 1990 to 2009: Medline[®], Embase, EBM Reviews–The Cochrane Library, AMED, Cinahl[®], SPORTDiscus with Full Text, Academic Search Elite, Health Source, Science Citation Index Expanded (via Web of Science[®]), Scopus[®], BIOSIS Previews[®], and PubMed. Additional searches of the Grey Literature were conducted in Conference Papers Index, Computer Retrieval of Information on Scientific Projects (CRISP), Scopus[®], as well as government websites by the U.S. Food and Drug Administration and Health Canada. Databases that yielded included studies (Medline[®], Embase, Central, and CINAHL) were searched again in September 2009 to identify recently published studies.

Search terms were selected by scanning search strategies of systematic reviews on similar topics and by examining index terms of potentially relevant studies. A combination of subject headings and textwords were adapted for each electronic resource which included terms for rotator cuff ('rotator cuff*' or 'rotator interval*' or 'supraspin?tus' or infraspin?tus or "teres minor" or 'subscapularis' or 'anterosuperior' or 'posterosuperior') and tear terms ('tear' or 'tears' or 'tore' or 'torn' or 'lesion*' or 'rupture*' or 'avuls*' or 'injur*' or 'repair*' or 'debride*'). Language restrictions were not applied. (See Appendix B for detailed search strategies)

Hand searches were conducted to identify literature from symposia proceedings from the following scientific meetings: Arthroscopy Association of North America (2007-2009), American Academy of Orthopaedic Surgeons (2007-2009), American Physical Therapy

Association (2006-2008), American Shoulder and Elbow Surgeons (2005-2008), American Society of Shoulder and Elbow Therapists (2004-2008), European Congress of Physical and Rehabilitation Medicine 2008, Congress of the European Society for Surgery of the Shoulder and the Elbow (2009) and the Mid-America Orthopaedic Association (2006-2008). Ongoing studies were identified by searching clinical trials registers (See Appendix B) in addition to contacting experts in the field. Reference lists of relevant reviews were searched to identify additional studies.

The results from the literature searches were entered into a Reference Manager for Windows bibliographic database version 11.0 (© 2004-2005 Thomson ResearchSoft) for management.

Criteria for Study Selection

The study inclusion and exclusion criteria were developed in consultation with the TEP (Table 2). In consultation with the TEP, a post hoc decision was made to exclude uncontrolled studies that were either retrospective or unclear in their direction, as well as case series. For the literature update, only comparative studies were included. The decision was made to include only operative studies published in English due to lack of translation resources. English, German and French publications were considered for studies examining nonoperative treatments and postoperative rehabilitation, since the literature on these interventions was sparse (n=7). This resulted in the exclusion of 80 of the 1010 studies (7.9 percent) retrieved for selection.

Table 2. Eligibility criteria for the review

Category	Criteria
Publication type	*Include:* Primary research published in 1990 or later *Exclude:* Non-English studies, with the exception of nonoperative studies published in French or German
Study design	*Include:* Any controlled study design and prospective uncontrolled studies (for update, only controlled designs) *Exclude:* Studies with ≤10 participants
Population	Adults (≥18 years) with partial- or full-thickness RC tear(s), confirmed by imaging or intraoperative findings. Excluded were studies whose primary intention is not the treatment of RC tears, or in which greater than 20% of participants have rheumatoid or other inflammatory arthritis (not OA), or are undergoing revision of failed RC tears.
Intervention	Any operative or nonoperative intervention or postoperative rehabilitation for the treatment of RC tears. Studies examining tendon transfers, arthroplasty or postoperative pain management were excluded.
Comparator	Any operative or nonoperative intervention or postoperative rehabilitation was an eligible comparator.
Outcomes of interest	Studies must report at least one of the following outcomes: quality of life, disability / function, time to return to work / activities, pain, range of motion, strength. Minimum duration of followup was 12 months for operative studies.

Article screening was conducted in two phases. First, two reviewers (AM, DJ, LH, JS, NH) independently screened the titles, keywords and abstracts (when available) to determine if an article met the general inclusion criteria. Each article was rated as "include," "exclude," or "unclear." The full text of all articles classified as "include" or "unclear" by one or both of the reviewers was retrieved for detailed review. Second, two reviewers independently assessed each study using a standard inclusion/exclusion form (Appendix C1). Disagreements were resolved by consensus or third-party adjudication. Non-English studies were assessed by only one reviewer.

Assessment of Methodological Quality

The internal validity of randomized controlled trials (RCTs) and controlled clinical trials (CCTs) was assessed using the Cochrane Collaboration Risk of Bias tool.[50] (Appendix C2) This tool consists of six domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and "other" sources of bias) and a categorization of the overall risk of bias. Each separate domain is rated "yes," "unclear," or "no." Blinding and incomplete outcome data were assessed separately for subjective outcomes (e.g., quality of life or function scales) and objective clinical outcomes (e.g., range of motion). The overall assessment was based on the responses to individual domains. If one or more individual domains were assessed as having a high risk of bias, the overall score was rated as high risk of bias. The overall risk of bias was considered low only if all components were rated as having a low risk of bias. The risk of bias for all other studies was rated as unclear. In addition, information was collected for each study on the source of funding[51] and whether an intention-to-treat analysis was performed.[52,53]

Observational analytic studies were assessed using modified cohort and case-control Newcastle-Ottawa Quality Assessment Scales (NOQAS) (Appendix C2).[54] The NOQAS includes seven items assessing sample selection, comparability of cohorts, and the assessment of outcomes. One star was allotted for each item that was adequately addressed in the study, with the exception of the comparability of cohorts, for which a maximum of two stars could be given. The overall score was calculated by tallying the stars, with a total possible score of eight stars. In addition, information regarding the source of funding was collected.[51]

The methodological quality of uncontrolled studies was assessed using a quality checklist developed by the UAEPC (Appendix C2). The checklist assessed three components theoretically associated with bias in observational studies: consecutive enrollment, incomplete outcome data and standardized/independent approach to outcome assessment. In addition, the source of funding was documented for each study.[51]

Two reviewers (JS, JRS, KB, SM) independently assessed the methodological quality of the included studies. Non-English studies were assessed by only one reviewer (LH, JS) due to limited translation resources. Each assessment form was pilot tested on a sample of studies. Decision rules regarding application of the tools was developed a priori through discussions with content and methodology experts. Discrepancies in quality assessment were resolved through consensus or third-party adjudication.

Data Extraction

Data were extracted using a standardized form and entered into a Microsoft Excel™ database (Microsoft Corp., Redmond, WA) (Appendix C3). Data were extracted by one reviewer (AM, JS, JRS, KB, LH, SM) and checked for accuracy and completeness by a second (JS, JRS, KB, SM). Extracted data included study characteristics, inclusion/exclusion criteria, participant characteristics, interventions, and outcomes. Reviewers resolved discrepancies in data extraction by consensus or in consultation with a third party.

Operative studies were divided into three broad categories by type of intervention: approach, technique, and augmentation. Studies which focused on the use of an open, mini-open or arthroscopic approach to RC repair (RCR), debridement, acromioplasty or other procedure were categorized as "operative approach." Studies that compared the effectiveness of different

suture or anchor types or configurations were labelled as investigating an "operative technique." "Operative augmentation" was reserved for studies that examined the use of a surgical augment, such as the use of grafts or patches in the repair of an RC tear.

Before-and-after (BA) studies were defined as single-arm studies that report both baseline and followup data scores. Cohort studies that compared the effectiveness of a single intervention across two patient populations (e.g., open repair in older vs. younger patients) were classified as "cohort studies with BA data." For the purposes of examining the effectiveness of operative procedures (Key Question 2), the data across the patient groups was combined and analysed as for a BA study. BA studies and cohort studies with BA data are collectively referred to as uncontrolled studies. The effects of prognostic variables on treatment outcomes were explored separately in Key Question 6.

A post hoc decision was made to extract data on cuff integrity as an additional outcome of interest for all the included studies. For the uncontrolled studies, the decision was made to examine only four key outcomes considered to be the most clinically relevant by the clinical investigators (DS, CL): health-related quality of life, functional outcomes, time to return to work, and cuff integrity.

Applicability

The applicability of the body of evidence was assessed following the PICOTS (population, intervention, comparator, outcomes, timing of outcome measurement, setting) format used to assess study characteristics. Factors that may potentially weaken the applicability of individual studies were extracted and presented in the evidence tables (Appendix E).

Rating the Body of Evidence

We used the EPC GRADE approach, based on the standard GRADE approach,[55,56] to assess the quality of the body of evidence for each outcome. The strength of evidence was assessed for four key outcomes identified by the clinical investigators to be most clinically important: health-related quality of life, functional outcomes, time to return to work, and cuff integrity. The following four major domains were examined: risk of bias (low, medium, high), consistency (no inconsistency, inconsistency present, unknown or not applicable), directness (direct, indirect), and precision (precise, imprecise). When no studies were available for an outcome or comparison of interest, the evidence was simply graded as insufficient. Each key outcome on each comparison of interest was given an overall evidence grade based on the ratings for the individual domains. The overall strength of evidence was graded as high (further research is very unlikely to change our confidence in the estimate of effect), moderate (further research may change our confidence in the estimate of effect and may change the estimate), low (further research is likely to change the confidence in the estimate of effect and is likely to change the estimate) or insufficient (evidence either is unavailable or does not permit estimation of an effect). The body of evidence was graded by one reviewer (LH).

Data Analysis

The following data assumptions were made and imputations performed to transform reported data into the form required for analysis. Graphical data was extracted using CorelDRAW® 9.0 (Corel Corp., Ottawa, Canada). If necessary, means were approximated by

14

medians, and 95 percent confidence intervals (95% CI) were used to calculate approximate standard deviations (SD).

Evidence tables and qualitative description of results are presented for all included studies. When appropriate, meta-analyses were performed to support inferences on the effectiveness of nonoperative and operative interventions for treatment of RC tears. We reported outcomes only if numeric data were available in the study or could be derived from graphs. Outcomes that were only described qualitatively (e.g., "pain improved by 6 weeks") or reported only as a p-value were not included in the evidence tables or data analysis.

Decision-making criteria regarding the instances in which pooled estimates should be derived from individual studies were established a priori. Comparative studies were considered appropriate to combine if the study design, study population, interventions being compared, and outcomes were sufficiently similar. Trials (RCTs and CCTs) and cohort studies were analysed separately. Study populations were considered similar if the type of tear (full-thickness or partial-thickness) and size of tear was common among eligible studies. More than two studies comparing the same intervention arms were necessary in order to conduct a meta-analysis. Finally, studies were only combined when they reported the use of similar outcome measures. Scales were classified as being either health-related quality of life measures or as functional outcome scales, and meta-analyses were only conducted within scales of the same classification.

Graphs were created to display the preoperative and postoperative scores of uncontrolled studies, cohort studies and trials, over the duration of the study followup period. Due to the low level of evidence represented by uncontrolled studies, these studies were not analyzed quantitatively.

Quantitative results were meta-analyzed in Review Manager version 5.0 (The Cochrane Collaboration, Copenhagen, Denmark). For continuous variables measured on the same scale (e.g., range of motion), mean differences were calculated for individual studies, and weighted mean differences (WMD) was calculated for the pooled estimates. For continuous variables measured on different scales (e.g., health-related quality of life or functional outcome scales), mean differences were calculated for separate studies and standardized mean differences (SMD) were calculated for the pooled estimates. All results are reported with 95% CI when possible. Statistically significant results were considered to be clinically relevant if they exceeded a minimal clinically important difference of ten percent on any given scale.[57]

Results were combined using random effects models. Statistical heterogeneity was quantified using the I-squared (I^2) statistic. A value greater than 50 percent was considered to be substantial heterogeneity.[58,59]

Chapter 3. Results

Literature Search

The search strategy identified 5,677 citations from electronic databases. After screening titles and abstracts, 1008 studies were assessed to be potentially relevant. Two additional study were identified for further examination by hand searching the reference lists from previous systematic reviews and conference proceedings. The full text articles of twenty-nine studies could not be retrieved through the university interlibrary loan service (Appendix F). Therefore, the full text of 981 potentially relevant reports was retrieved and evaluated for inclusion in the review. The application of the selection criteria to the 981 reports resulted in 137 studies being included and 844 being excluded (Figure 2).

The five main reasons for excluding studies from this review were (1) ineligible study design (n=182), (2) the article did not report on primary research (n=153), (3) the diagnosis of RC tear was not confirmed using imaging or intraoperative findings (n=107), (4) no baseline data was reported in a single-arm study (n=89), and (5) the study was not published in English (n=79). Two hundred and thirty-four studies were excluded for other reasons (Figure 2). A complete list of excluded studies and reasons for exclusion is provided in Appendix F.

Thirteen studies were excluded because they were considered to be multiple publications; that is, they were either abstracts of full reports, reports published subsequent to the primary study or reported secondary outcomes. Generally, the report that provided the longest followup data or the largest sample size was regarded as the primary study. For one study, the initial publication was included since it reported full baseline data,[60] however the 10-year followup data from a subsequent publication was incorporated into the results.[61] In two instances, both the primary publication[62,63] and their respective secondary publications[64,65] were included in the review, since the articles focused on different key questions.

Figure 2. Flow-diagram for study retrieval and selection

Total number of citations retrieved from electronic literature searches
N = 5677

References selected for further examination of titles and abstracts
N = 1008

Potentially relevant references identified by hand searching; **N = 2**

Not retrieved; **N = 29**

Articles retrieved and evaluated in full for inclusion
N = 981

Reasons for exclusions
- Ineligible study design = **182**
- Not primary research = **153**
- Not confirmed RC tear = **107**
- No baseline data = **89**
- Non-English = **79**
- Primary intention not tx of RCT = **59**
- Not intervention of interest = **47**
- No numeric outcome of interest = **39**
- Enrolled ≤10 participants = **34**
- Follow-up <12 mo = **23**
- Multiple publication = **13**
- Not population of interest = **15**
- Published before 1990 = **4**

Included
N = 137

Excluded
N = 844

Description of Included Studies

One hundred and thirty-seven studies provided evidence on the six key questions addressed in this report. Appendix F describes the key characteristics of the studies included in the review. One study[66] examined the effect of early vs. late surgical RCR (Question 1). All of the included studies addressed the effectiveness of an intervention for the treatment of RC tears (Questions 2 to 4). Operative treatments (Question 2) were evaluated in 113 (82 percent) studies,[60,62-65,67-174] while postoperative rehabilitation procedures (Question 2) were examined in 11 (8 percent) studies.[175-185] Ten (7 percent) studies[165,186-194] examined the effectiveness of nonoperative treatments (Question 3) and five (4 percent) studies[66,165,195-197] compared nonoperative therapy to operative intervention (Question 4). One of the studies[165] included four study arms (two operative and two nonoperative) and was included in three categories: operative interventions, nonoperative interventions and nonoperative vs. operative interventions. Complications (Question 5) were addressed in 85 studies.[63-68,70,73-78,80-84,88,91-99,101,103,107-114,117-122,124,127,129-132,134,136-140,145-147,151-153,155-159,161-163,167,169-171,173,174,176,179,180,182,184,186,189,190,194]

Prognostic factors (Question 6) were examined in 72 studies.[60,62,64,65,68,70-77,80,83,84,86,89,90,92,93,99-101,103-105,107-110,112,114-117,119-125,128,130,131,133-135,141,142,144,145,147-149,151,154,157,160,162,164,166,173-175,180,181,184,187,188,197]

The studies were published between 1990 and 2010 (median=2005 [interquartile range (IQR): 2003 to 2007]). All of the studies were published as peer reviewed articles, with the

exception of four abstracts.[87,140,183,195] Studies were conducted in the United States (n=49, 36 percent), Europe (n=56, 41 percent), Asia (n=18, 13 percent) and other regions (n=14, 10 percent). The studies were published in English, with the exception of four French (two nonoperative[186,190] and two postoperative rehabilitation[177,181]) and three German (two nonoperative[188,193] and one postoperative rehabilitation[182]) studies. The number of participants in the studies ranged from 12 to 224 (median=55 [IQR: 33 to 93]). The mean age of study participants ranged from 41.2 to 80 years.

Of the 137 included studies, 21 (15 percent) were RCTs. All were parallel, two-arm, superiority trials. One RCT[194] examined nonoperative interventions, twelve[71,73,78,81,96-98,102,105,109,133,136] evaluated operative interventions and six[178-180,182,184,185] assessed postoperative rehabilitation and two studies[66,195] compared operative and nonoperative treatments. Six (4 percent) of the included studies were CCTs, of which five assessed operative treatments[114,117,137,143,163] and one[176] assessed postoperative rehabilitation. Thirteen prospective cohort studies were included. Operative interventions were evaluated in eleven,[64,72,77,85,88,112,118,129,140,147,148] while one study[196] compared operative to nonoperative treatments, and one[177] evaluated postoperative rehabilitation. There were 26 retrospective cohort studies included in the review, including two postoperative rehabilitation study,[181,183] 22 operative studies,[63,68,75,87,94,106,113,119,125,132,134,138,139,154,157,159,165,167,170-173] one nonoperative study[191] and two studies comparing nonoperative vs. operative treatments.[165,197]

There were 71 uncontrolled studies, including 55 BA studies, 10 prospective cohorts with BA data, and five retrospective cohort with BA data. Of the BA studies, six[186,187,189,190,192,193] evaluated a nonoperative intervention, 48 examined an operative intervention,[60,65,67,69,70,74,76,79,80,82-84,89-91,95,99-101,103,104,108,110,111,115,116,120-124,127,130,131,142,145,151-153,155,156,158,160,161,166,168,169,174] and one[175] assessed postoperative rehabilitation. Nine of 10 prospective cohort studies with BA data evaluated operative interventions,[62,86,92,93,107,126,141,144,146] while the remaining study[188] examined a nonoperative intervention. All five retrospective cohorts with BA data examined operative interventions.[128,135,149,150,162] One case-control BA study[164] assessed an operative procedure.

Methodological Quality of Included Studies

The methodological quality of each included study was assessed by two independent reviewers and the consensus ratings are presented in Appendix D, Tables D1 to D3. A summary of the overall quality trends by study design is presented below.

Randomized Controlled and Controlled Clinical Trials

The risk of bias assessments for each of the RCTs and CCTs is presented in Appendix D, Table D1. All of the 21 RCTs were rated as having high risk of bias for both patient-rated and clinically assessed outcomes. The allocation sequence was adequately generated in 16 trials.[66,73,78,96-98,102,105,109,133,136,178-180,182,185] Allocation concealment was adequate in eight trials,[66,78,96,98,105,133,136,179] inadequate in three trials,[73,81,178] and unclear in the remaining trials. No trial used sufficient methods to ensure the blinding of participants and outcome assessors for either patient-reported or clinically assessed outcomes. Half of the RCTs adequately addressed incomplete outcome data (n=11).[66,73,78,81,97,102,105,109,136,182,194] All but two studies[136,195] were free of selective outcome reporting, and other sources of bias were identified in five trials.[78,109,136,182,184] Five trials reported conducting an intention-to-treat analysis.[66,96,98,136,182]

The six CCTs were similarly all rated as having high risk of bias. None of these trials reported adequate sequence generation, allocation concealment or blinding. Three trials addressed incomplete outcome data adequately.[114,117,163] All of the trials were free of suggestion of selective outcome reporting. The impact of other sources of bias was unclear in four studies.[114,137,163,176] Intention-to-treat analysis was reported in one CCT.[176]

The source of funding was not reported in the majority of the trials (n=15, 56 percent). For studies that reported funding, sources included an academic institution,[136,179] government,[109,136,178] foundation[136,185] and industry.[78,109,182] Five studies reported receiving no funding.[73,105,117,143,180]

Cohort Studies

The Newcastle-Ottawa quality assessment of the 39 cohort studies is presented in Appendix D, Table D2. Data was prospectively collected in 13 cohort studies[64,72,77,85,88,112,118,129,140,147,148,177,196] and retrospective in 26 studies.[63,68,75,87,94,106,113,119,125,132,134,138,139,154,157,159,165,167,170-173,181,183,191,197] Overall, the methodological quality of the cohort studies was moderate (median score=5/8 stars; IQR: 4 to 6). The majority enrolled patients that were rated to be truly or somewhat representative of average patients in the community (n=28, 72 percent). The nonexposed cohort was drawn from the same community as the exposed cohort in 36 studies; in three studies, the nonexposed cohort was drawn from a different source.[94,139,197] All studies ascertained the exposure status from a secure source, most commonly from surgical records. Nearly half of the studies (n=18, 46 percent) controlled for potential confounding variables in their design or analysis.[72,75,77,87,112,119,125,134,147,148,154,159,165,167,170,173,181,196] In four studies, there was independent blind outcome assessment;[112,134,147,148] the remaining studies had self-reported outcomes (n=20, 51 percent), were described as unblinded (n=6, 15 percent), or did not describe methods for outcome assessment (n=9, 23 percent). All of the cohort studies had a followup duration of at least 12 months, with the exception of two postoperative rehabilitation studies[177,183] and one nonoperative study.[191] The rate of followup was considered unlikely to introduce bias in the majority of studies (n=24, 62 percent); however, nine studies were rated as having inadequate followup,[72,113,119,129,132,134,157,167,177] and six did not describe the followup rate.[85,87,94,106,138,140]

Source of funding was not reported by 29 of the cohort studies (74 percent). One study received government funding,[148] one received foundation and government funding,[72] and one received industry funding.[134] The remaining seven studies reported receiving no funding.[68,75,94,106,125,147,170]

Uncontrolled Studies

The methodological quality of the 55 BA studies, 15 cohort studies with BA data, and one case-control study with BA data was assessed for three domains: consecutive enrollment, incomplete outcome data, and approach to outcome assessment. The quality assessment is presented in Appendix D, Table D3. Of the 71 studies, 45 (63 percent) reported consecutive enrollment of participants, three (4 percent) did not use consecutive enrollment[76,79,93] and the remaining 23 studies were unclear. The majority of studies (n=55, 77 percent) adequately addressed incomplete outcome data. Seven studies[69,116,131,142,160,175,187] had inadequate followup and nine were unclear.[89,107,123,124,149,158,186,189,190] A standardized approach was used to assess

outcomes in 29 studies (41 percent). Of the remaining studies, 31 (44 percent) were unclear and 11 used no standardized assessment approach.[80,90,93,100,101,131,149,160,161,168,175]

Source of funding was not reported in the majority of studies (n=44, 62 percent). No funding was received in 22 studies (31 percent).[74,80,83,99,100,107,110,111,120-123,127,131,135,141,144,153,158,160,164,174] The remaining studies were supported through foundations,[116,168,187] industry,[193] or professional associations.[175]

Results of Included Studies

This section is organized by the six key research questions addressed in this report. For each intervention category, the evidence from comparative studies (trials and cohorts) and uncontrolled studies is presented separately. A summary of key findings is provided, followed by a description of the characteristics and findings of the individual trials and cohort studies. Tables summarizing the general patient and summary characteristics, as well as the outcome data, are presented for each comparative study. In addition, a grading of the body of evidence is based on the comparative studies only and presented by key outcome. The uncontrolled studies are described in aggregate form and the results are presented visually for each intervention category. Appendix E presents detailed evidence tables on each of the included studies.

Question 1. Early Surgical Repair vs. Late Surgical Repair

One RCT recently conducted by Moosmayer et al.[66] provided data for the comparison of early vs. delayed surgical RCR. One hundred and three patients with small or medium-sized full-thickness RC tears were randomly assigned to nonoperative treatment consisting of manual techniques and exercises (n=51) or immediate surgical repair (n=52); 102 were followed for a minimum of 12 months. Nine of the patients initially randomized to nonoperative treatment were not satisfied with their degree of improvement after completing 15 treatment sessions, and were offered secondary surgery; these patients constituted the late surgery group. Health-related quality of life was assessed using the Short Form-36 Health Survey (SF-36) scale, while function was measured using the Constant-Murley score (CMS), the American Shoulder and Elbow Surgeons (ASES) index. In addition, cuff integrity was evaluated in the two surgical groups using magnetic resonance imaging (MRI). SF-36 scores were not reported for the secondary surgical group. Both the early and delayed surgical groups showed clinically important improvement from baseline to 12 month assessments. The improvement in the ASES score was similar between the early and late surgery groups (improvement of 47.1 and 46.8 points, respectively), however the improvement in the early surgical group was superior to the late surgical group on the CMS (improvement of 41.5 points and 33.6 points, respectively. The level of significance between these difference scores was not reported. Comparisons between the early surgery group and the nonoperative treatment arm are presented under Question 5 (nonoperative vs. operative treatment).

No other studies directly compared the effectiveness of early vs. late surgical repair of RC tears. However, a number of studies conducted a subgroup or regression analysis to assess whether time to surgery was a significant factor in predicting operative outcomes. Results of these studies are presented under Question 6 (prognostic variables).

Table 3. Study and patient characteristics for studies assessing early RCR vs. delayed RCR

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Moosmayer S,[66] 2010	**G1:** PT (51) **G2:** Open / mini-open RCR (early) (52) **G3:** Secondary surgery (late) (9)* RCT	**G1:** 61±7.6 yr / Males: 36 (71) **G2:** 59±7.5 yr / Males: 37 (71) **G3:** NR	FTT; Sm, Med **G1:** 9.8±9.8 mo; **G2:** 12.3±18.7 mo; **G3:** NR

FTT = full-thickenss tear; med = medium; mo = month; RCT = rotator cuff tear; SD = standard deviation; sm = small; yr = year
*Subset of patients who were initially randomized to PT, however later underwent secondary surgery due to lack of improvement; total sample size is 103 patients

Table 4. Outcome data for studies assessing early RCR vs. delayed RCR

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 / Group 3 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Moosmayer S,[66] 2010	**G1:** PT (51) **G2:** Open / mini-open repair (early) (51) **G3:** Secondary surgery (late) (9)† 12 mo	SF-36 (95%CI) 6 mo 12 mo 6 mo 12 mo	PCSS: 38.6 (36.2–41.1) 47.3 (44.7–50.0) 48.9 (46.0–51.7), p=NR MCSS: 57.3 (54.7–59.9) 57.6 (55.5–59.7) 57.5 (55.4–59.5), p=NR	PCSS: 38.2 (36.6–39.9) 47.9 (45.3–50.4) 50.7 (47.8–53.6), p=NR MCSS: 54.1 (50.9–57.3) 57.5 (55.0–60.0) 56.2 (53.7–58.8), p=NR **G3:** NR	G1 vs. G2: PCSS: 0.84>p>0.10‡ MCSS: 0.92>p>0.29‡ G2 vs. G3: NR
		ASES*(95%CI) 6 mo 12 mo	48.2 (44.1–52.2) 75.8 (70.2–81.4) 79.2 (72.7–85.5), p=NR	45.5 (41.5–49.6) 84.5 (80.3–88.6) 92.6 (88.6–96.6), p=NR **G3:** 42.1 (30.1–54.2) Pre-op§: 48.9 (32.6–65.2) 6 mo: 75.4 (59.2–91.7) 12 mo: 88.9 (77.4–100.0), p=NR	G1 vs. G2: p<0.0005‡ G2 vs. G3: NR
		CMS* (95%CI) 6 mo 12 mo	38.4 (34.4–42.4) 64.1 (58.5–69.7) 66.8 (60.6–73.1), p=NR	35.3 (31.6–39.0) 64.9 (60.2–69.7) 76.8 (72.6–80.9), p=NR **G3:** 36.2 (27.3–45.2) Pre-op§: 35.9 (26.9–44.9) 6 mo: 57.9 (43.8–72.0) 12 mo: 69.8 (55.1–84.4), p=NR	G1 vs. G2: p=0.002‡ G2 vs. G3: NR
		Cuff integrity n/N (%), MRI 12 mo	NR	38/50 (76) ‖ **G3:** 8/9 (89)	G1 vs. G2: NR G2 vs. G3: p=0.67‡

ABD = abduction; ASES = American Shoulder and Elbow Surgeon score; CI = confidence interval; cm = centimetre; CMS = Constant-Murley Score; G = group; mo = month; MCSS = mental component summary score; MRI = magnetic resonance imaging; NR = not reported; PCSS = physical component summary score; PT = physical therapy; SF-36 = Short Form-36 Health Survey; VAS = visual analogue scale
Subscores reported
†Subset of patients who were initially randomized to PT, however later underwent secondary surgery due to treatment failure; total sample size is 103 patients
‡Calculated by UAEPC
§Score after failed PT, prior to surgery
‖ One case was unable to undergo MRI

Table 5. Strength of evidence for early RCR vs. delayed RCR

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Early vs. late RCR	1; 103 (102)	HRQL	RCT Medium	Unknown	Direct	Unknown	Absent	Low
	1; 103 (102)	Function	RCT Medium	Unknown	Direct	Unknown	Absent	Low
	1; 103 (102)	Cuff integrity	RCT Medium	Unknown	Direct	Unknown	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

HRQL = health-related quality of life; n/a = not applicable; RCR = rotator cuff repair; RCT = randomized controlled trial

Question 2. Comparative Effectiveness of Operative Interventions and Postoperative Rehabilitation

One hundred and thirteen studies examined the comparative effectiveness of operative interventions, while an additional eleven studies evaluated postoperative rehabilitation therapies. Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, debridement), technique (i.e., suture or anchor type or configuration) or augmentations for RCR.

Overall, operative approaches were examined in 90 studies (32 comparative studies, 58 uncontrolled studies). Operative techniques were evaluated in 15 comparative studies. Augmentations for RCR were assessed in eight studies (three comparative studies, five uncontrolled studies). Eleven studies examined postoperative rehabilitation (10 comparative studies, one uncontrolled study).

Operative Approach—Comparative Studies

Summary. Thirty-two controlled studies making 13 comparisons assessed the effectiveness of different operative approaches for RCR. The following is a summary of results by comparison:

- One RCT[136] and two retrospective cohort studies[68,106] compared open RCR against mini-open RCR. Overall there was no statistically significant difference in function; however, the two cohort studies demonstrated significantly earlier return to work or sports by approximately 1 month for mini-open repairs. The individual studies showed no statistical or clinically important differences between groups for health-related quality of life, range of motion, or strength.
- Ten studies (one CCT,[114] two prospective[85,148] and seven retrospective cohort studies[119,125,154,157,167,171,173]) compared mini-open vs. arthroscopic RCR. All studies measured function and overall there was no difference between groups. However, heterogeneity was observed between the CCT and cohort studies, with the cohort studies showing more conservative results. Other outcomes were assessed across the studies and no differences were found for range of motion (n=5), strength (n=2), cuff integrity (n=2), and pain VAS (n=4). While the majority of these studies were retrospective cohorts, the studies were relatively well done and scored moderate or high on the relevant quality assessment instrument.
- One prospective[112] and two retrospective cohort studies[87,134] compared open RCR vs. arthroscopic RCR. Two prospective cohort studies[72,77] compared open/mini-open RCR with arthroscopic RCR. There were no differences between the groups for function. One study[77] found better pain relief for the group receiving arthroscopic repair than the open/mini-open group at final followup.
- Two CCTs[137,143] and two retrospective cohort studies[139,165] compared open RCR with open or arthroscopic debridement. Overall, improvement in function was significantly greater for open RCR. The magnitude of the difference varied across studies from an absolute difference of 2.2 on a 35-point scale[143] to 11.5 on an 83-point scale;[165] the cohort studies showed larger absolute differences than the trials. One of the cohort studies[165] showed a significantly shorter time to maximum range of motion in the arthroscopic debridement group (3.2 vs. 6.8 months).

- Two RCTs[102,133] compared arthroscopic RCR vs. arthroscopic RCR with acromioplasty, while one prospective cohort study[140] compared arthroscopic RCR vs. acromioplasty alone. No differences in function were reported between the groups.
- Seven additional studies compared different operative approaches: biceps tenotomy vs. tenodesis,[75] RCR vs. palliative treatment (partial repair or biceps tenotomy),[94] arthroscopic RCR plus superior labral from anterior to posterior (SLAP) lesion repair vs. arthroscopic RCR plus biceps tenotomy,[96] arthroscopic RCR plus tenodesis with proximal biceps detachment vs. without proximal biceps detachment,[97] arthroscopic debridement with tenotomy vs. without tenotomy,[63] complete open RCR vs. partial open RCR vs. debridement,[138] and open RCR plus classic open acromioplasty vs. open RCR plus modified open acromioplasty.[163] There were few clinically important differences between groups being compared across studies. No differences in function were observed for five of the comparisons.[63,75,97,138,163] One study[94] found a significant difference in function favouring RCR over palliative treatment. Another study[96] showed greater postoperative University of Califonia Los Angeles (UCLA) index scores for arthroscopic RCR with biceps tenotomy compared with arthroscopic RCR plus SLAP repair; however, the absolute difference of 4 points on the 35-point scale is of questionable clinical importance.

Overall conclusions for operative approaches are challenging due to the wide variation in comparisons across studies. Generally, the studies showed few differences in function between interventions. One exception was greater improvement for open RCR compared with arthroscopic debridement; the strength of evidence for this finding was considered moderate. In addition, watertight anatomical repair was favoured for function compared with palliative treatment in patients with massive RC tears, and one small study[96] suggested greater postoperative function for arthroscopic RCR with biceps tenotomy compared to arthroscopic RCR plus SLAP repair; the strength of evidence for these findings was low and needs replication in future studies before general conclusions can be made.

Results by individual study. Thirty-two comparative studies[63,68,72,75,77,85,87,94,96,97,102,106,112,114,119,125,133,134,136-140,143,148,154,157,163,165,167,171,173] examined the effectiveness of different operative approaches for RCR. Five of the studies were RCTs, four were CCTs, six were prospective cohort designs, and 17 were retrospective cohort designs. The median sample size was 77 patients (IQR: 53 to 101). The following operative approaches were assessed: open vs. mini-open RCR,[68,106,136] mini-open vs. arthroscopic RCR,[85,114,119,125,148,154,157,167,171,173] open vs. arthroscopic RCR,[87,112,134] open or mini-open RCR vs. arthroscopic RCR,[72,77] open RCR vs. arthroscopic debridement,[137,139,143,165] arthroscopic RCR vs. acromioplasty,[102,133,140] biceps tenotomy vs. tenodesis,[75] complete repair vs. palliative treatment (partial repair with biceps tenotomy),[94] arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy,[96] RCR with tenodesis with proximal biceps detachment vs. RCR with tenodesis without proximal biceps detachment,[97] arthroscopic debridement with biceps tenotomy vs. without biceps tenotomy,[63] complete open RCR vs. partial open RCR vs. debridement.[138] open RCR with classic vs. modified acromioplasty.[163] Five comparisons contained studies that were sufficiently similar in terms of conditions, interventions, and outcomes that meta-analysis was possible: open RCR vs. mini-open RCR, mini-open vs.

arthroscopic RCR, open vs. arthroscopic RCR; open or mini-open RCR vs. arthroscopic RCR, and open RCR vs. arthroscopic debridement. Table 21 summarizes the rating of the body of evidence for operative approaches.

Open vs. mini-open RCR. Three studies (one RCT[136] and two cohort studies[68,106]) compared open RCR against mini-open RCR. Pooled results are shown in Figure 3 and Figure 4. Patient and study characteristics and outcome data are presented in Table 6 and Table 7, respectively.

Mohtadi et al.[136] conducted a RCT in patients with small to massive full-thickness tears. Seventy-three patients were randomly assigned to the interventions (37 to open surgical repair and acromioplasty, 36 to mini-open repair with arthroscopic acromioplasty) and 60 were followed up for at least 2 years. Patient quality of life was assessed using the RC-QOL and function was assessed using the ASES, Shoulder Rating Questionnaire (SRQ), range of motion (flexion, external and internal rotation), and functional shoulder elevation test (FSET). At the 2-year followup, mean RC-QOL score had improved for both groups, but the differences were not statistically significant (p=0.94). Mean ASES and SRQ scores had improved for both groups, but there was no statistically significant differences between the postoperative scores (p=0.94 and p=0.806, respectively). Range of motion and FSET were assessed at 12 months. Both groups showed some improvement in range of motion measures at 12 months; however, the difference between groups was not statistically significant. Both groups also showed improvement in FSET scores; however, the differences in postoperative scores were not statistically significant (p=0.899).

Baker et al.[68] conducted a retrospective cohort study in patients with small, medium, and large full-thickness tears. Thirty-six patients were evaluated (20 received open repair with acromioplasty, 16 received mini-open repair with arthroscopic acromioplasty), and all patients were followed for at least 2 years. The mean followup was 3.3 years. Patients were evaluated using the UCLA score, range of motion (flexion, external rotation, and abduction), strength (flexion, external rotation, and abduction), and time to return to work. At final postoperative followup, the two groups both demonstrated improvement in the UCLA score and range of motion, but the difference between the two groups was not statistically significant (p>0.05). Strength scores also improved from baseline to endpoint, however there were no significant differences between the groups at endpoint except in abduction strength (p=0.002), which favored mini-open repair. The mean time to return to work was 5.6 months (range: 4.2 to 7.2) for the open repair group and 4.5 months (range: 3.7 to 6.5) for the mini-open group. Cuff integrity was examined at final followup using arthrography. In the open RCR group, 10 patients (50 percent) had an intact cuff, compared with nine patients (52.9 percent) in the mini-open group. There was no significant difference between the groups for cuff integrity.

Hata et al.[106] conducted a retrospective cohort study in patients with small, medium, and large RC tears. Seventy-eight patients were evaluated (43 received open repair with acromioplasty, 35 received mini-open repair with acromioplasty), and all patients were followed for at least 2 years. The mean followup was 4 years. Patient function was assessed using the UCLA score and time to return to work. At the 2-year followup, mean UCLA score improved for both groups; however, the difference between the postoperative scores was not statistically significant. For the mini-open group, the mean time to return to work or sports activities (2.4 months) was significantly shorter than in the open repair group (3.4 months) (p≤0.05). Cuff integrity was examined at 12 months using MRI. No ruptures were detected in either group.

One RCT[136] and two cohort studies[68,106] provided data for a meta-analysis of the effects of open vs. mini-open RCR on functional outcome measures (Figure 3). Data from the trial at various time points (3, 6, 12, 24 months) and two cohorts is presented separately. The ASES is presented for the RCT,[136] while the cohort studies both used the UCLA score. For all studies, mean change scores between preoperative and postoperative scores were compared between groups. The combined estimate of change in function for the cohort studies shows no significant difference between the interventions, yet favors mini-open repair (SMD=-0.40; 95% CI, -0.95 to 0.15). There was moderate heterogeneity between the studies (p=0.16; I^2=49 percent). Differences in the patient population may account for some of the heterogeneity between studies, since the study population for Baker et al.[68] included a substantial proportion of both recreational athletes and manual laborers.

Figure 3. Open vs. mini-open RCR on measures of functional outcome

Study or Subgroup	Open RCR Mean	SD	Total	Mini-open RCR Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
1.2.1 RCT/CCT - 3 months								
Mohtadi 2008	13.6	20.52	30	18	21.69	33	100.0%	-0.21 [-0.70, 0.29]
Subtotal (95% CI)			30			33	100.0%	-0.21 [-0.70, 0.29]
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.81 (P = 0.42)								
1.2.2 RCT/CTT - 6 months								
Mohtadi 2008	20.7	21.1	30	26.9	19.34	33	100.0%	-0.30 [-0.80, 0.19]
Subtotal (95% CI)			30			33	100.0%	-0.30 [-0.80, 0.19]
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.19 (P = 0.23)								
1.2.3 RCT/CTT - 12 months								
Mohtadi 2008	37	16.71	30	32.3	18.17	33	100.0%	0.27 [-0.23, 0.76]
Subtotal (95% CI)			30			33	100.0%	0.27 [-0.23, 0.76]
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.05 (P = 0.30)								
1.2.4 RCT/CTT - 24 months								
Mohtadi 2008	39.3	16.41	30	36.1	13.19	33	100.0%	0.21 [-0.28, 0.71]
Subtotal (95% CI)			30			33	100.0%	0.21 [-0.28, 0.71]
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.84 (P = 0.40)								
1.2.5 Cohort Studies								
Baker 1995	22.1	1.4	20	22.2	1.4	17	40.5%	-0.07 [-0.72, 0.58]
Hata 2004	18.7	1.4	43	19.6	1.4	35	59.5%	-0.64 [-1.09, -0.18]
Subtotal (95% CI)			63			52	100.0%	-0.40 [-0.95, 0.15]
Heterogeneity: Tau² = 0.08; Chi² = 1.96, df = 1 (P = 0.16); I² = 49%								
Test for overall effect: Z = 1.44 (P = 0.15)								

Std. Mean Difference
IV, Random, 95% CI

-1   -0.5   0   0.5   1
Favours Mini-open RCR   Favours Open RCR

Data from two cohort studies[68,106] was pooled for time to return to work (Figure 4). The pooled estimate indicates significantly shorter time to return to work for the mini-open RCR group compared with the open RCR group (mean difference=1.08 months; 95% CI, 0.63 to 1.52 months). There was no evidence of heterogeneity between the two studies (p=0.85, I^2=0 percent).

Figure 4. Open vs. mini-open RCR on time to return to work

Study or Subgroup	Open RCR Mean [Months]	SD [Months]	Total	Mini-open RCR Mean [Months]	SD [Months]	Total	Weight	Mean Difference IV, Random, 95% CI [Months]
1.9.1 Cohort Studies								
Baker 1995	5.6	0.8	20	4.5	0.78	17	75.4%	1.10 [0.59, 1.61]
Hata 2004	3.4	2	43	2.4	2	35	24.6%	1.00 [0.11, 1.89]
Subtotal (95% CI)			63			52	100.0%	1.08 [0.63, 1.52]
Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 1 (P = 0.85); I² = 0%								
Test for overall effect: Z = 4.76 (P < 0.00001)								
Total (95% CI)			63			52	100.0%	1.08 [0.63, 1.52]
Heterogeneity: Tau² = 0.00; Chi² = 0.04, df = 1 (P = 0.85); I² = 0%								
Test for overall effect: Z = 4.76 (P < 0.00001)								
Test for subgroup differences: Not applicable								

Favours open   Favours mini-open

Table 6. Study and patient characteristics for studies assessing open vs. mini-open RCR

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)

Baker CL,[68] 1995	**G1:** Open RCR (20)
	G2: Mini-open RCR (16)
	
	Retrospective cohort
		G1: 62 yr (38–81)/Males: 12 (60)
		  Athletes: 4 (20)
		  Manual laborers: 6 (30)
		G2: 59 yr (41–71)/Males: 9 (56)
		  Athletes: 4 (25)
		  Manual laborers: 5 (31)
			FTT; Sm, Med, Lg
			
			NR

Hata Y,[106] 2004	**G1:** Open RCR (43) **G2:** Mini-open RCR (35) Retrospective cohort	**G1:** 58.1 yr (31–78)/Males: 25 (58) **G2:** 60.6 yr (39–71)/Males: 21 (60)	NR; Sm, Med, Lg NR
Mohtadi NG,[136] 2008	**G1:** Open RCR (37) **G2:** Mini-open RCR (36) RCT	**G1:** 56.2 yr (44–77)/Males: 22 (60) **G2:** 57 yr (33–82)/Males: 20 (55)	FTT; Sm, Med, Lg, Mass >3 mo

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small

Table 7. Outcome data for studies assessing open vs. mini-open RCR

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Baker CL,[68] 1995	**G1:** Open RCR (20) **G2:** Mini-open RCR (16) 3.3 yr	UCLA*	9.1 / 31.2, p≤0.05	10.5 / 32.7, p≤0.05	p>0.05
		Time to return to work (mo)	5.6 (4.2–7.2)	4.5 (3.7–6.5)	NR
		ROM (degrees)	F: 99 / 153, p≤0.05 ER: 30 / 155, p≤0.05 ABD: 96 / 47, p≤0.05	F: 104 / 161, p≤0.05 ER: 34 / 49, p≤0.05 ABD: 100 / 159, p≤0.05	p>0.05 p>0.05 p>0.05
		Strength	F: 2.4 / 4.5, p≤0.05 ER: 3 / 4.2, p≤0.05 ABD: 3.2 / 4.4, p≤0.05	F: 2.7 / 4.6, p≤0.05 ER: 2.9 / 4.8, p≤0.05 ABD: 3.4 / 4.7, p≤0.05	NR NR p=0.002
		Cuff integrity n/N (%), arthrography	10/20 shoulders (50)	9/17 shoulders (52.9)	p=1.0‡
Hata Y,[106] 2004	**G1:** Open RCR (43) **G2:** Mini-open RCR (35) 4 yr (2–6.8)	UCLA* 2 yr	14.3 (6–26) / 33.0, p<0.01	13.8 (6–26) / 33.4, p<0.01	p>0.05†
		Time to return to work (mo)	3.4	2.4	p≤0.05
		Cuff integrity n/N (%), MRI 12 mo	0/43 (0)	0/35 (0)	NA
Mohtadi NG,[136] 2008	**G1:** Open RCR (29) **G2:** Mini-open RCR (31) 2 yr	RC-QOL 3 mo 6 mo 12 mo 2 yr	40.9 (95% CI, 35.5–46.2) 55.6 (47.5–63.7) 72.4 (65.0–79.8) 85.0 (79.2–90.8) 86.9 (81.8–92.0)	45.5 (95% CI, 38.5–52.5) 71.3 (63.8–78.9) 82.3 (78.3–86.3) 88.5 (84.1–92.9) 87.2 (80.6–93.8)	p=0.005 p=0.015 p=0.34 p=0.94
		ASES 3 mo 6 mo 12 mo 2 yr	48.2 (95% CI, 40.7–55.6) 61.8 (54.8–68.7) 68.9 (61.7–76.1) 85.2 (79.5–90.9) 87.5 (81.9–93.1)	53.8 (95% CI, 47.1–60.5) 71.8 (64.4–79.1) 80.7 (74.2–87.3) 86.1 (79.9–92.2) 89.9 (85.4–94.4)	p=0.048 p=0.016 p=0.84 p=0.94
		SRQ 3 mo 6 mo 12 mo 2 yr	46.7 (95% CI, 41.3–52.1) 63.3 (57.5–69.1) 73.6 (68.2–79.1) 83.4 (78.1–88.8) 85.1 (80.2–90.1)	50.3 (95% CI, 45.2–55.4) 69.4 (62.6–76.3) 79.8 (74.7–84.9) 85.2 (81.2–89.2) 85.9 (81.7–90.0)	p=0.170 p=0.096 p=0.587 p=0.806
		ROM(degrees) 12 mo	F: 147.7±35.1 / 162.3±19.2 ER on side: 46.1±15.3 / 54.1±28.6 ER at 90°: 73.1±27.6 / 78.4±16.7 IR§ (range): 2.3 (-1– +9) / 1.2 (-5– +7)	F: 155.2±35.2 / 158.3±22.61 ER on side: 46.6±22.3 / 48.1±29.7 ER at 90°: 78.8±16.8 / 79.0±13.6 IR§ (range, n): 3.0 (-3 –+12) / 0.96 (-5–+5)	F: p=0.46‡ ER on side: p=0.43‡ ER at 90°: p=0.88‡
		FSET 6 mo 12 mo	31.4 (19.2–43.6) (95% CI) 53.4 (35.7–71.1) 74.8 (61.0–88.5)	34.1 (21.6–46.6) (95% CI) 58.7 (46.0–71.4) 75.9 (63.3–88.5)	p=0.601 p=0.899

ABD = abduction; ASES = American Shoulder and Elbow Scale; ER = external rotation; F = flexion; FSET = functional shoulder elevation test; G = group; IR = internal rotation; mo = month; MRI = magnetic resonance imaging; N = number; NA = not applicable; NR = not reported; RCR = rotator cuff repair; RC-QOL = rotator cuff quality of life scale; ROM = range of motion; SD = standard deviation; SRQ = Shoulder Rating Questionnaire; UCLA = University of California Los Angeles Scale
*Subscales reported; †No significant differences were detected between groups at 3, 6, 12 mo or 2 yr; ‡Calculated by UAEPC; §Vertebral level, involved-uninvolved difference

Mini-open vs. arthroscopic RCR. Ten studies (one CCT,[114] two prospective cohort studies[85,148] and seven retrospective cohort studies[119,125,154,157,167,171,173]) compared mini-open RCR against arthroscopic RCR. Pooled results are shown in Figure 5 and Figure 6. Patient and study characteristics and outcome data are presented in Table 8 and Table 9, respectively.
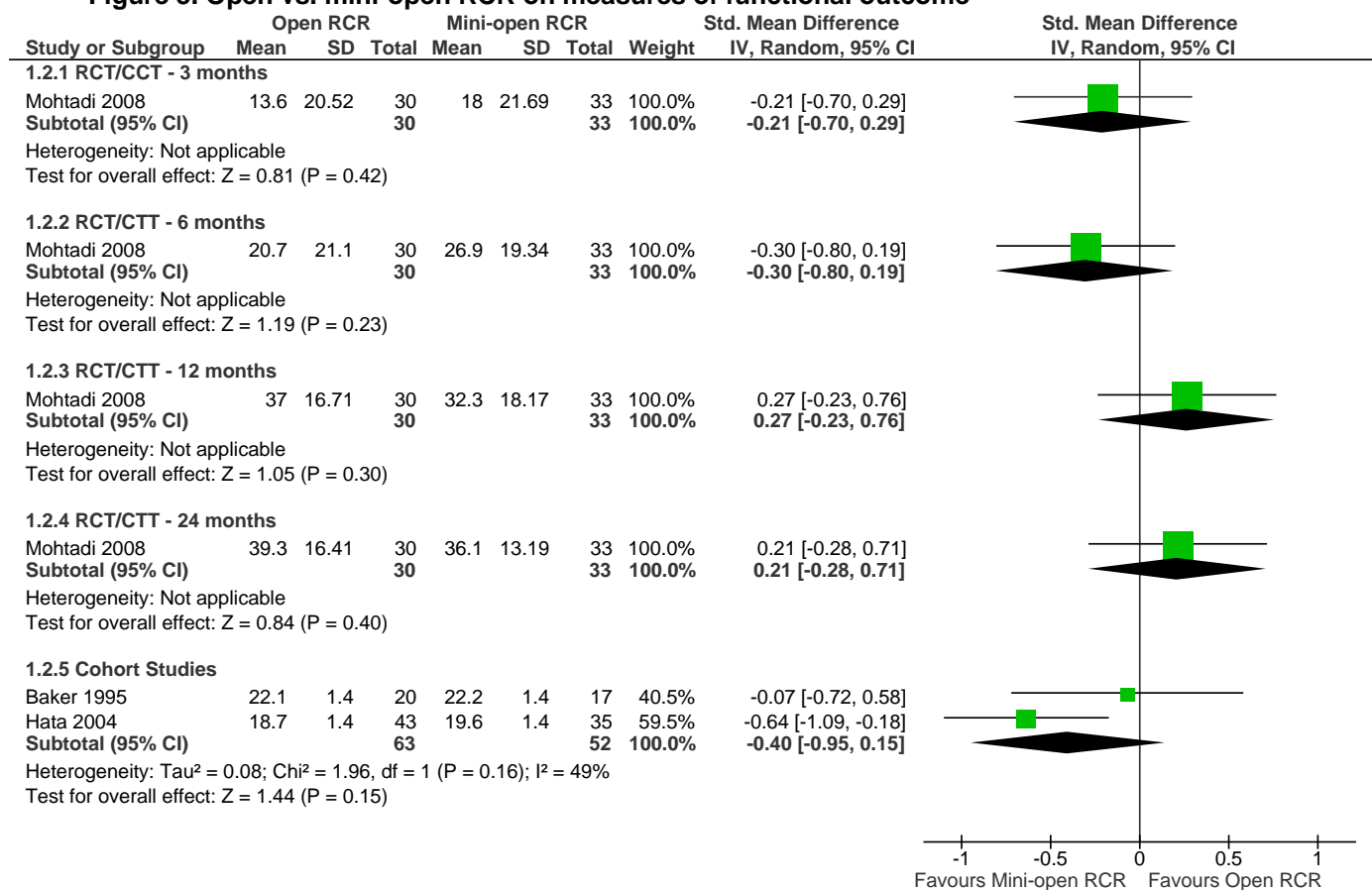
Colgate-Stone and colleagues[85] compared mini-open vs. arthroscopic RCR in a prospective cohort study. Patients with tear sizes exceeding 30 mm underwent mini-open repair (n=31), while those with tears less than 30 mm were treated with arthroscopic repair (n=92). Patients were followed for 24 months and were evaluated using the CMS, the DASH and the Oxford Shoulder Score. In both groups, scores significantly improved between baseline and endpoint. There was a significant difference between the groups at 12 months (p≤0.05), yet not at 3, 6 or 24 months.

Kim et al.[114] conducted a CCT in patients with medium or large full-thickness tears. Seventy-six patients were analyzed in the two treatments (34 received mini-open repair with acromioplasty, 42 received all-arthroscopic repair with acromioplasty) and were followed for at least 2 years. The mean followup was 3.3 years (2.0 to 5.3 years). Patients were evaluated on ASES and UCLA scores, percent function on a visual analogue scale, pain, range of motion, and strength. Shoulder scores improved in all ratings in both groups (p≤0.05) at followup; however, no statistically significant differences were seen between the two groups at study endpoint (p>0.05).

Kose et al.[119] conducted a retrospective cohort study with patients with small, medium, and large tears. Fifty-seven patients were selected and 50 evaluated (25 received mini-open repair with acromioplasty, 25 received arthroscopic repair with acromioplasty) at 2.2 years (range: 12 months to 6.8 years). Patients' function was evaluated using the Constant-Murley Score (CMS) and UCLA score. The improvements between pre- and postoperative CMS and UCLA scores were statistically significant within both groups (p<0.01); however, the difference in postoperative scores between the two groups was not significant (p=0.24 and p=0.63, respectively).

Liem et al.[125] conducted a retrospective cohort study of patients with small, medium, and large tears. Seventy-seven patients were selected and 38 evaluated (19 received mini-open repair with acromioplasty, 19 received arthroscopic repair with acromioplasty) at a minimum of 12 months. Patient function was evaluated using the CMS and early range of motion (flexion, abduction, and external rotation). At followup, both groups showed statistically significant improvement in the CMS (p=0.0001) and for all range of motion tests, except abduction and external rotation in the open RCR group. However, the between group differences in all scores were not statistically significant. Cuff integrity was evaluated at followup using MRI. Seven patients in the mini-open group and six in the all-arthroscopic group experienced retears; the difference between the groups was not statistically significant.

In a prospective cohort study, Pearsall et al.[148] compared mini-open vs. arthroscopic repair among patients with medium and large full-thickness tears. Fifty-two (25 receiving mini-open repair, 27 receiving arthrscopic repair) of the 54 patients enrolled were evaluated using the UCLA, Simple Shoulder Test (SST), pain visual analogue scale, and range of motion. There was statistically significant improvement in all outcomes from baseline to a mean followup of 4.2 years, however no significant differences between the two groups for any outcome measure.

Sauerbrey et al.[154]conducted a retrospective cohort study in patients with medium, large, and massive full-thickness tears. Sixty-three patients were selected and 54 evaluated (26 received

mini-open repair with acromioplasty, 28 received all-arthroscopic repair with acromioplasty) at 2.1 years (range: 13 months to 4 years). At followup, both groups showed significant improvement in ASES score (p<0.05); however, the difference between postoperative scores was not statistically significant (p=0.33).

Severud et al.[157] conducted a retrospective cohort study with patients with small, medium, and large partial- and full-thickness tears. Sixty-four of 82 enrolled shoulders were evaluated (29 shoulders received mini-open repair with subacromial decompression, 35 received all-arthroscopic repair with subacromial decompression) at a minimum of 24 months. The mean followup time was 3.7 years (range: 2 to 6.8 years). Patient function was evaluated using the ASES and UCLA scores. At followup, there were no statistically significant differences between the groups for either ASES or UCLA scores.

Verma et al.[167] conducted a retrospective cohort study with patients with small and large full-thickness tears. One hundred twenty-seven patients were selected (58 received mini-open repair with acromioplasty, 69 received arthroscopic repair with acromioplasty), of which 71 were evaluated at a minimum of 2 years. The mean followup was 3.2 years (range: 2 to 8.1 years). Patient function was assessed using the ASES, Insalata, and SST. Pain on a visual analogue scale and range of motion were also assessed. Preoperative and postoperative measures were not compared for any outcome. At followup, there were no statistically significant differences between groups for any of the outcome measures. Cuff integrity was found in 17 (68 percent) and 20 (90.9 percent) patients in the mini-open and arthroscopic repair groups, respectively; the difference between the groups was not significant.

Warner et al.[171] conducted a retrospective cohort study in patients with full-thickness tears. Twenty-one patients were selected (12 received mini-open repair with acromioplasty, nine received all-arthroscopic repair with acromioplasty). All patients were evaluated at a minimum of 2.3 years. The mean followup duration was 4.2 years. Patients were assessed using the SST, pain, range of motion (flexion and external rotation) and strength. Postoperative pain scores for both groups were significantly improved from preoperative measures (p<0.01). A statistically significant improvement in strength (p<0.01) was also observed in the arthroscopic group. Within and between group differences for all remaining outcome measures were not statistically significant.

Youm et al.[173] conducted a retrospective cohort study in patients with small, medium, and large tears. Ninety-five patients were selected and 84 evaluated (42 received mini-open repair with acromioplasty, 42 received all-arthroscopic repair with acromioplasty) at a mean of 3.0 years (range: 2 to 5.8 years). Patient function was assessed using the ASES and UCLA scores. At followup, the differences between groups for both scores were not statistically significant.

One CCT and nine cohort studies (two prospective and seven retrospective) provided data for meta-analysis of the effects of mini-open vs. arthroscopic repair on functional outcome measures (Figure 5). Data from the trial and cohort studies was analyzed separately. The following outcome measures were included in the meta-analysis: ASES,[154,157,167,173] CMS,[119,125] DASH,[85] SST[171] and the UCLA.[114,148] and The mean change between preoperative and postoperative scores was compared for four studies.[85,114,119,125,154] The remaining studies provided no baseline data, therefore the endpoint scores are compared between groups.[148,157,167,171,173] There were no significant differences between the mini-open and arthroscopic repair groups on functional outcome measures, either for the one CCT or the pooled estimate of nine cohort studies. The CCT favored mini-open repair (MD=0.32; 95% CI, -0.13 to

0.78). The combined estimate of functional outcomes from cohort studies slightly favored arthroscopic repair (SMD=-0.11, 95% CI, -0.28 to 0.06) There was no evidence of heterogeneity between the pooled studies (p=0.67; I^2=0 percent).

Figure 5. Mini-open vs. arthroscopic RCR on measures of functional outcome

Study or Subgroup	Mini-Open RCR Mean	SD	Total	Arthroscopic RCR Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
2.2.1 RCT/CCT								
Kim 2003	15	3.4	34	14	2.8	42	100.0%	0.32 [-0.13, 0.78]
Subtotal (95% CI)			34			42	100.0%	0.32 [-0.13, 0.78]
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.38 (P = 0.17)								
2.2.2 Cohort Studies								
Colegate-Stone 2009	54.09	33.8	31	62.92	33.8	92	17.7%	-0.26 [-0.67, 0.15]
Kose 2008	33.96	13.64	25	37.36	11.45	25	9.5%	-0.27 [-0.82, 0.29]
Liem 2007	30.2	33.84	19	30.1	33.72	19	7.3%	0.00 [-0.63, 0.64]
Pearsall 2007	27	11.3	25	24	11.3	27	9.9%	0.26 [-0.29, 0.81]
Sauerbrey 2005	37	11.1	26	44	14.15	28	9.9%	-0.54 [-1.08, 0.00]
Severud 2003	90	33.8	29	91.7	33.7	35	12.2%	-0.05 [-0.54, 0.44]
Verma 2006	95.1	9.3	33	94.6	8.9	38	13.5%	0.05 [-0.41, 0.52]
Warner 2005	12	0.92	12	12	2.36	9	3.9%	0.00 [-0.86, 0.86]
Youm 2005	90.2	14.8	42	91.1	15.4	42	16.1%	-0.06 [-0.49, 0.37]
Subtotal (95% CI)			242			315	100.0%	-0.11 [-0.28, 0.06]
Heterogeneity: Tau² = 0.00; Chi² = 5.76, df = 8 (P = 0.67); I² = 0%								
Test for overall effect: Z = 1.22 (P = 0.22)								

Favours arthroscopic   Favours mini-open

Two cohort retrospective studies provided data for meta-analysis of the effects of mini-open vs. arthroscopic repair on cuff integrity (Figure 6). The pooled estimate of effect showed no significant difference between the surgical approaches on the proportion of patients with intact RCs, however there was a trend favoring arthroscopic RCR (relative risk=0.80; 95% CI, 0.62 to 1.02). There was no evidence of heterogeneity between the two studies (p=0.44, I^2=0 percent).

Figure 6. Mini-open vs. arthroscopic RCR on cuff integrity

Study or Subgroup	Mini-Open RCR Events	Total	Arthroscopic RCR Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
2.11.1 Cohort Studies						
Liem 2007	12	19	13	19	29.8%	0.92 [0.58, 1.46]
Verma 2006	17	25	20	22	70.2%	0.75 [0.55, 1.01]
Subtotal (95% CI)		44		41	100.0%	0.80 [0.62, 1.02]
Total events	29		33			
Heterogeneity: Tau² = 0.00; Chi² = 0.59, df = 1 (P = 0.44); I² = 0%						
Test for overall effect: Z = 1.78 (P = 0.08)						

Favours arthroscopic   Favours mini-open

Table 8. Study and patient characteristics for studies assessing mini-open vs. arthroscopic RCR

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Colegate-Stone T,[85] 2009	**G1:** Mini-open RCR (31) **G2:** Arthroscopic RCR (92) Prospective cohort	**G1:** 62 yr/Males: 16 (52) **G2:** 57 yr/Males: 44 (48)	NR; **G1:** >30 mm, **G2:** <30 mm
Kim SH,[114] 2003	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) CCT	**G1:** 58±9 yr (42–68)/Males: 22 (65) **G2:** 55±10.5 yr (42–75)/Males: 27 (64)	FTT; Med, Lg NR
Kose KC,[119] 2008	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) Retrospective cohort	**G1:** 62±10 yr (32–75)/Males: 4 (16) **G2:** 55±7.6 yr (34–72)/Males: 7 (28)	NR; Sm, Med, Lg NR
Liem, D,[125] 2007	**G1:** Mini-open RCR (24) **G2:** Arthroscopic RCR (53) Retrospective cohort	**G1:** 62.9±6.7 yr/Males: 16 (67) **G2:** 61.9±6.6 yr/Males: 16 (30)	NR; Sm, Med, Lg **G1:** 10.6±7.9 mo, **G2:** 9.6±5.2 mo
Pearsall AW,[148] 2007	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) Prospective cohort	**G1:** 58 yr (41–76)/Males: 10 (40) WCB: 0; Smokers: 8 (32) **G2:** 55 yr (38–78)/Males: 11 (41) WCB: 0; Smokers: 3 (11)	FTT; Med, Lg NR
Sauerbrey AM,[154] 2005	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) Retrospective cohort	**G1:** 57 yr (40–84)/Males: 16 (62) Athletes: 16 (62) **G2:** 56 yr (38–86) / Males: 16 (57) Athletes: 9 (32)	FTT; Med, Lg, Mass NR
Severud EL,[157] 2003	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) Retrospective cohort	**G1:** 63.3 yr/Males: 18 (62) WCB: 3 (10) **G2:** 58.7 yr/Males: 21 (60) WCB: 6 (17)	FTT/PTT; Sm, Med, Lg **G1:** 10.8 mo, **G2:** 15.7 mo
Verma NN,[167] 2006	**G1:** Mini-open RCR (58) **G2:** Arthroscopic RCR (69) Retrospective cohort	**G1:** 60.7±10.4 yr/Males: 23 (40) **G2:** 59.5±8.6 yr/Males: 22 (32)	FTT; Sm, Med, Lg, Mass NR
Warner JJ,[171] 2005	**G1:** Mini-open RCR (12) **G2:** Arthroscopic RCR (9) Retrospective cohort	**G1:** 55±8 yr/Males: 8 (67) WCB: 1 (8) **G2:** 53±10 yr/Males: 5 (56) WCB: 0 (0)	FTT; NR **G1:** 9±4 mo, **G2:** 12±4 mo
Youm T,[173] 2005	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) Retrospective cohort	**G1:** 60 yr/NR **G2:** 57.9 yr/NR	NR; Sm, Med, Lg NR

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; N = number; NR = not reported; PTT = partial-thickness tear; RCR = rotator cuff repair; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 9. Outcome data for studies assessing mini-open vs. arthroscopic RCR

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Colegate-Stone T,[85] 2009	**G1:** Mini-open RCR (NR) **G2:** Arthroscopic RCR (NR) 2 yr	CMS 3 mo 6 mo 12 mo 24 mo	33.7 46.1 47.4 54.0 75.1,‡ p<0.05	44.8 52.2 60.1 73.3 97.6,‡ p<0.05	p>0.05 p>0.05 p>0.05 p≤0.05
		DASH 3 mo 6 mo 12 mo 24 mo	66.3 52.1 50.4 42.1 34.5,‡ p<0.05	53.5 53.4 35.3 33.0 28.1,‡ p<0.05	p>0.05
		OSS 3 mo 6 mo 12 mo 24 mo	42.4 41.3 29.3 28.8 23.3,‡ p<0.05	37.1 32.5 24.3 25.6 14.2,‡ p<0.05	p>0.05
Kim SH,[114] 2003	**G1:** Mini-open RCR (34) **G2:** Arthroscopic RCR (42) 3.3 yr (2.0–5.3)	ASES	59±12 (30–80)/95±7.3 (75–100), p<0.001	61±16 (34–87)/95±7.2 (75–100), p<0.001	p=0.67
		UCLA	18±2.6 (12–22)/33±3.4 (25–35), p<0.001	19±4.3 (12–26)/33±2.8 (26–35), p<0.001	p=0.65
		Percent Function (VAS)	54±12 (30–80)/93±8.3 (70–100), p<0.001	57±16 (20–80) / 93±8.8 (70–100), p<0.001	p=0.99
		Pain (VAS)	3.2±1.6 (1–6)/1.0±1.5 (0–6), p<0.001	4.2±2.5 (1–8) / 0.7±1.1 (0–5), p<0.001	p=0.81
		ROM (degrees)	F: 30±26 (0–130)/4.0±6.9 (0–25), p<0.001 ER: 16±19 (0–35)/1.3±2.6 (0–10), p<0.001 IR: 4±2.6 (0–8)/0.6±1.2 (0–4), p<0.001	F: 27±21 (0–110)/3.2±6.8 (0–25), p<0.001 ER: 12±18 (0–35)/1.1±2.6 (0–10), p<0.001 IR: 4±3.2 (0–9)/0.4±0.9 (0–3), p<0.001	F: p=0.51 ER: p=0.50 IR: p=0.31
		Strength grade (gr), manual muscle testing, n (%)	gr 5: 9 (27)/25 (73), p<0.001 gr 4: 17 (50)/6 (18) gr 3: 8 (23)/3 (9)	gr 5: 11 (26)/35 (83), p<0.001 gr 4: 24 (57)/4 (10) gr 3: 7 (18)/3 (7)	p=0.33
Kose KC,[119] 2008	**G1:** Mini-open RCR (25) **G2:** Arthroscopic RCR (25) 2.2 yr (12 mo–6.8 yr)	CMS*	45.6±12.4/79.56±13.64, p<0.01	46.2±11.8/83.56±11.45, p<0.01	p=0.24
		UCLA*	10.6±4.5/28.8±3.42, p<0.01	11.2±5.6/29.76±4.5, p<0.01	p=0.63

ABD = abduction; ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; GH = glenohumeral elevation; gr = grade; IR = internal rotation; Insalata = Insalata Shoulder Rating Questionnaire; mo = month; MRI = magnetic resonance imaging; NR = not reported; OSS = Oxford Shoulder Score; pre-op = preoperative; post-op = postoperative; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SST = simple shoulder test; UCLA = University of California Los Angeles Scale; VAS = visual analogue scale; yr = year
*Subscores reported
†Calculated by UAEPC; ‡ Data extrapolated from graph

Table 9. Outcome data for studies assessing mini-open vs. arthroscopic RCR (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value	
Liem D,[125] 2007	**G1:** Mini-open RCR (19) **G2:** Arthroscopic RCR (19) 12 mo (minimum)	CMS*	53.5 / 83.7, p=0.0001	53.8/83.9, p=0.0001	NR	
		ROM (degrees)	F: 154 / 175, p=0.01 ABD: 148 / 164, p=0.22 ER: 52 / 56, p=0.43	F: 155/176, p=0.006 ABD: 149/173, p=0.016 ER: 47/59, p=0.011	p>0.05	
		Cuff integrity n/N (%), MRI	12/19 (63.1)	13/19 (68.4)	p=1.0†	
Pearsall AW,[148] 2007 4.2 yr (2.3–7)	**G1:** Mini-open RCR (25) **G2:** Arthroscopic RCR (27)	UCLA	NR / 27	NR/24	p=0.34 G1+G2: pre-op vs. post-op: p<0.0001	
		SST improvement	NR / 4.7	NR/5.1	p=0.66 G1+G2: pre-op vs. post-op: p<0.0001	
		Pain improvement (VAS)	NR / 4.8	NR/3.9	p=0.29 G1+G2: pre-op vs. post-op: p<0.0001	
		ROM Improvement (degrees)	F (active): NR / 18 ABD (active): NR / 14 GH: NR / 7.0 ER @ 0: NR / 12 ER @ 90: NR / 16 IR @ 90: NR / 11	F (active): NR/35 ABD (active): NR/21 GH: NR/8.3 ER @ 0: NR/11 ER @ 90: NR/19 IR @ 90: NR/8	p=0.16 p=0.18 p=0.7 p=0.7 p=0.7 p=0.7	G1+G2: pre-op vs. post-op: p=0.01 p=0.07 p=0.01 p=0.03 p=0.001 p=0.14
Sauerbrey AM,[154] 2005 2.1 yr (13 mo–4 yr)	**G1:** Mini-open RCR (26) **G2:** Arthroscopic RCR (28)	ASES*	52 (17–75) / 89 (56–100), p≤0.05	42 (9–47)/86 (43–100), p≤0.05	p=0.33	
Severud EL,[157] 2003 3.7 yr (2–6.8)	**G1:** Mini-open RCR (29 shoulders) **G2:** Arthroscopic RCR (35 shoulders)	ASES	NR / 90.0	NR/91.7	p>0.05	
		UCLA	NR / 31.4	NR/32.6	p>0.05	
Verma NN,[167] 2006 3.2 yr (2–8.1)	**G1:** Mini-open RCR (33) **G2:** Arthroscopic RCR (38)	ASES	NR / 95.1±9.3	NR/94.6±8.9	p>0.05	
		Insalata	NR / 94.2±8.8	NR/92.7±9.0	p>0.05	
		SST	NR / 11.3±1.4	NR/11.4±0.9	p>0.05	
		Pain (VAS)	NR / 0.4±1.0	NR/0.7±1.2	p>0.05	
		ROM (degrees)	F: NR / 169.4± 6.9 ABD: NR / 168.9± 8.4 ER: NR / 70.2±14.4 IR: NR / 9.2±3.1	F: NR/170.5±6.9 ABD: NR/169.6±7.5 ER: NR/68.2±16.7 IR: NR/9.8±3.1	p>0.05	
		Cuff integrity n/N (%)	17/25 (68.0)	20/22 (90.9)	p=0.079†	

Table 9. Outcome data for studies assessing mini-open vs. arthroscopic RCR (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Warner JJ,[171] 2005	**G1:** Mini-open RCR (12) **G2:** Arthroscopic RCR (9) 4.2±1.3 yr (2.3–7.1)	SST	NR/12 (9–12)	NR/12 (5–12)	p=0.28
		Pain (VAS)	7 (6–9)/0 (0–2), p<0.01	7 (5–8)/0 (0–2), p<0.01	p=0.92
		ROM (degrees)	F: 150 (30–160)/155 (110–170), p>0.2 ER: 50 (30–50)/50 (25–60), p>0.2	F: 145 (120–160)/160 (130–170), p>0.2 ER: 50 (40–60)/50 (30–60), p>0.2	F: p=0.25 ER: p=0.80
		Strength grade	4 (2–5)/4 (4–5), p=0.26	4 (3–5)/5 (4–5), p<0.01	p=0.08
Youm T,[173] 2005	**G1:** Mini-open RCR (42) **G2:** Arthroscopic RCR (42) 3.0 yr (2.0–5.8)	ASES	NR/90.2±14.8	NR/91.1±15.4	p>0.05
		UCLA	NR/32.3±3.3	NR/33.2±2.5	p>0.05

Open RCR vs. arthroscopic RCR. Three cohort studies (one prospective[112] and two retrospective[87,134]) compared open RCR against arthroscopic RCR. Patient and study characteristics and outcome data are presented in Table 11 and Table 12, respectively.

A retrospective cohort study was conducted by Costouros et al.[87] comparing open vs. arthroscopic repair in patients with full-thickeness tears. Thirty-seven patients were enrolled, of whom 19 received open repair and 18 received arthrosopic repair. Patients were evaluated using the CMS at an average of 21.1 months (range: 12 months to 4 years). Patients in both groups improved significantly from baseline to followup (p=0.02 and p<0.001 in the open and arthroscopic group, respectively), however no differences were seen between treatment groups.

Ide et al.[112] conducted a prospective cohort study in patients with small, medium, large, and massive full-thickness tears. One hundred patients were evaluated (50 received open repair with acromioplasty, 50 received all-arthroscopic repair with acromioplasty) at a mean of 4.1 years (range: 2.1 to 6.9 years). Patient function was assessed using UCLA and Japanese Orthopaedic Association (JOA) index scores. At followup, statistically significant differences were observed within both groups for both scores (p<0.0001); however, the differences between the two groups were not statistically significant (p>0.05).

Millar et al.[134] conducted a retrospective cohort study evaluating RCR in patients with full-thickness tears of all sizes. A total of 159 patients were enrolled, of which 49 received open repair, 53 received arthroscopic knotted repair, and 57 received arthroscopic knotless repair. Overall, 20, 29 and 38 patients were analyzed at 2 years followup, respectively. Reported outcomes included the ASES, Overall Shoulder Function score, Rotator Cuff Functional Index, pain at rest and at night, range of motion (abduction, flexion, external rotation), strength (supraspinatus, external rotation, liftoff) and cuff integrity. Patients in all three groups showed a significant improvement from baseline to followup. There were significant differences between the open RCR and combined arthroscopic RCR groups for the ASES (p<0.001) and external rotation (p<0.001). In addition, there was a significant difference between open repair and arthroscopic knotless repair for strength in supraspinatus (p<0.05) and external rotation strength (p<0.05). Differences between the two arthroscopic procedures are reported in the operative technique section. There were no significant between-group differences for any of the other outcomes.

Two retrospective[87,134] and one prospective[112] provided data for meta-analysis of the effects of open vs. arthroscopic repair on functional outcome measures (Table 10). The following outcome measures were included in the meta-analysis: ASES,[134] CMS,[87] and UCLA.[112] The mean change between preoperative and postoperative scores was compared for all of the studies. There were no significant differences between the open and arthroscopic repair groups on functional outcome measures (SMD=-0.49; 95% CI, -1.12 to 0.13). There was significant heterogeneity between the studies (p=0.003; I^2=83 percent), where Ide[112] showed no difference between the repair approaches and the other two studies favoured arthroscopic RCR. There were no apparent differences between the three studies with regard to the patient age, type of tear, or tear size. Some differences that may have contributed to the varying effect estimates include the prospective direction of Ide et al, and that outcomes were assessed at a longer followup duration compared to the other studies (4.1 years vs. 2 years). It is possible that there may be an initial advantage of arthroscopic repair on functional outcomes, yet that this benefit is not sustained over longer durations of followup.

Table 10. Open vs. arthroscopic RCR on measures of functional outcome

Study or Subgroup	Open RCR Mean	SD	Total	Arthroscopic RCR Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
Cosouros	18	7.05	19	24	7.05	18	27.8%	-0.83 [-1.51, -0.16]
Ide 2005	16.1	3.176	50	15.9	2.042	50	35.5%	0.07 [-0.32, 0.47]
Millar 2009	24	7	49	31.96	11.26	110	36.6%	-0.78 [-1.13, -0.43]
Total (95% CI)			118			178	100.0%	-0.49 [-1.12, 0.13]

Heterogeneity: Tau² = 0.25; Chi² = 11.57, df = 2 (P = 0.003); I² = 83%
Test for overall effect: Z = 1.54 (P = 0.12)

Favours Arthroscopic RCR   Favours Open RCR

Table 11. Study and patient characteristics for studies assessing open vs. arthroscopic RCR

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Costouros JG,[87] 2006	**G1:** Open RCR (19) **G2:** Arthroscopic RCR (18) Retrospective cohort	**G1:** 57 yr (40–75)/Males: 14 (74) **G2:** 54 yr (34–65)/Males: 12 (67)	FTT; NR NR
Ide J,[112] 2005	**G1:** Open RCR (NR) **G2:** Arthroscopic RCR (NR) Prospective cohort	**G1:** 57.1 yr (24–72)/Males: 39 (78) Athletes: 2 (4) **G2:** 57 yr (25–78)/Males: 41 (82) Athletes: 3 (6)	FTT; Sm, Med, Lg, Mass **G1:** 8 mo (2–24), **G2:** 6.4 mo (2–36)
Millar NL,[134] 2009	**G1:** Open RCR (49) **G2:** Arthroscopic knotted RCR (53) **G3:** Arthroscopic knotless RCR (57) Retrospective cohort	**G1:** 58 yr (28–87)/Males: 21 (43) **G2:** 64 yr (40–90)/Males: 24 (45) **G3:** 69 yr (34–86)/Males: 28 (49)	FTT; Sm, Med, Lg, Mass **G1:** 15 mo (0.71–81), **G2:** 7.2 mo (1–39), **G3:** 6.6 mo (0.5–31)

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; mo = month; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small; yr = year

Table 12. Outcome data for studies assessing open vs. arthroscopic RCR

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Costouros JG,[87] 2006	**G1:** Open RCR (NR) **G2:** Arthroscopic RCR (NR) 21.1 mo (12–48)	CMS	52/70, p=0.02	51/75, p<0.001	NS
Ide J,[112] 2005	**G1:** Open RCR (50) **G2:** Arthroscopic RCR (50) 4.1 yr (2.1–6.9)	UCLA JOA*	15.5 (7–26)/31.6 (26–35), p<0.0001 56.9 (27–68)/92.1 (67–100), p<0.0001	16.1 (8–24)/32.0 (21–35), p<0.0001 58.7 (32–64)/94.0 (60–100), p<0.0001	p>0.05 p>0.05
Millar NL,[134] 2009	**G1:** Open RCR (20) **G2:** Arthroscopic knotted RCR (29) **G3:** Arthroscopic knotless RCR (38) 2 yr	ASES† 6 mo 2 yr	43±1 61±2 67±1, p<0.001	47±1 74±2 80±2, p<0.001 **G3**: 48±1 78±2 79±1, p<0.001	G1 vs. G2: p<0.001 G1 vs. G3: p<0.001

ABD = abduction; ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; ER = eternal rotation; G = group; JOA = Japanese Orthopaedic Association scale; mo = month; N = number; NR = not reported; NS = not significant; OSF = Overall Shoulder Function; RCF Index = rotator cuff function index; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SS = supraspinatus; UCLA = University of California Los Angeles Scale; US = ultrasound; yr = year
* Subscores reported
† Values are expressed as mean ± standard error of the mean

Table 12. Outcome data for studies assessing open vs. arthroscopic RCR (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Millar NL,[134] 2009 (continued)		OSF† (1–5) 6 mo 2 yr	2.3±0.1 3.9±0.1 4.4±0.1, p<0.001	2.0±0.2 4.2±0.1 4.3±0.1, p<0.001 **G3**: 2.4±0.1 4.1±0.1 4.4±0.1, p<0.001	G1 vs. G2: NS G1 vs. G3: NS
		RCF Index† 6 mo 2 yr	-16±3 -1±3 -8±4, p<0.001	-25±3 3±3 -4±2, p<0.001 **G3**: -20±3 -1±2 -3±3, p<0.001	G1 vs. G2: NS G1 vs. G3: NS
		Pain at rest† (0–4) 6 mo 2 yr	2.4±0.2 1.0±0.1 0.5±0.1, p<0.001	2.2±0.1 1.0±0.1 0.6±0.1, p<0.001 **G3**: 1.7±0.2 0.7±0.1 0.6±0.1, p<0.001	G1 vs. G2: NS G1 vs. G3: NS
		Night Pain† (0–4) 6 mo 2 yr	2.5±0.2 1.4±0.1 0.9±0.2, p<0.001	2.3±0.2 1.0±0.1 0.9±0.1, p<0.001 **G3:** 2.2±0.1 0.8±0.1 0.9±0.1, p<0.001	G1 vs. G2: NS G1 vs. G3: NS
		ROM†(degrees) 6 mo 2 yr	ABD: 135±5 154±4 149±5, p<0.01 F: 151±4 163±4 164±4, p<0.01 ER: 53±3 53±2 52±2, NS	ABD: 112±6 159±5 141±5, p<0.001 F: 123±7 163±4 165±4, p<0.001 ER: 47±2 66±3 62±2, p<0.01 **G3**: ABD:133±5.5 163±3.3 152±4, p<0.01 F: 146±5 168±2.5 165±3, p<0.001 ER: 54±2.7 69±2.5 68±3, p<0.001	ABD: G1 vs. G2: NS G1 vs. G3: NS F: G1 vs. G2: NS G1 vs. G3: NS ER: G1 vs. G2: p<0.001 G1 vs. G3: p<0.001

41

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Millar NL,[134] 2009 (continued)		Strength† (newton) 6 mo 2 yr	SS: 29±3 50±3 48±3, p<0.001 ER: 39±3 62±4 50±2, p<0.05 Liftoff: 29±2 45±4 57±2, p<0.01	SS: 23±2 52±3 50±2, p<0.001 ER: 32±2 60±3 52±3, p<0.01 Liftoff: 20±2 38±3 49±4, p<0.001 **G3**: SS: 37±3 56±2.8 57±2, p<0.001 ER: 46±2.7 61±2.7 62±3, p<0.001 Liftoff: 29±2.6 40±2.1 50±2, p<0.001	SS: G1 vs. G2: NS G1 vs. G3: p<0.05 ER: G1 vs. G2: NS G1 vs. G3: p<0.05 Liftoff: G1 vs. G2: NS G1 vs. G3: NS
		Cuff integrity† n/N (%), US	12/20 (60)	19/29 (65) **G3**: 31/38 (82)	G1 vs. G2: NS G1 vs. G3: NS

Open or mini-open RCR vs. arthroscopic RCR. Two prospective cohort studies[72,77] compared open or mini-open RCR against arthroscopic RCR. These studies are presented as a separate category, since the study outcome data was not reported separately for patients who received open or mini-open repair. Pooled results are shown in Figure 7. Patient and study characteristics and outcome data are presented in Table 13 and Table 14, respectively.

Bishop et al.[72] conducted a prospective cohort study in patients with small, large, and massive full-thickness tears. One hundred and two patients were selected and 72 evaluated (32 received open repair [24 patients] or mini-open repair [8 patients] and 40 received arthroscopic repair) at 1 year. Patient function was assessed using the ASES score, CMS, pain, and range of motion (forward elevation and external rotation). Within group differences for all measures were statistically significant. All between group differences were not significant with the exception of an improvement in external rotation, which was significantly greater for the open and mini-open group (p≤0.05). Cuff integrity was evaluated using MRI at 12 months; 22 patients (69 percent) and 21 patients (52.5 percent) had intact cuffs in the open or mini-open vs. arthroscopic group, respectively. The difference between groups was not significant.

Buess et al.[77] conducted a prospective cohort study in patients with all tear sizes. Ninety-six patients (99 shoulders) were selected and 92 evaluated (29 received open or mini-open repair and 63 received arthroscopic repair) at a mean followup of 2 years (range: 15 months to 3.3 years). Patients were evaluated on the SST, a visual analogue scale for pain, and number of days until pain free. The arthroscopic group had significantly better pain relief on the visual analogue scale than the open / mini-open group at final followup (p=0.02). Postoperative SST scores were not statistically significant between the groups (p=0.33). Both groups showed similar duration in the mean number of days until pain free (95.6 for the open and mini-open group, 94.4 for the arthroscopic group).

A meta-analysis was conducted using visual analogue pain data from the two cohort studies (Figure 7).[72,77] The mean preoperative to postoperative change scores for both treatment arms were compared. The studies both found a statistically significant difference between the groups; in Bishop et al.[72] the open or mini-open group was favored, while in Buess et al.[77] the arthroscopic group was favored. The combined estimate of change in pain scores showed no difference between the interventions (SMD=-0.58; 95% CI, -2.64 to 1.48). There was significant heterogeneity between the studies (p<0.0001; I^2=97 percent). The heterogeneity may be attributable, in part, to differences between the study populations. Buess et al.[77] included younger patients, of which a large proportion were manual laborers (nearly 50 percent), while the population in Bishop et al.[72] was significantly older.

Figure 7. Open or mini-open vs. arthroscopic RCR for pain VAS

Study or Subgroup	Open or Mini-Open RCR			Arthroscopic RCR			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Bishop2006	-7.1	2.05	32	-3.7	2.05	40	49.7%	-1.64 [-2.18, -1.10]	
Buess 2005	-5.7	1.5	30	-6.4	1.5	66	50.3%	0.46 [0.03, 0.90]	
Total (95% CI)			**62**			**106**	**100.0%**	**-0.58 [-2.64, 1.48]**	

Heterogeneity: Tau² = 2.15; Chi² = 35.21, df = 1 (P < 0.00001); I² = 97%
Test for overall effect: Z = 0.55 (P = 0.58)

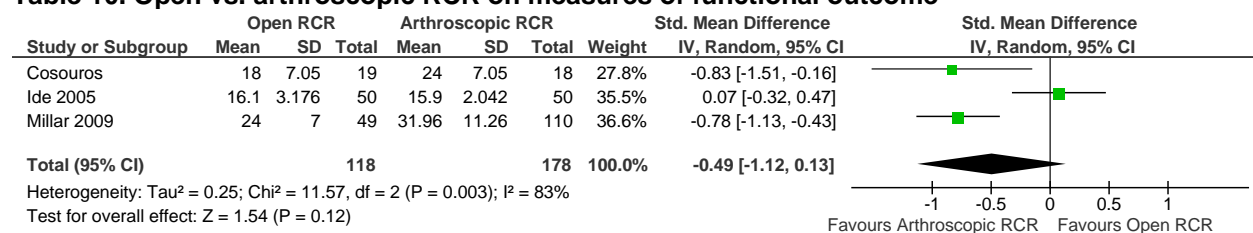Favours Open or Mini-Open   Favours Arthroscopic

Table 13. Study and patient characteristics for studies assessing open or mini-open vs. arthroscopic RCR

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Bishop J,[72] 2006	**G1:** Open or mini-open RCR (47) **G2:** Arthroscopic RCR (55) Prospective cohort	**G1:** 64 yr/NR **G2:** 64 yr/NR	FTT; Sm, Lg, Mass NR
Buess E,[77] 2005	**G1:** Open or mini-open RCR (32 shoulders) **G2:** Arthroscopic RCR (67 shoulders) Prospective cohort	**G1:** 48.3 yr (18–73)/Males: 21 (72) Manual laborers: 13 (45) **G2:** 53.2 yr (20–77)/Males: 44 (70) Manual laborers: 30 (48)	NR; Sm, Med, Lg, Mass NR

FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; N = number; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small; yr = year

Table 14. Outcome data for studies assessing open or mini-open vs. arthroscopic RCR

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Bishop J,[72] 2006	**G1:** Open or mini-open RCR (32) **G2:** Arthroscopic RCR (40) 12 mo	ASES	40/85, p<0.0001	46/84, p<0.0001	p=0.73
		CMS	53/80, p<0.0001	52/75, p<0.0001	p=0.13
		Pain (VAS)	8.2/1.1, p<0.0001	5.2/1.5, p<0.0001	p=0.41
		ROM (lb)	F: 6.2/12.8, p<0.005 ER: 10/18, p<0.01	F: 5.8/10.4, p<0.01 ER: 9.5/13.6, p<0.01	F: p=0.220 ER: p≤0.05
		Cuff integrity n/N (%), MRI	22/32 (69)	21/40 (53)	p=0.23*
Buess E,[77] 2005	**G1:** Open or mini-open RCR (29) **G2:** Arthroscopic RCR (63) 2 yr (15 mo–3.3 yr)	SST	NR/8.7	NR / 9.7	p=0.33
		Pain (VAS)	7.8 (4.5–10)/NR	8.0 (2.5–10) / NR	p=0.02
		Days until pain free, mean (range)	95.6 (7–360)	94.4 (2–375)	NR

ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; lb = pound; mo = month; MRI = magnetic resonance imaging; N = number; NR = not reported; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SST = simple shoulder test; VAS = visual analogue scale; yr = year
* Calculated by UAEPC

Open RCR vs. open or arthroscopic debridement. Four studies (two CCTs,[137,143] and two cohort studies[139,165]) compared open RCR vs. arthroscopic debridement. Pooled results are shown in Figure 8. Patient and study characteristics and outcome data are presented in Table 15 and Table 16, respectively.

Montgomery et al.[137] conducted a CCT comparing open RCR vs. arthroscopic debridement. All patients had full-thickness tears; tear size ranged from small to massive. One hundred and six patients (107 shoulders) were randomly assigned to the interventions (58 to open repair and acromioplasty, 49 to arthroscopic debridement and subacromial decompression) and 87 patients (88 shoulders) were included in final analysis. Followup evaluations were conducted 2 to 5 years postoperatively. The UCLA shoulder scale was used to evaluate patient function. There was improvement from the preoperative to postoperative scores in both groups. At final evaluation, there was a significant difference between two groups (p=0.0028), in favor of the open RCR group.

Motycka et al.[139] conducted a retrospective cohort study comparing open RCR vs. open or arthroscopic debridement in patients with large and massive tears. Overall, 76 patients were enrolled in the study; of these, 64 were included in the final analyses (33 received open repair with acromioplasty, 31 received open debridement with acromioplasty [15] or all-arthroscopic debridement and acromioplasty [16]). The mean length of followup was 5.7 years (range: 2.1 to 14.2). Patients were evaluated using the CMS. There was no statistically difference between the endpoint scores of the two groups (p=0.73).

Ogilvie-Harris et al.[143] conducted a CCT comparing open RCR vs. arthroscopic debridement in patients with RC tears 1 to 4 cm in size. Fifty patients were assigned to the interventions (25 patients received open repair with acromioplasty, 25 received all-arthroscopic debridement with acromioplasty); 45 were included in the final analyses. Followup duration ranged from 2 to 5 years. Patient function was evaluated using the UCLA scale. Both groups showed a significant improvement in UCLA subscores (pain, function, active forward flexion, and strength of forward flexion) from preoperative to postoperative measures. The difference between the postoperative scores of the two groups was statistically significant (p=0.017), favoring the open RCR group.

Vad et al.[165] conducted a retrospective cohort study comparing open RCR vs. arthroscopic debridement in patients with massive full-thickness tears. Sixty-eight patients were enrolled in the two operative arms (36 received open repair, 32 received all-arthroscopic debridement). All patients were followed up for at least 2 years; mean follow up duration was 3.2 years (range: 2 to 7). Patients were evaluated using the Insalata shoulder rating scale, range of motion (abduction), and time to maximal range of motion. For both groups, there were statistically significant improvement between the preoperative and postoperative scores for the Insalata rating and range of motion (p<0.05). The Insalata scores at final followup were significantly different between groups, favoring open repair. The time to maximal range of motion differed between the groups, with 6.8 months for the open RCR group and 3.2 months in the arthroscopic debridement group.

Two CCTs[137,139] and two cohort studies[143,165] provided data for meta-analysis of the effects of open repair vs. arthroscopic debridement on functional outcome measures (Figure 8). Data from the trials and cohort studies was analyzed separately. The following measures were included in the meta-analysis: CMS,[139] UCLA score,[137,143] and the Insalata shoulder rating scale.[165] The preoperative to postoperative change score was compared between groups for Vad

et al.[165] and Montgomery et al;[137] the remaining studies did not report baseline data, therefore the postoperative scores were compared between groups. The combined estimate of changes in measures of functional outcomes indicated a significant improvement in favor of open RCR for both the trials (SMD=0.59; 95% CI, 0.15 to 1.03) and the cohort studies (SMD=1.00; 95% CI, 0.11 to 1.90). There was no evidence of heterogeneity for the trials (p=0.22; I^2=32 percent), however there was substantial heterogeneity for the cohort studies (p=0.03; I^2=79 percent).

Figure 8. Open RCR vs. open or arthroscopic debridement for measures of functional outcome

Study or Subgroup	Open RCR Mean	SD	Total	Debridement Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
5.2.1 RCT/CCT								
Montgomery 1994	19.5	9.5	50	12.1	9.5	38	54.6%	0.77 [0.33, 1.21]
Ogilvie-Harris 1993	29.1	6.72	23	26.9	6.88	22	45.4%	0.32 [-0.27, 0.91]
Subtotal (95% CI)			73			60	100.0%	0.59 [0.15, 1.03]
Heterogeneity: Tau² = 0.03; Chi² = 1.47, df = 1 (P = 0.22); I² = 32%								
Test for overall effect: Z = 2.65 (P = 0.008)								
5.2.2 Cohort Studies								
Motycka 2004	76.03	20.2	33	65.06	20.1	16	47.8%	0.54 [-0.07, 1.14]
Vad 2002	50.6	7.92	32	39.1	7.8	36	52.2%	1.45 [0.91, 1.99]
Subtotal (95% CI)			65			52	100.0%	1.00 [0.11, 1.90]
Heterogeneity: Tau² = 0.33; Chi² = 4.85, df = 1 (P = 0.03); I² = 79%								
Test for overall effect: Z = 2.20 (P = 0.03)								

Std. Mean Difference IV, Random, 95% CI

-2 -1 0 1 2
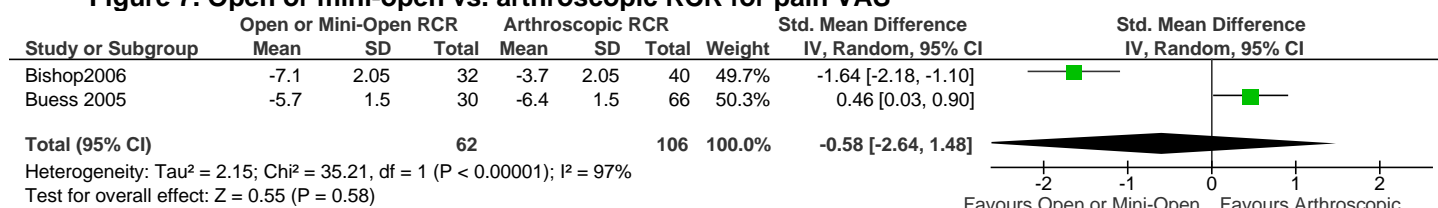Favours debridement   Favours open RCR

Table 15. Study and patient characteristics for studies assessing open RCR vs. arthroscopic debridement

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Montgomery TJ,[137] 1994	**G1:** Open RCR (58 shoulders) **G2:** Arthroscopic debridement (49 shoulders) CCT	**G1:** 58±11.6 yr (32–79)/NR **G2:** 60±12.2 yr (36–79)/NR	FTT; Sm, Med, Lg, Mass NR
Motycka T,[139] 2004	**G1:** Open RCR (NR) **G2:** Open or arthroscopic debridement (NR) Retrospective cohort	**G1:** NR/NR **G2:** NR/NR	NR; Lg, Mass NR
Ogilvie-Harris DJ,[143] 1993	**G1:** Open RCR (25) **G2:** Arthroscopic debridement (25) CCT	**G1:** NR/NR **G2:** NR/NR	NR; Sm, Med, Lg NR
Vad VB,[165] 2002	**G3*:** Open RCR (36) **G4:** Arthroscopic debridement (32) Retrospective cohort	**G3:** 59.4 yr/NR **G4:** 62.9 yr/NR	FTT; Mass 6.3 mo (1–17)

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; Sm = small
*Groups 1 and 2 are nonoperative interventions

Table 16. Outcome data for studies assessing open RCR vs. arthroscopic debridement

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Montgomery TJ,[137] 1994	**G1:** Open RCR (50 shoulders) **G2:** Arthroscopic debridement (38 shoulders) 2–5 yr	UCLA*	11/30.5	13/25.1	p=0.0028
Motycka T,[139] 2004	**G1:** Open RCR (33) **G2:** Open or arthroscopic debridement (31) 5.7 yr (2.1–14.2)	CMS*	NR/76 (16–100)	NR/65.1 (10–98)	p=0.73
Ogilvie-Harris DJ,[143] 1993	**G1:** Open RCR (23) **G2:** Arthroscopic debridement (22) 2–5 yr	UCLA*	NR/29.1	NR/26.9	p=0.017
Vad VB,[165] 2002	**G3†:** Open RCR (36) **G4:** Arthroscopic debridement (32) 3.2 yr (2–7)	Insalata*	33±1.2/83.6±1.4, p≤0.05	42.3±1.4/81.4±1.3, p≤0.05	p≤0.01‡
		ROM (degrees)	ABD: 72/116, p≤0.05	ABD: 74/110, p≤0.05	NR
		Time to maximal ROM, mean (range)	6.8 mo (4–16)	3.2 mo (1–8)	NR

ABD = abduction; CMS = Constant-Murley score; G = group; Insalata = Insalata Shoulder Rating Questionnaire; NR = not reported; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; UCLA = University of California Los Angeles Scale; yr = year
*Subscores reported
†Groups 1 and 2 are nonoperative interventions
‡Calculated by UAEPC

Arthroscopic RCR vs. acromioplasty. Two RCTs[102,133] compared arthroscopic RCR vs. arthroscopic RCR with acromioplasty, while one prospective cohort study compared arthrosopic RCR vs. acromioplasty alone.[140] Pooled results are shown in Figure 9. Patient and study characteristics and outcome data are presented in Table 17 and Table 18, respectively.

Gartsman et al.[102] conducted a RCT in patients with full-thickness tears limited to the supraspinatus tendon. Ninety-three patients were randomized (47 received all-arthroscopic repair with acromioplasty, 46 received all-arthroscopic repair with no additional procedures). All patients were followed up for at least 1 year; the mean followup duration was 15.6±3.3 months. In the group treated with arthroscopic RCR and acromioplasty, the mean tear size was 2.1 cm; in the group treated with arthroscopic RCR alone, the mean tear size was 2.3 cm. The ASES index was used to evaluate patient function. There was no statistical difference in the postoperative endpoint scores between the two groups (p=0.39).

Milano et al.[133] conducted a RCT in patients with full-thickness tears. Overall, 80 patients were randomly assigned to the interventions (40 received arthroscopic repair and acromioplasty, 40 received arthroscopic repair without acromioplasty); 71 were included in the final analyses. Followup duration was 2 years. Patients were evaluated using the CMS, the Disabilities of the Arm, Shoulder and Hand (DASH) score, and the Work-DASH score. Endpoint scores were comparable between the groups, with the arthroscopic group with acromioplasty scoring slightly higher on the postoperative CMS, and the group without acromioplasty scoring somewhat higher on the DASH and Work-DASH. Baseline and p-values for between and within-group differences were not reported.

Mullett et al.[140] compared arthroscopic RCR vs. acromioplasty without repair in a prospective cohort study. A total of 210 patients with small and medium sized tears were enrolled (114 received acromioplasty/subacromial decompression without repair, 96 received arthroscopic RCR). Patients were evaluated at 3 years followup using the CMS. The arthoscopic repair group had a higher postoperative score (86.4) compared with the acromioplasty group (69.8), however baseline values and the significance of the difference between groups were not reported.

Two RCTs[102,133] provided data for meta-analysis of the effects of arthroscopic repair with acromioplasty vs. without acromioplasty on functional outcomes (Figure 9). Outcome measures used in the analysis include the ASES index[102] and the CMS.[133] The difference between endpoint scores was analyzed in both studies.

Figure 9. Arthroscopic RCR with acromioplasty vs. RCR without acromioplasty for measures of functional outcome

Study or Subgroup	RCR with acromioplasty			RCR without acromioplasty			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Gartsman 2004	91.5	10.3	47	89.2	15.1	46	57.1%	0.18 [-0.23, 0.58]	
Milano 2007	103.6	19.59	34	96.1	19.59	37	42.9%	0.38 [-0.09, 0.85]	
Total (95% CI)			81			83	100.0%	0.26 [-0.04, 0.57]	

Heterogeneity: Tau² = 0.00; Chi² = 0.40, df = 1 (P = 0.52); I² = 0%
Test for overall effect: Z = 1.68 (P = 0.09)

Favours no acromioplasty   Favours acromioplasty
-0.5   -0.25   0   0.25   0.5

Table 17. Study and patient characteristics for studies assessing arthroscopic RCR vs. acromioplasty

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Gartsman GM,[102] 2004	**G1:** Arthroscopic RCR & acromioplasty (47) **G2:** Arthroscopic RCR (46) RCT	**G1:** 59.3 yr (39–81)/Males: 27 (57) **G2:** 60 yr (37–79)/Males: 24 (52)	FTT; **G1:** 2.1 cm, **G2:** 2.3 cm NR
Milano G,[133] 2007	**G1:** Arthroscopic RCR & acromioplasty (40) **G2:** Arthroscopic RCR (40) RCT	**G1:** 61±7 yr/Males: 20 (50) **G2:** 59.7±9.7 yr/Males: 19 (48)	FTT; NR NR
Mullett H,[140] 2006	**G1:** Arthroscopic acromioplasty (114) **G2:** Arthroscopic RCR (96) Prospective cohort	**G1:** NR/Males: NR **G2:** NR/Males: NR	NR; Sm, Med NR

cm = centimetre; FTT = full-thickness tear; G = group; Med = medium; mo = month; N = number; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small; yr = year

Table 18. Outcome data for studies assessing arthroscopic RCR vs. acromioplasty

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Gartsman GM,[102] 2004	**G1:** Arthroscopic RCR & acromioplasty (47) **G2:** Arthroscopic RCR (46) 15±3.3 mo (NR)	ASES	31.1 (20–46.7)/91.5±10.3	31 (18.3–41.7)/89.2±15.1	p=0.39
Milano G,[133] 2007	**G1:** Arthroscopic RCR & acromioplasty (37) **G2:** Arthroscopic RCR (34) 2 yr	CMS	NR/103.6	NR/96.1	NR
		DASH	NR/18.2	NR/23.1	NR
		Work-DASH	NR/23.7	NR/26.2	NR
Mullett H,[140] 2006	**G1:** Arthroscopic acromioplasty (NR) **G2:** Arthroscopic RCR (NR) 3 yr	CMS	NR/69.8	NR/86.4	NR

ASES = American Shoulder and Elbow Surgeon scale; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand scale; G = group; mo = month; N = number; NR = not reported; RCR = rotator cuff repair; SD = standard deviation; yr = year

Other operative approaches. There were seven studies (two RCTs,[96,97] one CCT,[163] and four retrospective cohort studies[63,75,94,138]) that could not be classified into one of the above categories. The intervention comparisons examined in these studies included: biceps tenotomy vs. tenodesis,[75] RCR vs. palliative treatment (partial repair and biceps tenotomy),[94] arthroscopic repair with SLAP repair vs. arthroscopic repair with biceps tenotomy,[96] arthroscopic RCR plus tenodesis with proximal biceps detachment vs. without proximal biceps detachment,[97] arthroscopic debridement with biceps tenotomy vs. without biceps tenotomy,[63] complete RCR vs. partial RCR vs. debridement,[138] and classical vs. modified open acromioplasty.[163] None of the studies could be pooled in a meta-analysis, as each study examined a different treatment comparison. Patient and study characteristics and outcome data are presented in Table 19 and Table 20, respectively.

Boileau et al.[75] conducted a retrospective cohort study in patients with massive irreparable tears. Overall, 78 patients (82 shoulders) were enrolled in the study; of these, 68 patients (72 shoulders) were included in analyses (39 shoulders received biceps tenotomy, 33 shoulders received biceps tenodesis). The mean length of followup was 2.9 ± 0.6 years(range: 2 to 6.3 years). Patients were evaluated using the CMS and active and passive range of motion (flexion, external and internal rotation). Together, the groups showed significant improvement in the CMS and active flexion from preoperative to postoperative measures ($p<0.001$), however the mean change from baseline to endpoint was not reported separately by group. There was no statistically significant between-group differences at endpoint scores.

Favard et al.[94] conducted a retrospecitve cohort study comparing watertight anatomical repair vs. palliative treatment in a sample of patients younger than 65 years with a massive RC tear. A total of 192 patients were enrolled; 103 received RCR, while 89 received palliative treatment, including tenotomy of the long head of biceps (n=48) or partial repair (n=41). Patients were evaluated using the CMS at an average of 4.1 years and 6.2 years for the repair and palliative treatment groups, respectively. A significant difference was observed between baseline and endpoint scores in both groups. In addition, there was a significant difference between the groups ($p<0.05$), in favour of the anatomical repair group.

Franceschi et al.[96] conducted a RCT in patients with RC tears limited to supraspinatus and infraspinatus tendon; tear size ranged from small to large. Sixty-three patients were randomly assigned to the interventions (31 received arthroscopic repair with SLAP repair, 32 received arthroscopic repair with biceps tenotomy) and evaluated at a mean length of followup of 5.2 years (range: 2.9 to 7.8 years). Patients were assessed using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative to postoperative scores ($p<0.001$). Moreover, there was a significant difference in total postoperative UCLA scores and range of motion between the two groups, in favour of the arthroscopic RCR with biceps tenotomy group ($p\leq0.05$).

Franceschi et al.[97] conducted a RCT in patients with massive full-thickness tears. Twenty-two patients were randomly assigned to the interventions (11 to tenodesis without detachment, 11 to tenodesis with detachment) and followed for a mean of 3.9 years (range: 3 to 4.9 years). All patients were evaluated using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative to postoperative scores ($p\leq0.05$).

However, neither the difference between the groups in total postoperative UCLA scores nor in range of motion was statistically significant (p>0.05).

Klinger et al.[63] conducted a retrospective cohort study in patients with massive irreparable tears. Forty-one patients were enrolled in the study (24 received arthroscopic debridement and acromioplasty, 17 received arthroscopic debridement, acromioplasty and biceps tenotomy). All patients were followed up for at least 2 years; mean followup was 2.6 years (range: 2 to 4 years). All patients were assessed using the CMS. There was no statistically significantly difference between the groups in the endpoint score (p>0.05).

Moser et al.[138] conducted a retrospective cohort study in patients with massive full-thickness tears. Thirty-eight patients were enrolled in the study (21 received open repair, 11 received partial open repair, 6 received debridement). All patients were evaluated using the Shoulder Pain and Disability Index (SPADI) score, range of motion (protraction, external and internal rotation) and strength (protraction, external rotation), and for at least 2 years. There were no significant endpoint differences between the groups on any outcome, with the exception of external rotation range of motion (p=0.029), which favored complete RCR.

Torrens et al.[163] conducted a CCT in patients with small to massive tears. Forty-two patients were enrolled in the study (20 received open repair with classic open acromioplasty, 22 received open repair with modified acromioplasty). All patients were followed up for at least 1 year; the mean followup was 18 months. The CMS was used to evaluate patient function. For both groups, the CMS improved from baseline to endpoint.
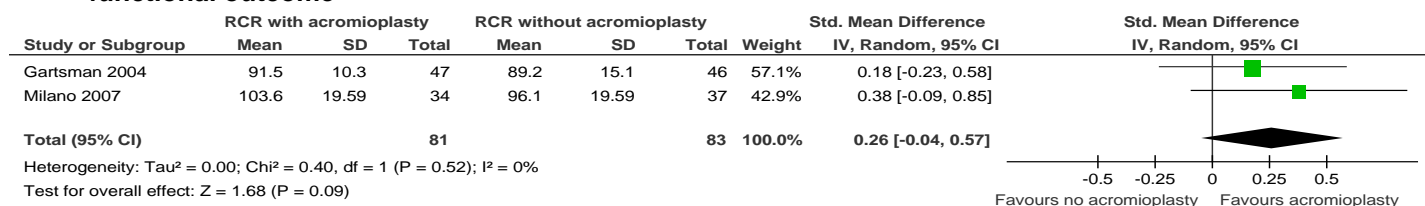
Table 19. Study and patient characteristics for studies assessing other operative approaches

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range)/Males, N (%) Other characteristics	Type of tear; Size of tear Duration of symptoms (mo), mean±SD (range)
Boileau P,[75] 2007	**G1:** Biceps tenotomy (NR) **G2:** Biceps tenodesis (NR) Retrospective cohort	**Total:** 68 yr (52–85)/Males: 26 (38)	FTT; Mass NR
Favard L,[94] 2009	**G1:** Watertight anatomical RCR (103) **G2:** Palliative treatment (89) Retrospective cohort	**G1:** 55.2±6.2 yr/Males: NR **G2:** 57.1±5.5 yr/Males: NR	FTT; Mass NR
Franceschi F,[96] 2008	**G1:** Arthroscopic RCR & SLAP repair (31) **G2:** Arthroscopic RCR & biceps tenotomy (32) RCT	**G1:** 61.8 yr (51–79)/Males: 18 (58) **G2:** 64.7 yr (53–81)/Males: 15 (47)	NR; Sm, Med, Lg 21 mo
Franceschi F,[97] 2007	**G1:** Tenodesis without detachment (11) **G2:** Tenodesis with detachment (tenotomy) (11) RCT	**G1:** 60.3±12.4 yr (41–79)/Males: 6 (55) Manual laborers: 3 (27) **G2:** 58.1±14.5 yr (40–81)/Males: 5 (46) Manual laborers: 3 (27)	FTT; Mass NR
Klinger HM,[63] 2005	**G1:** Arthroscopic debridement (24) **G2:** Arthroscopic debridement & biceps tenotomy (17) Retrospective cohort	**G1:** 66 yr (61–79)/Males: 15 (63) **G2:** 68 (63–82)/Males: 10 (59)	FTT; Mass **G1:** 11 mo (6–23), **G2:**10 mo (6–18)
Moser M,[138] 2007	**G1:** Complete RCR (21) **G2:** Partial RCR (11) **G3:** Debridement (6) Retrospective cohort	**Total:** 62.5 yr (33–81)/Males: 28 (74)	NR; Mass NR
Torrens C,[163] 2003	**G1:** Classical open acromioplasty (20) **G2:** Modified open acromioplasty (22) CCT	**G1:** 55.9 yr/Males: 4 (20) **G2:** 63.8 yr/Males: 4 (18)	NR; Sm, Med, Lg, Mass NR

CCT = controlled clinical trial; FTT = full-thickness tear; G = group; Lg = large; Med = medium; Mass = massive; NR = not reported; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small; yr = year

Table 20. Outcome data for studies assessing other approaches

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Boileau P,[75] 2007	**G1:** Biceps tenotomy (39 shoulders) **G2:** Biceps tenodesis (33 shoulders)	CMS	NR/61.2±18	NR/72.8±12	p>0.05
		ROM	F (active): NR/146.2±34.8 F (passive): NR/166.4±21.3 ER (active): NR/32.2±22.0 ER (passive): NR/51.3±16.8 IR: NR/L3	F (active): NR/164.2±27.6 F (passive): NR/173±10.5 ER (active): NR/40.5±20.9 ER (passive): NR/52.3±16.9 IR: NR/L3	p>0.05
	2.9±0.6 yr (2–6.3)				
Favard L,[94] 2009	**G1:** Watertight anatomical repair (NR) **G2:** Palliative (NR) **G1:** 50.1±27 **G2:** 74.4±36.6	CMS	37.7±17.1/70±15.2, p<0.01	40.6±13.3/64±16.6, p<0.01	p<0.05
Franceschi F,[96] 2008	**G1:** Arthroscopic RCR + SLAP repair (31) **G2:** Arthroscopic RCR + biceps tenotomy (32) 5.2 yr (2.9–7.8)	UCLA*	10.4 (6–14)/27.9 (24–35), p<0.001	10.1 (5–14)/32.1 (30–35), p<0.001	p≤0.05
		ROM (degrees)	F: 107 (30–140)/139 (120–170), p<0.001 ER: 81.7 (65–95)/121.4 (90–140), p<0.001 IR: 26.0 (20–33)/34.4 (26–40), p<0.001	F: 99 (30–140)/166 (140–170), p<0.001 ER: 76.6 (60–90)/134.3 (90–140), p<0.001 IR: 29.1 (21–35)/40.0 (30–45), p<0.001	p≤0.05
Franceschi F,[97] 2007	**G1:** Tenodesis without detachment (11) **G2:** Tenodesis with detachment (tenotomy) (11) 3.9 yr (3–4.9)	UCLA	10.5 (5–15)/33 (29–35), p≤0.05	11.1/32.9, p≤0.05	p>0.05
		ROM (degrees)	F: 102 (30–140)/161 (150–170), p≤0.05 ER: 37 (30–60)/59 (45–70), p≤0.05 IR†: L5 - T10/T11 - T5	F: 110 (30–150)/159 (140–170), p≤0.05 ER: 41 (30–60)/60 (45–90), p≤0.05 IR†: L5 - T12/T12 - T5	p>0.05
Klinger HM,[63] 2005	**G1:** Arthroscopic debridement (24) **G2:** Arthroscopic debridement + biceps tenotomy (17) 2.6 yr (2–4)	CMS	39 (19–54)/67 (41–87)	41 (16–60)/69 (49–87)	p>0.05

ASES = American Shoulder and Elbow Scale; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; ER = external rotation; F = flexion; IR = internal rotation; ft-lbs = foot pounds; G = group; Nm = nanometer; NR = not reported; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SLAP = superior labral tear from anterior to posterior; SPADI = Shoulder Pain and Disability Index; UCLA = University of California Los Angeles Scale; yr = year
*Subscores reported
†vertebral level

Table 20. Outcome data for studies assessing other approaches (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Moser M,[138] 2007	**G1:** Complete RCR (NR) **G2:** Partial repair (NR) **G3:** Debridement (NR) 2 yr (minimum)	SPADI*	NR/17.9	NR/29.5 **G3:** NR/38.4	p=0.235
		ROM (degrees)	Protraction: NR/124.5 ER: NR/45.6 IR: NR/T9	Protraction: NR/120 ER: NR/27 IR: NR/T11 **G3:** Protraction: NR/110.8 ER: NR/41.6 IR: NR/T5	Protraction: p=0.78 ER: p=0.029 IR: p=0.08
		Strength	Protraction: NR/16.1 Nm, 11.9 (ft-lbs) ER: NR/19.3 Nm, 14.2 (ft-lbs)	Protraction: NR/16.8 Nm, 12.4 (ft-lbs) ER: NR/16.9 Nm, 12.5 (ft-lbs) **G3:** Protraction: NR/12.9 Nm, 9.5 (ft-lbs) ER: NR/10.03 Nm, 7.4 (ft-lbs)	Protraction: p=0.48 ER: p=0.08
Torrens C,[163] 2003	**G1:** Classical open anterior acromioplasty (20) **G2:** Modified open anterior acromioplasty (22) 18 mo (NR)	CMS	46.7/74	53.3/80	NR

Table 21. Strength of evidence for operative approaches

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Open RCR vs. mini-open RCR	1; 73 (60)	HRQL	RCT	Unknown	n/a	Imprecise	Absent	Low
	3; 187 (174)	Function	RCT, cohorts Medium	Consistent	Direct	Precise	Present	Moderate
	2; 114	Cuff integrity	Cohorts Medium	Consistent	Direct	Precise	Present	Moderate
	2; 114	Time to return to work	Cohorts Medium	Consistent	Direct	Precise	Present	Moderate
Mini-open RCR vs. arthroscopic RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	10; 768 (683)	Function	CCT, Cohorts Medium	Consistent	Direct	Precise	Present	Moderate
	2; 204 (109)	Cuff integrity	Cohorts Medium	Consistent	Direct	Precise	Absent	Moderate
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Open RCR vs. arthroscopic RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	3; 296 (224)	Function	Cohorts Medium	Inconsistent	Direct	Imprecise	Absent	Low
	1; 159 (87)	Cuff integrity	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Open or mini-open RCR vs. arthroscopic RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	2; 198 (194)	Function	Cohorts Medium	Consistent	Direct	Imprecise	Absent	Moderate
	1; 102	Cuff integrity	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Open RCR vs. open or arthroscopic debridement	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	4	Function	RCT, CCT, Cohorts Medium	Consistent	Direct	Precise	Present	Moderate
	0	Cuff integrity	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Arthroscopic RCR vs. RCR plus acromioplasty	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	2; 173 (164)	Function	RCTs, Cohort Medium	Consistent	Direct	Precise	Absent	Moderate
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

CCT = controlled clinical trial; HRQL = health-related quality of life; n/a = not applicable; RCR = rotator cuff repair; RCT = randomized controlled trial; SLAP = superior labral tear from anterior to posterior

* number analyzed if different from number studied

Table 21. Strength of evidence for operative approaches (continued)

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Arthroscopic RCR vs. acromioplasty alone	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 210	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Biceps tenotomy vs. tenodesis	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 78 (68)	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
RCR vs. palliative treatment	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 192	Function	Cohort Medium	Unknown	Direct	Unknown	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 63	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Arthoscopic RCR plus tenodesis with detachment vs. without detachment	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 22	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Arthroscopic debridement with vs. without biceps tenotomy	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 41	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Complete open RCR vs. partial open RCR vs. debridement	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 38	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Open RCR with classic open vs. modified open acromioplasty	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 42	Function	CCT Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

Operative Approach—Uncontrolled Studies

Fifty-eight uncontrolled studies (43 BA,[60,65,69,70,74,76,79,80,82-84,89-91,95,100,101,103,104,108,110,111,115,116,120-124,127,130,131,142,145,151,153,156,158,160,161,166,168,169] 9 prospective cohorts with BA data,[62,86,92,93,107,126,141,144,146] 5 retrospective cohorts with BA data[128,135,149,150,162] and one case-control study with BA data[164]) assessed the effectiveness of operative approaches in the RC tear population. The studies were published from 1993 to 2009 (median=2005; IQR: 2002 to 2007).

Open RCR. Fourteen uncontrolled studies (10 BA,[60,79,83,103,108,115,131,145,151,153] one prospective cohorts with BA data,[86] two retrospective cohorts with BA data,[128,135] and one case-control study with BA data[164]) evaluated the effectiveness of open RCR. The studies were published from 1993 to 2007, with 2001 the median year of publication (IQR: 1995 to 2005).

The number of participants enrolled in the studies ranged from 25 to 224 (median=57; IQR: 43 to 97). The median followup duration was 2.2 years (IQR: 18 months to 4 years). The mean age of the participants ranged from 41 to 65 years. Of the 10 studies that reported type of tear, eight studies included only patients with full-thickness tears (80 percent) and two studies[108,164] examined patients with partial- or full-thickness tears (20 percent). All tear sizes were included in six studies,[79,83,115,135,145,151] small to large tears were included in two studies,[60,86] medium to massive[164] and large to massive[153] in one study each. The tear size was not clearly described in four studies.[103,108,128,131] Recreational athletes were included in three studies,[60,83,135] and smokers in one study.[128] One study reported the proportion of patients in jobs with strenuous manual labour[135] and three studies included patients with a workers' compensation board (WCB) claim.[60,135,164]

Health-related quality of life was reported in one study,[131] while 10 studies used a functional outcome measure.[60,79,86,103,108,128,131,135,151,153] Three studies reported either the time until patients returned to work,[60] or the proportion of patients that returned to work.[83,135] Cuff integrity was reported in one study.[103]

The figures below present the preoperative and postoperative functional scores over time for the BA studies (Figure 10), cohort studies (Figure 11), and trials (Figure 12) that examine open RCR. For one uncontrolled study, data from a 10-year followup publication[61] was incorporated into the initial publication.[60] The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study), the studies all indicate improvement in functional score from baseline to final followup.

Figure 10. Uncontrolled examining functional outcomes for open RCR
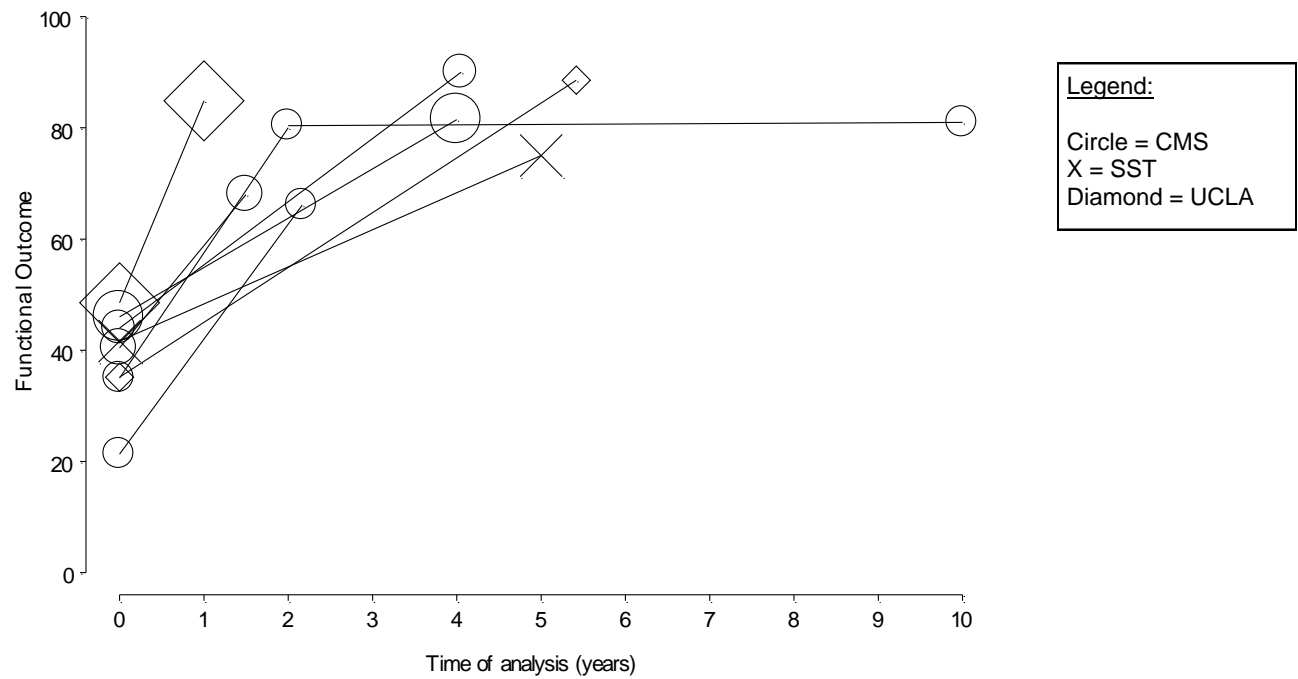
Figure 11. Cohort studies examining functional outcomes for open RCR
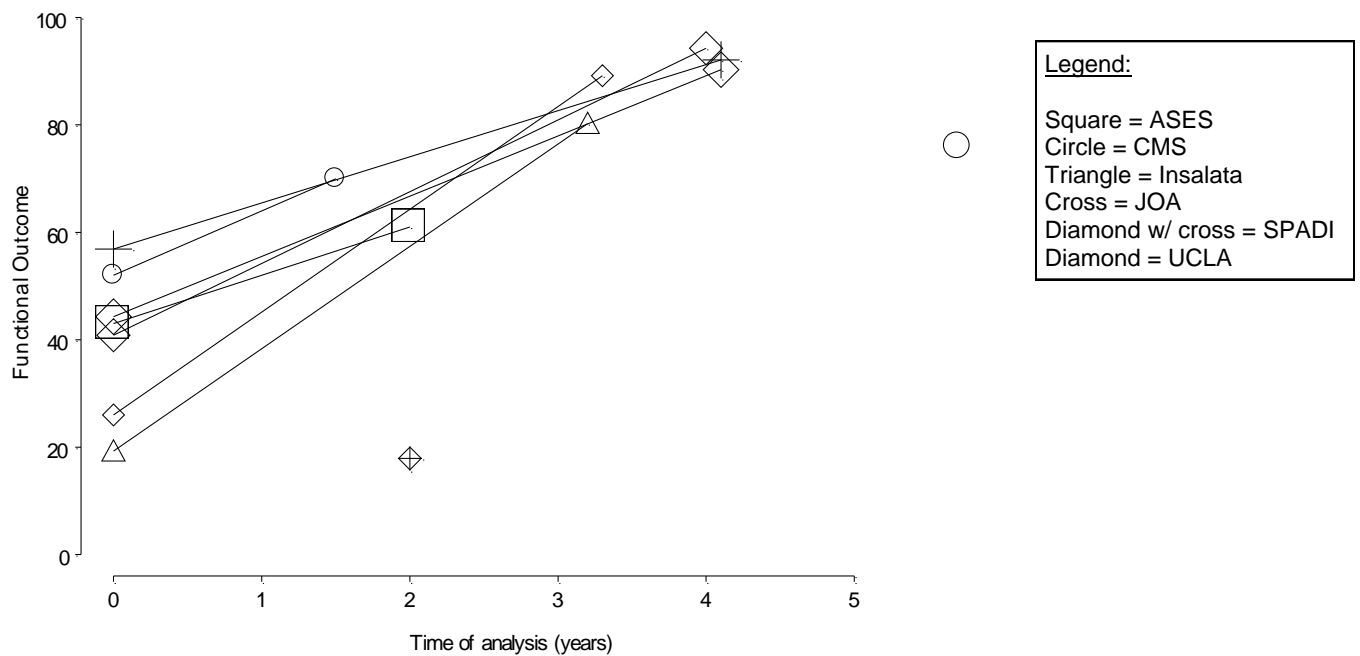
Figure 12. Trials examining functional outcomes for open RCR
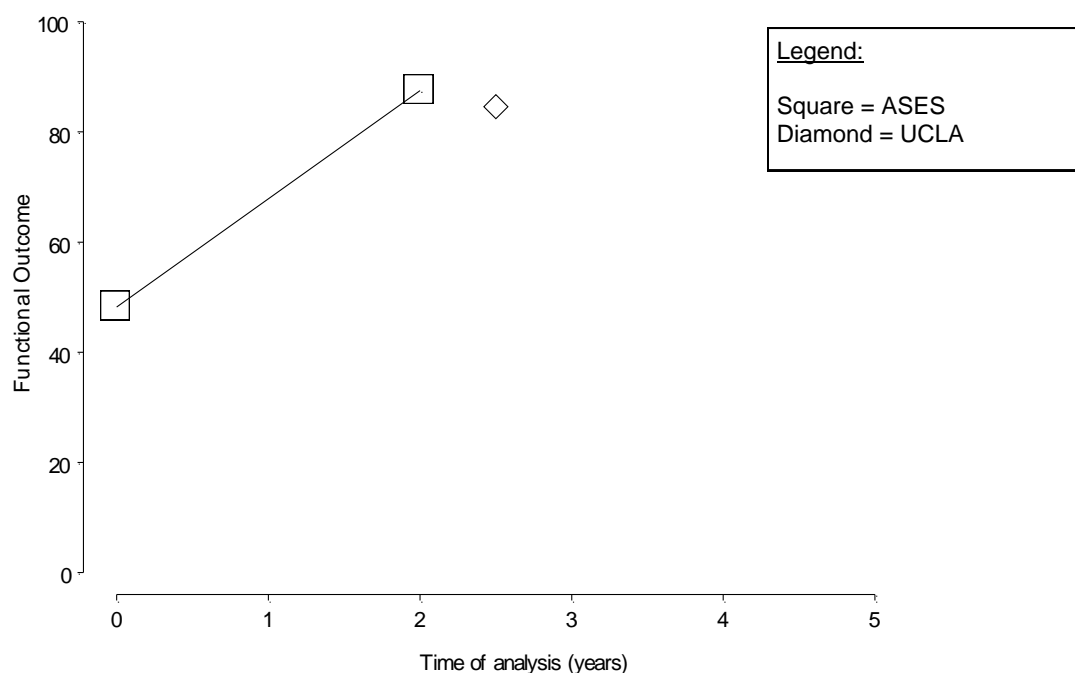
Mini-open RCR. Two BA studies[69,76] examined the effectiveness of mini-open RCR. The studies were published in 2004[76] and 2005.[69] The number of enrolled participants was 84 in both studies. The mean followup was 12 mo.[69] and 35 mo.[76] The mean ages were 53[69] and 54 years.[76] One study[69] included full-thickness tears of all sizes and participants with WCB claims (n=20, 24 percent), while tear characteristics were not reported in the other study.[76]

The reported outcomes included functional outcome scales,[69,76] and return to work.[69] The figures below present the preoperative and postoperative functional scores over time for the uncontrolled studies (Figure 13), cohort studies (Figure 14), and trials (Figure 15) that examine mini-open RCR. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. The studies all indicate improvement in functional score from baseline to final followup, regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study).

Figure 13. Uncontrolled studies examining functional outcomes for mini-open RCR
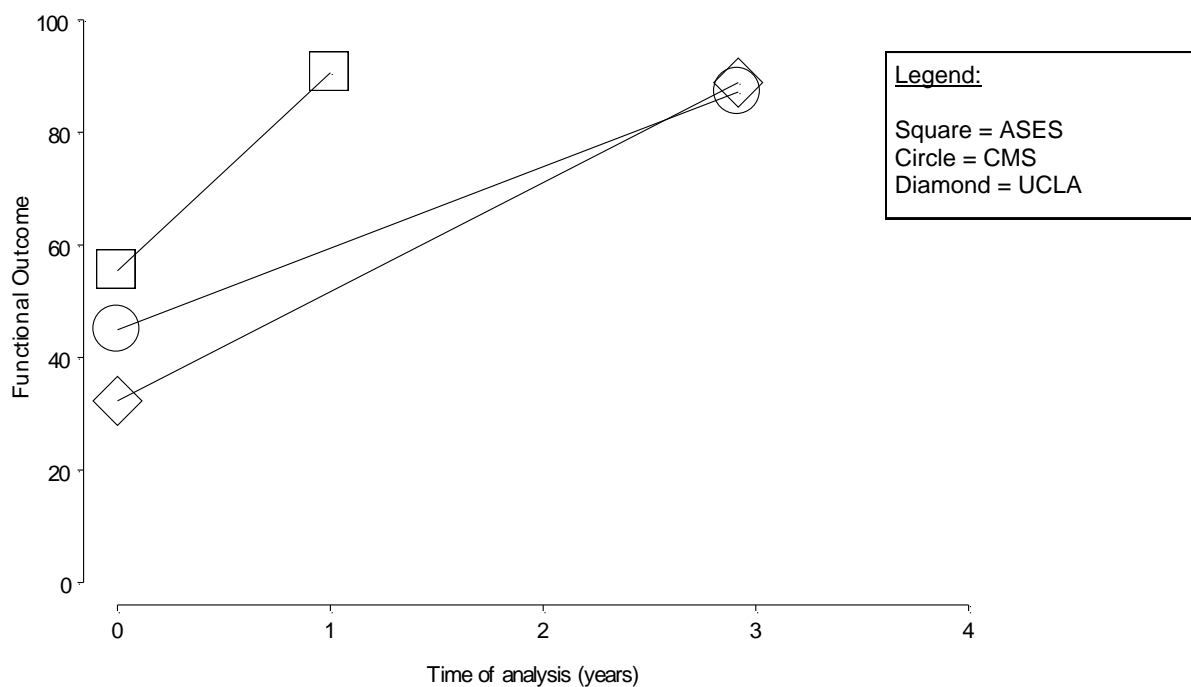
Figure 14. Cohort studies examining functional outcomes for mini-open RCR
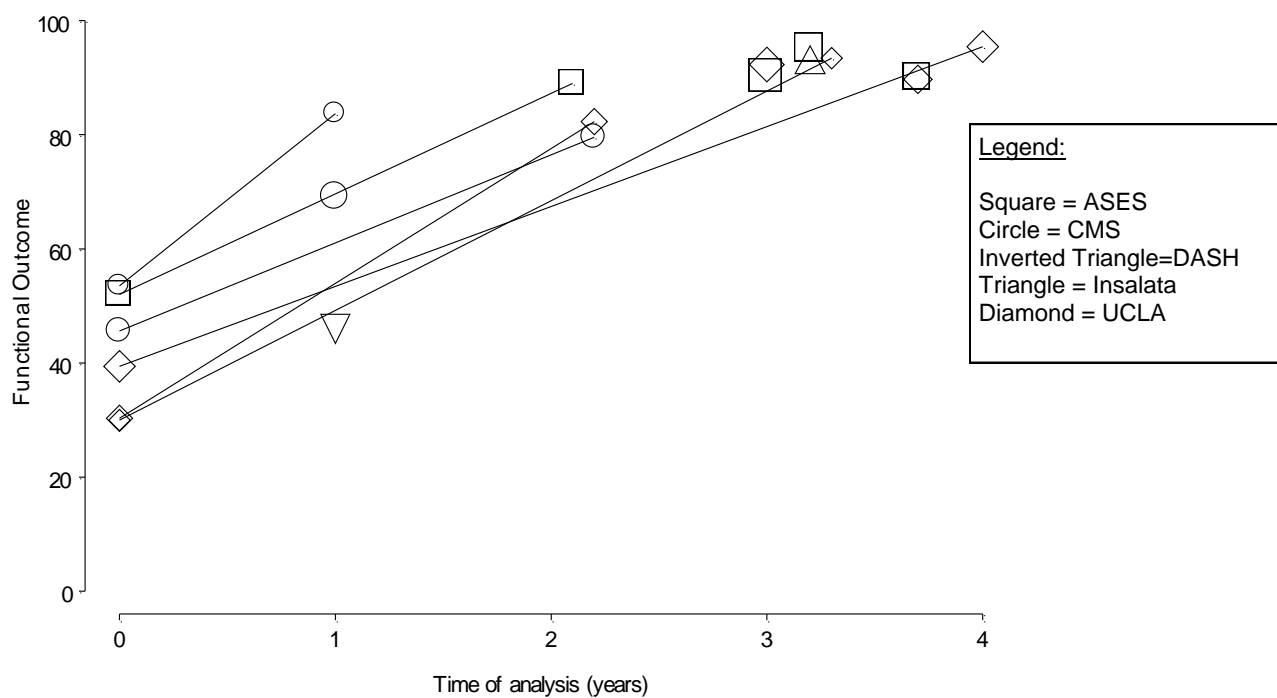
Figure 15. Trials examining functional outcomes for mini-open RCR

Legend:

Square = ASES
Diamond = UCLA
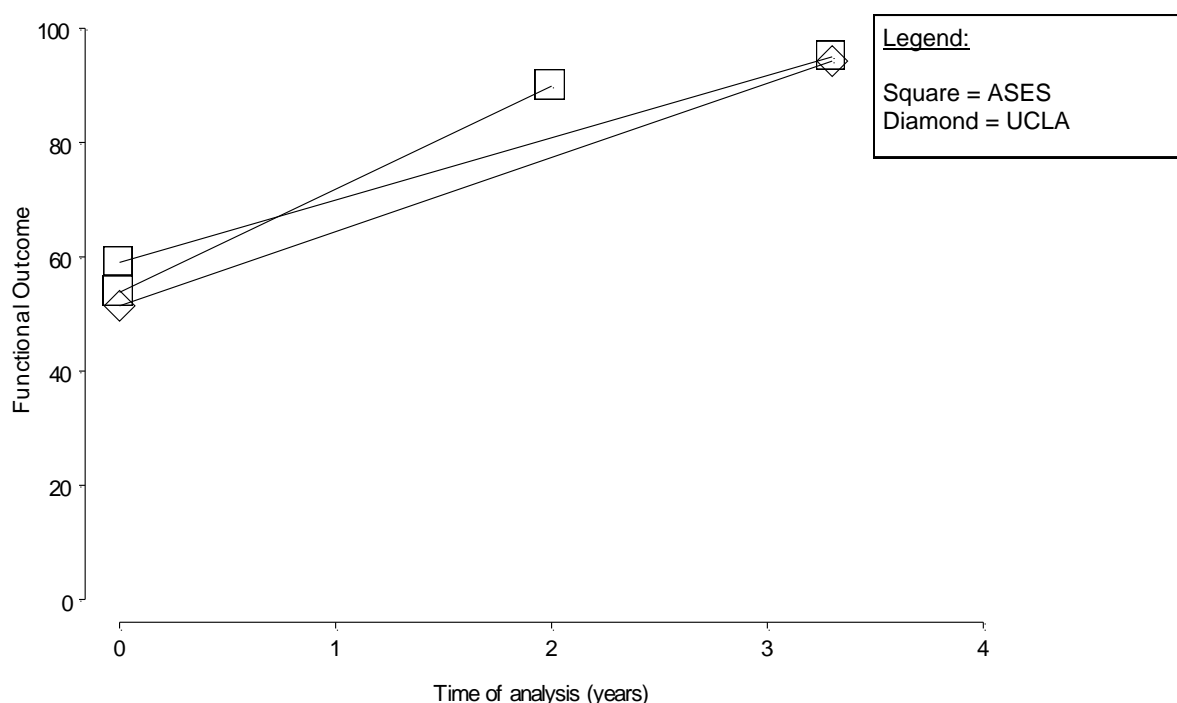
Arthroscopic RCR. Twenty-seven uncontrolled studies (19 BA,[70,74,80,84,90,91,100,110,111,120-124,130,142,158,161,169] five prospective cohorts with BA data,[62,92,93,141,146] three retrospective cohorts with BA data[149,150,162]) examined the effectiveness of arthroscopic repair in patients with RC tears. The studies were published from 1993 to 2009 (median=2006; IQR: 2004 to 2007).

The total number of participants enrolled in the studies ranged from 16 to 193 (median=48 [IQR: 34 to 77]). The median duration of followup was 2.7 years (IQR: 2.2 to 3). The mean age of participants ranged from 42 to 70 years. The majority of the studies included on patients with full-thickness RC tears (n=15 studies, 56 percent), while the remaining studies included only partial-thickness tears,[91,111,169] both tear types[90,120,122,146,149,150] or did not report type of tear.[123,142,161] Of the studies that reported tear size categories, eight included all tear sizes,[84,93,121,123,130,141,142,158] two included small to large tears,[74,122] three included small or medium tears only,[70,90,110] and one study included only massive tears.[62] One study reported including a small proportion of patients who were recreational athletes,[91] while two studies including smokers.[90,142] Manual labour jobs were reported in one study.[80] Six studies reported including patients with a WCB claim[74,80,84,91,130,149] and four studies reported excluding WCB patients.[90,110,111,141]

Health-related quality of life was reported in four studies,[84,90,100,130] and all of the studies reported at least one functional outcome measure. Two studies reported return to work[123] or physical activity.[90] Cuff integrity was examined in 12 studies.[74,80,84,90,92,110,121-124,142,158]

The figures below present the preoperative and postoperative functional scores over time for the uncontrolled studies (Figure 16), cohort studies (Figure 17), and trials (Figure 18) that examine arthroscopic RCR. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Regardless of the outcome measure used and the study design (trial, cohort or uncontrolled study), the studies

all indicate improvement in functional score from baseline to final followup. Figure 19 plots the proportion of patients with and intact cuff after arthroscopic RCR over the followup period. The results were variable across the studies and showed no pattern with respect to study design.

Figure 16. Uncontrolled examining functional outcomes for arthroscopic RCR
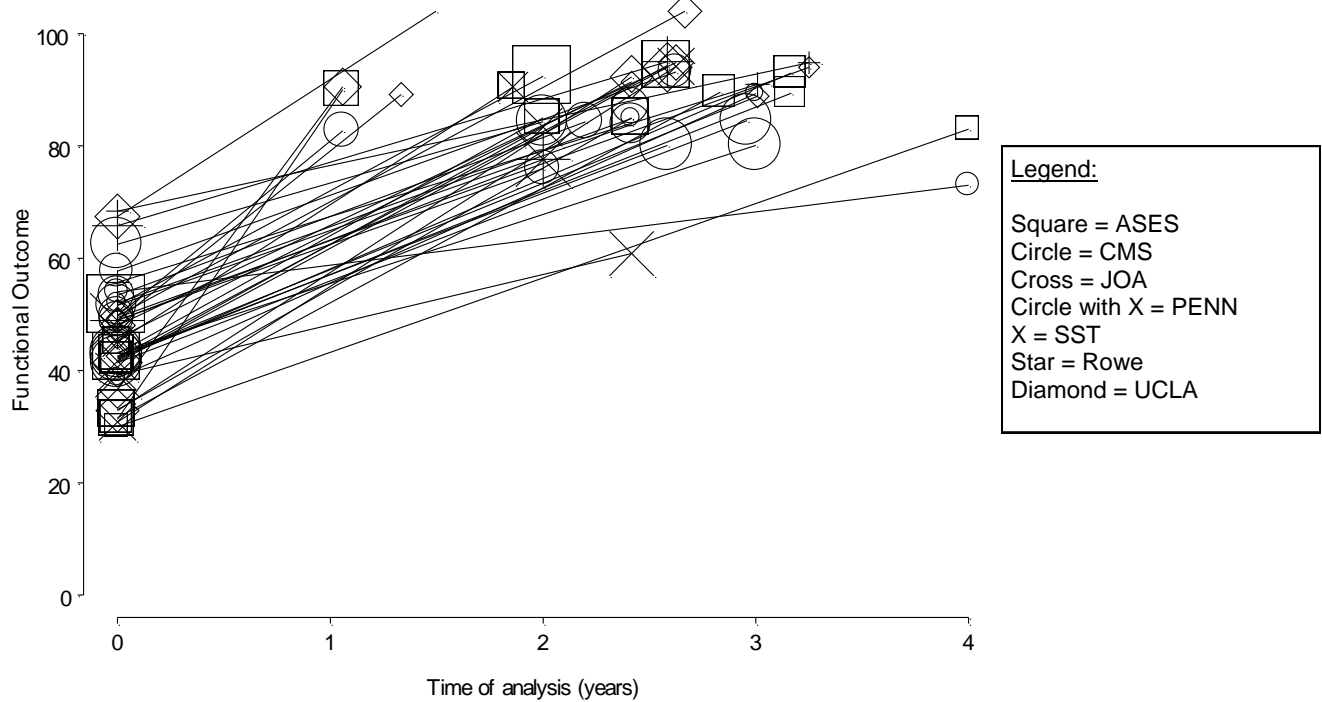
Figure 17. Cohort studies examining functional outcomes for arthroscopic RCR
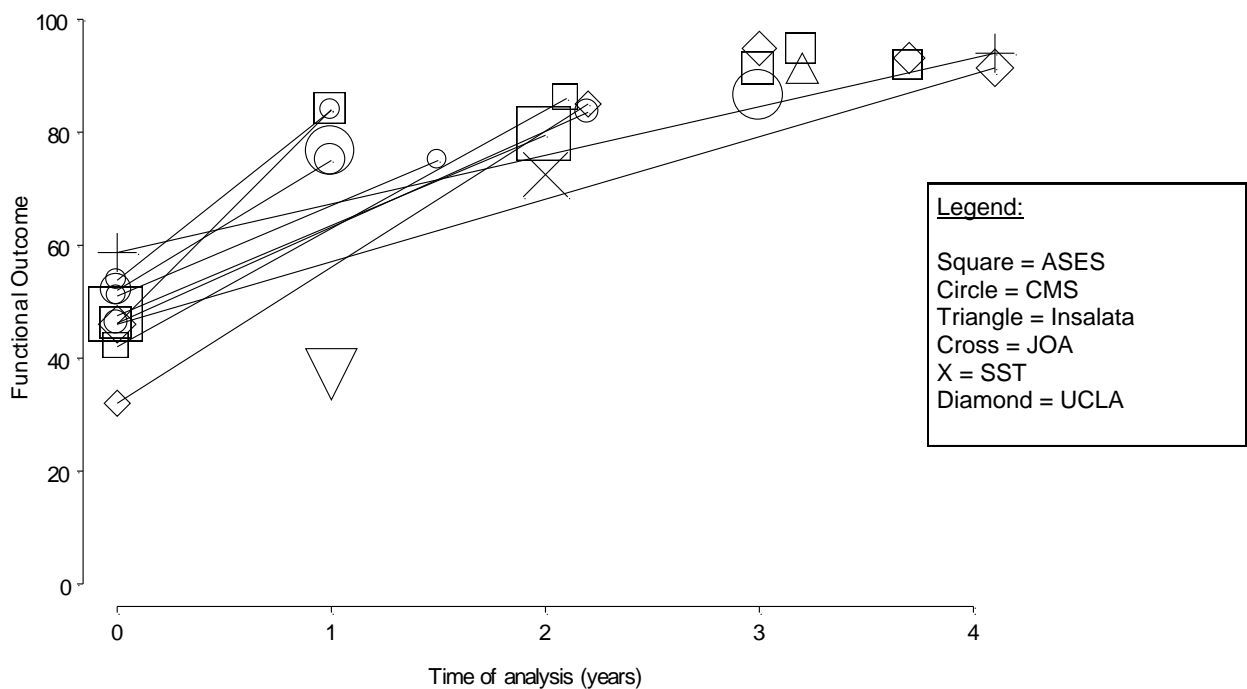
Figure 18. Trials examining functional outcomes for arthroscopic RCR
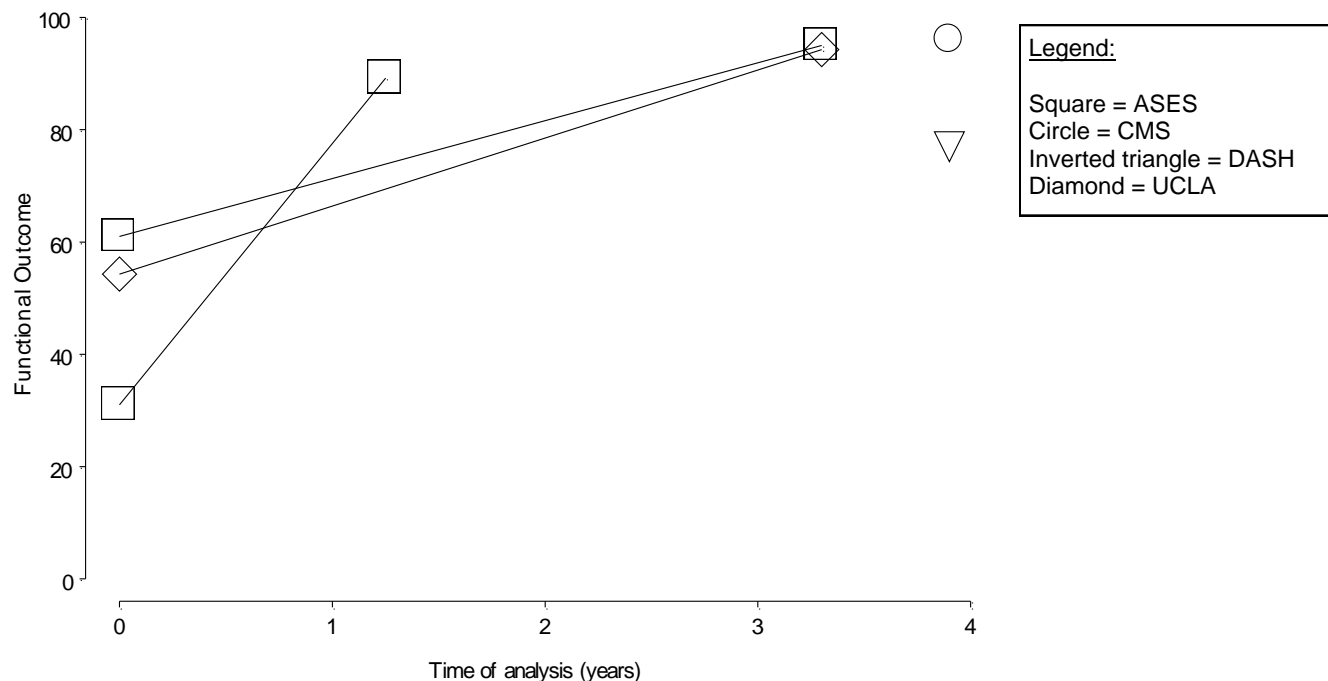
Figure 19. Studies examining cuff integrity for arthroscopic RCR
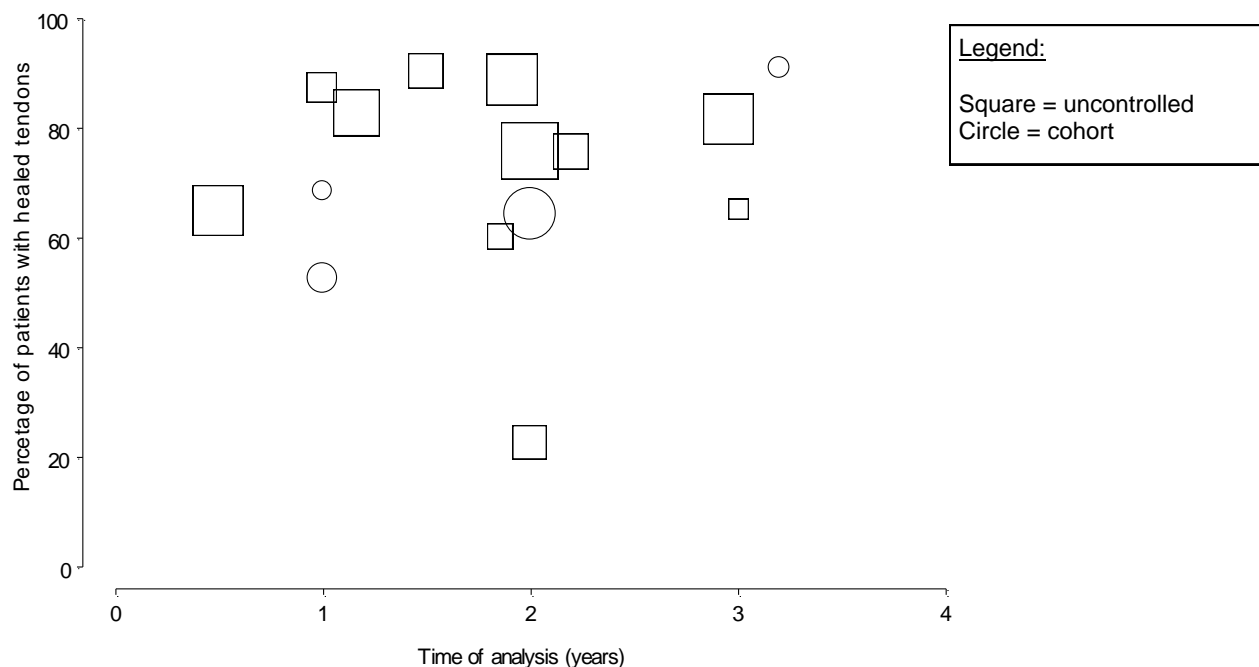
RCR combination approaches. Seven uncontrolled studies (five BA[89,104,116,160,168] and two prospective cohorts with BA data[107,144]) examined the effectiveness of RCR using a combination of approaches. Two studies used either an open or mini-open approach,[116,168] two used either an

open or arthroscopic approach,[89,144] and three used one of open, mini-open or arthroscopic approaches when performing RCRs on the study participants.[104,107,160] The studies were published between 2000 and 2008 (median=2007; IQR: 2005 to 2008).

The number of participants enrolled in the studies ranged from 38 to 125 (median=87 [IQR: 55 to 125]). The median duration of the followup period was 12 months (IQR: 12 to 14). Mean ages in the studies ranged from 56 to 64 years. Six studies included only patients with full-thickness tears, while the remaining study did not specify type of tear.[168] All of the three studies reporting tear size included patients with a range of tear sizes.[116,144,160] One study[107] included patients with manual labour jobs, those with WCB claims and smokers.

Reported outcomes included health-related quality of life,[107,160,168] functional measures,[89,104,107,116,144,160] and cuff integrity.[104,116,144] None of the studies reported time to return to work. Figure 20 presents the preoperative and postoperative functional scores over time for the all studies that examine a combination of RCR approaches. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. The studies all indicate improvement in score from baseline to followup, with the exception of one study in which CMS remained relatively stable over the 2 year followup period.

Figure 20. Studies examining functional outcomes for combined RCR approaches
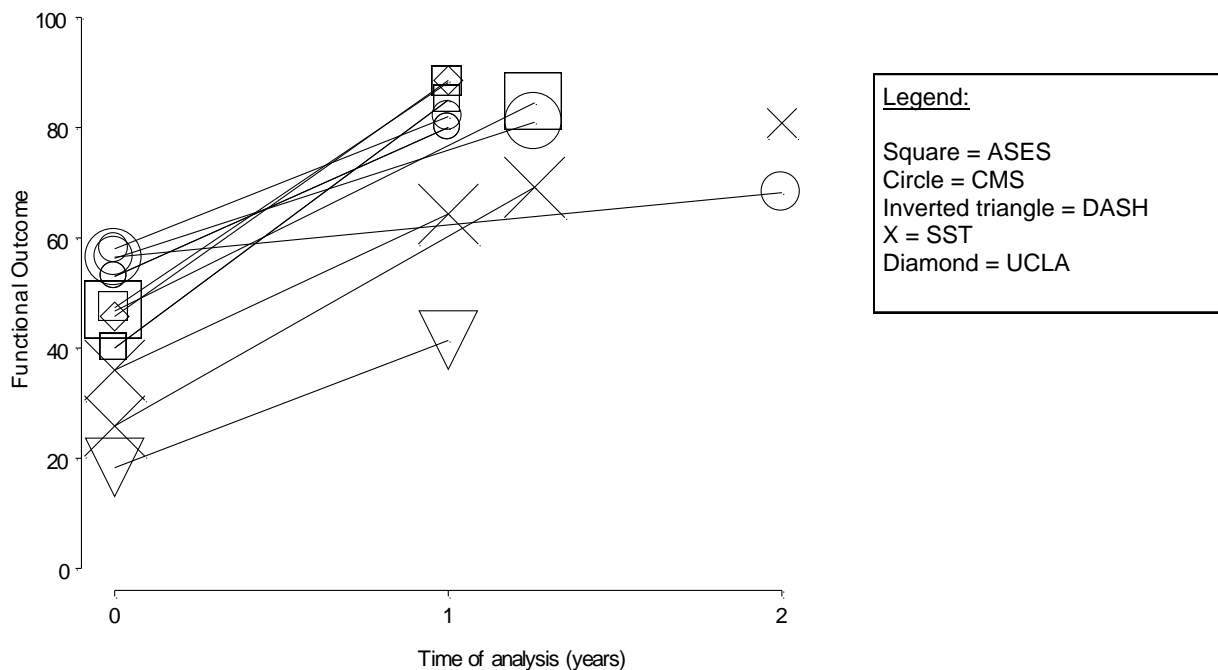
Arthroscopic debridement. Three BA studies,[65,156,166] assessed the effectiveness of the arthroscopic debridement in the RC tear population. The studies were published from 2000 to 2005 (median=2004; IQR: 2002 to 2005). The number of participants enrolled in the studies ranged from 14 to 33 (median=22 [IQR: 18 to 28]). The median followup duration was 3.1 years (IQR: 2.8 to 3.2). The mean age of participants was 69 years in two studies[65,156] and not reported for one study.[166] Two studies included only full-thickness tears[65,156] and one study[166] examined

patients with partial- or full-thickness tears. For the two studies that reported tear size, one[65] included only large RC tears and one[156] included only massive RC tears.

All studies assessed function,[65,156,166] while one study also assessed time to return to work.[166] Health-related quality of life and cuff integrity were not examined in any of the studies. The preoperative and postoperative scores for all studies examining arthroscopic debridement are plotted in Figure 21. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Similar to the other operative approaches, the scores consistently show marked improvement over time, regardless of the study design and outcome measure used.

Figure 21. Studies examining functional outcomes for arthroscopic debridement
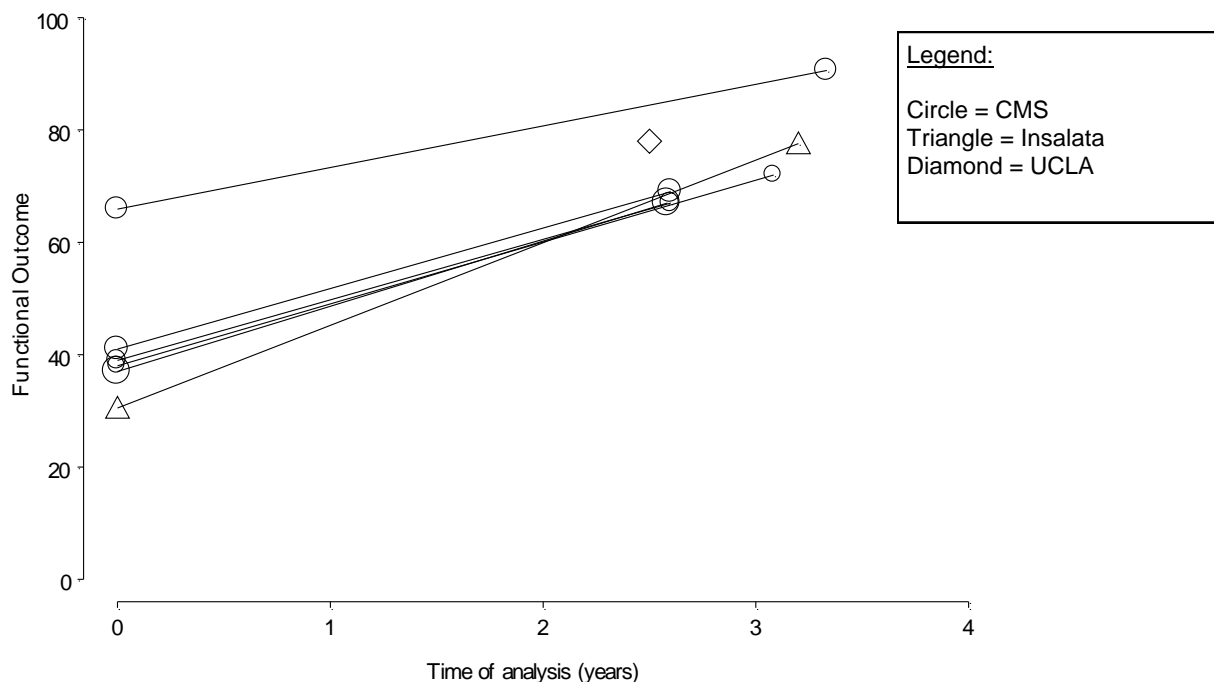
Other approaches. Five BA studies[82,95,101,126,127] assessed various other operative approaches in RC tear population. The studies were published from 1997 to 2007 (median=2005; IQR: 2002 to 2005). The number of participants enrolled in the studies ranged from 15 to 33 (median=21 [IQR: 19 to 23]). The median followup duration was 2.3 years (IQR: 2 to 2.7). For the four studies[82,95,101,127] that reported age of participants, the mean age ranged from 51 to 63 years. Of the four studies that reported type of tear, three studies[82,101,126] included only full-thickness RC tears and one study[95] included partial- or full-thickness tears. Two studies[95,101] included only massive RC tears, while tear characteristics were not reported in the other studies.[82,126,127] Recreational athletes were included in one study.[82] One study reported the proportion of patients manual labor jobs[95] and two studies included patients with a workers' compensation board (WCB) claim.[95,101]

Four studies[95,101,126,127] used a functional outcome measure. Since the interventions varied widely, the preoperative and postoperative outcomes were not plotted on a graph.

Operative Technique—Comparative Studies

Summary. The variety of operative techniques compared across the included studies precludes conclusions and recommendations regarding most techniques. For all patient groups, regardless of technique, there were significant improvements in the postoperative functional, pain and range of motion outcome measures compared to preoperative scores. However, few of the techniques demonstrated clinically important differences between their respective groups on any of the postoperative measures. Overall the methodological quality of the studies was modest. There were six RCTs,[71,73,78,81,98,105] one CCT[117] and eight cohort studies.[64,88,118,129,132,147,159,172]

The most frequently studied techniques were single-row vs. double-row suture anchor fixation, which were compared in six studies.[78,81,98,105,147,159] There was moderate evidence in favour of double-row repair for function based on a meta-analysis of all six studies. While the meta-analysis showed statistically significant results, the absolute differences in the change scores were small, rarely exceeding 5 points on an 100-point scale[159] which puts into question the clinical importance of this finding. One study[147] showed "clinically" and statistically significant difference in function favouring the double-row technique among the subgroup of patients with large or massive tears. There was also moderate evidence for cuff integrity: four of the studies[78,81,98,159] examined this outcome, two of which reported a significant difference favouring double-row fixation.[81,159] There was a low level of evidence for return to work: only one study[81] examined return to work and found no significant difference between the two techniques.

A variety of other techniques were studied across the remaining nine studies. Two studies[117,118] comparing mattress stitch vs. single stitch fixation. Each of the other seven studies examined a different comparison of techniques. Overall the level of evidence was low for these techniques. The outcome most often assessed was function. Only three studies found a significant difference between the groups examined: metal suture anchors vs. headed bioabsorbable corkscrews,[88] bioabsorbable tacs vs. suture tying,[64] and side-to-side vs. tendon-to-bone fixation[71] showed a 15, 14 and 12 point differences on 100-point scales, respectively. Cuff integrity was assessed in five studies: a statistically significant difference was reported for mattress stitch vs. simple stitch in two studies,[117,118] while no significant difference was found for non-absorbable vs. absorbable suture.[73] No comparison was possible for transosseus vs. mattress suture,[129] and staple fixation vs. side-to-side suture and anchor repair[172] due to incomplete data reporting.

In summary, there is some evidence that double-row fixation may perform better than single-row in terms of cuff integrity but results suggest little difference for function. There are insufficient or low levels of evidence for the remaining operative techniques.

Results by individual study. Fifteen studies[64,71,73,78,81,88,98,105,117,118,129,132,147,159,172] examined the effectiveness of different operative techniques for the repair of RC tears. The median sample size was 78 patients (IRQ: 55 to 100). The following operative techniques were assessed: single-row vs. double-row suture anchor repairs,[78,81,98,105,147,159] bioabsorbable tacs vs. suture tying,[64] side-to-side repair vs. tendon-to-bone fixation,[71] nonabsorbable suture with Mason-Allen technique vs. absorbable sutures with Kessler technique,[73] headed bio-corkscrews vs. metal anchor suture,[88] mattress vs. simple stitch,[117,118] mattress vs. single transosseous suture,[129] ultrasonic suture welding vs. hand-tied knots,[132] and staple fixation vs. side-to-side suture and anchor repair.[172] With the exception of studies comparing single-row vs. double-row suture anchor repairs, the

studies could not be pooled because the operative techniques were different. Patient and study characteristics, as well as study outcome data, are presented in Table 22 and Table 23, respectively. A grading of the body of evidence for operative technique studies is available in Table 24.

Single-row vs. double-row suture anchor repairs. Six studies (four RCTs[78,81,98,105] and two cohort studies[147,159]) compared single-row vs. double-row suture anchor repairs. Pooled results are shown in Figure 22 and Figure 23.

Burks et al.[78]conducted a RCT comparing single-row vs. double-row fixation in patients with full-thickness tears. Twenty patients were randomly assigned to each intervention and followed for 12 months. The average tear size was 18 mm and 19 mm in the double-row and single-row groups, respectively. All patients were followed for 12 months and evaluated using the WORC, ASES, CMS, Single Assessment Numeric Evaluation tool, UCLA, strength and cuff integrity. There were significant preoperative to postoperative differences across all outcomes in both treatment arms, however no significant different were found between the groups. Eighteen of 20 patients in each group were found to have an intact rotator cuff based on MRI evaluation.

Charousset et al.[81] conducted a RCT comparing single-row vs. double-row suture anchor repairs in patients who underwent arthroscopic RCR. Sixty-six patients were randomly assigned to the interventions (31 to double-row RCR, 35 to single-row RCR). All patients were followed for at least 2 years; mean followup was 2.3 years (range: 2 to 3.3). Patient function was evaluated using the CMS. At the date of last followup, the CMS had improved for both groups, but there was no statistically significant difference between the groups in the postoperative scores. Overall, more than 85 percent of patients who were employed prior to surgery returned to work. For the single-row group, the mean time to return to work was 5.3 months (range: 1 to 20); for the double-row group, it was 4.2 months (range: 1 to 12). The difference was not statistically significant (p=0.28). Cuff integrity was assessed using CT arthrography at 6 months following surgery. Anatomic healing was obtained in 14 (40.0 percent) cases in the single-row group compared with 19 (61.3 percent) in the double-row group. The difference was statistically significant (p=0.03), in favor of the double-row group.

Franceschi et al.[98] conducted a RCT comparing single-row vs. double-row fixation in patients with large and massive full-thickness RC tears. All patients underwent arthroscopic RCR. Sixty patients were randomly assigned to the interventions (30 to each group); 52 (86.7 percent) were included in the final analyses. The mean length of followup was 22.5 months (range: 18 months to 2.1 years). Patients were evaluated using the UCLA shoulder scale and range of motion (flexion, external and internal rotation). For both groups, there was significant improvement in total UCLA scores and range of motion from preoperative assessment to the final postoperative evaluation. However, the differences between the groups in the postoperative scores for all measures were not statistically significant. Cuff integrity was assessed using MRI arthrography at 2 years following surgery. Intact tendons were shown in 14 (53.8 percent) patients in the single-row group compared with 18 (69.2 percent) in the double-row group. The difference between groups was not statistically significant.

Grasso et al.[105] and colleagues conducted a RCT comparing single-row vs. double-row repair in 80 patients with large and massive full-thickness tears (40 patients per group). A total of 37 and 35 patients were evaluated at two year followup in the double-row and single-row fixation groups, respectively. Patients were assessed using the CMS, DASH, DASH-Work scales and strength. Substantial improvement was observed from preoperative to postoperative scores,

however the statistical significance of these improvements were not reported. There were no significant between-group differences on any of the outcome measures.

Park et al.[147] conducted a prospective cohort study comparing single-row vs. double-row fixation in patients undergoing arthroscopic RCR. Eighty-five patients were enrolled in the study (42 received double-row RCR, 43 received single-row RCR); 78 (91.7 percent) were included in the final analyses. All patients had full-thickness tears; tear size ranged from small or medium (n=46) to large or massive (n=32). The mean length of followup was 2.1 years (range: 22 months to 2.5 years). Patients were evaluated using the ASES index, the CMS and the Shoulder Strength Index (SSI; abduction, internal rotation and external rotation). For all patients, the mean postoperative ASES index and CMS improved significantly from the preoperative levels. The differences between the two groups on their postoperative scores for either measure were not statistically significant. Similarly, both groups had significant improvement in SSI after surgery, but the difference between the two groups was not statistically significant. The authors conducted a subgroup analysis of patients with tears less than 3 cm and those whose tears were greater than 3 cm. For patients with large or massive tears (>3 cm), the double-row fixture group showed clinically and statistically significant improvements in the ASES index, CMS, and SSI (abductor) than the single-row repair groups.

Sugaya et al.[159] conducted a retrospective cohort study comparing single-row vs. double-row fixation in patients undergoing arthroscopic RCR. All patients had full-thickness tears; tear size ranged from small to massive. The mean length of followup was 2.9 years (range: 2 to 5). Patients were evaluated using the ASES index and the UCLA shoulder scale. Overall, 104 patients (106 shoulders) were enrolled in the study (55 received double-row RCR, 51 received single-row RCR). Of these, 80 (76.9 percent) were included in the final analyses. For all patients, the mean postoperative ASES and UCLA scores improved significantly from the preoperative levels. However, the differences between the two groups on their postoperative scores were not statistically significant. Postoperative MRI examination revealed 18 (46.2 percent) and 30 (73.2 percent) intact cuffs in the single-row vs. double-row anchorage groups, respectively. The difference between the groups was statistically significant (p<0.01).

The four RCTs[78,81,98,105] and two cohort studies[147,159] provided data for meta-analysis of the effects of single-row vs. double-row suture anchor fixation on functional outcome measures. Data from the trials and cohort studies was analyzed separately. The following measures were included in the meta-analysis: ASES,[78] CMS,[81] DASH,[105] UCLA score,[98] and the ASES index.[147,159] For all of the studies, the average change between preoperative and postoperative scores were compared between groups. The pooled estimate of change in function indicates a significant improvement in favor of double-row fixation (SMD=0.55; 95% CI, 0.02 to 1.07 for trials; SMD=0.78; 95% CI, 0.46 to 1.11 for cohort studies). There was heterogeneity between the trials (p=0.008; I^2=75 percent); however, no evidence of heterogeneity between the two cohort studies (p=0.41; I^2=0 percent).

Figure 22. Single-row vs. double-row fixation on measures of functional outcome

Study or Subgroup	Double row			Single row			Weight	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total		
16.1.1 RCT/CCT								
Burks 2009	47.9	20	20	44.9	14	20	23.0%	0.17 [-0.45, 0.79]
Charousset 2007	29.1	8.78	31	24.1	7.83	35	26.0%	0.60 [0.10, 1.09]
Franceschi 2007a	23.2	1.22	30	21.4	1.47	30	24.4%	1.32 [0.75, 1.88]
Grasso 2009	25.1	10.1	35	23.5	15.6	37	26.7%	0.12 [-0.34, 0.58]
Subtotal (95% CI)			**116**			**122**	**100.0%**	**0.55 [0.02, 1.07]**

Heterogeneity: Tau² = 0.22; Chi² = 11.89, df = 3 (P = 0.008); I² = 75%
Test for overall effect: Z = 2.03 (P = 0.04)

Study or Subgroup	Double row			Single row			Weight	Std. Mean Difference IV, Random, 95% CI
16.1.2 Cohort Studies								
Park 2008	52.15	2.27	38	48.81	4.48	40	48.1%	0.92 [0.46, 1.39]
Sugaya 2005	54.2	9.3	41	47.1	12.1	39	51.9%	0.65 [0.20, 1.10]
Subtotal (95% CI)			**79**			**79**	**100.0%**	**0.78 [0.46, 1.11]**

Heterogeneity: Tau² = 0.00; Chi² = 0.66, df = 1 (P = 0.41); I² = 0%
Test for overall effect: Z = 4.73 (P < 0.00001)

-2   -1   0   1   2
Favours single row   Favours double row

Three RCTs[78,81,98] and one retrospective cohort study[159] provided data for a meta-analysis of the effects of single-row vs. double-row fixation on cuff integrity (Figure 23). Data from the trials and cohort study is presented separately. The pooled risk ratio from the trials shows no significant difference between double-row fixation over single-row fixation (RR=1.20; 95% CI, 0.86 to 1.68). There was evidence of heterogeneity between the three RCTs (p=0.08; I²=60 percent), although this was not significant. The heterogeneity appears to be attributable to the addition of Burks et al;[78] however, no differences between the patient characteristics across studies were apparent, with the exception of tear size. Burks[78] included patients with medium tears, while patients in Franceschi[98] had large or massive tears (tear size was not reported in Chraousset et al). Therefore, it is possible that double-row fixation may be result in greater probability of cuff integrity for patients with larger tears. The one cohort study showed a statistically significant difference in the proportion of patients whose cuff was found to be intact, in favor of the double-row group.

Figure 23. Single-row vs. double-row fixation on cuff integrity

Study or Subgroup	Double row Events	Double row Total	Single row Events	Single row Total	Weight	Risk Ratio M-H, Random, 95% CI
16.11.1 RCT/CCT						
Burks 2009	18	20	18	20	46.0%	1.00 [0.81, 1.23]
Charousset 2007	19	31	14	35	25.4%	1.53 [0.94, 2.51]
Franceschi 2007a	18	26	14	26	28.6%	1.29 [0.83, 1.99]
Subtotal (95% CI)		**77**		**81**	**100.0%**	**1.20 [0.86, 1.68]**
Total events	55		46			
Heterogeneity: Tau² = 0.05; Chi² = 4.99, df = 2 (P = 0.08); I² = 60%						
Test for overall effect: Z = 1.05 (P = 0.29)						
16.11.2 Cohort Studies						
Sugaya 2005	30	41	17	39	100.0%	1.68 [1.12, 2.51]
Subtotal (95% CI)		**41**		**39**	**100.0%**	**1.68 [1.12, 2.51]**
Total events	30		17			
Heterogeneity: Not applicable						
Test for overall effect: Z = 2.52 (P = 0.01)						

Risk Ratio M-H, Random, 95% CI scale: 0.5 0.7 1 1.5 2
Favours single row   Favours double row

Bioabsorbable tacs vs. suture tying. Bennett et al.[64] conducted a prospective cohort study comparing repair of the subscapularis tendon using 8 mm bioabsorbable tacs (Suretac; Accufex, Mansfield MA) with suture tying techniques using No. 2 Tevdeks and 5 mm metal screws (Metal Corkscrew; Arthrex, Naples FL). All patients had full-thickness tears and underwent arthroscopic repair and debridement. Thirty-one patients were enrolled in the study; 19 were included in the analysis (nine in the bioabsorbable tacs group, 10 in the suture tying group). Patients were allocated to the interventions based on tear patterns. Patients were followed for a minimum of 2 years (range: 2 to 4). Patient function was assessed using the ASES index, the CMS and a single question of percent function compared with the contralateral shoulder. A visual analogue scale was used to evaluate pain. Both groups showed significant improvement at endpoint compared to their baseline score (p<0.05) across all outcomes. The ASES score at final followup was significantly different between groups, favoring the bioabsorbable tacs group. All other outcomes showed no significant differences between groups.

Side-to-side vs. tendon-to-bone fixation. Bigoni and colleagues[71] conducted a RCT comparing side-to-side repair vs. tendon-to-bone fixation in 50 patients with small, medium and large full-thickness tears. Twenty-five patients were randomized to each group. Patients were followed for 12 months and evaluated using the CMS and external and internal rotation strength. Significant improvement was shown in each of the study arms across all three outcomes. Further, there was a statistically significant difference between groups for the CMS and strength outcomes, favouring tendon-to-bone fixation.

Nonabsorbable vs. absorbable sutures. Boehm et al.[73] conducted a RCT comparing transosseous repair using a modified Mason-Allen technique with nonabsorbable sutures (No. 3 Ethibond) vs. a modified Kessler technique with absorbable sutures (1.0 mm polydioxanone cord). All patients had full-thickness tears and underwent open RCR with acromioplasty. One hundred patients were randomly assigned to the interventions (50 to each group). All patients were followed for at least 2 years; mean followup was 2.3 years (range: 2 to 2.5) in the Mason-Allen group and 2.2 years (range: 2 to 2.4) in the Kessler group. Patients were assessed using the CMS and a visual

analogue scale for pain. At the date of last followup, the CMS had improved for both groups, but there was no statistically significant difference between the groups in the postoperative scores. Similarly, there was no difference between the groups in terms of pain. Ultrasound was used to evaluate cuff integrity. There was no significant difference between the proportion of intact cuffs in the Mason-Allan group (77.5 percent) compared with the Kessler group (81.8 percent).

Headed bioabsorbable corkscrew vs. metal suture anchor. Cummins et al.[88] conducted a prospective cohort study comparing Mitek RC metal suture anchors (Norwood, MA) vs. Headed Bio-Corkscrews (Arthrex, Naples, FL), a knotless device made of L-polylactic acid. All patients were treated with open RCR and acromioplasty. Twenty-seven patients were enrolled in the study (18 received metal suture anchors, 9 received corkscrews) and all were included in the analysis. In the group treated with suture anchors (n=18), the mean tear size was 1.9 ± 1.0 cm^2 (p=0.03); in the group treated with bioabsorbable screws (n=9), the mean tear size was 1.1 ± 0.9 cm^2. The CMS scoring system was used to assess shoulder function at 12 months following surgery. Based on the CMS, the suture anchors group demonstrated significantly higher function than the bioabsorbable screws group (88 ± 9 vs. 73 ± 17, p=0.016). Abduction improved for both groups, however there was a statistically significant difference at the 12 month followup favoring the metal suture anchor group (p<0.01). From 6 weeks to 12 months following surgery, the suture anchors group graded their "overall" shoulder rating higher than the corkscrew group (p<0.1); however, for both groups the overall rating was "fair."

Mattress vs. simple stitch. Two studies compared the effectiveness of mattress stitch vs. simple stitch. Ko et al.[118] conducted a prospective cohort study comparing a modified mattress locking stitch (MMLS), a simple modification of the Mason-Allen stitch, vs. a simple stitch in patients with a tear size ranging from 1.5 to 3.0 cm. The mean length of followup was 2.6 years (range: 2 to 3.1). Patients were evaluated using the ASES index, the UCLA shoulder scale and a visual analogue scale (VAS) for pain. Overall, 78 patients were enrolled in the study (39 per group). For all patients, the mean postoperative ASES index, UCLA score and VAS improved significantly from the preoperative levels. The differences between the two groups on their postoperative scores for all measures were not statistically significant. At 6 months to 3 years following surgery, MRIs were performed on 69 patients to examine cuff integrity. Repaired cuffs remained intact in 30 of 36 (83.3 percent) cases in the MMLS group compared with 24 of 33 (72.7 percent) in the simple stitch group (p=0.03).

 In a second study, Ko and colleagues[117] conducted a controlled clinical trial comparing a massive cuff stitch (mattress) repair with a simple stitch in patients with a tear size ranging from 0.5 to 1.5 cm. the mean followup was 2.8 years (range 2 to 3.4 years). A total of 38 and 39 patients were enrolled, and 35 and 36 patients were analyzed in the mattress stitch and simple stitch groups, respectively. There was significant improvement from preoperative to postoperative assessment for the ASES activities of daily living subscore, the UCLA and pain VAS. However, the only outcome that was significantly different between groups was cuff integrity, where 83 percent (30 of 36) of patients had an intact cuff in the the mattress stitch group, compared with 73 percent (24 of 33) of patients in the simple stitch group.

 Figure 24 and Figure 25 below display the functional outcomes and cuff integrity of these two studies. Pooled estimates were not calculated, since the study designs differed (CCT vs. prospective cohort). Mattress stitch was favoured over simple stitch for functional outcomes in one study, while the second study showed no difference. Both studies found superior rates of

cuff integrity in the mattress stitch group, however the differences between groups were not statistically significant.

Figure 24. Mattress stitch vs. simple stitch for measures of functional outcome

Study or Subgroup	Matress locking stitch Mean	SD	Total	Simple Stitch Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
18.1.1 RCT/CCT								
Ko 2009	20	2.04	35	17.8	2.38	36	100.0%	0.98 [0.49, 1.47]
Subtotal (95% CI)			35			36	100.0%	0.98 [0.49, 1.47]
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.89 (P < 0.0001)								
18.1.2 Cohort								
Ko 2008	19.3	55.5	39	18.2	48.9	39	100.0%	0.02 [-0.42, 0.46]
Subtotal (95% CI)			39			39	100.0%	0.02 [-0.42, 0.46]
Heterogeneity: Not applicable								
Test for overall effect: Z = 0.09 (P = 0.93)								

Std. Mean Difference IV, Random, 95% CI
-1 -0.5 0 0.5 1
Favours simple stitch   Favours matress locking

Figure 25. Mattress stitch vs. simple stitch for cuff integrity

Study or Subgroup	Matress locking stitch Events	Total	Simple Stitch Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
18.3.1 RCT/CCT						
Ko 2009	30	35	26	36	100.0%	1.19 [0.93, 1.51]
Subtotal (95% CI)		35		36	100.0%	1.19 [0.93, 1.51]
Total events	30		26			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.38 (P = 0.17)						
18.3.2 Cohort						
Ko 2008	30	36	24	33	100.0%	1.15 [0.89, 1.48]
Subtotal (95% CI)		36		33	100.0%	1.15 [0.89, 1.48]
Total events	30		24			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.05 (P = 0.30)						

Risk Ratio M-H, Random, 95% CI
0.5 0.7 1 1.5 2
Favours Simple Stitch   Favours Matress locking stitc

Mattress vs. single transosseous suture. A prospective cohort study was conducted by Matis et al.[129] to compare single transosseous suture vs. transosseous mattress suture in patients who underwent arthroscopic RCR and acromioplasty. Patients with full- and partial-thickness tears were included; tear size ranged from small to medium. Seventy-five patients were treated with transosseous sutures; the mean followup period was 2.2 years (range: 5 months to 4.9 years). Twenty-four patients were treated with mattress sutures; mean length of followup was 14.4 months (range: 4.8 months to 2.8 years). Patients were evaluated using the CMS. At the date of last followup, the CMS had improved for both groups. Cuff integrity was assessed by ultrasonography for the transosseus suture group. Intact tendons were shown in 66 cases (88 percent).

Ultrasonic suture welding vs. hand-tied knots. McIntyre et al.[132] conducted a retrospective cohort study comparing ultrasonic suture welding using No. 2 polypropylene to fix the tendon vs. hand tied knots using No. 2 braided polyester suture. All patients were treated with a mini-open RCR and acromioplasty. The mean tear size was 3.4 cm (range: 1 to 6 cm) and 3.0 cm (range: 1 to 6 cm) in the suture welding and hand tied knot groups, respectively. The type of tear was not

reported. Patients were evaluated using the UCLA shoulder scale. The mean length of followup for the suture weld group was 2.3 years (range: 18 months to 3.3 years). For patients treated with hand tied knots, 40/55 (72.7 percent) were available for followup compared to 47/50 (94.0 percent) for the suture weld group. For both groups, the mean postoperative UCLA score improved significantly from the preoperative levels. However, the difference between the two groups on their postoperative scores was not statistically significant.

Staple fixation vs. side-to-side suture. Wilson et al.[172] conducted a retrospective cohort study comparing staple fixation (Instrument Makar, Okemos, MI) vs. side-to-side suture and anchor repair (G-4 or Stealth, Mitek, Westwood MA) in patients undergoing arthroscopic RCR. All patients had small to large sized full-thickness tears. One hundred patients were enrolled and included in the analysis (35 received staple fixation, 65 received side-to-side suture and anchor). The mean length of followup for the staple group was 7.9 years (3 to 14); for the suture anchors group it was 4 years (2 to 7). Patients were evaluated using the UCLA shoulder scale. For all patients, the mean postoperative UCLA score significantly improved from the preoperative levels. However, the difference between the two groups on their postoperative scores was not statistically significant. Cuff integrity was assessed in the staple fixation group. Of the 33 patients evaluated, the tendon was completely healed in 22 (66.7 percent).

Table 22. Study and patient characteristics for studies assessing operative techniques

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Bennett WF,[64] 2003	**G1:** Bioabsorbable tacs (NR) **G2:** Suture tying (NR) Prospective cohort	**G1:** 58 yr / Males: 5 (56) **G2:** 64 yr / Males: 7 (70)	FTT; NR NR
Bigoni M,[71] 2009	**G1:** Side-to-side repair (25) **G2:** Tendon-to-bone fixation (25) RCT	**G1:** NR / Males: 10 (40) WCB: 0 **G2:** NR / Males: 14 (56) WCB: 0	FTT; Sm, Med, Lg NR
Boehm TD,[73] 2005	**G1:** Nonabsorbable sutures (Mason-Allen technique) (50) **G2:** Absorbable sutures (Kessler technique) (50) RCT	**G1:** 56 yr (38–69) / Males: 36 (72) WCB: 5 (10) **G2:** 57 yr (41–71) / Males: 32 (64) WCB: 4 (8)	FTT; Sm, Med, Lg NR
Burks RT,[78] 2009	**G1:** Double-row anchor RCR (20) **G2:** Single-row anchor RCR (20) RCT	**G1:** 57 (41–81) / Males: NR Smokers: 0 **G2:** 56 (43–74) / Males: NR Smokers: 0	FTT; G1: 18 mm, G2: 19 mm NR
Charousset C,[81] 2007	**G1:** Double-row anchor RCR (31) **G2:** Single-row anchor RCR (35) RCT	**G1:** 60 yr (37–62) / Males: 16 (52) Athletes: competitive 2 (6.5), recreational 2 (7) Manual Labourers: 6 (19) WCB: 2 (7) **G2:** 58 yr (32–74) / Males: 15 (43) Athletes: competitive 1 (3), recreational 5 (14) Manual Labourers: 10 (29) WCB: 4 (11)	NR; NR **G1:** 14.7 (1–73), **G2:** 11.9 (1–52)
Cummins CA,[88] 2003	**G1:** Metal suture anchors (18) **G2:** Headed bio-corkscrews (9) Prospective cohort	**G1:** 63±8 yr / Males: 12 (67) **G2:** 58±10 yr / Males: 7 (78)	NR; **G1:** 1.9 cm², **G2:** 1.1 cm² NR
Franceschi F,[98] 2007	**G1:** Double-row anchor RCR (30) **G2:** Single-row anchor RCR (30) RCT	**G1:** 59.6 yr (45–80) / Males: 16 (53) **G2:** 63.5 yr (43–76) / Males: 12 (40)	FTT; Lg, Mass ≥ 3 mo
Grasso A,[105] 2009	**G1:** Double-row anchor RCR (40) **G2:** Single-row anchor RCR (40) RCT	**G1:** 55.2±6.5 / Males: 18 (45) **G2:** 58.3±10.3 / Males: 16 (40)	FTT; NR NR

cm = centimeter; FTT = full-thickness tear; G = group; Lg = large; Mass = massive; Med = medium; NR = not reported; PTT = partial-thickness tear; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 22. Study and patient characteristics for studies assessing operative techniques (continued)

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Ko SH,[117] 2009	**G1:** Massive cuff stitch (38) **G2:** Simple stitch (39) CCT	**G1:** 53.6 (40–68) / Males: 18 (47) **G2:** 52.4 (15–68) / Males: 17 (44)	FTT; 0.5–1.5 cm NR
Ko SH,[118] 2008	**G1:** Modified mattress locking stitch (39) **G2:** Simple stitch (39) Prospective cohort	**Total:** 53.4 yr (39–68)	FTT; 1.5–3 cm NR
Matis N,[129] 2006	G1: Transosseous single suture (75) G2: Transosseous mattress suture (24) Prospective cohort	**G1:** 58.2 yr (35–75) / Males: 51 (68) **G2:** 58.0 yr (35–75) / Males: 16 (67)	FTT / PTT; Sm, Med
McIntyre LF,[132] 2006	**G1:** Suture welding (50) **G2:** Hand-tied knots (55) Retrospective cohort	**G1:** 55.7 yr (37–78) / Males: 29 (58) **G2:** 54.7 yr (17–78) / Males: 38 (69)	NR; **G1:** 3.4 cm (1–6), **G2:** 3.0 cm (1–6) **G1:** 9.9 mo (1–36), **G2:** 10.4 mo (1–36)
Park JY,[147] 2008	**G1:** Double-row anchor RCR (42) **G2:** Single-row anchor RCR (43) Prospective cohort	G1 : 54.4 yr (28–76) / Males : 22 (52) **G2 :** 57 yr (39–78) / Males : 20 (47)	FTT; Sm, Med, Lg, Mass NR
Sugaya H,[159] 2005	**G1:** Double-row anchor RCR (55 shoulders) **G2:** Single-row anchor RCR (51 shoulders) Retrospective cohort	**G1 :** 58.1 yr (36–73) / Males : 28 (51) **G2 :** 57.7 yr (34–72) / Males : 28 (55)	FTT; Sm, Med, Lg, Mass NR
Wilson F,[172] 2002	**G1:** Staple fixation (35) **G2:** Side-to-side suture & anchor (65) Retrospective cohort	**G1 :** 49 yr (20–69) / Males : 27 (77) **G2 :** 52 yr (32–70) / Males : 38 (59)	FTT; Sm, Med, Lg **G1:** 48 wk (1–312), **G2:** 46 wk (2–312)

Table 23. Outcome data for studies assessing operative techniques

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Bennett WF,[64] 2004	**G1:** Bioabsorbable tacs (9) **G2:** Suture tying (10) NR (2–4 yr)	ASES	33±15 / 88±12, p=0.001	31±23 / 72±11, p=0.002	p=0.003‡
		CMS*	50±10 / 77±12, p=0.001	55±16 / 77±8, p=0.001	p=1.0‡
		percent function	36±16 / 86±17, p=0.001	47±16 / 83±12, p=0.002	p=0.66‡
		VAS pain	7±2 / 1±1, p=0.001	7±3 / 2±2, p=0.002	p=0.16‡
Bigoni M,[71] 2009	**G1:** Side-to-side repair (NR) **G2:** Tendon-to-bone fixation (NR) 12 mo	CMS 3 mo 6 mo 12 mo	32 (22–40) 41 (32–52) 70 (58–80) 78 (71–87), p<0.05	30 (22–38) 46 (38–53) 73 (58–83) 88 (81–94), p<0.05	p<0.05
		ER Strength (% peak torque) 3 mo 6 mo 12 mo	39 (32–56) 34 (38–47) 28 (22–38) 21 (12–30), p<0.05	37 (31–42) 32 (26–44) 24 (16–33) 12 (-22–26), p<0.05	p<0.05
		IR Strength (% peak torque) 3 mo 6 mo 12 mo	34 (25–40) / 30 (26–55) 25 (18–35) 17 (11–25),p<0.05	32 (27–37) / 25 (10–32) 14 (5–20) 9 (-8–20), p<0.05	p<0.05
Boehm TD,[73] 2005	**G1:** Nonabsorbable sutures (Mason-Allen technique) (49) **G2:** Absorbable sutures (Kessler technique) (44) 2.2 yr (2–2.5)	CMS	NR / 78	NR / 76	p=0.33
		Pain (VAS–15 point)	NR / 13.1	NR / 12.9	p=0.65
		Cuff integrity n/N (%), US	38/49 (77.5)	36/44 (81.8)	p=0.37
Burks RT,[78] 2009	**G1:** Double-row anchor RCR (20) **G2:** Single-row anchor RCR (20) 12 mo	WORC	31.8±19.4 / 87.9±20.0, p<0.0001	30.3±17.7 / 84.8±18.4, p<0.0001	p=0.236
		ASES	37.6±19.3 / 85.5±20.0, p<0.0001	41.0±21.5 / 85.9±14.0, p<0.0001	p=0.673
		CMS	45.6±20.3 / 74.4±18.4, p<0.0001	44.1±18.8 / 77.8±9.0, p<0.0001	p=0.980
		SANE	40.8 ±21.6 / 89.9±20.0,p<0.0001	40.8±23.3 / 90.9±11.0, p<0.0001	p=0.527
		UCLA	13.6±4.6 / 29.5±5.6, p<0.0001	12.1±3.9 / 28.6±3.6, p<0.0001	p=0.165

ABD = abduction; ADL = activities of daily living; ASES = American Shoulder and Elbow Surgeons score; CMS = Constant-Murley score; CTA = computed tomography arthrogram; ER = external rotation; F = flexion; G = group; IR = internal rotation; MRI = magnetic resonance imaging; N = number; NR = not reported; NS = not significant; OSR = Overall Shoulder Rating; RCR = rotator cuff repair; ROM = range of motion; SANE = Single Assessment Numeric Evaluation; SD = standard deviation; SSI = shoulder strength index; UCLA = University of California Los Angeles; US = ultrasonography; VAS = visual analogue scale

*Subscales reported

†Data extrapolated from graph

‡Calculated by UAEPC

§ adjusted for baseline scores only

|| adjusted for baseline score, age, and gender

Table 23. Outcome data for studies assessing operative techniques (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Burks RT,[78] 2009 (continued)		Strength (Nm)	ER: 9.6±6.0 / 16.7±7.5, p<0.000 IR: 18.1±11.6 / 28.8±14.4, p<0.0001	ER: 8.7±4.6/ 17.2±7.7,p<0.0001 IR: 15.8±7.9 / 28.1±13.8, p<0.0001	p=0.862 p=0.687
		Cuff integrity n/N (%), MRI	18/20 (90)	18/20 (90)	NS
Charousset C,[81] 2007	**G1:** Double-row anchor RCR (28) **G2:** Single-row anchor RCR (33) 2.3 yr (2–3.3)	CMS*	53.6 (17–75) / 82.7 (58–94), p<0.001	56.6 (33–77) / 80.7 (62–95), p<0.001	p=0.4
		Return to work, mean (range) mo; Number of patients	4.2 (1–12); 12	5.3 (1–20); 14	p=0.28
		Cuff integrity n/N (%), CTA 6 mo	19/31 (61.3)	14/35 (40.0)	p=0.03
Cummins CA,[88] 2003	**G1:** Metal suture anchors (18) **G2:** Headed bio-corkscrews (9) 12 mo	CMS	NR / 88±9	NR / 73±17	p=0.016
		ABD (degrees) 6 wk 3 mo 6 mo 12 mo	113.6±8.1 112.8±7.3 120.8±8.0 144.8±4.6 164.4†	116.7±18.7 80.5±11.0 99.9±11.7 126.31±7.1 141.1±9.9†	p<0.01
		OSR 6 wk 3 mo 6 mo 12 mo	1.4±0.6 3.1±0.2 3.3±0.2 3.4±0.2 3.6±0.1	1.1±1.3 2.3±0.3 2.5±0.2 2.5±0.4 3.1±0.3	p<0.1 (significant)
Franceschi F,[98] 2007	**G1:** Double-row anchor RCR (26) **G2:** Single-row anchor RCR (26) 22.5 mo (18 mo–2.1 yr)	UCLA	10.1 (5–14) / 33.3 (30–35), p<0.05	11.5 (6–14) / 32.9 (29–35), p<0.05	p>0.05
		ROM (degrees)	F: 100 (30–150) / 156 (140–170), p <0.05 ER: 79.6 (62–93) / 131.3 (85–137), p <0.05 IR: 28.6 (22–35) / 40.3 (26–43), p <0.05	F: 110 (30–140) / 159 (150–170), p<0.05 ER: 83.2 (65–95) / 132.4 (90–140), p<0.05 IR: 27.3 (20–33) / 37.3 (27–42), p<0.05	p>0.05
		Cuff integrity n/N (%), MRI 2 years	18/26 (69.2)	14/26 (53.8)	p>0.05

Table 23. Outcome data for studies assessing operative techniques (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Grasso A,[105] 2009	**G1:** Double-row anchor RCR (37) **G2:** Single-row anchor RCR (35) 24.8±1.4 mo	CMS§	73.2±19 / 100.5±17.8	77.5±14.7 / 104.9±21.8	p=0.378
		DASH ||	37.8±18.2 / 12.7±10.1	38.9±15.8 / 15.4±15.6	p=0.482
		DASH-Work ||	44.3±24.2 / 16.0±22.0	38.8±24.4 / 9.6±13.3	p=0.212
		Strength (lb) ||	8.5±4.3 / 12.7±5.7	9.9±5.7 / 12.9±7.0	p=0.382
Ko SH,[117] 2009	**G1:** Massive cuff stitch (35) **G2:** Simple stitch (36) 2.8 yr (2–3.4)	ASES ADL	10.1 / 26.8, p<0.05	10.7 / 26.6, p<0.05	p>0.05
		UCLA	12.7 / 32.7, p<0.05	14.1 / 31.9, p<0.05	p>0.05
		Pain VAS	7.0 / 1.1, p<0.05	7.0 / 1.1, p<0.05	p>0.05
		ROM (degrees)	F: NR / 165.9	F: NR / 165.8	p>0.05
		Cuff integrity n/N (%), US	30 / 35 (86)	26 / 36 (72)	p<0.05
Ko SH,[118] 2008	**G1:** Modified mattress locking stitch (NR) **G2:** Simple stitch (NR) 2.6 yr (2–3.1)	ASES (ADL score only)	11 / 27, p<0.05	10.6 / 27.1, p<0.05	p=0.99
		UCLA	13.4 / 32.7, p<0.05	13.7 / 31.9, p<0.05	p>0.99
		Pain (VAS)	6.5 / 0.9, p<0.05	7 / 1.1, p<0.05	p=0.08
		Cuff integrity n/N (%), MRI (6-37 mo post-op)	30/36 (83)	24/33 (73)	p=0.03
Matis N,[129] 2006	**G1:** Transosseous single suture (75) **G2:** Transosseous mattress suture (21) 23.8 mo (5 mo–4.9 yr)	CMS*	55.8 (29–78) / 80.4 (59–105), p=NR	59 (32–75) / 83 (65–100), p=NR	NR
		Cuff integrity n/N (%), US	66/75 (88)	NR	NR
McIntyre LF,[132] 2006	**G1:** Suture welding (47) **G2:** Hand-tied knots (40) 2.3 yr (18 mo–3.3 yr)	UCLA	12.5 / 29.6, p<0.05	13.2 / 31.5, p<0.05	p=0.297
Park JY,[147] 2008	**G1:** Double-row anchor RCR (38) **G2:** Single-row anchor RCR (40) 2.1 yr (22 mo–2.5 yr)	ASES	40.82±16.8 / 92.97±2.27, p<0.01	42.79 ±19.23 / 91.6±4.48, p<0.01	p=0.09
		CMS	44.16±6.96 / 79.66±4.52, p<0.01	41.63±9.84 / 76.68±8.56, p<0.01	p=0.06
		SSI	ABD: 0.53±0.22 / 0.79±0.11, p<0.01	ABD: 0.52±0.25 / 0.74±0.14, p<0.01	p=0.81
			ER: 0.66±0.18 / 0.77±0.15, p<0.01	ER: 0.64±0.23 / 0.79±0.14, p<0.01	p=0.57
			IR: 0.71±0.16 / 0.81±0.11, p<0.01	IR: 0.69±0.20 / 0.78±0.15, p=0.39	p=0.78

Table 23. Outcome data for studies assessing operative techniques (continued)

Author, year	Intervention (N analysed) Followup, mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Sugaya H,[159] 2005	**G1:** Double-row anchor RCR (41)	ASES*	40.4±12.3 (10–65) / 94.6±9.3 (60–100), p <0.01	45.8±19.4 (5–70) / 92.9±12.1 (45–100), p <0.01	p=0.49
	G2: Single-row anchor RCR (39)	UCLA*	14.4±4.5 (5–21) / 33.1±3.4 (19–35), p<0.01	14.8±5.8 (3–22) / 32.4±4.7 (16–35), p <0.01	p=0.44
	2.9 yr (2–5)	Cuff integrity n/N (%), MRI	30/41 (73.2) [mean 14.4 mo]	18/39 (46.2) [mean 13.6 mo]	p<0.01
Wilson F,[172] 2002	**G1:** Staple fixation (35) **G2:** Side-to-side suture & anchor (65)	UCLA*	18.6 / 31.5 (14–35), p=NR	21.1 / 32.5 (16–35), p=NR	p>0.05
	5 yr (2–14)	Cuff integrity n/N (%), Arthroscopy	22/33 (66.7)	NR	NR

Table 24. Strength of evidence for operative techniques

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Single-row vs. double-row fixation	1; 40	HRQL	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	6; 435 (388)	Function	RCTs, cohorts Medium	Inconsistent	Direct	Precise	Absent	Moderate
	4; 270 (238)	Cuff integrity	RCTs, cohort Medium	Inconsistent	Direct	Precise	Absent	Moderate
	1; 66	Time to return to work	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
Bioabsorbable tacs vs. suture tying	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 31 (19)	Function	Cohort Low	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Side-to-side vs. tendon-to-bone fixation	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1	Function	RCT Moderate	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Nonabsorbable vs. absorbable sutures	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 100	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	1; 100	Cuff integrity	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Bio-corkscrews vs. metal suture	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 27	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Mattress stitch vs. simple stitch	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	2; 155 (149)	Function	CCT, cohort Medium	Inconsistent	Direct	Imprecise	Present	Low
	2; 155 (140)	Cuff integrity	CCT, cohort Medium	Consistent	Direct	Imprecise	Present	Moderate
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

CCT = controlled clinical trial; HRQL = health-related quality of life; n/a = not applicable; RCR = rotator cuff repair; RCT = randomized controlled trial

* Number analyzed if different from number studied

Table 24. Strength of evidence for operative techniques (continued)

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Transosseous mattress vs. single suture	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 99	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Ultrasonic welding vs. hand-tied knots	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 105	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Staple fixation vs. side-to-side suture	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 100	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	1; 100 (35)	Cuff integrity	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

Operative Augmentation—Comparative Studies

Summary. Three small comparative studies (32, 31, and 28 participants) were identified that assessed biologic augmentation of a RCR. One RCT[109] and one retrospective cohort study[170] comparing porcine small intestine submucosa xenograft vs. no augmentation found no statistically significant differences in functional scores or cuff integrity. In addition, the retrospective cohort study found a slower rate of resolution of pain during activities in the augmentation group and an almost global loss of strength, except for strength in external rotation, compared to the no augmentation group. The trial was at high risk of bias due to lack of blinding and baseline imbalances between groups, while the cohort study was limited by its retrospective design. One retrospective cohort study[113] compared patch graft vs. no augmentation and found no statistically significant difference in function. The study evaluated range of motion for three movements and found a statistically significant difference favoring the patch for abduction (absolute difference between groups of 40 degrees), but no differences for flexion and external rotation. The study suffered from several methodological limitations including retrospective design, no control for confounding, and 25 percent loss to followup. Overall, the level of evidence is low for operative augmentations, which precludes any definitive conclusions in this area.

Results by individual study. Three studies (one RCT[109] and two retrospective cohort studies[113,170]) compared the use of an operative biologic augmentation of RCR vs. no augmentation. The studies could not be pooled because operative augmentation devices or study designs were different. Patient and study characteristics, as well as study outcome data, are presented in Table 25 and Table 26, respectively. Grading of the body of evidence is presented in Table 27.

Porcine small intestine submucosa vs. no augmentation. Two studies compared augmention with porcine small intestine submucosa with no augmentation. Iannotti et al.[109] conducted a RCT comparing porcine small intestine submucosa augmentation (Restore Orthobiologic Implant, DuPuy Orthopaedics, USA) vs. no augmentation in patients who underwent open RCR. All patients had large or massive full-thickness tears of the supraspinatus and infraspinatus tendons (two-tendon tears). Thirty-two patients were randomly assigned to the interventions (16 to each group); 30 were included in the final analyses. The mean length of followup was 14 months (12 mo to 2.2 yr). Patients were evaluated using the University of Pennsylvania Shoulder Score (PENN), which showed no significant difference between the groups at followup (p=0.07). Cuff integrity was assessed using MRI at 12 months following surgery. Anatomic healing was obtained in 4 (26.7 percent) cases in the porcine small intestine submucosa augmentation group compared with 9 (60 percent) in the group without augmentation. The difference was not statistically significant (p=0.11). The study authors suggest that the lack of statistically significant difference between the groups is attributable to the small sample size; this study was aborted early since it appeared that augmentation would not improve the rates of cuff integrity, the primary study outcome.

Walton et al.[170] conducted a retrospective cohort study comparing porcine small intestine submucosa augmentation (Restore Orthobiologic Implant, DuPuy Orthopaedics, USA) vs. no augmentation using patients from an aborted RCT. Fifteen subjects (16 shlds) repaired with the xenograft were retrospectively matched to a group of 16 (16 shlds) subjects repaired by

conventional RCR with no augmentation performed by the same surgeon and usually in the same time period. With matching, the control group was similar to the augmentation group with respect to the number of subjects, mean age, mean tear size and gender. All patients had poor tendon quality or large to massive tears with an intact subscapularis tendon. Patients were evaluated for pain during activity, strength, and cuff integrity during the 2 year followup period. No statistical difference in pain during activity was found, except at 3 months where patients with augmentation had significantly more pain with activity ($p<0.01$). In addition, patients with augmentation had significantly less participation in sports at the end of followup ($p<0.05$). Patients with xenograft had significantly less strength in liftoff, internal rotation and adduction ($p<0.05$) than patients with no augmentation. However, no significant differences in supraspinatus strength ($p=0.08$) and external rotation strength ($p=0.105$) were found between the groups. Cuff integrity was assessed using MRI at 2 years after surgery and the difference was not statistically significant. Anatomic healing was obtained in 4 (40.0 percent) cases in the xenograft group compared with 5 (41.6 percent) controls in the no augmentation group from participants available for imaging. Based on these findings, the authors do not recommend the use of the RESTORE Orthobiologic Implant.

Patch graft vs. no augmentation. Ito et al.[113] conducted a retrospective cohort study comparing use of patch grafts, consisting of a double layer of freeze-dried fascia lata (Biodynamics, Germany), vs. no augmentation in patients with large or massive full-thickness RC tears. All patients underwent open RCR with acromioplasty. A total of 28 patients were enrolled in the study; 21 were included in the final analyses (9 in the patch graft group, 12 in the no augmentation group). The mean length of followup was 3 years (2 to 8.4). Patients were evaluated using the JOA score and range of motion (flexion, abduction, external rotation). For both groups, there was a significant difference in the JOA score, flexion and abduction from baseline to followup. A significant between-group difference was found for abduction range of motion, in favor of the patch graft group; for all other outcome measures, there were no significant differences between the patch and no patch groups.

Table 25. Study and patient characteristics for studies assessing operative augmentations

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Iannotti JP,[109] 2006	**G1:** Porcine small intestine submucosa augmentation (16) **G2:** No augmentation (16) RCT	**G1:** 58 yr / Males: 11 (73) WCB : 3 (20) **G2:** 57 yr / Males: 6 (40) WCB: 0 (0)	FTT; Lg, Mass ≥ 3 mo
Ito J,[113] 2003	**G1:** Patch graft (NR) **G2:** No augmentation (NR) Retrospective cohort	**G1:** 62.8±6.9 (49–70) yr / Males: 6 (67) **G2:** 52.3±8.6 (36–66) yr / Males: 10 (83)	FTT; Lg, Mass **G1:** 4.1±2.9 mo, **G2:** 5.8±4.7 mo
Walton JR,[170] 2007	**G1:** Porcine small intestine submucosa augmentation (15) **G2:** No augmentation (16) Retrospective cohort	**G1:** 60.2±3.5 yr / Males: 10 (67) **G2:** 59.6±3.1 yr / Males: 11 (69)	FTT; Lg, Mass NR

FTT = full-thickness tear; G = group; Lg = large; mass = massive; NR = not reported; RCT = randomized controlled trial; SD = standard deviation; WCB = workers' compensation board

Table 26. Outcome data for studies assessing operative augmentations

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range)	Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range)	Group 1 vs. Group 2 Post-op p-value
Iannotti JP,[109] 2006	**G1:** Porcine small intestine submucosa augmentation (15) **G2:** No augmentation (15) 14 mo (12 mo–2.2 yr)	PENN*	42 / 83 (IQR: 70–92)	34 / 91 (IQR: 81–99)	p=0.07
		Cuff integrity n/N (%), MRI at 12 mo	4/15 (26.7)	9/15 (60.0)	p=0.11
Ito J,[113] 2003	**G1:** Patch graft (9) **G2:** No augmentation (12) 3 yr (2–8.4)	JOA*	47.9±13.3 / 91.7±7.0, p=0.0077	54.2±9.7 / 92±7.6, p=0.0022	p=0.19†
		ROM (degrees)	F: 84.4±32.4 / 159.6±14.8, p=0.0005 ABD: 62.2±31.1 / 163.3±28.7, p=0.0007 ER: 43.9±16.9 / 41.7±24.7, p>0.05	F: 94.6±43.9 / 145.8±27.1, p=0.0032 ABD: 85.0±43.9 / 146.4±27.1, p=0.0019 ER: 36.3±44.6 / 35.4±37.8, p>0.05	F: p=0.10† ABD: p=0.008† ER: p=0.93†

ABD = abduction; ADD = adduction; ER = external rotation; F = flexion; G = group; IR = internal rotation; IQR = interquartile range; JOA = Japanese Orthopaedic Association scale; lb = pound; mo = month; MRI = magnetic resonance imaging; N = number; NR = not reported; NS = not significant; PENN = University of Pennsylvania Shoulder Score; pre-op = preoperative; post-op = postoperative; ROM = range of motion; SD = standard deviation; SE = standard error; SS = supraspinatus; yr = year
*Subscales reported
†Calculated by UAEPC
‡Data extrapolated from a graph
§Results expressed as the mean and standard error

Table 26. Outcome data for studies assessing operative augmentations (continued)

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Pre-op mean±SD (range)/ Post-op mean±SD (range)	Group 2 Pre-op mean±SD (range)/ Post-op mean±SD (range)	Group 1 vs. Group 2 Post-op p-value
Walton JR,[170] 2007	**G1:** Porcine small intestine submucosa augmentation (15) **G2:** No augmentation (16)	Pain during activities§ 3 mo 6 mo‡ 12 mo‡ 2 yr‡	11.0±1.4‡ 9.9±1.6 4.0±1.6 3.1 1.7	10.1±1.4‡ 4.0±1.3 4.3±2 3.7±1.3 3.1±1.2	NS p<0.01 NS NS NS
	2 yr	Strength§ (newton)	ER: NR / 47±5 IR: NR / 63±6 ADD: NR / 70±7 Lift-off: NR / 28±4 SS: NR / 37±7	ER: NR / 67±11 IR: NR / 99±11 ADD: NR / 100±12 Lift-off: NR / 61±11 SS: NR / 58±9	p=0.105 p<0.01 p<0.05 p<0.01 p=0.08
		Participation in sports	2/15 (13.3)	11/16 (68.8)	p<0.01
		Cuff integrity n/N (%), MRI	4/10 (40.0)	5/12 (41.6)	NS

Table 27. Strength of evidence for operative augmentation

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Porcine small intestine submucosa vs. no augmentation	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 32 (30)	Function	RCTs Medium	Unknown	Direct	Imprecise	Absent	Low
	2; 63 (52)	Cuff integrity	RCT, cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Patch graft vs. no augmentation	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 28 (21)	Function	Cohort Low	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

HRQL = health-related quality of life; n/a = not applicable; RCT = randomized controlled trial
*number analyzed if different from number studied

Operative Augmentation—Uncontrolled Studies

Five BA studies[67,99,152,155,174] evaluated the effectiveness of the operative augmentation in RC repair. Four studies[67,99,155,174] assessed augmentation with open RCR, and one study[152] assessed arthroscopic RCR with platelet-rich plasma augmentation. The studies were published from 2006 to 2008 (median=2007; IQR: 2006 to 2008).

The number of participants enrolled in the study ranged from 13 to 39 (median=23 [IQR: 20 to 32]). The median followup duration was 3.2 years (IQR: 2 to 3.6). The mean age of participants ranged from 54 to 67 years. All these studies included only patients with full-thickness tears. Medium to massive tears were included in one study,[155] only massive RC tears in one study,[174] and only large RC tears in one study.[67] Tear size was not reported in two studies[99,152]. One study included smokers.[155]

All studies assessed function, while four assessed cuff integrity.[67,99,155,174] Health-related quality of life and time to return to work were not reported for any of the studies. Figure 26 presents the preoperative and postoperative functional scores over time for all studies that examine operative augmentation with repair. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Although the studies evaluated different types of augmentations, measured outcomes using different scales, had various followup durations and different study designs, they all indicate improvement in functional score from baseline to final followup. Figure 27 shows the proportion of patients with an intact rotator cuff at followup. While the BA studies showed a consistent trend of moderate to high cuff integrity, the one trial[109] showed a poor outcome.

Figure 26. Studies examining functional outcomes for operative augmentation with repair
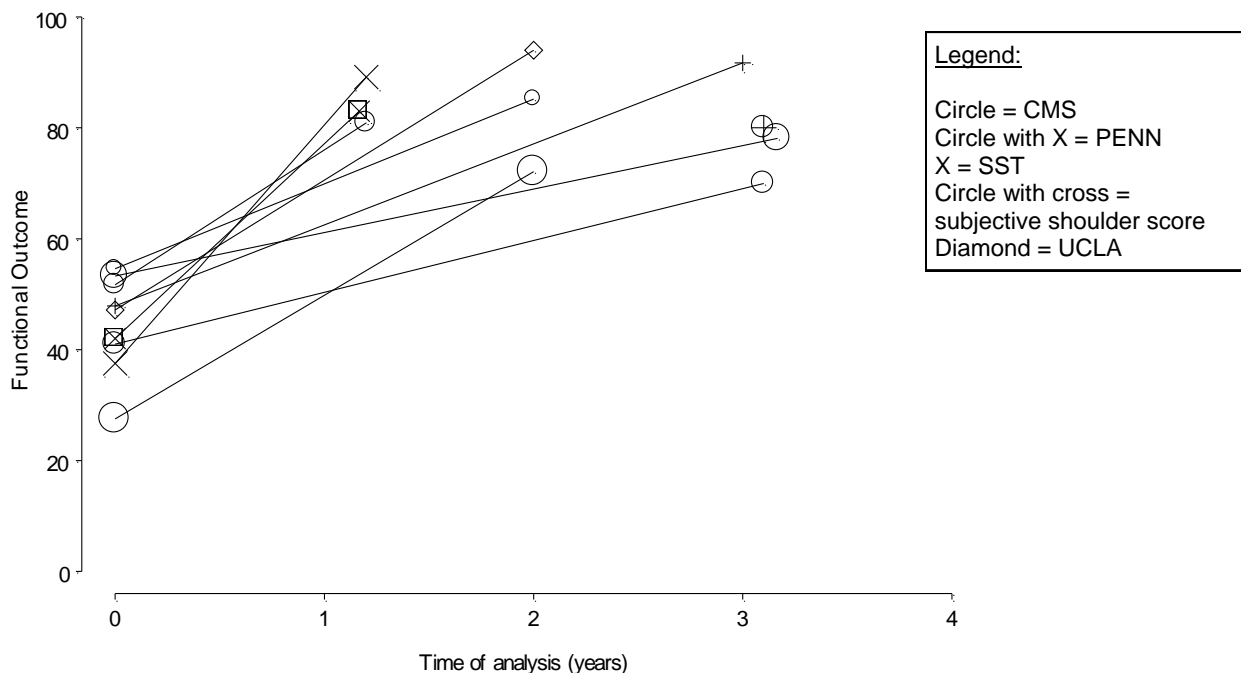
Figure 27. Studies examining cuff integrity for operative augmentation with repair
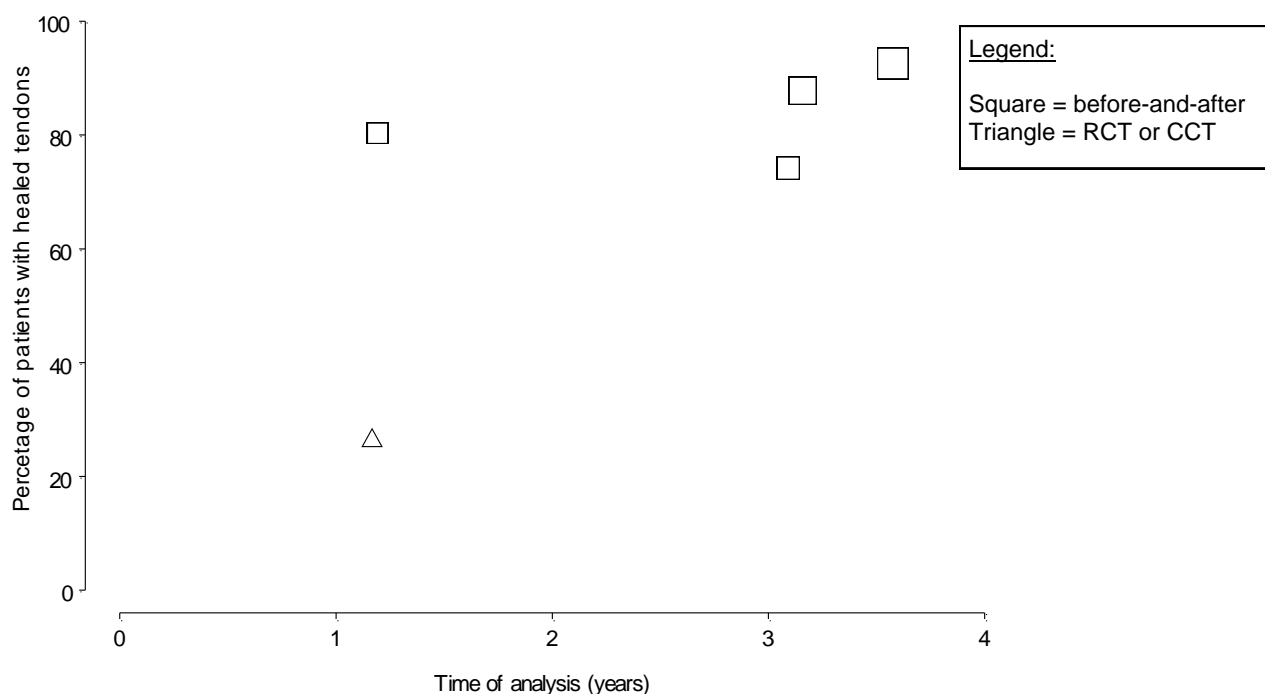
Postoperative Rehabilitation—Comparative Studies

Summary. Ten comparative studies evaluated postoperative rehabilitation. While most studies included some physical therapy component, the comparisons varied across studies.

- Three RCTs[180,182,184] studied the addition of continuous passive motion to physical therapy. Overall, there was moderate evidence showing no difference in function or pain. One study[182] showed a difference favouring continuous passive motion for time to 90 degrees abduction and time to return to work (absolute difference of 12 and 21 days, respectively). This suggests that continuous passive motion may affect the course of recovery over the short-term but not result in functional differences over the long-term. The trials were all at high risk of bias due to lack of blinding and inadequate allocation concealment.
- One CCT[176] evaluated aquatic therapy in addition to a land-based program and found no differences in function or range of motion at the end of the study (12 weeks); however, there were significant differences between groups in flexion at the 3 and 6-week time-points (absolute differences 46.6 and 28.6 degrees, respectively). The study involved only 18 patients and had substantial methodological flaws.
- A prospective cohort study[177] compared inpatients with day patients, all of whom underwent a structured rehabilitation regime. There were no significant differences in pain or range of motion over the 60-day followup.
- One RCT[178] evaluated individualized physical therapy in addition to home exercise vs. home exercise alone and found no significant differences for function, range of motion, or strength over the 24 week followup.

- One RCT[179] comparing a rehabilitation program with progressive loading to one with traditional loading found greater improvement in pain during activity and at rest (p<0.05), favouring the progressive loading group. No differences were found in function, range of motion or strength.
- One retrospective cohort study[181] compared outcomes between inpatients in a rehabilitation center vs. outpatients attending rehabilitation at a private practice specializing in Concept Global d'Epaule. The Concept Global d'Epaule group had significantly less pain, yet no differences were found between groups for the CMS and strength scores.
- A retrospective cohort study[183] comparing standardized vs. non-standardized physical therapy found that patients receiving standardized treatment had significantly greater improvement in function.
- One RCT[185] compared videotape-based vs. physical therapy-based home exercise instruction and found no differences in function over the 54 week followup.

The evidence does not clearly identify treatments or treatment variations that alter the postoperative course of patients following RCRs; the overall level of evidence was low with few studies comparing any single therapeutic approach. There were significant differences over the course of postoperative followup for all patients but few significant differences between study groups. This may suggest a "ceiling effect:" patients may achieve their final functional outcome regardless of the type or intensity of the specific intervention. One issue that was consistently problematic across the studies was the poor reporting of physical therapy, both in terms of intervention components and delivery (frequency, intensity, dosage, etc). The studies in this area also suffer from a number of methodological flaws. Though there was a large proportion of RCTs, representing the highest level of evidence for therapeutic interventions, these were all at high risk of bias due to lack of blinding, missing outcome data, and/or inadequate concealment of allocation. Moreover, the studies tended to measure intermediate or surrogate outcomes (e.g., range of motion) rather than outcomes that may be most important to the patients, healthcare practitioners, and decisionmakers (e.g., health-related quality of life, time to return to work).

Results by individual study. Ten studies (six RCTs,[178-180,182,184,185] one CCT[176] and three cohort studies[177,181,183]) evaluated the effectiveness of various postoperative rehabilitation treatments. The median sample size was 61 patients (IQR: 36 to 80). The following postoperative rehabilitation techniques were assessed: continuous passive motion with physical therapy vs. physical therapy alone,[180,182,184] aquatic and land-based therapy vs. land-based therapy alone,[176] inpatient vs. day patient rehabilitation,[177] home exercise with vs. without the addition of an individualized physical therapy program,[178] progressive loading vs. traditional loading,[179] inpatient rehabilitation vs. rehabilitation in a private practice specializing in Concept Global d'Epaule,[181] standardized vs. non-standardized physical therapy program[183] and videotape vs. physical therapy home exercise instruction.[185] The outcomes of three studies evaluating the addition of continuous passive motion to physical therapy could be pooled in a meta-analysis, shown in Figure 28 and Figure 29. Patient and study characteristics, as well as study outcome data, are presented in Table 28 and Table 29, respectively. The grading of the body of evidence for postoperative rehabilitations studies is found in Table 30.

Continuous passive motion with physical therapy vs. physical therapy. Three studies assessed use of continuous passive motion, however the protocols and followup durations varied across the studies. Lastayo et al.[180] conducted a RCT comparing the addition of continuous passive motion

using a mechanical device (Thera-kinetics, Mount Laurel, New Jersey) vs. no continuous passive motion in patients who received manual range of motion and strengthening exercises. The former group received continuous passive motion for flexion and external rotation for four hours per day (three or four periods, each lasting 1–1.5 hours). All patients had undergone open RCR. Tear sizes ranged from small to large and were balanced between the two groups. Thirty-one patients (32 shoulders) were randomly assigned to the interventions (17 to continuous passive motion, 15 to no continuous passive motion). The mean length of followup was 22±9.8 months (6 months to 3.8 years). Patients were evaluated using the pain VAS score, passive and active range of motion, and isometric strength. There were no significant between-group differences in any of the outcome measures at any time points (p>0.05).

Michael et al.[182] conducted a RCT comparing continuous passive motion using a mechanical device (five times per day at 20 minutes per session) plus a physical therapy program vs. physical therapy alone in patients who underwent open or mini-open RCR. The same physical therapy program was provided for both group and consisted of passive and active range of motion and strengthening exercise. All patients had partial- or full-thickness tears limited to the supraspinatus tendon. Sixty-one patients were randomly assigned to the interventions (40 to the continuous passive motion plus physical therapy group, 21 to the physical therapy group); 55 were included in the final analyses. The followup period was 56 days. Patients were evaluated using the CMS, the pain VAS score, time until 90 degree abduction was achieved, and time to return to work. There were no significant between-group differences for the CMS and pain scores. However, there was a significant difference between the groups in the postoperative duration needed until 90 degree abduction was achieved (p=0.03), in favour of the continuous passive motion group (31 vs. 43 days). The time to return to work was 21 days sooner in continuous passive motion group.

Rabb et al.[184] conducted a RCT comparing continuous passive motion (8 hours per day) using a mechanical device (Thera-kinetics, Mount Laurel, New Jersey) plus a physical therapy program vs. physical therapy alone in patients who had RCR for a partial- or full-thickness tear. Tear size ranged from small to massive. The continuous passive motion plus physical therapy group had a much greater proportion of patients with large or massive tears (57 percent) compared to the physical therapy alone group (25 percent). Forty-one patients were randomly assigned to the interventions; 26 were included in the final analyses (14 in the continuous passive motion plus physical therapy group, 12 in the physical therapy group). Patients were evaluated at 3 months following surgery using a 100-point shoulder score. For both groups, there was no significant difference in the Shoulder score from baseline to endpoint (p>0.05). Similarly, there was no significant difference between the groups in the endpoint shoulder score (p>0.05).

Two RCTs[182,184] provided data for meta-analysis of the effects of continuous passive motion vs. no continuous passive motion on functional outcome measures (Figure 28). The CMS of Michael et al.[182] and the shoulder score of Rabb[184] were used in the analysis. The baseline to endpoint change scores were compared between groups. The pooled estimate showed no difference between the studies (SMD=0.08; 95% CI, -0.37 to 0.52). There was no evidence of heterogeneity between the studies (p=0.63; I^2=0 percent).

Figure 28. Continuous passive motion with physical therapy vs. physical therapy alone for measures of functional outcome

Study or Subgroup	Passive Motion Mean	SD	Total	PT program alone Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
Michael 2005	30	15.71	34	30	18.26	21	66.9%	0.00 [-0.54, 0.54]	
Raab 1996	15	20.65	14	10	20.65	12	33.1%	0.23 [-0.54, 1.01]	
Total (95% CI)			48			33	100.0%	0.08 [-0.37, 0.52]	

Heterogeneity: Tau² = 0.00; Chi² = 0.24, df = 1 (P = 0.63); I² = 0%
Test for overall effect: Z = 0.34 (P = 0.73)

Favours PT program alone   Favours Passive Motion

A meta-analysis was conducted comparing continuous passive motion vs. no continuous passive motion for pain using two RCTs (Figure 29). The pain VAS in Michael et al.[182] was compared with the pain subscore of the shoulder score index in Raab et al.[184] using change scores. No differences was found between the interventions for pain (SMD=-0.12; 95% CI, -1.08 to 0.83) There was substantial heterogeneity between the two studies (p=0.05; I^2=75 percent). The heterogeneity may be partly attributable to a difference in the timing of outcome assessment; Michael et al.[182] followed patients for 2 months, compared to Rabb et al.[184] assessed patient outcomes at 3 months postoperatively.

Figure 29. Forest plot comparing pain in continuous passive motion vs. no continuous passive motion groups

Study or Subgroup	Passive Motion Mean	SD	Total	PT program alone Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
Michael 2005	-21	41	34	-33	29	21	54.5%	0.32 [-0.23, 0.87]	
Raab 1996	-36	20.65	14	-22	20.65	12	45.5%	-0.66 [-1.45, 0.14]	
Total (95% CI)			48			33	100.0%	-0.12 [-1.08, 0.83]	

Heterogeneity: Tau² = 0.36; Chi² = 3.93, df = 1 (P = 0.05); I² = 75%
Test for overall effect: Z = 0.25 (P = 0.80)

Favours Passive Motion   Favours PT program alone
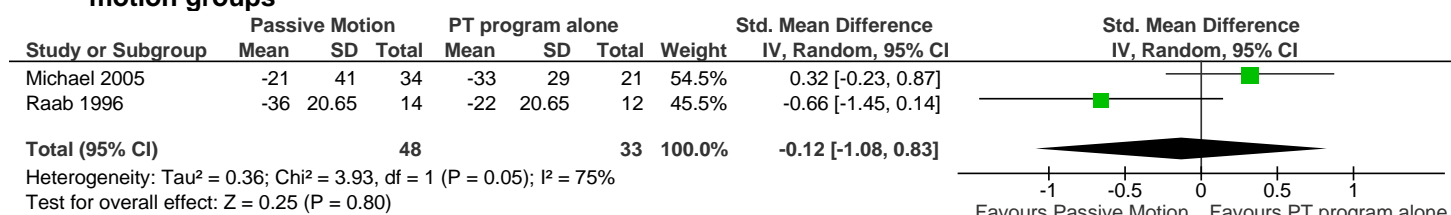
Aquatic therapy with land-based therapy vs. land-based therapy. Brady et al.[176] conducted a CCT comparing a combination aquatic and land-based program vs. a land-based program alone in patients who underwent RCR. Tear size ranged from small to massive and were balanced between groups. Eighteen patients were enrolled in the study (12 received aquatic and land-based treatment, 6 received only land-based treatment). All patients were evaluated at 3, 6, and 12 weeks postoperatively. The WORC Index and range of motion (flexion and external rotation) were used to assess patients. For both groups, there were significant differences in the WORC Index and range of motion from baseline to endpoint scores (p<0.0001). There were no significant differences between the groups at endpoint in the WORC Index or external rotation at any measurement point. At 3 and 6 weeks postoperatively, there were significant differences in flexion between the groups (p=0.005 and p=0.01, respectively), but not at 12 weeks (p>0.05).

Inpatients vs. day patient rehabilitation. Delbrouck et al.[177] conducted a prospective cohort study comparing inpatient vs. day patient rehabilitation in patients who had undergone RCR. Patients had partial- or full-thickness tears; tears sizes ranged from small to massive and were similar between groups. Seventy-nine patients (84 shoulders) were enrolled in the study; 71 (76 shoulders) were included in the final analyses (53 in the inpatient group, 23 in the day patient group). Pain and range of motion were used to evaluate patients at various points over the 60-day followup period. Only one statistically significant difference was observed: pain at day 15 was less among the inpatient group, yet no difference was found at 30 days. Inpatients were more frequently prescribed NSAIDs and calcitonin for pain management compared with outpatients (11 and 4 patients, respectively). No other differences in pain or range of motion were observed.

Individualized physical therapy program with home exercise vs. home exercise. Hayes et al.[178] conducted a RCT comparing individualized physical therapy with home exercise program vs. a home exercise program alone in patients who underwent open RCR. All patients received the same standardized home exercise regime, which was issued by the treating surgeon. Patients in the home exercise group received no other rehabilitation. For patients in the individualized physical therapy group, treatment content, rate of rehabilitation progression and total number of sessions were determined by the treating physical therapist. The treatment regime in this group may have consisted of any combination of exercises, manual therapy techniques, physical modalities of ice and moist heat, and rehabilitation and home exercise advice. Patients with full- and partial-thickness tears were included; the mean tear size was 5 cm^2 in the individualized physical therapy with home exercise program group and 6 cm^2 in the home exercise program group. Fifty-eight patients were randomly assigned to the interventions (26 to physical therapy and home exercise, 32 to the home exercise alone); 42 were included in the final analyses. Patients were revaluated at 6, 12, and 24 weeks postoperatively. The Shoulder Service Questionnaire (SSQ), passive range of motion (flexion, abduction, and external rotation), and manual muscle test for strength were used to assess patients. There were no differences between groups in any of the outcomes or measurement time points ($p>0.05$).

Progressive loading vs. traditional loading. A RCT was conducted by Klintberg and colleagues[179] to compare the effectiveness of two physical therapy rehabilitation protocols, progressive vs. traditional loading, following RC surgery. In the progressive group, dynamic and specific muscle activation of the RC and passive range of motion was initiated the day after surgery. Loading of the shoulder progressively increased following 4 weeks of immobilization. In contrast, the traditional group was protected from RC loading and no specific exercises were introduced during the 6-weeks immobilization period. Eighteen patients were enrolled (nine per group) and 14 were assessed at 2-year followup. Patients were evaluated using the CMS, Functional Index of the Shoulder, pain VAS, active range of motion (abduction, flexion, internal rotation, external rotation, and extension) and strength (internal rotation, external rotation, and flexion). Significant preoperative to postoperative improvement was reported on the CMS for the progressive group, on abduction range of motion for the traditional group, and for the Functional Index of the Shoulder and pain scores in both groups. The only significant differences between the progressive and traditional groups were in pain during activity and at rest ($p<0.05$), favouring the progressive loading group.

Inpatient rehabilitation vs. outpatient rehabilitation focusing on Concept Global d'Epaule. A retrospective cohort study conducted by Marc et al.[181] compared inpatient rehabilitation vs. rehabilitation in an outpatient center specializing in Concept Global d'Epaule (CGE) following RCR. A third study arm initially received inpatient rehabilitation and subsequently underwent outpatient care due to insufficiently improvement. CGE is a rehabilitation protocol based on three principles: (1) movements are done with pressure on humeral head to increase the subacromial space, (2) gradual progression from passive to active movement at patients tolerance, and (3) an attempt to restore dynamic equilibrium between muscles responsible for elevating the humeral head and the rotator cuff muscles. A total of 80 patients were enrolled, including 26, 38 and 16 in the inpatient, outpatient and combination groups, respectively. Patients were followed for a minimum of 2 years. Outcomes of interest included the CMS, pain and strength. The significance of baseline to endpoint scores was not reported. There was a significant difference between groups for pain, favouring the outpatient CGE group and the

group with both inpatient rehabilitation and outpatient CGE treatment. No differences were found between groups for the CMS and strength scores.

Standardized vs. non-standardized physical therapy program. Milroy et al.[183] conducted a retrospective cohort study comparing a standardized vs. non-standardized physical therapy program in patients who had had RCR. The treatment components of the physical therapy programs were not described. Sixty-seven patients were enrolled in the study (28 received standardized physical therapy, 39 received non-standardized physical therapy). Patients were evaluated using the DASH score and a numeric pain rating scale. There was significantly greater improvement on the DASH in the standardized physical therapy group ($p \leq 0.05$). However, there were no differences between the groups in pain scores ($p > 0.05$).

Videotape vs. physical therapy home exercise instruction. Roddey et al.[185] conducted a RCT comparing videotape-based vs. physical therapy instruction home exercise programs in patients who had undergone arthroscopic repair. Patients in the first group received exercise instruction solely through a videotape given them by a physical therapist during their hospital stay. The second group received four one-on-one instruction sessions with a physical therapist throughout the course of the study. All patients had full-thickness RC tears. The mean tear size was 2.5 cm (1 to 5 cm) for the videotape-based instruction group and 2.6 cm (1.5 to 4.0) in the physical therapy instruction group. Overall, 129 patients were randomly assigned to the interventions, of which 108 were included in the final analyses (54 in each group). Patients were evaluated at 12, 24, and 54 weeks following surgery. The SPADI and the PENN shoulder scores were used to assess patients. There were no differences between the groups at any measurement time point for both the SPADI and the PENN indices ($p > 0.05$).

Table 28. Study and patient characteristics for studies assessing postoperative rehabilitations

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Brady B,[176] 2008	**G1:** Land-based & aquatic therapy program (12) **G2:** Land-based program (6) CCT	**G1:** 56.3±9 yr (41–67) / Males: 8 (67) **G2:** 53.5±16 yr (26–69) / Males: 3 (50)	NR; Sm, Med, Lg, Mass NR
Delbrouck C,[177] 2003	**G1:** Inpatient rehabilitation (NR) **G2:** Day patient rehabilitation (NR) Prospective cohort	**G1:** 52.7±8 yr / Males: 25 (47) **G2:** 55±5 yr / Males: 16 (70)	PTT; Sm, Med, Lg, Mass NR
Hayes K,[178] 2004	**G1:** Individualized PT & standard home exercise regime (26) **G2:** Standardized home exercise regime (32) RCT	**G1:** 58±10 yr (41–81) / Males: 20 (77) WCB: 4 **G2:** 62±11 yr (42–83) / Males: 20 (63) WCB: 6	PTT, FTT; **G1:** 5.0 cm², **G2:** 6.0 cm² **G1:** 12±16 mo (0–48 mo), **G2:** 19±27 mo (1–96 mo)
Klintberg IH,[179] 2009	**G1:** Progressive loading (9) **G2:** Traditional loading (9) RCT	**G1:** NR / Males: NR **G2:** NR / Males: NR	FTT; Med, Lg, Mass NR
LaStayo PC,[180] 1998	**G1:** CPM (17 shoulders) **G2:** Manual passive ROM exercises (15 shoulders) RCT	**G1:** 62.8 yr (30–80) / Males: 8 (47) **G2:** 63.7 yr (45–75) / Males: 6 (40)	NR; Sm, Med, Lg NR
Marc T,[181] 2009	**G1:** Inpatient in rehab centre (26) **G2:** Private practice in CGE (38) **G3:** Inpatient and outpatient in CGE (16) Retrospective cohort	**Total:** 61 (36–80) / Males: 49 (61)	FTT; NR NR
Michael J,[182] 2005	**G1:** CPM & PT program (40) **G2:** PT program (21) RCT	**G1:** 58 yr (35–70) / Males: 25 (63) Manual Labourers (light, moderate, heavy, overhead):12, 12, 6, 4 **G2:** 58 yr (43–71) / Males: 12 (57) Manual Labourers (light, moderate, heavy, overhead): 8, 6, 6, 1	PTT, FTT; NR NR
Milroy DR,[183] 2008	**G1:** Standardized PT (28) **G2:** Non-standardized PT (39) Retrospective cohort	**G1:** 57±10.9 yr / Males: 16 (57) **G2:** 57.8±9.81 yr / Males: 27 (69)	NR; NR NR

CCT = controlled clinical trial; CPM = continuous passive motion; FTT = full-thickness tear; G = group; Mass = massive; Med = medium; Lg = large; NR = not reported; PT = physical therapy; PTT = partial-thickness tear; RCT = randomized controlled trial; ROM = range of motion; SD = standard deviation; Sm = small; WCB = workers' compensation board

Table 28. Study and patient characteristics for studies assessing postoperative rehabilations (continued)

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Raab MG,[184] 1996	**G1:** CPM & PT (NR) **G2:** PT only (NR) RCT	**G1:** 54 yr / Males: 9 (64) **G2:** 58 yr / Males: 9 (75)	PTT, FTT; Sm, Med, Lg, Mass NR
Roddey TS,[185] 2002	**G1:** Videotape instruction (NR) **G2:** PT instruction (NR) RCT	**G1:** 58.7±10.6 yr (34.6–78.0) / Males: 36 (67) **G2:** 57.2±9.1 yr (40.0–75.8) / Males: 33 (61)	FTT; **G1:** 2.5 cm (1–5 cm), **G2:** 2.6 cm (1.5–4.0 cm) NR

Table 29. Outcome data for studies assessing postoperative rehabilitation

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Brady B,[176] 2008	**G1:** Land-based & aquatic therapy program (NR) **G2:** Land-based program (NR) 12 wk	WORC (95% CI) 3 wk 6 wk 12 wk	1163 (925–1402) 1468±490† 1267±289† 635±260†, p<0.0001	1003 (482–1525) 1502±226† 1335±500† 728±421†, p<0.0001	p>0.05
		ROM (degrees) (95% CI)	F: 135 (125–145) ER: 31 (22–40)	F: 141 (120–161) ER: 30 (14–46)	
		3 wk	F: 59.8±26.6† ER: 18.7±8.0†	F: 106.4±17.2† ER: 22.1±14.7†	F/3 wks: p=0.005 ER/p>0.05
		6 wk	F: 94.3±26.6† ER: 28.9±15.1†	F: 122.9±16.8† ER: 30.9±17.6†	F/6 wks: p=0.01 ER/p>0.05
		12 wk	F: 148.7±16.8†, p<0.0001 ER: 67.5±17.4†, p<0.0001	F: 160.1±9.8†, p<0.0001 ER: 57.7±12.3†, p<0.0001	p>0.05
Delbrouck C,[177] 2003	**G1:** Inpatient rehabilitation (53 shoulders) **G2:** Day patient rehabilitation (23 shoulders) 60 days	Pain (VAS) day 15 day 30 day 45 day 60	NR 1.1 1.3 1.2 0.7	NR 2.3 2.0 2.2 1.2	day 15: p=0.012 day 30, 45, 60: p>0.05
		ROM (degrees)	ABD: 146 / 118 F: 141 / 122 ER: 55 / 30	ABD: 153 / 128 F: 153 / 130 ER: 61 / 31	p>0.05
		day 30	ABD: 102 F: 109 ER: 18	ABD: 91 F: 104 ER: 22	
		day 45	ABD: 100 F: 107 ER: 20	ABD: 125 F: 119 ER: 23	
Hayes K,[178] 2004	**G1:** Individualized PT & standard home exercise regime (20) **G2:** Standardized home exercise regime (22) 24 wk	SSQ (95% CI) 6 wk 12 wk 24 wk	65 (57–73) 35 (28–42) 24 (15–33) 14 (7–21)	75 (67–83) 35 (28–42) 30 (20–40) 32 (21–43)	p>0.05 p>0.05 p>0.05

ABD = abduction; ADD = adduction; CI = confidence interval; CMS = Constant-Murley score; CGE = Concept Global d'Epaule; CPM = continuous passive motion; DASH = Disabilities of the Arm, Shoulder and Hand; ER = external rotation; EX = extension; FIS = Functional Index of the Shoulder; G = group; IR = internal rotation; F = flexion; NR = not reported; NS = not significant; PT = physical therapy; pts = patients; ROM = range of motion; SD = standard deviation; SE = standard error; SSQ = Shoulder Service Questionnaire; SPADI = Shoulder Pain and Disability Index; UCLA = University of California Los Angeles Scale; PENN = University of Pennsylvania Shoulder Score; VAS = visual analogue scale; wk = week; WORC = Western Ontario Rotator Cuff Index; yr = year

* Subscales reported

† Data extrapolated from graph

‡ Values are presented as medians (range)

Table 29. Outcome data for studies assessing postoperative rehabilitation (continued)

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Hayes K,[178] 2004 (continued)		ROM (passive, degrees) (95% CI)	F: 148 (139–157) ABD: 133 (122–144) ER: 55 (49–61)	F: 134 (122–146) ABD: 120 (108–132) ER: 47 (40–54)	
		6 wk	F: 130 (118–142) ABD: 108 (93–123) ER: 34 (26–36)	F: 111 (99–123) ABD: 95 (85–105) ER: 31 (26–36)	p>0.05
		12 wk	F: 141 (129–153) ABD: 125 (110–140) ER: 42 (34–50)	F: 136 (125–147) ABD: 119 (106–132) ER: 41 (34–48)	p>0.05
		24 wk	F: 150 (142–158) ABD: 142 (130–154) ER: 51 (46–56)	F: 144 (132–156) ABD: 130 (117–143) ER: 43 (36–50)	p>0.05
		Strength manual muscle test grades (median, 95% CI)	IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4.5–5)	IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–4.5)	
		6 wk	IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–5)	IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–4.5)	p>0.05
		12 wk	IR: 5 (5–5) ER: 5 (5–5) F: 4.5 (4–5)	IR: 5 (5–5) ER: 5 (4.5–5) F: 4.5 (4–5)	p>0.05
		24 wk	IR: 5 (5–5) ER: 5 (5–5) F: 5 (4.5–5)	IR: 5 (5–5) ER: 5 (5–5) F: 5 (4.5–5)	p>0.05
Klintberg IH,[179] 2009	**G1:** Progressive loading (7) **G2:** Traditional loading (7)	CMS‡ (100-point) 6 mo 12 mo 2 yr	NR 60 (50–84) 80 (67–97) 82 (72–93), NR	NR 76 (21–86) 78 (48–93) 77 (54–95), NR	NR
	2 yr	CMS‡ (75-point) 6 mo 12 mo 2 yr	35 (20–55) 51 (43–70) 69 (57–75) 71 (64–75), p<0.05	45 (24–75) 67 (21–74) 71 (45–75) 73 (51–75), NR	NR
		FIS‡ 6 mo 12 mo 2 yr	54 (42–85) 34 (22–74) 19 (4–37) 1 (0–48), p<0.05	44 (6–77) 25 (5–64) 10 (0–50) 18 (0–36), p<0.05	NR

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Klintberg IH,[179] 2009 (continued)		Pain‡ during activity 6 mo 12 mo 24 mo	73 (54–98) 28 (8–52) 10 (5–50) 2 (0–7), p<0.05	60 (0–77) 7 (0–50) 7 (0–76) 0 (0–40), p<0.05	12 mo: NS† 24 mo: p<0.05
		Pain‡ at rest 6 mo 12 mo 24 mo	27 (12–64) 1 (0–27) 0 (0–0) 0 (0–3), p<0.05	4 (0–97) 0 (0–15) 0 (0–38) 0 (0–12), NR	12 mo: p<0.05 24 mo: p<0.05
		Active ROM‡ (degrees)	ABD: 140 (35–180) F: 150 (90–170) IR: 40 (35–65) ER (in ADD): 50 (30–60) ER (in ABD): 50 (5–90) EX: 40 (10–60)	ABD: 110 (40–180) F: 150 (40–170) IR: 43 (40–90) ER (ADD): 40 (10–50) ER (ABD): 70 (40–110) EX: 45 (25–50)	NR
		6 mo	ABD: 163 (130–175) F: 140 (110–165) IR: 48 (25–75) ER (in ADD): 43 (30–60) ER (in ABD): 65 (25–100) EX: 40 (25–45)	ABD: 170 (150–180) F: 140 (60–165) IR: 40 (30–55) ER (in ADD): 30 (20–60) ER (in ABD): 70 (40–100) EX: 40 (30–50)	
		12 mo	ABD: 170 (140–180) F: 150 (135–165) IR: 50 (35–70) ER (in ADD): 40 (30–55) ER (in ABD): 70 (15–90) EX: 50 (30–60)	ABD: 175 (100–180) F: 150 (110–175) IR: 45 (40–70) ER (in ADD): 45 (20–60) ER (in ABD): 90 (40–100) EX: 50 (30–60)	
		2 yr	NR	NR, p<0.05	
		Strength‡	IR (J): 19 (12–32) ER (J): 20 (9–33) F (Nm): 107 (50–139)	IR (J): 28 (5–63) ER (J): 21 (1–37) F (Nm): 94 (0–214)	NR
		6 mo	IR (J): 24 (16–50) ER (J): 15 (10–28) F (Nm): 108 (56–165)	IR (J): 28 (11–41) ER (J): 25 (5–29) F (Nm): 112 (0–197)	
		12 mo	IR (J): 28 (14–42) ER (J): 16 (10–32) F (Nm): 110 (62–186)	IR (J): 37 (14–56) ER (J): 30 (7–36) F (Nm): 124 (0–209)	
		2 yr	NR	NR	

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Marc T,[181] 2009	**G1:** Inpatient in rehab centre (26) **G2:** Private practice in CGE (38) **G3:** Inpatient and outpatient in CGE (16) 2 yr (minimum)	CMS	45 / 80, NR	50 / 85, NR	p=NS
				G3: 43 / 80, NR	
		Pain improvement	5.3, NR	7.0, NR	G1 vs. G2: p<0.05 G1 vs. G3: p<0.05
				G3: 7.3, NR	
		Strength (kg)	3.5 / 6.5, NR	4.5 / 7.5, NR	p=NS
				G3: 3.5 / 6.5, NR	
Lastayo PC,[180] 1998	**G1:** CPM (NR) **G2:** Manual passive ROM exercises (NR) 22±9.8 mo (6 mo–3.8 yr)	Pain VAS 1 wk 2 wk 4 wk	NR 4.9 3.8 1.7†	NR 8.0 5.9 1.6†	p>0.05
		Passive ROM (deg) 12 wk 6 mo 12 mo 2 yr	ER: NR 48.4 63.3 80.5 102.5† F: NR 128.2 141.8 155.7 170.7†	ER: NR 56.3 76.2 99.4 129.8† F: NR 128.2 146.3 164.7 185.1†	p>0.05
		Active ROM (deg) 12 wk 6 mo 12 mo 2 yr	ER: NR 58.1 62.4 66.7 71.6† F: NR 114.1 128.1 142.5 158.4†	ER: NR 55.0 61.6 66.7 71.6† F: NR 102.0 113.3 124.6 137.2†	p>0.05
		Strength kg (SE) 6 mo 12 mo	ER: NR 9.9 (9.3–10.5) 11.1 (10.4–11.9) † F: NR 9.4 (8.9–9.9) 10.3 (9.4–11.3) †	ER: NR 9.0 (8.4–9.9) 9.6 (8.8–10.4) † F: NR 8.0 (7.4–8.5) 9.6 (8.5–10.5) †	p>0.05

Table 29. Outcome data for studies assessing postoperative rehabilitation (continued)

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
Michael J,[182] 2005	**G1:** CPM & PT program (34) **G2:** PT program (21) 56 days	CMS	39 (7–74) / 69 (28–94)	36 (13–57) / 66 (27–96)	NR
		Pain VAS	62 / 41	62 / 29	NR
		Time until 90° ABD (days)	31 days	43 days	p=0.03
		Return to work (mean days)	(21 days sooner than G2)	NR	NR
Milroy DR,[183] 2008	**G1:** Standardized PT (NR) **G2:** Non-standardized PT (NR) NR	Mean difference on DASH (pts, 95% CI)	12.4 (-1.60, -23.2)		p≤0.05
		Improvement in pain scores	NR	NR	p>0.05
Rabb MG,[184] 1996	**G1:** CPM & PT (14) **G2:** PT only (12) 3 mo	Shoulder Score*	68 / 83, p>0.05	63 / 73, p>0.05	p>0.05
Roddey TS,[185] 2002	**G1:** Videotape instruction (54) **G2:** PT instruction (54) 52 wk (NR)	SPADI 12 wk 24 wk 52 wk	60.4±22.1 32.0±19.7 18.1±16.1 12.3±14.3	52.3±21.6 26.7±18.8 15.3±15.2 12.4±14.4	p=0.17 p=0.40 p=0.99
		PENN 12 wk 24 wk 52 wk	37.9±15.7 62.6±17.7 79.4±15.5 85.6±13.8	40.9±16.3 66.2±17.5 79.6±17.3 85.9±16.7	p=0.32 p=0.95 p=0.94

Table 30. Strength of evidence for postoperative rehabilitation

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Continuous passive motion with PT treatment vs. PT treatment	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	3; 133 (122)	Function	RCTs	Consistent	Direct	Precise	Absent	Moderate
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 61 (55)	Time to return to work	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
Aquatic therapy with land-based therapy vs. land-based therapy	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 18	Function	CCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Inpatient vs. day patient rehabilitation	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Function	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Individualized PT program with home exercise vs. home exercise	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 58 (42)	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Progressive vs. traditional loading	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 18 (14)	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Inpatient rehab vs. outpatient CGE	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 80	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Standardized vs. non-standardized PT program	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 67	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Videotape vs. PT home exercise instruction	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 129 (108)	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

CGE = Concept Global d'Epaule; HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy; RCT = randomized controlled trial;

*Number analyzed if different from number sudied

Postoperative Rehabilitation—Uncontrolled Studies

Only one BA study evaluated a postoperative rehabilitation program consisting of passive and active stretching and strengthening exercises.[175] The study was published in 2007 and enrolled 118 patients with a mean age of 67 years. The type and size of patient RC tears was not reported. There were 14 (12 percent) smokers among the included patients. The only outcome measure used to assess patients was the DASH scale. Since only one uncontrolled study evaluated postoperative rehabilitation, a visual display of the preoperative and postoperative scores is not presented.

Question 3. Comparative Effectiveness of Nonoperative Treatments

The comparative effectiveness of nonoperative interventions was examined in a total of 10 studies (three comparative and seven uncontrolled studies). Various types of interventions were examined across the individual studies, including stretching and strengthening, steroid injections, oral medications.

Nonoperative—Comparative Studies

Summary. Only three comparative studies were identified that assessed nonoperative interventions. Pooling of data was not possible as the interventions compared in each study varied. One RCT[194] compared sodium hyaluraonate vs. dexamethasone in terms of function and range of motion. The authors reported results comparing patients who were and were not satisfied with their degree of improvement within each group, therefore the data available did not allow for a head-to-head comparison regarding the relative efficacy of the two interventions under study. The trial was at high risk of bias due to a number of methodological weaknesses; in particular, the patient self-selection of treatment at 4 weeks based on satisfaction is an important source of bias. One retrospective cohort study[191] compared rehabilitation focusing on protecting the cuff through reliance on other muscles (deltoid, pectoralis major and latissimus dorsi) vs. no rehabilitation and found statistically significant and clinically important differences favoring the rehabilitation group in terms of function (absolute difference between groups of 26.9 points on a 100-point scale). The study had several methodological limitations, most importantly a loss to followup of 46 percent. Differential loss to followup across the groups may yield exaggerated estimates of treatment effects. While rehabilitation may appear to be a promising intervention based on statistically and clinically important differences when compared to no rehabilitation, there is no evidence regarding how rehabilitation would compare to other interventions, such as steroid injections. Finally, a retrospective cohort study[165] compared steroid injection vs. no steroid injection among participants undergoing physical therapy (not specified) and receiving oral medications (not specified). The results showed a significant difference in terms of function (absolute difference of 11 on an 83-point scale) and time to maximum range of motion (absolute difference of 4 months). The study had several methodological limitations which may bias the effects observed including retrospective timing and self-reporting of outcomes; further, the authors studied a select group which may affect generalizability of results beyond the population studied.

Overall, the level of evidence is low for nonoperative interventions due the variety of interventions examined across the body of evidence and methodological limitations of the individual studies. Treatment components were poorly described across the studies, both in term

of content (e.g., components included in "physical therapy" treatment) and delivery (e.g., frequency, intensity), limiting the usefulness of the studies to clinicians attempting to determine the most effective ways to manage patients nonoperatively. In addition, outcomes such as range of motion were insufficiently described, as it was unclear whether active, active-assisted or passive motion was being assessed.

Results by individual study. Three studies (one RCT[194] and two retrospective cohort studies[165,191]) compared the effectiveness of nonoperative treatments in patients with RC tears. The studies could not be pooled because different nonoperative interventions were compared in each study. Patient and study characteristics, as well as study outcome data, are presented in Table 31 and Table 32, respectively. Grading of the body of evidence is presented in Table 33.

Sodium hyaluraonate vs. dexamethasone. Shibata et al.[194] conducted a RCT comparing glenohumeral injection with sodium hyaluraonate or dexamethasone steroid in patients with full-thickness RC tears. The size of tears was not reported. Seventy-eight patients were randomly assigned to each intervention (38 to sodium hyaluraonate, 40 to dexamethasone). In addition, patient in both groups received Loxoprofen (180 mg/day) and physical therapy including heat and cuff strengthening exercise. All patients were evaluated at 4 weeks, at which point patients who were unsatisfied with their degree of improvement could elect to have surgical RCR. Only satisfied patients, who continued the nonoperative treatment to which they had been allocated, were assessed at 24 weeks using the UCLA shoulder score and range of motion (abduction, external and internal rotation). Compared to satisfied patients, those who were unsatisfied and opted for surgery at 4 weeks were more likely to have a manual labour job (p<0.01). At 4 weeks, there were significant differences between the satisfied and unsatisfied patients in the endpoint UCLA score and abduction, regardless of the type of nonoperative intervention to which they had been assigned. Satisfied patients showed significant improvement in UCLA score, abduction, and external rotation, but not internal rotation at 24 weeks compared with baseline measures. Head-to-head comparison of the two nonoperative interventions was not made.

Rehabilitation vs. no rehabilitation. Leroux et al.[191] conducted a retrospective cohort study comparing rehabilitation with no rehabilitation in patients with full-thickness tears. The rehabilitation program focused on protecting the cuff through reliance on other muscles (deltoid, pectoralis major and latissimus dorsi). Overall, 112 patients were enrolled in the study; of these, 60 were included in the final analyses (42 in the rehabilitation group, 18 in the no rehabilitation group). The mean length of followup was 3.8 months (range: 5 days to 2 years). Patients were evaluated using the Scapular functional index, a 100-point functional scale with five components (pain, motility, function, power and stability). The difference in Scapular functional score from baseline to endpoint score was significant in the rehabilitation group (p≤0.05); however, this difference was not significant in the no rehabilitation group. There was a statistically significantly difference between the groups in the endpoint postoperative Scapular function score (p<0.001), in favour of the rehabilitation group.

Steroid vs. no steroid injection. Vad et al.[165] conducted a retrospective cohort study comparing physical therapy with oral medication vs. physical therapy with oral medication and steroid injection. The study did not specify the components of the physical therapy treatment protocol, the type of oral medication or steroid, or specific site of steroid injection. All patients had

massive full-thickness RC tears. Forty patients were enrolled in the study (12 received the steroid injection, 28 received no steroid). All patients were followed for at least 2 years; the mean followup duration was 3.2 years (range: 2 to 7). Patients were evaluated using the Insalata shoulder rating scale, range of motion (abduction), and time to maximum range of motion. For both groups, there were significant differences in the Insalata scores and range of motion from preoperative to postoperative scores ($p \leq 0.05$). Moreover, there were significant and clinically important differences between the group endpoint Insalata scores and time to maximum range of motion ($p \leq 0.05$), in favour of physical therapy with oral medication and steroid injection group.

Table 31. Study and patient characteristics for studies assessing nonoperative interventions

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
Shibata Y,[194] 2001	**G1:** Sodium hyaluraonate (38) **G2:** Dexamethasone (40) RCT	**G1:** 59.5±9.1 yr / Males: 27 (71) Manual Labourers: 10 (26) **G2:** 62.4±8.6 yr / Males: 28 (74) Manual Labourers: 11 (28)	FTT; NR **G1:** 5.8±5.4 mo, **G2:** 4.7±5.7 mo
Leroux JL,[191] 1993	**G1:** No rehabilitation (NR) **G2:** Rehabilitation (NR) Retrospective cohort	**G1 and G2:** 61.5 yr (36–85) / Males: (61)	FTT; NR 7.5±0.5 mo
Vad VB,[165] 2002	**G1:** PT & oral medication (28) **G2:** PT & oral medication & steroid injections (12) Retrospective cohort	**G1 and G2:** 63.2 yr / Males: NR	FTT; Mass 6.3 mo (1–17)

FTT = full-thickness tears; G = group; Mass = massive; NR = not reported; PT = physical therapy; RCT = randomized controlled trial; SD = standard deviation

Table 32. Outcome data for studies assessing nonoperative interventions

Author, year	Intervention (N) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)		Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)		Group 1 vs. Group 2 p-value
Shibata Y, 2001[194]	**G1:** Sodium hyaluraonate (38) **G2:** Dexamethasone (40) 24 wk	UCLA*	Satisfied patients (n=16)	Unsatisfied patients (n=22)	Satisfied patients (n=15)	Unsatisfied patients (n=25)	Satisfies vs. unsatisfied at 4wks:
		Preoperative 4 wk 24 wk	13.6±2.6 27.6±3.1,p<0.0001 26.2±3.1,p<0.0001	12.8±3.5 14.9±4.4 NR	11.9±3.6 26.5±2.0, p<0.0001 25.3±2.5, p<0.0001	12.6±3.9 15.0±4.0 NR	Group1: p<0.0001 Group2: p<0.0001
		ROM (deg) 4 wk 24 wk	ABD:122.8±32.1 151.6±10.6,p<0.01 147.7±9.9, p≤0.05	ABD:124.3±44.2 130.7±36.8 NR	ABD:111.0±37.6 143.7±47.3, p<0.01 139.6±13.8, p≤0.05	ABD:117±47.3 112.4±38.2 NR	Satisfies vs. unsatisfied at 4wks:
			ER: 43.8±12.7 52.2±10.6, p<0.001 49.6±9.0, p≤0.05	ER: 54.1±22.8 55.5±19.7 NR	ER: 37.3±15.1 45.3±7.2, p≤0.05 46.5±8.5, p≤0.05	ER: 46.8±20.0 39.0±18.3 NR	Group1: ABD: p≤0.05 ER: p>0.05 IR: p>0.05
			IR †: T12.3±1.8 T11.3±2.0, p≤0.05 T11.8±2.6, p>0.05	IR † : T12.2±3.0 T10.6±3.1 NR	IR †: L1.1±4.0 T12.3±2.8, p>0.05 NR, p>0.05	IR †: L1.2±2.9 T12.6±3.1 NR	Group2: ABD: p≤0.01 ER: p>0.05 IR: p>0.05
Leroux JL, 1993[191]	**G1:** No rehabilitation (18) **G2:** Rehabilitation (42) 3.8 mo (5 days–2 yr)	SFI, baseline to endpoint change	-6.6±5.2, p>0.05		+20.3±2.5, p≤0.05		p<0.001
Vad VB, 2002[165]	**G1:** PT & oral medication (28) **G2:** PT & oral medication & steroid injections (12) 3.2 yr (2–7)	Insalata*	44.4±1.7 / 63.6, p≤0.05		44.4±1.7 / 74.5, p≤0.05		p≤0.05
		ROM (degrees)	ABD: 68 / 108, p<0.05				NR
		Time to maximum ROM (mo)	9.3 (3–18)		5.3 (1–11)		p≤0.05

ABD = abduction; deg = degree; ER = external rotation; G = group; Insalata = Insalata Shoulder Rating Questionnaire; IR = internal rotation; NR = not reported; PT = physical therapy; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SFI = Scapular Functional Index; UCLA = University of California Los Angeles Scale; wk = week; yr = year
* Subscales reported
† vertebral level (active ROM)

Table 33. Strength of evidence for nonoperative interventions

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Sodium hyaluraonate vs dexamethasone	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 78	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Rehabilitation vs. no rehabilitation	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 112 (60)	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
PT, oral medications and steroid injection vs. PT, oral medications and no steroid injection	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 40	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy; RCT = randomized controlled trial

*Number analyzed if different from number studied

Nonoperative Treatments—Uncontrolled Studies

Seven uncontrolled studies, including six BA[186,197,189,190,192,193] and one prospective cohort with BA data,[188] examined the effectiveness of nonoperative treatment for RC tears. Interventions evaluated in the studies included exercise protocols,[187,188] programs consisting of analgesic, NSAID, steroid injection and reeducation interventions,[186,190] pulsed radiofrequency ablation,[189] anterior deltoid rehabilitation program,[192] and early functional physical therapy and active shoulder support.[193] The studies were published from 1991 to 2008, with 2006 the median year of publication (IQR: 2000 to 2008).

The number of participants enrolled in the studies ranged from 12 to 59 (median=29 [IQR: 21 to 42]). The median followup duration ranged from 25 days to 7 years (median=6 months). The mean age of participants ranged from 59 to 80 years. Full-thickness tears were included in three studies,[187,190,192] both partial- and full-thickness tears were included in two studies,[186,188] and two did not report type of tear.[189,193] Only two studies reported tear size; one included all sizes[187] and one included only massive tears.[192] Recreational athletes and smokers were not reported in any of the studies. WCB patients were included in one study[187] and manual labourers in another.[186]

Functional outcome measures were reported in all but one study.[193] Only one study reported health-related quality of life[186] and three reported proportion of patients who returned to work.[186,187,190] Function was reported in six studies.[186-190,192] Tendon healing were not reported in any of the nonoperative studies. Figure 30 presents the preoperative and postoperative functional scores over time for all studies that examine nonoperative treatments. The shape of the markers indicates the outcome scale used in the study, while the size is proportionate to the square root of the study sample size. Followup durations and the degree of improvement in outcome scores varied considerably across studies.

Figure 30. Studies examining functional outcomes for nonoperative treatments
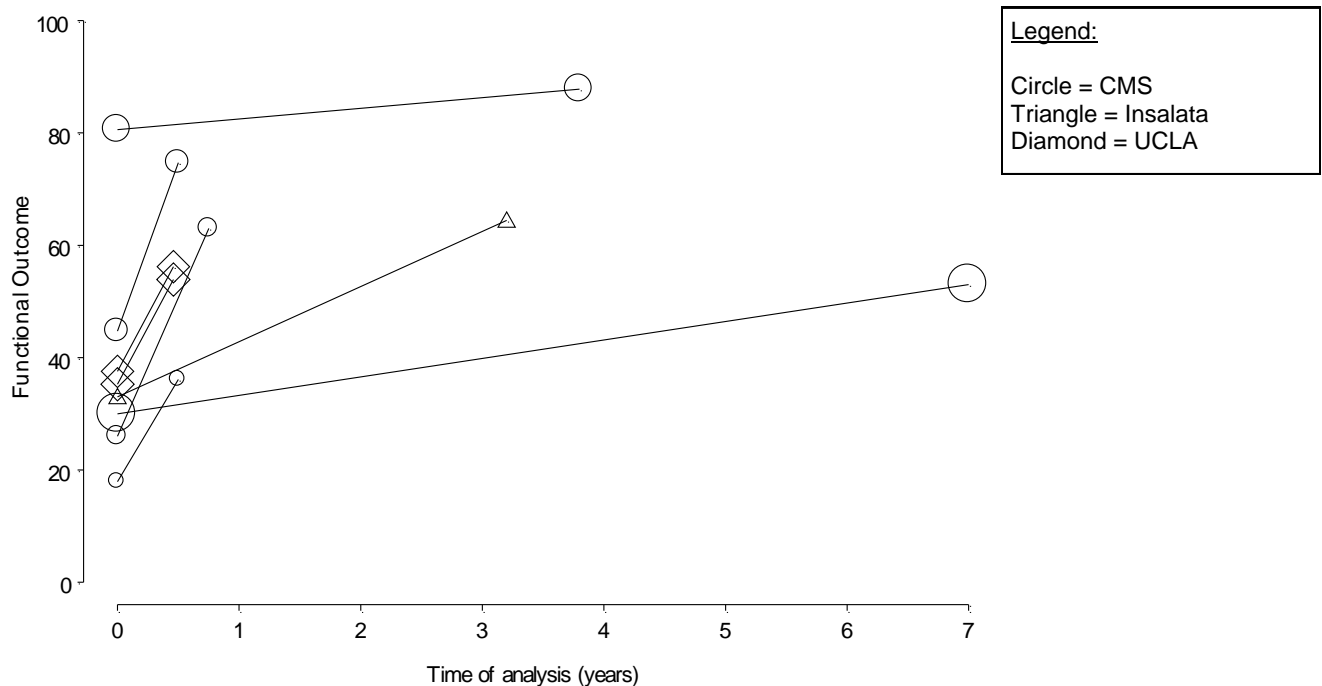
Question 4. Comparative Effectiveness of Nonoperative vs. Operative Treatments

The comparative effectiveness of nonoperative vs. operative interventions was examined in five comparative studies.

Nonoperative vs. Operative Treatments—Comparative Studies

Summary. Two RCTs and three cohort studies compared nonoperative treatment vs. operative RCR. The nonoperative treatments across the five studies varied in their components. Four studies[66,165,196,197] included either physical therapy (treatment components not specified) or stretching and strengthening exercises, with or without the addition of steroid injections, oral medications, activity modification or manual therapy. One study[195] examined the use of shock wave therapy. Nonoperative treatments were compared to either open or mini-open RCR. One study included a third comparison group undergoing arthroscopic debridement.[165] All groups showed significant improvements over the study period regardless of the intervention. The majority of the studies showed significant difference in function, favouring repair over nonoperative interventions. However, the results were highly heterogeneous, with one study showing an absolute difference of 24.5 points on an 83-point scale in favour of the operative repair.[165] This same study showed a significantly shorter time to maximum range of motion among the group undergoing arthroscopic debridement (3.2 months) compared to the nonoperative and open repair groups (6.8 months each). In general the level of evidence is low for nonoperative vs. operative interventions. The findings were inconsistent within and across studies. Further, as with complex interventions, it is difficult to determine the relative contributions of each of the components in the nonoperative treatment regimes.

Results by individual study. Five studies (two RCTs[66,195] and three cohort studies[165,196,197]) compared nonoperative with operative treatment regimes. Pooled analyses are presented in Figure 31 and Figure 32. Summary tables of the patient characteristics and outcome data are available in Table 34 and Table 35. The body of evidence for key outcomes was graded and is shown in Table 36.

Shock wave therapy vs. mini-open RCR. De Carli et al.[195] conducted a RCT investigating the effectiveness of extracorporeal shock wave therapy vs. mini-open RCR. Shock wave therapy was conducted using an electromagnetic generator, however no additional information on the treatment protocol was reported. All patients had full-thickness tears. A total of 30 patients were enrolled, however the sample sizes of each group and tear sizes were not reported. Patients were followed for an average of 19 months and 24 months in the shock wave and RCR groups, respectively. The difference in all scores was significant from baseline to followup. In addition, patients in the mini-open repair group showed a statistically greater improvement on the ASES and UCLA scores compared to the shock wave group.

Steroid injection, physical therapy and activity modification vs. open RCR. Lunn et al.[196] conducted a prospective cohort study comparing nonoperative treatment consisting of steroid injections, physical therapy and activity modification vs. open repair. The type and injection site of the steroid, physical therapy treatment components and type of activity modification of the nonoperative group were not reported in the study. All patients had full-thickness RC tears. The

mean length of followup was 4.2 years (range: 2 to 6.6). Nineteen patients were enrolled in the study (14 received nonoperative interventions, 5 received open RCR). All patients were evaluated using the CMS, range of motion (flexion, external and internal rotation), and strength. For both groups, there was a significant difference between the preoperative and postoperative CMS (p=0.009). However, the difference between the groups at endpoint was not significant (p=0.61). For both range of motion and strength, data was not presented separately by treatment group. Range of motion differed between the affected and normal side at final followup (158 vs. 176 degrees in flexion, 48 vs. 58 degrees in external rotation, and T12 vs. T7 in internal rotation). Similarly, there was a significant difference in strength between the affected and normal side at final followup (p<0.001). Cuff integrity was assessed using MRI at an average of 4.2 years. Anatomic healing was obtained in 3 cases (60 percent) in the operative group; cuff healing was not assessed in the nonoperative group.

Physical therapy (manual therapy and strengthening and stability exercises) vs. open or mini-open RCR. Moosmayer et al.[66] examined the effectiveness of a physical therapy program vs. open or mini-open repair in a RCT. The physical therapy protocol consisted of manual therapy and exercises aimed at strengthening and stabilizing the shoulder muscles. Treatment session were 40 minutes and were provided on average twice weekly during the first 12 weeks, and then less frequently during the subsequent 6 to 12 weeks. The treatment goals and methods were specified before the study, however they were provided in a non-standardized manner according to the examination findings and treatment progression. One hundred and three patients with small or medium-sized full-thickness tears were randomly assigned to physical therapy (51 patients) or open/mini-open repair (52 patients). All but one patient in the repair group were followed for 12 months and included in the analysis. In the physical therapy group, 9 patients showed inadequate improvement from baseline after 15 sessions, and underwent secondary surgery. Their final assessment after the 15 sessions was carried forward for the 6 and 12 month analyses. There was no difference between physical therapy and RCR on the SF-36 physical or mental component summary scores, however a significant difference was found for the ASES (p<0.0005) and CMS (p=0.002), in favour of the surgical repair group. Cuff integrity was measured using MRI in the operative group only, where 38 of 50 patients were found to have an intact rotator cuff.

Physical therapy, oral medication and steroid injection vs. open RCR vs. arthroscopic debridement. Vad et al.[165] conducted a retrospective cohort study comparing four treatment arms: physical therapy and oral medication alone and with the addition of steroid injection, open RCR and arthroscopic debridement. The physical therapy treatment components, type of oral medication and steroid, and the steroid injection site were not specified in the study. One hundred and eight patients with massive full-thickness RC tears were enrolled in the study (28 received nonoperative treatment without steroid, 12 received nonoperative treatment with steroid, 36 received open RCR and 32 received debridement). The study reported combined outcome data for the two nonoperative treatment arms. All patients were followed for a minimum of 2 years; the mean followup duration was 3.2 years. Patients were evaluated using the Insalata shoulder rating questionnaire, range of motion (abduction), and time to maximum range of motion. For all groups, there were significant differences in the Insalata score and range of motion from preoperative to postoperative scores (p≤0.05). In addition, there were significant between-group differences in the Insalata score at final followup, favoring surgery over

111

nonoperative treatment. The time to maximal range of motion was significantly different between the groups, with 6.8 months for the nonoperative and open RCR groups, and 3.2 months for the arthroscopic debridement group.

Steroid injection, stretching and strengthening vs. open RCR. Yamada et al.[197] conducted a retrospective cohort study comparing nonoperative treatment vs. open repair with acromioplasty. Patients in the nonoperative groups received a mixture of 1% lidocaine (4 mL) and dexamethasone sodium phosphate (2 mg) injected into the subacromial bursa once or twice per week, as well as heat treatments, passive stretching and strengthening exercises. Forty patients with massive tears enrolled in the study (14 received the nonoperative treatment, 26 received surgical repair). All patients were followed for a mean length of 4 years (12 months to 23 years). The JOA shoulder scale and strength score were used to evaluate patients. There was significant improvement in the JOA score for both the nonoperative treatment group (p=0.0012) and the operative group (p<0.0001). However, the difference in the JOA score between the groups at final followup was not significant (p>0.05). At study endpoint, muscle strength was greater in the operative group than the nonoperative group; however the statistical significance of this difference was not reported.

Separate meta-analyses were conducted for the two trials and three cohort studies comparing the effects of nonoperative treatment vs. surgical repair on functional outcome measures (Figure 31). The scales used to measure function included the ASES,[66] CMS,[196] Insalata,[165] JOA,[197] and the UCLA.[195] Both of the trials significantly favoured repair over nonoperative treatments for functional outcomes. For the cohort studies, the pooled estimate of change in function shows no significant difference between groups, although the surgical repair is favored (SMD=-1.34; 95% CI, -2.95, 0.27). There was substantial heterogeneity between the three studies (p<0.0001, I^2=92 percent), which may be attributed to differences in the nonoperative treatment components and the characteristics of the patients enrolled in each study.

Figure 31. Nonoperative treatment vs. RCR for measures of functional outcome

Study or Subgroup	Non-operative treatment Mean	SD	Total	RCR Mean	SD	Total	Weight	Std. Mean Difference IV, Random, 95% CI
35.1.1 RCT/CCT								
De Carli	16	3	15	21	3	15	38.7%	-1.62 [-2.46, -0.78]
Moosmayer	31	22.95	51	47.1	14.72	52	61.3%	-0.83 [-1.23, -0.43]
Subtotal (95% CI)			66			67	100.0%	-1.14 [-1.89, -0.38]
Heterogeneity: Tau² = 0.20; Chi² = 2.77, df = 1 (P = 0.10); I² = 64%								
Test for overall effect: Z = 2.95 (P = 0.003)								
35.1.2 Cohort Studies								
Lunn 2008	15.6	3.4	14	16.5	3.4	5	31.6%	-0.25 [-1.28, 0.77]
Vad 2002	26.1	8.9	40	50.6	7.92	36	34.3%	-2.87 [-3.52, -2.22]
Yamada 2000	17.86	14.63	14	27.12	9.13	26	34.1%	-0.80 [-1.48, -0.13]
Subtotal (95% CI)			68			67	100.0%	-1.34 [-2.95, 0.27]
Heterogeneity: Tau² = 1.86; Chi² = 26.66, df = 2 (P < 0.00001); I² = 92%								
Test for overall effect: Z = 1.63 (P = 0.10)								

Std. Mean Difference
IV, Random, 95% CI
-2 -1 0 1 2
Favours RCR   Favours n-o treatment

Two cohort studies[196,197] provided data for meta-analysis for the effects of nonoperative treatment vs. surgical repair on pain (Figure 32). The pain subscales of the CMS[196] and JOA[197] scales were used in this analysis. Baseline to followup change scores were compared between groups. The pooled analysis showed no statistically significant difference between the two

treatments for pain (SMD=0.81; 95% CI, -1.26 to 2.88). Heterogeneity between the studies was substantial (p=0.001, I^2=90).

Figure 32. Nonoperative treatment vs. RCR for pain

Study or Subgroup	Non-operative treatment			RCR			Weight	Std. Mean Difference IV, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
	Mean	SD	Total	Mean	SD	Total			
Lunn 2008	-4.6	1.4	14	-4.2	1.4	5	48.7%	-0.27 [-1.30, 0.75]	
Yamada 2000	-10.71	4.97	14	-17.88	3.06	26	51.3%	1.84 [1.06, 2.61]	
Total (95% CI)			28			31	100.0%	0.81 [-1.26, 2.88]	
Heterogeneity: Tau² = 2.01; Chi² = 10.35, df = 1 (P = 0.001); I² = 90%									
Test for overall effect: Z = 0.77 (P = 0.44)									

Favours n-o treatment   Favours RCR

Table 34. Study and patient characteristics for studies assessing operative vs. nonoperative interventions

Author, year	Intervention (N participants enrolled) Study design	Age (yr), mean±SD (range) / Males, N (%) Other characteristics	Type of tear; size of tear Duration of symptoms (mo), mean±SD (range)
De Carli,[195] 2006	**G1:** Shock wave therapy (NR) **G2:** Mini-open RCR (NR) RCT	**G1:** NR / NR **G2:** NR / NR	FTT; NR NR
Lunn JV,[196] 2008	**G1:** Steroid injection, PT & activity modification (14) **G2:** Open RCR (5) Prospective cohort	**G1:** 47.1 yr (30–66) / Males: 1 (7) **G2:** 46.2 yr (38–59) / Males: 3 (60)	FTT; NR 4.3 yr (6 mo–10 yr)
Moosmayer S,[66] 2010	**G1:** PT (51) **G2:** Open / mini-open repair (52) **G3:** Secondary surgery (9)§ RCT	**G1:** 61±7.6 yr / Males: 36 (71) **G2:** 59±7.5 yr / Males: 37 (71)	FTT; Sm, Med **G1:** 9.8±9.8 mo; **G2:** 12.3±18.7 mo
Vad VB,[165] 2002	**G1:** PT & oral medication (28) **G2:** PT, oral medication & steroid injection (12) **G3:** Open RCR (36) **G4:** Arthroscopic debridement (32) Retrospective cohort	**G1 & 2:** 63.2 yr / NR **G3:** 59.4 yr / NR **G4:** 62.9 yr / NR	FTT; Mass 6.3 mo (1–17 mo)
Yamada N,[197] 2000	**G1:** Steroid injection, stretching, strengthening (14) **G2:** Open RCR (26) Retrospective cohort	**G1:** 70 yr (55–81) / Males: 9 (64) **G2:** 62 yr (47–82) / Males: 24 (92)	FTT; Mass **G1:** 44 mo (12 mo–11 yr); **G2:** 13 mo (1 mo–4.5 yr)

FTT = full-thickness tear; G = group; Mass = massive; Med = medium; mo = month; NR = not reported; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial; SD = standard deviation; Sm = small; yr = year

Table 35. Outcome data for studies assessing operative vs. nonoperative interventions

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
De Carli,[195] 2006	**G1:** Shock wave therapy (NR) **G2:** Mini-open RCR (NR) **G1:** 24 (12–36) mo **G2:** 19 (12–26) mo	ASES	47 / 70, p<0.05	50 / 87, p<0.05	p<0.05
		CMS	33 / 67, p<0.05	30 / 77, p<0.05	NR
		UCLA	11 / 27, p<0.05	11 / 32, p<0.05	p<0.05
Lunn JV, 2008[196]	**G1:** Steroid injection, PT & activity modification (14) **G2:** Open RCR (5) 4.2 yr (2–6.6)	CMS*	53 (32–78.5) / 69.5 (44–95), p=0.009	51 (24.5–65) / 66.6 (37.5–87), p=0.009	p=0.61
		ROM (degrees; affected, normal sides)	NR	F: NR / 158, 176 (NR by group) ER: NR / 48, 58 IR: NR/ T12, T7	NR
		Strength (kg; affected, normal sides)	NR	ER: NR / 3.2, 6, p<0.0001 (NR by group)	NR
		Cuff integrity n/N (%), MRI	3 / 5 (60)	NR	NA
Moosmayer S,[66] 2010	**G1:** PT (51) **G2:** Open / mini-open repair (51) **G3:** Secondary surgery (9)§ 12 mo	SF-36 (95%CI) 6 mo 12 mo	PCSS: 38.6 (36.2–41.1) 47.3 (44.7–50.0) 48.9 (46.0–51.7), p=NR MCSS: 57.3 (54.7–59.9) 57.6 (55.5–59.7) 57.5 (55.4–59.5), p=NR	PCSS: 38.2 (36.6–39.9) 47.9 (45.3–50.4) 50.7 (47.8–53.6), p=NR MCSS: 54.1 (50.9–57.3) 57.5 (55.0–60.0) 56.2 (53.7–58.8), p=NR **G3:** NR	G1 vs. G2: PCSS: 0.84>p>0.10‡ MCSS: 0.92>p>0.29‡ G2 vs. G3: NR
		ASES*(95%CI) 6 mo 12 mo	48.2 (44.1–52.2) 75.8 (70.2–81.4) 79.2 (72.7–85.5), p=NR	45.5 (41.5–49.6) 84.5 (80.3–88.6) 92.6 (88.6–96.6), p=NR **G3:** 42.1 (30.1–54.2) Pre-op||: 48.9 (32.6–65.2) 6 mo: 75.4 (59.2–91.7) 12 mo: 88.9 (77.4–100.0), p=NR	G1 vs. G2: p<0.0005‡ G2 vs. G3: NR

ABD = abduction; ASES = American Shoulder and Elbow scale; CI = confidence interval; CMS = Constant-Murley score; ER = external rotation; F = flexion; G = group; Insalata = L'Insalata Shoulder Rating Questionnaire; IR = internal rotation; JOA = Japanese orthopaedic association; kg = kilogram; MCSS = mental component summary score; mo = month; MRI = magnetic resonance imaging; NR = not reported; PCSS = physical component summary score; PT = physical therapy; RCR = rotator cuff repair; ROM = range of motion; SD = standard deviation; SF-36 = Short Form-36; UCLA = University of California Los Angeles scale; yr = year;
*Subscales reported
†No group specification
‡Calculated by UAEPC
§ Subset of patients who underwent secondary surgery following failed PT
|| Score after failed PT, prior to surgery
¶One case was unable to undergo MRI. Two subjects had inconclusive MRI assessment (not included in the result)

Table 35. Outcome data for studies assessing operative vs. nonoperative interventions (continued)

Author, year	Intervention (N analysed) Followup mean (range)	Outcome	Group 1 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 2 Baseline mean±SD (range)/ Endpoint mean±SD (range)	Group 1 vs. Group 2 p-value
		CMS* (95%CI) 6 mo 12 mo	38.4 (34.4–42.4) 64.1 (58.5–69.7) 66.8 (60.6–73.1), p=NR	35.3 (31.6–39.0) 64.9 (60.2–69.7) 76.8 (72.6–80.9), p=NR	G1 vs. G2: p=0.002‡
				G3: 36.2 (27.3–45.2) Pre-op‖: 35.9 (26.9–44.9) 6 mo: 57.9 (43.8–72.0) 12 mo: 69.8 (55.1–84.4), p=NR	G2 vs. G3: NR
		Cuff integrity n/N (%), MRI 12 mo	NR	38 / 50 (76) ¶ 8 / 9 (89)	G1 vs. G2: NR G2 vs. G3: p=0.67‡
Vad VB, 2002[165]	**G1 & G2:** PT & oral medication (± steroid injection) (40) **G3:** Open RCR (36) **G4:** Arthroscopic debridement (32) 3.2 yr (2–7)	Insalata	**G1 & G2:** 44.4±1.7 / 70.5±1.4, p≤0.05	**G3:** 33±1.2 / 83.6±1.4, p≤0.05 **G4:** 42.3±1.4 / 81.4±1.3, p≤0.05	p<0.01‡ p<0.01‡
		ROM (degrees)	**G1 & G2:** ABD: 68 / 108, p≤0.05	**G3:** ABD: 72 / 116, p≤0.05 **G4:** ABD: 74 / 110, p≤0.05	NR
		Time to maximal ROM	**G1 & G2:** 6.8 mo (2–16)	**G3:** 6.8 mo (4–16) **G4:** 3.2 mo (1–8)	NR
Yamada N, 2000[197]	**G1:** Steroid injection, stretching, strengthening (14) **G2:** Open RCR & acromioplasty (26) 4 yr (12 mo–23 yr)	JOA*	53.2 (40–65) / 71.1 (48–88), p=0.0012	58.8 (43–73) / 85.9 (67–100), p<0.0001	p>0.05
		Strength score (Manual muscle test)	ABD & ER: NR / 4- (n=3)	ABD & ER: NR / 5- (n=9)	NR

Table 36. Strength of evidence for nonoperative vs. operative treatment

Technique	Number of studies; subjects (analyzed)*	Outcome	Strength of evidence domains					Strength of evidence
			Risk of bias	Consistency	Directness	Precision	Confounding	
Shock wave therapy vs. mini-open RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 30	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Steroid injection, PT, and activity modification vs. open RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 19	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
PT vs. open or mini-open RCR	1; 102	HRQL	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	1; 102	Function	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	1; 50	Cuff integrity	RCT Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
PT, oral medication, and steroid injection vs. arthroscopic debridement vs. open RCR	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 108	Function	Cohort Medium	Unknown	Direct	Imprecise	Absent	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient
Passive stretching, strengthening, and corticosteroid injection vs. open RCR with acromioplasty	0	HRQL	n/a	n/a	n/a	n/a	n/a	Insufficient
	1; 40	Function	Cohort Medium	Unknown	Direct	Imprecise	Present	Low
	0	Cuff integrity	n/a	n/a	n/a	n/a	n/a	Insufficient
	0	Time to return to work	n/a	n/a	n/a	n/a	n/a	Insufficient

HRQL = health-related quality of life; n/a = not applicable; PT = physical therapy; RCR = rotator cuff repair
*Number analyzed if different from number studied

Question 5. Complications

Summary. Overall, 85 of the 137 studies included in this review reported data on complications across all interventions. Sixty-four studies reported at least one event of the 34 different complications identified, while 21 studies reported no complications and 52 studies did not report any data on complications. In general, the rates of complications were low and the majority of complications were not deemed to be clinically important or were reported only in a few studies. Throughout, "rate" refers to the number of patients experiencing complications during the study period. Study lengths vary, so no standardized time period is used. A priori, we identified the following complications to be the most clinically important:

- Retears: This complication was reported in 14 studies. Among the 9 studies examining operative approaches, the rates of retear were generally low (≤0.10). One retrospective cohort study[113] investigating operative augmentation using McLaughlin procedure vs. patch graft found retear rates of 0 vs. 0.18. Three studies examining postoperative rehabilitation reported low rates (≤0.14). In addition, retears due to technical failures were reported in 16 studies. In 12 studies investigating operative approaches, the reported rates of technical failure were low (≤0.07). Rates for technical failure for a variety of operative techniques ranged from 0 to 0.33, and for one operative augmentation study[67] the rate was 0.03.
- Infection: 32 studies reported data on infection. Among 25 studies that examined operative approaches, the rate of infection was low with the majority of studies reporting no infections. Studies of operative techniques and augmentations generally reported low rates of infection (≤0.05). Three studies examining postoperative rehabilitation reported low rates of infection, except in one study[179] for a progressive rehabilitation program reporting a rate of 0.29.
- Stiffness: 24 studies provided data on stiffness following treatment. The rates were low (≤0.08) among 20 studies examining operative approaches. Higher rates of postoperative stiffness were observed for mini-open RCRs with two of the six studies reporting rates of 0.14[157] and 0.17.[171] Likewise, two of the 10 studies examining arthroscopic RCR reported rates of 0.08[80] and 0.11.[171] One study[81] examining a single vs. double-row operative technique and one[109] on augmentation both reported low rates of postoperative stiffness, with 0.06 and 0, respectively. Similarly, two nonoperative studies reported low rates of 0.04[190] and 0.07.[186]
- Reflex sympathetic dystrophy: In general the rates of reflex sympathetic dystrophy were low (≤0.02) across the seven studies examining operative approaches; however, higher rates were observed in a BA study[122] of arthroscopic RCR (0.12) and a retrospective cohort study[63] of arthroscopic debridement with tenotomy (0.13). One study[180] evaluating postoperative rehabilitation reported one case of reflex sympathetic dystrophy among the 15 patients studied.
- Neurological injury: The rates of postoperative neurological injury were low (≤0.06) in 12 studies examining operative approaches, techniques or augmentations.

Results by complication. Of the 137 studies included in this review, 85 studies reported on 34 different complications for nonoperative and operative interventions (see tables below); 52 studies (eight trials,[71,102,105,133,143,178,185,195] five prospective cohort studies,[72,85,148,177,196] nine retrospective cohort studies,[87,106,125,154,165,172,181,183,197] 18 BA studies,[60,69,79,89,90,100,104,115,116,123,142,160,166,168,175,187,192,193] eleven cohort studies providing BA data,[62,86,126,128,135,141,144,149,150,188,191] and one case-control study[164]) did not report any data on complications (Table 61). The tables report complications for study arms separately. The

majority of complications were reported for operative studies; only two studies[186,190] reported complications associated with nonoperative treatments, one study reported complications with nonoperative vs. operative treatments,[66] while four postoperative rehabilitation studies[179,180,182,184] reported complications. Complication rates for studies focusing on postoperative rehabilitation may be attributable to either the preceding surgery or the rehabilitation components.

Twenty-one studies (seven trials,[78,96-98,163,176,194] one prospective cohort,[159] two retrospective cohorts,[132,138] and 11 BA studies[84,91,95,99,111,121,131,158,162,174,189]) reported that no complications occurred during the course of the study (Table 60). The remaining 63 studies reported at least one event in the course of a nonoperative, operative, or postoperative rehabilitation treatment. Of these 63, twelve were trials: seven[73,81,109,114,117,136,137] that compared operative interventions, four[179,180,182,184] that compared postoperative rehabilitation, and one that compared nonoperative and operative interventions.[66] Twenty-one studies used a cohort design,[63,64,68,75,77,88,94,112,113,118,119,129,134,139,140,147,157,167,170,171,173] all of which compared operative interventions. Thirty-one studies used a BA design: 29 studies,[65,67,70,74,76,80,82,83,92,93,101,103,107,108,110,120,122,124,127,130,145,146,151-153,155,156,161,169] examined operative interventions and two[186,190] examined nonoperative interventions. No BA studies provided data on complications for postoperative rehabilitation.

Retears. Fourteen studies (Table 37) reported postoperative retears (three trials,[179,182,184] five cohort studies,[77,112,113,157,173] six uncontrolled studies[70,83,127,151-153]). These studies used clinical evaluation or imaging to identify the presence of retears in patients who were unsatisfied with their postoperative outcome. It should be noted that not all retears are symptomatic (e.g., associated with pain, stiffness, reduced function), therefore some retears may have been undetected in patients who were satisfied with their clinical outcome. Studies which systematically examined all patients using imaging to investigate what proportion had an intact cuff are reported under the key outcome "tendon integrity" above. Overall, the rates of retears from 10 studies that examined operative approach were consistent and rates ranged from 0 to 0.10. Rates of retears for McLaughlin procedure, patch graft[113] and platelet-rich plasma augmentation[152] with arthroscopic repair were 0, 0.18, and 0.07, respectively. Studies examining physical therapy alone[182,184] and physical therapy with continuous passive motion[184] reported rates ranging from 0 to 0.05, while one study[179] reported a rate of 0.14 for a traditional postoperative rehabilitation program and no events for a progressive rehabilitation program.

Table 37. Re-tear

Intervention	Author, year Category Design	Patients evaluation; Evaluation criteria (imaging/ clinical)	Events	Sample size	Rate (95% CI)
Operative					
Open RCR	Cofield 2001[83] Operative approach BA	Unsatisfied; Clinical	3‡	105	0.03 (0.01–0.08)
	Prasad 2005[151] Operative approach BA	Unsatisfied; Clinical	1	40	0.03 (0.004–0.13)
	Rokito 1999[153] Operative approach BA	Unsatisfied; Clinical	3	30	0.1 (0.03–0.26)
Mini-open RCR	Severud 2003[157] Operative approach Retrospective cohort	Unsatisfied; Clinical	1	29	0.03 (0.01–0.17)
	Youm 2005[173] Operative approach Retrospective cohort	Unsatisfied; Clinical	3	42	0.07 (0.02–0.19)
Arthroscopic RCR	Bennett 2003[70] Operative approach BA	Unsatisfied; Clinical	1	24	0.04 (0.01–0.20)
	Buess 2005[77] Operative approach Prospective cohort	Unsatisfied; Clinical	2§	66	0.03 (0.008–0.10)
	Ide 2005[112] Operative approach Prospective cohort	Unsatisfied; MRI	1	50	0.02 (0.003–0.10)
	Severud 2003[157] Operative approach Retrospective cohort	Unsatisfied; Clinical	0	35	0 (0.00–0.07)
	Youm 2005[173] Operative approach Retrospective cohort	Unsatisfied; Clinical	1	42	0.02 (0.004–0.12)
Open or mini-open RCR	Buess 2005[77] Operative approach Prospective cohort	Unsatisfied; Clinical	0	30	0 (0.00–0.08)
Stabilization of LHB & open RCR	Maier 2007[127] Operative approach BA	Unsatisfied; Clinical	2	21	0.10 (0.03–0.29)
McLaughlin procedure RCR	Ito 2003[113] Operative augmentation Retrospective cohort	Unsatisfied; Clinical	0	13	0 (0.00–0.17)
Patch graft RCR	Ito 2003[113] Operative augmentation Retrospective cohort	Unsatisfied; Clinical	3	17	0.18 (0.06–0.41)
Arthroscopic RCR & platelet-rich plasma augmentation	Randelli 2008[152] Operative augmentation BA	Unsatisfied; Clinical	1*	14	0.07 (0.01–0.3)

BA = before-and-after; CI = confidence interval; LHB = long head of biceps; MRI = magnetic resonance imaging; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial
*Re-tear due to injury. Patient unavailable for last followup and sample size represents the number of patients enrolled.
† No group specified.
‡Retear due to injury (2) and aggressive PT (1)
§ One patient experienced retear and stiffness

Table 37. Re-tear (continued)

Intervention	Author, year Category Design	Patients evaluation; Evaluation criteria (imaging/ clinical)	Events	Sample size	Rate (95% CI)
Postoperative Rehabilitation					
PT alone	Michael 2005[182] Post-operative rehabilitation RCT	Unsatisfied; Clinical	1	21	0.05 (0.01–0.23)
Continuous passive motion & PT	Michael 2005[182] Post-operative rehabilitation RCT	Unsatisfied; Clinical	0	34	0 (0.00–0.07)
Continuous passive motion & PT program vs. PT alone	Raab 1996[184] Post-operative rehabilitation RCT	Unsatisfied; Clinical	1†	26	0.04 (0.007–0.19)
Progressive group	Klintberg 2009[179] Post-operative rehabilitation RCT	Unsatisfied; Clinical	0	7	0 (0.00–0.28)
Traditional group	Klintberg 2009[179] Post-operative rehabilitation RCT	Unsatisfied; Clinical	1	7	0.14 (0.03–0.51)

BA = before-and-after; CI = confidence interval; LHB = long head of biceps; MRI = magnetic resonance imaging; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial
*Re-tear due to injury. Patient unavailable for last followup and sample size represents the number of patients enrolled.
† No group specified.
‡Retear due to injury (2) and aggressive PT (1)
§ One patient experienced retear and stiffness

Technical failure. Sixteen studies reported failure of anchors or other surgical constructs (seven cohort studies[88,112,118,134,147,157,167] and nine uncontrolled studies[67,74,82,92,110,122,146,161,169]) (Table 38). Overall, the rates of technical failure from twelve studies that examined operative approach ranged from 0 to 0.07, with only one study[82] reporting a rate higher than 0.05. Rates for technical failure in 4 studies for a variety of operative techniques were provided and ranged from 0 to 0.33. One operative augmentation study had a rate of 0.03.

Table 38. Technical failure

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	0	20	0 (0.00–0.12)
Mini-open RCR	Severud 2003[157] Operative approach Retrospective cohort	0	29	0 (0.00–0.09)
	Verma 2006[167] Operative approach Retrospective cohort	0	33	0 (0.00–0.08)

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair
*No group specification

Table 38. Technical failure (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Arthroscopic RCR	Boileau 2005[74] Operative approach BA	0	65	0 (0.00–0.04)
	Deutsch 2008[92] Operative approach Cohort – BA data	2	39	0.05 (0.01–0.17)
	Ide 2007[110] Operative approach BA	0	20	0 (0.00–0.12)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Lafosse 2007[122] Operative approach BA	0	17	0 (0.00–0.14)
	Park 2004[146] Operative approach Cohort – BA data	0	42	0 (0.00–0.06)
	Severud 2003[157] Operative approach Retrospective cohort	0	35	0 (0.00–0.07)
	Tauro 2004[161] Operative approach BA	1	42	0.02 (0.004–0.12)
	Verma 2006[167] Operative approach Retrospective cohort	1	38	0.03 (0.005–0.13)
	Waibl 2005[169] Operative approach BA	1	22	0.05 (0.008–0.22)
Arthroscopic RCR & biceps tenodesis	Checchia 2005[82] Operative approach BA	1	15	0.07 (0.01–0.30)
Single-row fixation	Park 2008[147] Operative technique Prospective cohort	1	40	0.03 (0.004–0.13)
Double-row fixation	Park 2008[147] Operative technique Prospective cohort	1	38	0.03 (0.005–0.13)
Simple stitch	Ko 2008[118] Operative technique Prospective cohort	9	39	0.23 (0.005–0.13)
Modified mattress locking stitch	Ko 2008118 Operative technique Prospective cohort	6	36	0.17 (0.08–0.32)
Mitek metal suture anchor (open RCR)	Cummins 2003[88] Operative technique Prospective cohort	0	18	0 (0.00–0.13)
Headed bio-corkscrews (open RCR)	Cummins 2003[88] Operative technique Prospective cohort	3	9	0.33 (0.12–0.65)
Arthroscopic knotted	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	1	29	0.03 (0.006–0.17)

Table 38. Technical failure (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Arthroscopic knotless	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	0	38	0 (0.00–0.07)
Mattress suture vs. transosseus suture (arthroscopic RCR)	Matis 2006[129] Operative technique Prospective cohort	1*	90	0.01 (0.002–0.06)
Open RCR & augmentation	Audenaert 2006[67] Operative augmentation BA	1	39	0.03 (0.005–0.13)

Infection. Thirty-two studies reported data on infection (five trials,[73,136,179,180,182] eleven cohort studies,[63,68,75,77,88,94,112,113,119,147,157] and 16 uncontrolled studies[65,74,80,82,83,101,103,108,110,122,124,130,145,146,155,161]) (Table 39). Overall, the rates of infection from 25 studies that examined operative approach ranged from 0 to 0.06 with many studies reporting no infections. Rates of infection for various operative techniques and augmentations were provided and ranged from 0 to 0.05. Three RCTs[179,180,182] investigating postoperative rehabilitation provided data on infection rates but the events are likely related to surgery and may not necessarily be attributed to the rehabilitation program.

Table 39. Infection

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Baker 1995[68] Operative approach Retrospective cohort	1	20	0.05 (0.01–0.24)
	Cofield 2001[83] Operative approach BA	2	105	0.02 (0.005–0.07)
	Gazielly 1994[103] Operative approach BA	0	100	0 (0.00–0.03)
	Hsu 2007[108] Operative approach BA	0	47	0 (0.00–0.05)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Mohtadi 2008[136] Operative approach RCT	0	29	0 (0.00–0.09)
	Pai 2001[145] Operative approach BA	2	58	0.03 (0.01–0.10)
Mini-open RCR	Baker 1995[68] Operative approach Retrospective cohort	1	17	0.06 (0.01–0.27)
	Kose 2008[119] Operative approach Retrospective cohort	1	25	0.04 (0.007–0.20)

BA = before-and-after; CI = confidence interval; LHB = long head of biceps; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial
*Sample size represents the number of participants enrolled in the study because the patient with the complication was excluded from the analysis.
†No group specification

Table 39. Infection (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Mini-open RCR (continued)	Mohtadi 2008[136] Operative approach RCT	0	31	0 (0.00–0.08)
	Severud 2003[157] Operative approach Retrospective cohort	0	29	0 (0.00–0.09)
Arthroscopic RCR	Boileau 2005[74] Operative approach BA	0	65	0 (0.00–0.04)
	Buess 2005[77] Operative approach Prospective cohort	0	66	0 (0.00–0.04)
	Charousset 2008[80] Operative approach BA	0	104	0 (0.00–0.03)
	Ide 2007[110] Operative approach BA	0	20	0 (0.00–0.12)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Kose 2008[119] Operative approach Retrospective cohort	0	25	0 (0.00–0.10)
	Lafosse 2007[122] Operative approach BA	0	17	0 (0.00–0.14)
	Lichtenberg 2006[124] Operative approach BA	0	53	0 (0.00–0.05)
	McBirnie 2005[130] Operative approach BA	1	53	0.02 (0.003–0.10)
	Severud 2003[157] Operative approach Retrospective cohort	0	35	0 (0.005–0.15)
Arthroscopic RCR (continued)	Park 2004[146] Operative approach Cohort – BA data	0	42	0 (0.00–0.06)
	Tauro 2004[161] Operative approach BA	1	42	0.02 (0.004–0.12)
Open or mini-open RCR	Buess 2005[77] Operative approach Prospective cohort	1	30	0.03 (0.006–0.17)
Arthroscopic RCR & biceps tenodesis	Checchia 2005[82] Operative approach BA	0	15	0 (0.00–0.15)
Open debridement & acromioplasty	Gartsman 1997[101] Operative approach BA	1	33	0.03 (0.005–0.15)
Arthroscopic debridement	Klinger 2005[65] Operative approach BA	0	33	0 (0.00–0.08)

Table 39. Infection (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic debridement with tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	24	0 (0.00–0.10)
Arthroscopic debridement without tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	17	0 (0.00–0.14)
Biceps tenotomy vs. tenodesis	Boileau 2007[75] Operative approach Retrospective cohort	1†	72	0.01 (0.002–0.07)
Watertight anatomical repair	Favard 2009[94] Operative approach Retrospective cohort	2	103	0.02 (0.005–0.07)
Palliative treatment (partial repair or LHB tenotomy)	Favard 2009[94] Operative approach Retrospective cohort	1	89	0.01 (0.002–0.06)
Double-row fixation	Park 2008[147] Operative technique Prospective cohort	0	38	0 (0.00–0.07)
Single-row fixation	Park 2008[147] Operative technique Prospective cohort	2	40	0.05 (0.01–0.17)
Mason-Allen technique with non-absorbable sutures	Boehm 2005[73] Operative technique RCT	2	49	0.04 (0.01–0.14)
Kessler technique with absorbable sutures	Boehm 2005[73] Operative technique RCT	1	44	0.02 (0.004–0.12)
Open RCR & augmentation	Scheibel 2007[155] Operative augmentation BA	1	23*	0.04 (0.008–0.21)
McLaughlin procedure RCR	Ito 2003[113] Operative augmentation Retrospective cohort	0	17	0 (0.00–0.14)
Patch graft RCR	Ito 2003[113] Operative augmentation Retrospective cohort	0	13	0 (0.00–0.17)
Postoperative Rehabilitation				
Continuous passive motion & PT program	LaStayo 1998[180] Post-operative rehabilitation RCT	1	17	0.06 (0.01–0.27)
	Michael 2005[182] Post-operative rehabilitation RCT	2	34	0.06 (0.02–0.19)
PT alone	LaStayo 1998[180] Post-operative rehabilitation RCT	0	15	0 (0.00–0.15)
	Michael 2005[182] Post-operative rehabilitation RCT	1	21	0.05 (0.01–0.23)
Progressive group	Klintberg, 2009[179] Post-operative rehabilitation RCT	2	7	0.29 (0.08–0.64)
Traditional group	Klintberg, 2009[179] Post-operative rehabilitation RCT	0	7	0 (0.00–0.28)

Stiffness. Twenty-four studies provided data on stiffness following treatment (four trials,[81,109,136,137] seven cohort studies,[77,94,112,157,167,171,173] three cohort studies with BA data,[92,107,146] and ten BA studies[65,74,76,80,110,124,145,151,186,190]) (Table 40). Overall, the rates of postoperative stiffness from 21 studies that examined operative approach ranged from 0 to 0.17 with six studies reporting no events.[109,110,112,124,136,146] Rates for operative techniques and nonoperative treatment ranged from 0 to 0.6 and 0.04 to 0.07, respectively. One study[109] examining operative augmentation reported no events.

Table 40. Stiffness

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0.00–0.15)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Mohtadi 2008[136] Operative approach RCT	0	29	0 (0.00–0.09)
	Montgomery 1994[137] Operative approach CCT	1	50	0.02 (0.004–0.11)
	Pai 2001[145] Operative approach BA	1	58	0.02 (0.003–0.09)
	Prasad 2005[151] Operative approach BA	1	40	0.03 (0.004–0.13)
Mini-open RCR	Boszotta 2004[76] Operative approach BA	1	84	0.01 (0.002–0.06)
	Mohtadi 2008[136] Operative approach RCT	0	31	0 (0.00–0.08)
	Severud 2003[157] Operative approach Retrospective cohort	4	29	0.14 (0.06–0.31)
	Verma 2006[167] Operative approach Retrospective cohort	0	33	0 (0.00–0.08)
	Warner 2005[171] Operative approach Retrospective cohort	2	12	0.17 (0.05–0.45)
	Youm 2005[173] Operative approach Retrospective cohort	0	42	0 (0.00–0.06)
Open or mini-open RCR	Buess 2005[77] Operative approach Prospective cohort	1	30	0.03 (0.006–0.17)
Arthroscopic RCR	Boileau 2005[74] Operative approach BA	1	65	0.02 (0.003–0.08)
	Buess 2005[77] Operative approach Prospective cohort	4*	66	0.06 (0.02–0.15)

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; LHB = long head of biceps; NSAID = non-steroidal anti-inflammatory drug; RCR = rotator cuff repair; RCT = randomized controlled trial
*One patient experienced stiffness and retear

Table 40. Stiffness (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic RCR (continued)	Charousset 2008[80] Operative approach BA	8	104	0.08 (0.04–0.14)
	Deutsch 2008[92] Operative approach Cohort – BA data	1	39	0.03 (0.005–0.13)
	Ide 2007[110] Operative approach BA	0	20	0 (0.00–0.12)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Lichtenberg 2006[124] Operative approach BA	0	53	0 (0.00–0.05)
	Park 2004[146] Operative approach Cohort – BA data	0	42	0 (0.00–0.06)
	Severud 2003[157] Operative approach Retrospective cohort	0	35	0 (0.00–0.07)
	Verma 2006[167] Operative approach Retrospective cohort	1	38	0.03 (0.005–0.13)
	Warner 2005[171] Operative approach Retrospective cohort	1	9	0.11 (0.02–0.44)
	Youm 2005[173] Operative approach Retrospective cohort	2	42	0.05 (0.1–0.16)
Combination approach	Henn 2008[107] Operative approach Cohort – BA data	2	125	0.02 (0.004–0.06)
Arthroscopic debridement	Klinger 2005[65] Operative approach BA	1	33	0.03 (0.005–0.15)
	Montgomery 1994[137] Operative approach CCT	1	38	0.03 (0.005–0.13)
Watertight anatomical repair	Favard 2009[94] Operative approach Retrospective cohort	7	103	0.07 (0.03–0.13)
Palliative treatment (partial repair or LHB tenotomy)	Favard 2009[94] Operative approach Retrospective cohort	1	89	0.01 (0.002–0.06)
Single-row arthroscopic RCR	Charousset 2007[81] Operative technique RCT	2	33	0.06 (0.02–0.20)
Double-row arthroscopic RCR	Charousset 2007[81] Operative technique RCT	0	28	0 (0.00–0.09)
Open RCR & porcine augmentation	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0.00–0.15)

Table 40. Stiffness (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Nonoperative				
Nonoperative treatment (analgesic, NSAID, steroid injection, reeducation program)	Koubaa 2006[190] Nonoperative BA	1	24	0.04 (0.007–0.20)
	Ghroubi 2008[186] Nonoperative BA	4	59	0.07 (0.03–0.16)

Reflex sympathetic dystrophy. Eight studies (one trial,[180] two cohort studies,[63,75] and five uncontrolled studies[103,108,122,130,145]) provided data on reflex sympathetic dystrophy (Table 41). Overall, the rates of dystrophy from seven studies that examined operative approach ranged from 0 to 0.13. One study[180] compared physical therapy alone with continuous passive motion and physical therapy and reported rates of 0.7 and 0, respectively.

Table 41. Reflex sympathetic dystrophy

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Hsu 2007[108] Operative approach BA	1	47	0.02 (0.004–0.11)
	Gazielly 1994[103] Operative approach BA	2	100	0.02 (0.006–0.07)
	Pai 2001[145] Operative approach BA	1	58	0.02 (0.003–0.09)
Arthroscopic RCR	Lafosse 2007[122] Operative approach BA	2	17	0.12 (0.03–0.34)
	McBirnie 2005[130] Operative approach BA	1	53	0.02 (0.003–0.10)
Arthroscopic debridement & tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	3	24	0.13 (0.04–0.31)
Arthroscopic debridement without tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	17	0 (0.00–0.14)
Biceps tenotomy vs. tenodesis	Boileau 2007[75] Operative approach Retrospective cohort	1†	72	0.01 (0.002–0.07)
Postoperative Rehabilitation				
Continuous passive motion & PT program	LaStayo 1998[180] Post-operative rehabilitation RCT	0	17	0 (0.00–0.14)
PT alone	LaStayo 1998[180] Post-operative rehabilitation RCT	1	15	0.07 (0.01–0.30)

BA = before-and-after; CI = confidence interval; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial
†No group specification

Neurologic injury. Twelve studies (Table 42) (three trials,[109,114,137] two cohort studies,[112,113] and seven uncontrolled studies[65,74,103,108,110,145,161]) provided data on neurologic injury. Overall, the rates of injury from 10 studies that examined operative approach were consistent and ranged from 0 to 0.06. Two studies examining operative augmentation reported no events.

Table 42. Neurological injury

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Gazielly 1994[103] Operative approach BA	2	100	0.02 (0.006–0.07)
	Hsu 2007[108] Operative approach BA	0	47	0 (0.00–0.05)
	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0.00–0.15)
	Ide 2005[112] Operative approach Prospective cohort	3	50	0.06 (0.02–0.16)
	Montgomery 1994[137] Operative approach CCT	1	50	0.02 (0.004–0.11)
	Pai 2001[145] Operative approach BA	2	58	0.03 (0.01–0.12)
Mini-open RCR	Kim 2003[114] Operative approach CCT	0	34	0 (0.00–0.07)
Arthroscopic RCR	Boileau 2005[74] Operative approach BA	0	65	0 (0.00–0.04)
	Ide 2007[110] Operative approach BA	1	20	0.05 (0.01–0.24)
	Ide 2005[112] Operative approach Prospective cohort	0	50	0 (0.00–0.05)
	Kim 2003[114] Operative approach CCT	0	42	0 (0.00–0.06)
	Tauro 2004[161] Operative approach BA	0	42	0 (0.00–0.06)
Arthroscopic debridement	Klinger 2005[65] Operative approach BA	0	33	0 (0.00–0.08)
	Montgomery 1994[137] Operative approach CCT	0	38	0 (0.00–0.07)
Arthroscopic debridement with tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	24	0 (0.00–0.10)
Arthroscopic debridement without tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	17	0 (0.00–0.14)

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair; RCT = randomized controlled trial

Table 42. Neurological injury (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR & porcine augmentation	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0.00–0.15)
McLaughlin procedure RCR	Ito 2003[113] Operative technique Retrospective cohort	0	17	0 (0.00–0.14)
Patch graft RCR	Ito 2003[113] Operative technique Retrospective cohort	0	13	0 (0.00–0.17)

Reoperation—NOS. Nine studies provided data on the need for reoperation (three trials,[114,136,137] four cohort studies,[75,88,134,140] and two uncontrolled studies[83,108]) (Table 43). Overall, the rates of reoperation from eight studies that examined operative approach ranged from 0 to 0.24. Rates of reoperation for a variety of operative techniques were provided and ranged from 0.06 to 0.18.

Table 43. Reoperation—NOS

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Cofield 2001[83] Operative approach BA	5 (hypertrophic bursal scar excision (2); glenohumeral arthritis (1); impaired healing due to renal failure (1); unknown (1)	105	0.05 (0.02–0.11)
	Hsu 2007[108] Operative approach BA	0	47	0 (0.00–0.05)
	Mohtadi 2008[136] Operative approach RCT	0	29	0 (0.00–0.09)
	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	4†	20	0.2 (0.08–0.42)
	Montgomery 1994[137] Operative approach CCT	4	50	0.08 (0.03–0.19)
Mini-open RCR	Kim 2003[114] Operative approach CCT	0	34	0 (0.00–0.07)
	Mohtadi 2008[136] Operative approach RCT	1†	31	0.03 (0.006–0.16)
Arthroscopic RCR	Kim 2003[114] Operative approach CCT	0	42	0 (0.00–0.06)
	Mullett 2006[140] Operative approach Prospective cohort	3	96	0.03 (0.01–0.09)

AC = acromioclavicular; BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair; RCT = randomized controlled trial   *No group specification   †Due to traumatic events

Table 43. Reoperation—NOS (continued)

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic subacromial decompression	Mullett 2006[140] Operative approach Prospective cohort	26	114	0.23 (0.16–0.31)
Arthroscopic debridement	Montgomery 1994[137] Operative approach CCT	9	38	0.24 (0.13–0.39)
Biceps tenotomy vs. tenodesis	Boileau 2007[75] Operative approach Retrospective cohort	2*	72	0.03 (0.008–0.10)
Mitek metal suture anchor (open RCR)	Cummins 2003[88] Operative technique Prospective cohort	1	18	0.06 (0.01–0.26)
Headed bio-corkscrews (open RCR)	Cummins 2003[88] Operative technique Prospective cohort	1	9	0.11 (0.02–0.43)
Arthroscopic knotted	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	4†	29	0.14 (0.05–0.31)
Arthroscopic knotless	Millar NL, 2009[134] Operative approach/technique Retrospective cohort	7†	38	0.18 (0.09–0.33)

Postoperative sudden pain/impingement syndrome. One RCT[182] provided data on postoperative sudden pain and impingement syndrome (Table 44). The rate of ostoperative sudden pain ranged from 0 in physical therapy alone to 0.03 in continuous passive motion with physical therapy program, while the rate of postoperative impingement syndrome ranged from 0 in continuous passive motion with physical therapy program to 0.05 in physical therapy alone.

Table 44. Postoperative pain or impingement syndrome

Intervention	Author, year Category Design	Posoperative pain/Impingement		
		Events	Sample size	Rate (95% CI)
Postoperative Rehabilitation				
Continuous passive motion & PT program	Michael 2005[182] Post-op rehabilitation RCT	1 / 0	34	0.03 (0.005–0.15) / 0 (0–0.07)
PT alone	Michael 2005[182] Post-op rehabilitation RCT	0 / 1	21	0 (0–0.11) / 0.05 (0.009–0.23)

CI = confidence interval; PT = physical therapy; RCT = randomized controlled trial

Glenohumeral instability. One postoperative rehabilitation study[180] provide data on glenohumeral instability in patients undergoing continuous passive motion or manual passive range of motion exercises (Table 45). Only one case of glenohumeral instability was reported in the manual passive range of motion exercise group.

Table 45. Glenohumeral instability

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Postoperative Rehabilitation				
Continuous passive motion	LaStayo 1998[180] Post-op rehabilitation RCT	0	17	0 (0.00–0.14)
Manual passive ROM exercises	LaStayo 1998[180] Post-op rehabilitation RCT	1	15	0.07 (0.01–0.30)

CI = confidence interval; RCT = randomized clinical trial; ROM = range of motion; post-op = postoperative

Fracture of the greater tuberosity. One prospective cohort study[129] provide data on fracture of the greater tuberosity of humerus bone (Table 46). The rate of fracture of the greater tuberosity was 0.01 in the study.

Table 46. Fracture of the greater tuberosity

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Mattress suture vs. transosseus suture (arthroscopic RCR)	Matis 2006[129] Operative technique Prospective cohort	1*	90	0.01 (0.002–0.06)

CI = confidence interval; RCR = rotator cuff repair
*No group specification

Biceps pathology. Two BA studies[122,127] provided data on sublaxation or secondary rupture of the long head of biceps (LHB) tendon (Table 47). The rate of biceps complications in these studies investigating arthroscopic RCR and stabilization of LHB & open RCR was 0.12 and 0.14, respectively. One prospective cohort study[64] provided data on biceps tendon disruption/inflammation (Table 19). The rate of biceps tendon disruption/inflammation in arthroscopic RCR with PGA tacs vs. suture tying was 0.16 (0.05 for disruption/ 0.10 for inflammation) with no group specification.

Table 47. Biceps pathology

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic RCR	Lafosse 2007[122] Operative approach BA	2	17	0.12 (0.03–0.34)
Stabilization of LHB & open RCR	Maier 2007[127] Operative approach BA	3	21	0.14 (0.05–0.35)
Bioabsorbable PGA tacs vs. suture tying (arthroscopic RCR)	Bennett 2004[64] Operative technique Prospective cohort	3*	19	0.16 (0.06–0.38)

BA = before-and-after; CI = confidence interval; LHB = long head of biceps PGA = Polymerized lactic acid tack; RCR = rotator cuff repair
*No group specification

Deltoid disruption. Two studies (one trial[109] and one BA study[101]) reported no deltoid disruption from operative interventions including open RCR, open debridement, and open RCR with augmentation (Table 48).

Table 48. Deltoid disruption

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0.00–0.15)
Open debridement & acromioplasy	Gartsman 1997[101] Operative approach BA	0	33	0 (0.00–0.08)
Open RCR & porcine augmentation	Iannotti 2006[109] Augmentation RCT	0	15	0 (0.00–0.15)

Heterotopic bone formation. One retrospective cohort study[139] provide data on heterotopic bone formation (Table 49). The rate of heterotopic bone formation was 0.26 in the open or arthroscopic debridement group and 0.27 in the open RCR group.

Table 49. Heterotopic bone formation

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Motycka 2004[139] Operative approach Retrospective cohort	9	33	0.27 (0.15–0.44)
Open or arthroscopic debridement	Motycka 2004[139] Operative approach Retrospective cohort	8	31	0.26 (0.14–0.43)

CI = confidence interval; RCR = rotator cuff repair

Arthropathy. One retrospective cohort study[139] and one BA study[156] provided data on arthropathy (Table 50). The cohort study compared open RCR with open or arthroscopic debridement and rates of postoperative AC joint arthrosis for the two arms were 1.0 and 0.42, respectively. The BA study examined arthroscopic debridement and reported a rate of 0.04.

Table 50. Arthropathy

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Motycka 2004[139] Operative approach Retrospective cohort	29	29†	1 (0.91–1.0)
Open or arthroscopic debridement	Motycka 2004[139] Operative approach Retrospective cohort	10	24†	0.42 (0.24–0.61)
Arthroscopic debridement only	Scheibel 2004[156] Operative approach BA	1	23*	0.04 (0.008–0.21)

AC = acromioclavicular; BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair
*Sample size represents the number of participants enrolled in the study because the patient with the event had reoperation and was excluded from the analysis.
†Sample size represents the number of patients without preoperative arthrosis on radiograph.

Hematoma. Four studies (three BA studies[70,120,156] and one retrospective cohort study[63]) provided data on hematoma (Table 51). The rates from the three BA studies were consistent, 0.08, 0.06, and 0.05. The cohort study using arthroscopic debridement with and without tenotomy reported no events of hematoma in both groups.

Table 51. Hematoma

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic RCR	Bennett 2003[70] Operative approach BA	2	24	0.08 (0.02–0.26)
	Kreuz 2005[120] Operative approach BA	1*	16	0.06 (0.01–0.28)
Arthroscopic debridement	Scheibel 2004[156] Operative approach BA	1	22	0.05 (0.008–0.22)
Arthroscopic debridement with tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	24	0 (0.00–0.10)
Arthroscopic debridement without tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	17	0 (0.00–0.14)

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair
*The patient developed post-operative stiffness (frozen shoulder) due to hematoma.

Seroma. One RCT,[109] one retrospective cohort study[170] and five uncontrolled studies[76,83,92,93,101] provided data on seroma for operative approaches (Table 52). The rates of seroma were consistent for the uncontrolled studies, ranging from 0.01 to 0.06. However, two controlled studies examining the use of porcine augmentation with rotator cuff repair[109,170] both found high rates of hypersensitive reaction in patients receiving the graft, with event rates of 0.2 and 0.3.

Table 52. Seroma

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Cofield 2001[83] Operative approach BA	1 (at graft donor site)	105	0.01 (0.002–0.05)
	Iannotti 2006[109] Operative augmentation RCT	0	15	0 (0–0.15)
	Walton 2007[170] Operative augmentation Retrospective cohort	0	15	0 (0–0.15)
Mini-open RCR	Boszotta 2004[76] Operative approach BA	1 (in the area of incision)	84	0.01 (0.002–0.06)
	Deutsch 2008[92] Operative approach Cohort – BA data	1	39	0.03 (0.005–0.13)
	Ellman 1993[93] Operative approach Cohort – BA data	1	40	0.03 (0.004–0.13)
Open RCR & porcine augmentation	Iannotti 2006[109] Augmentation RCT	3 (reaction to graft)	15	0.2 (0.07–0.45)
	Walton 2007[170] Operative augmentation Retrospective cohort	4 (reaction to graft)	15	0.3 (0.11–0.52)
Open debridement & acromioplasty	Gartsman 1997[101] Operative approach BA	2	33	0.06 (0.02–0.20)

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair; RCT = randomized controlled trial

Lymphedema. One BA study[186] provided data on lymphedema (Table 53). The rate of lymphedema in the nonoperative treatment was 0.02.

Table 53. Lymphedema

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Nonoperative				
Nonoperative treatment (Analgesic, NSAID, steroid injection, reeducation program)	Ghroubi 2008[186] Nonoperative BA	1	59	0.02 (0.003–0.09)

BA = before-and-after; CI = confidence interval; NSAID = non-steroidal anti-inflammatory drug

Synovitis. Two BA studies[67,130] provided data on synovitis (Table 54). There were no reactive synovitis events in patients undergoing arthroscopic RCR or open RCR with augmentation.

Table 54. Reactive synovitis

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Arthroscopic RCR	McBirnie 2005[130] Operative approach BA	0	53	0 (0.00–0.05)
Open RCR & augmentation (polyester graft)	Audenaert 2006[67] Operative augmentation BA	0	39	0 (0–0.06)

BA = before-and-after; CI = confidence interval; RCR = rotator cuff repair

Local reaction to suture material. One retrospective cohort study[157] provided data on local reaction to suture material (Table 55). The rate of local reaction to suture material ranged from 0 in the mini-open RCR to 0.03 in the arthroscopic RCR.

Table 55. Local reaction to suture material

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Mini-open RCR	Severud 2003[157] Operative approach Retrospective cohort	0	29	0 (0.00–0.09)
Arthroscopic RCR	Severud 2003[157] Operative approach Retrospective cohort	1	35	0.03 (0.005–0.15)

CI = confidence interval; RCR = rotator cuff repair

Wound dehiscence. One CCT[137] provided data on wound dehiscence (Table 56). The rate of dehiscence ranged from 0 for arthroscopic debridement and 0.02 for open RCR.

Table 56. Wound dehiscence

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Open RCR	Montgomery 1994[137] Operative approach CCT	1	50	0.02 (0.004–0.11)
Arthroscopic debridement	Montgomery 1994[137] Operative approach CCT	0	38	0 (0.00–0.07)

CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair

Delayed wound healing. One prospective cohort study[147] provided data on wound healing (Table 57). The rate of delayed wound healing ranged from 0 in single-row arthroscopic RCR to 0.03 in double-row arthroscopic RCR.

Table 57. Delayed wound healing

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Single-row fixation	Park 2008[147] Operative technique Prospective cohort	0	40	0 (0.00–0.06)
Double-row fixation	Park 2008[147] Operative technique Prospective cohort	1	38	0.03 (0.005–0.13)

CI = confidence interval

Cosmetic deformity. Three studies (one trial,[114] one cohort study,[63] and one uncontrolled study[65]) provided data on cosmetic deformity for operative approaches (Table 58). The rates from the three studies were consistent among designs and ranged from 0 to 0.08.

Table 58. Cosmetic deformity

Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Operative				
Mini-open RCR	Kim 2003[114] Operative approach CCT	2	34	0.06 (0.02–0.19)
Arthroscopic RCR	Kim 2003[114] Operative approach CCT	0	42	0 (0.00–0.06)
Arthroscopic debridement only	Klinger 2005[65] Operative approach BA	1	33	0.03 (0.005–0.15)
Arthroscopic debridement with tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	2	24	0.08 (0.02–0.26)
Arthroscopic debridement without tenotomy	Klinger 2005[63] Operative approach Retrospective cohort	0	17	0 (0.00–0.14)

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; RCR = rotator cuff repair

Other medical complications. Eight studies reported on 12 other medical complications (Table 59): skin hypersensitivity,[114] skin bulla,[117] pneumonia,[83] deep vein thrombosis,[83,182] myocardial infarction,[83] postoperative depression,[83] laryngeal nerve palsy,[146] facial nerve palsy,[146] allergic reaction to oral anti-inflammatory drugs,[130] massive intraoperative swelling of the neck,[129] neck pain,[117] and polymyalgia rheumatica.[66] The rates for all events were consistent and ranged from 0 to 0.05 (Table 59).

Table 59. Other medical complications

Complication	Intervention	Author, year Category Design	Events	Sample size	Rate (95% CI)
Skin hypersensitivity	Mini-open vs. arthroscopic RCR	Kim 2003[114] Operative approach CCT	1*	76	0.01 (0.002–0.07)
Skin bulla	MCS repair	Ko S-H, 2009[117] Operative technique CCT	1	35	0.03 (0.005–0.15)
	Simple stitch repair	Ko S-H, 2009[117] Operative technique CCT	1	36	0.03 (0.005–0.14)
Pneumonia	Open RCR	Cofield 2001[83] Operative approach BA	1	105	0.01 (0.002–0.05)
DVT	Open RCR	Cofield 2001[83] Operative approach BA	1	105	0.01 (0.002–0.05)
	Continuous passive motion & PT program	Michael 2005[182] German Post-op rehab RCT	0	34	0 (0.00–0.07)
	PT alone	Michael 2005[182] German Post-op rehab RCT	1	21	0.05 (0.009–0.23)
MI	Open RCR	Cofield 2001[83] Operative approach BA	1	105	0.01 (0.002–0.05)
Postoperative depression	Open RCR	Cofield 2001[83] Operative approach BA	1	105	0.01 (0.002–0.05)
Laryngeal nerve palsy	Arthroscopic RCR	Park 2004[146] Operative approach Cohort – BA data	1	42	0.02 (0.004–0.12)
Facial nerve palsy	Arthroscopic RCR	Park 2004[146] Operative approach Cohort – BA data	1	42	0.02 (0.004–0.12)
Allergic reaction to oral anti-inflammatory drugs	Arthroscopic RCR	McBirnie 2005[130] Operative approach BA	1	53	0.02 (0.003–0.10)
Massive intraoperative swelling of the neck	Mattress suture vs. transosseus suture (arthroscopic RCR)	Matis 2006[129] Operative technique Prospective cohort	1*	90	0.01 (0.002–0.06)
Neck pain	MCS repair	Ko S-H 2009[117] Operative technique CCT	1	35	0.03 (0.005–0.15)
	Simple stitch repair	Ko S-H 2009[117] Operative technique CCT	1	36	0.03 (0.005–0.14)
Polymyalgia rheumatica	Open OR Mini-open RCR (+acromioplasty)	Moosmayer 2010[66] Non-operative vs. operative	0	52	0 (0.00–0.05)
	Nonoperative (PT)	Moosmayer 2010[66] Non-operative vs. operative	1	51	0.02 (0.003–0.10)

BA = before-and-after; CCT = controlled clinical trial; CI = confidence interval; DVT = deep vein thrombosis; MI = myocardial infarction; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial
*No group specification

Table 60. No complications

Intervention	Author, year Category Design
Open RCR	McCallister 2005[131] Operative approach BA
Arthroscopic RCR	Cole 2007[84] Operative approach BA – Report zeros
	Lafosse 2007[121] Operative approach BA
	Sugaya 2007[158] Operative approach BA
	Deutsch 2007[91] Operative approach BA
	Ide 2005[111] Operative approach BA
	Tauro 2006[162] Operative approach Cohort – BA data
Open debridement & tuberplasty	Fenlin 2002[95] Operative approach BA
Arthroscopic RCR & SLAP repair vs. arthroscopic RCR & biceps tenotomy	Franceschi 2008[96] Operative approach RCT
RCR & tenodesis with detachment vs. RCR & tenodesis without detachment	Franceschi 2007b[97] Operative approach RCT
Classic open acromioplasty vs. modified open acromioplasty	Torrens 2003[163] Operative approach CCT
Complete open RCR vs. partial open RCR vs. debridement	Moser 2007[138] Operative approach Retrospective cohort
Open RCR & augmentation	Zumstein 2008[174] Operative augmentation BA
	Fuchs 2006[99] Operative augmentation BA
Double-row vs. single-row arthroscopic RCR	Burks RT, 2009[78] Operative technique RCT
	Franceschi 2007a[98] Operative technique RCT
	Sugaya 2005[159] Operative technique Prospective cohort
Ultrasonic suture welding vs. hand-tied knots (mini-open RCR)	McIntyre 2006[132] Operative technique Retrospective cohort
Land-based & Aquatic therapy program vs. land-based program	Brady 2008[176] Post-operative rehabilitation CCT

BA = before-and-after; CCT = controlled clinical trial; RCR = rotator cuff repair; RCT = randomized controlled trial; SLAP = superior labrum from anterior to posterior

139

Table 60. No complications (continued)

Intervention	Author, year Category Design
Sodium hyaluraonate vs. dexamethasone	Shibata 2001[194] Nonoperative approach RCT
Pulsed radiofrequency ablation	Kane 2008[189] Nonoperative approach BA

Table 61. Complications not reported

Intervention	Author, year Category Design
Open RCR	Caniggia 1995[79] Operative approach BA
	Cools 2006[86] Operative approach Cohort – BA data
	Iannotti 1996[60] Operative approach BA
	Kirschenbaum 1993[115] Operative approach BA
	Mallon 2004[128] Operative approach Cohort – BA data
	Misamore 1995[135] Operative approach Cohort – BA data
	Trenerry 2005[164] Operative approach Case control – BA data
Mini-open RCR	Baysal 2005[69] Operative approach BA
Open _or_ mini-open RCR	Klepps 2004[116] Operative BA
	Vitale 2007[168] Operative approach BA
Open _or_ mini-open _or_ arthroscopic RCR	Gladstone 2007[104] Operative approach Cohort – BA data
	Tashjian 2006[160] Operative approach BA
Open _or_ arthroscopic RCR	Davidson 2000[89] Operative approach BA
	Oh 2008[144] Operative approach Cohort – BA data
Open vs. mini-open RCR	Hata 2004[106] Operative approach Retrospective cohort

BA = before-and-after; CCT = controlled clinical trial; PT = physical therapy; RCR = rotator cuff repair; RCT = randomized controlled trial

Table 61. Complications not reported (continued)

Intervention	Author, year Category Design
Open vs. arthroscopic RCR	Costouros 2006[87] Operative approach Retrospective cohort
Open or mini-open vs. arthroscopic RCR	Bishop 2006[72] Operative approach Prospective cohort
Mini-open vs. arthroscopic RCR	Colegate-Stone 2009[85] Operative approach Prospective cohort
	Liem 2007[125] Operative approach Retrospective cohort
	Pearsall 2007[148] Operative approach Prospective cohort
	Sauerbrey 2005[154] Operative approach Retrospective cohort
Arthroscopic RCR	Bennett 2003[62] Operative approach Cohort – BA data
	DeFranco 2007[90] Operative BA
	Levy 2008[123] Operative BA
	Nho 2009[142] Operative BA
Double-row vs. single row arthroscopic RCR	Grasso 2009[105] Operative technique RCT
Side-to-side repair vs. tendon to bone repair	Bigoni 2009[71] Operative technique RCT
Arthroscopic RCR: staple fixation vs. side-to-side suture	Wilson 2002[172] Operative technique Retrospective cohort
Mini-open RCR vs. shock wave therapy	De Carli 2006[195] Non-operative vs. operative RCT
Rehab as inpatient vs. outpatient	Delbrouck 2004[177] Postoperative rehabilitation Prospective cohort
Inpatient rehabilitation centre vs. private practice specializing in 'CGE'	Marc 2009[181] Postoperative rehabilitation Retrospective cohort
	Gartsman 1998[100] Operative approach BA
	Nam 2008[141] Operative approach Cohort – BA data
	Porcellini 2006[150] Operative approach Cohort – BA data

Table 61. Complications not reported (continued)

Intervention	Author, year Category Design
Inpatient rehabilitation centre vs. private practice specializing in 'CGE' (continued)	Pillay 1994[149] Operative approach Cohort – BA data
Open RCR vs. arthroscopic debridement	Ogilvie-Harris 1993[143] Operative approach CCT
Arthroscopic debridement only	Vaz 2000[166] Operative approach BA
Arthroscopic RCR & acromioplasty vs. arthroscopic RCR alone	Gartsman 2004[102] Operative approach RCT
	Milano 2007[133] Operative approach RCT
Arthroscopic decompression	Lim 2005[126] Operative approach Cohort – BA data
Rehabilitation vs. no rehabilitation	Leroux 1993[191] Post-operative rehabilitation Retrospective cohort
Individualized PT & home exercise program vs. home exercise program	Hayes 2004[178] Post-operative rehabilitation RCT
Home exercise: Videotape-based vs. PT instruction	Roddey 2002[185] Post-operative rehabilitation RCT
Standardized vs. non-standardized PT program	Milroy 2008[183] Post-operative rehabilitation Retrospective cohort
Postoperative rehabilitation	Boissonnault 2007[175] Post-operative rehabilitation BA
Nonoperative treatment	Hawkins 1995[187] Nonoperative approach BA (Exercise protocol)
	Heers 2005[188] Nonoperative approach Cohort – BA data (Home exercise program)
	Levy 2008[192] Nonoperative approach BA (Anterior deltoid rehabilitation program)
	Scheuermann 1991[193] Nonoperative BA (Early functional PT and active shoulder support)
Nonoperative treatment vs. RCR	Lunn 2008[196] Operative vs. nonoperative Prospective cohort
	Vad 2002[165] Operative vs. nonoperative Retrospective cohort
	Yamada 2000[197] Operative vs. nonoperative Retrospective cohort

Question 6. Evidence on the Role of Prognostic Factors on Treatment Outcomes

Summary. Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions are limited due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. Variations in findings may also be due to limited sample sizes and potential for type II errors, i.e., failing to find a difference when one actually exists.

Among operative studies, 65 of 113 studies examined prognostic factors. The factors most often examined were:

- Tear size (n=39): Twenty-two studies found evidence of worse outcomes for larger tears, while 16 studies found no impact of tear size. One study made no conclusions.[71] Most of the studies evaluated operative approaches and there were no patterns in terms of findings by specific operative approach.
- Age (n=28): Fifteen studies found evidence of worse outcomes among older patients, while 13 studies found no impact of age. Most of the studies evaluated operative approaches, and no patterns were seen by operative approach.
- Sex (n=16): Ten studies found no differences in outcomes for men and women. Six studies found differences, however the findings differed with three studies showing better outcomes for women (open RCR,[128] arthroscopic RCR,[100] nonabsorbable vs. absorbable sutures[73]) and three studies favouring men (open RCR,[83] arthroscopic RCR,[80] arthroscopic single row vs. double row[105]).
- WCB status (n=12): Ten studies found no impact of WCB status for open RCR (n=3), arthroscopic RCR (n=6), and nonabsorbable vs. absorbable sutures (n=1). Two studies (open RCR vs. mini-open vs. arthroscopic RCR,[107] arthroscopic RCR[80]) showed worse outcomes for patients with WCB claims.
- Duration of symptoms (n=13): Thirteen studies showed no evidence for different outcomes based on duration of symptoms. These included evaluations of arthroscopic RCR (n=6), mini-open or arthroscopic (n=1), open (n=4), arthroscopic debridement (n=1), and open vs. arthroscopic (n=1).
- Preoperative stiffness, range of motion, or strength (n=10): Five uncontrolled studies examining arthroscopic (n=2) and open (n=3) repairs and one controlled study examining arthroscopic repairs (n=1) showed worse outcomes with greater preoperative symptoms. In one study,[134] outcomes were similar for open and arthroscopic groups, depending on the preoperative symptoms investigated. The remaining three studies[114,141,144] showed no difference in outcomes based on preoperative symptoms.

Among the other interventions examined in this report, four of eleven studies that evaluated postoperative rehabilitation, two of 10 studies evaluating nonoperative interventions, and one of five studies comparing operative with nonoperative interventions examined the impact of various prognostic factors. The variation in interventions, factors that were examined, and findings across studies preclude any overall interpretations or conclusions.

Prognostic factors by intervention and outcome. We aimed to identify the role of prognostic factors (e.g., patient and clinical characteristics) as moderators of the treatment effect measured in nonoperative, operative and postoperative rehabilitation studies assessing RC tears. Overall,

the impact of prognostic factors on patient outcomes was assessed through either subgroup, regression or non-parametric analysis in 72 studies. Due to the small number of studies addressing each intervention and comparison, meta-regression analysis was not feasible. Therefore, the findings from the individual studies that reported data on the role of prognostic factors are presented.

Operative Studies

Of the 113 studies examining the effectiveness of operative interventions, 65 studies (five RCTs,[71,73,105,109,133] one CCT,[114] seven prospective cohort studies,[64,72,77,112,117,147,148] eight retrospective cohort studies,[68,75,119,125,134,154,157,173] 12 cohort studies with BA data,[62,86,92,93,107,128,135,141,144,149,162,164] and 32 BA studies[60,65,70,74,76,80,83,84,89,90,99-101,103,104,108,110,115,116,120-124,130,131,142,145,151,160,166,174]) explored the role of various patient or clinical factors as prognostic factors. Six of the studies focused on operative techniques,[64,71,73,105,117,147] three focused on augmentations,[99,109,174] and 55 studies examined operative approaches. One study investigated both operative approaches and techniques.[134] The prognostic factors were examined using subgroup analysis in 45 studies, regression analysis in 15 studies, both subgroup and regression in two studies, non-parametric tests in two studies, and both subgroup analysis and non-parametric tests in one study. The analysis was planned a priori in 39 studies, while 26 studies conducted the analysis post hoc.

Five studies[72,100,107,144,160] conducted an analysis of the role of prognostic factors on health-related quality of life. The studies used multiple regression models[160] or subgroup analysis[72,100,107,144] to examine a variety of prognostic factors, including age,[100] sex,[100] tear size,[72,100] WCB status,[107] number of comorbidities,[160] and preoperative stiffness.[144] A variety of potential confounding factors were controlled in two studies[144,160] but they were not explored in the analysis. The investigators of one study concluded that age, but not sex, influences health-related quality of life outcomes. They found that older patients had less improvement in the SF-36 after arthroscopic repair.[100] In studies investigating tear size, no significant differences in health related quality of life outcomes for patients with small and large tears were found.[72,100] The author conclusions for other prognostic factors are presented in Table 62.

Fifty-five studies[60,62,64,65,68,70-73,75-77,80,84,86,89,92,93,99-101,104,105,107,108,112,114,116,119-125,128,130,131,133-135,141,142,144,145,147-149,151,154,157,160,166,173,174] conducted an analysis of the role of prognostic factors on functional outcome measures. The studies used subgroup analysis,[60,62,64,65,68,70-72,76,77,84,92,93,99-101,107,108,112,114,116,119,120,123-125,130,131,135,141,144,145,147-149,151,154,157,166,173,174] multiple regression analysis[73,75,80,90,104,105,109,121,122,128,133,134,142,160] to examine a various prognostic factors, including age,[70,73,76,80,84,100,105,108,119,121,122,124,125,128,130,131,133,134,142,145,148,151,166] sex,[64,70,80,100,105,128,130,131,133,148,151,166] tear size,[60,68,71,72,76,77,92,93,100,104,105,112,114,116,121-125,128,130,134,142,145,147,148,151,154,157,173] duration of symptoms,[80,92,114,121,122,134,145,151] etiology of tear,[114,121,133] tear pattern,[76,92,105] tear type,[62,65,75,99,108,120,149,174] location,[105] number of tendons torn,[75,92,131,142,174] hand dominance,[73,80,105,133,166] preoperative strength,[86,105,114,134,145] preoperative shoulder stiffness,[134,141,144] preoperative range of motion,[65,145] preoperative latency,[166] mechanism of injury,[122] smoking status,[128,148,151] body mass index,[151] number of comorbidities,[160] WCB status,[60,73,80,84,107,121,122,130,135] upper-limb heavy work,[80] nature of work,[166] repair tension,[89] fatty infiltration,[75,104,105,122,133] muscle atrophy,[104] quality and condition of the biceps tendon,[60,76,92,105,122,124,133,148] tissue quality,[60,145,166] operative time,[134] surgical learning curve,[134] difficulty of repair,[60] tendon retraction,[105,124] acromion type,[76,114,133,166] acromiohumeral distance,[75,76] atrophy of teres minor,[75] duration of immobilization,[76] diabetes,[108,148] glenoid or

144

humeral osteoarthritis,[65,148] concomitant distal clavicle excision,[148] presence of subscapularis tear,[65,133] and superior migration of humeral head.[65] The majority of studies found that age was not associated with functional outcome,[70,76,80,119,121,122,128,131,134,145,148] while one found older age to predict better functional score[133] and three concluded older age to predict poorer scores.[73,105,151] Similarly, gender did not predict functional outcomes in six studies,[64,70,131,133,148,151] whereas three studies found males to have better[73,80,105] and two studies found males to have worse[100,128] outcomes compared with females. Authors' conclusions regarding the role of tear size on functional outcomes was inconsistent across studies. Studies reported that small tear size predicted better function,[60,68,72,76,93,100,112,114,116,123,142,145,147,151] or reported no influence of tear size on functional outcome.[73,77,92,104,105,121,122,124,125,128,130,148,154,157,173] All of the studies which examined the symptom duration found no effect on functional outcomes.[80,121,122,134,145,151] Authors' conclusions for the remaining factors are displayed in Table 62.

Seventeen studies[68,72,74,84,90,92,99,103,104,109,110,116,117,124,125,134,142] assessed the role of prognostic factors on cuff integrity. The studies used subgroup analysis[68,72,84,92,99,103,110,116,124,125] or multiple regression analysis[74,90,104,109,134,142] or non-parametric tests[117] to examine the effect of various patient factors on cuff integrity, including tear size,[68,72,74,92,103,104,109,110,116,117,124,125,134,142] age,[74,84,90,103,110,124,125,134,142] sex,[74] number of tendons torn,[92,142] duration of symptoms,[74,92,134] tendon retraction,[110,124] preoperative strength,[74,134] preoperative stiffness,[134] fatty infiltration and muscle atrophy,[99,104] tear pattern,[84,92,110,117] biceps pathology,[84,92,124] tear type,[99] time to surgery,[84] operative time,[134] surgical learning curve,[134] hand dominance,[84] WCB status,[74,84] and degree of occupational use.[103] The authors found that the most significant factors affecting cuff integrity were age and tear size. Older age was found to be associated with recurrent tears in all studies investigating this factor[74,84,90,103,110,124,125,142] but one.[134] Increased tear size was found to be a significant risk factor for tendon defects in several studies,[68,72,74,103,104,109,116,134,142] while four studies found no significant effect of tear size on cuff integrity.[92,110,124,125] No association was found between sex[74,84] or duration of preoperative symptoms[74,84,92,134] on cuff integrity. Table 62 presents the authors' conclusions for the role of the remaining prognostic factors on cuff integrity.

Sixteen studies[62,64,70,72,83,84,89,92,114,116,121,128,141,148,151,160] examined the role of prognostic factors on pain. The studies used subgroup analysis[62,64,70,72,83,84,92,114,116,128,141,148,151] or multiple regression analysis[89,121,160] to examine the effect of various prognostic factors on pain, including age,[70,83,84,121,128,148,151] sex,[64,70,83,84,128,148,151] tear size,[72,83,92,114,116,121,128,148,151] duration of preoperative symptoms,[83,84,92,114,121,151] WCB,[84,121,128] etiology of tear,[83,114,121] biceps pathology or procedure,[83,84,92,148] osteoarthritis,[148] diabetes,[148] concomitant distal clavicle excision,[148] smoking,[128,148,151] hand dominance,[83,84] acromion morphology,[83,114] tear pattern,[84,92] side affected,[83] location of tear,[83] repair tension,[89] number of tendons torn,[92] preoperative strength,[114] preoperative stiffness,[141] BMI,[151] and number of comorbidities.[160] The authors' conclusions on the role of these prognostic factors on pain were variable. Older patients were found to have significantly more pain,[84] and significantly less improvement in outcome,[151] in two studies, while three other studies found no association between age and pain level.[70,121,128,148] Sex was found not to effect outcomes in four studies,[64,70,148,151] yet one study found that men had significantly less postoperative pain than women.[83] For tear size, several studies found that smaller tear size was associated with less pain than large or massive tears, yet the difference was not statistically significant[72,83,116] in all but two studies.[148,151] Three studies found no effect of tear size on outcomes.[92,114,128] Symptom duration was consistently found not to influence the

outcome.[84,114,121,151] The author conclusions for other prognostic factors are presented in Table 62 below.

Ten studies[72,75,83,92,121,125,141,148,162,164] examined the role of prognostic factors on range of motion. The studies used subgroup analysis[72,83,92,125,141,148,162,164] or regression analysis[75,121] to examine various prognostic factors including age,[75,83,121,148,164] sex,[75,83,148,164] tear size,[72,83,92,125,148,162,164] duration of preoperative symptoms,[92,121,164] biceps pathology,[92,121,148] concomitant distal clavicle excision,[148] osteoarthritis,[148] diabetes,[148] etiology of tear,[121,164] WCB,[121,164] time to followup,[75] preoperative function,[75] number of tendons torn,[92] preoperative stiffness,[141] hand dominance,[164] tear type,[164] and presence of comorbidities.[164] Author conclusions regarding the prognostic factors for range of motion varied. Cofield[83] reported that older age was associated with lower active range of motion, whereas the results from two studies[92,148] indicated that age had no affect. Cofield[83] further reported that men demonstrated significantly better active abduction than women. Four authors[92,121,125,148] found that tear size had no affect on range of motion, comparatively, two[72,83] studies found that smaller tears showed better range of motion outcomes after surgery than larger tear sizes. Tauro[162] reported tear size was positively correlated to range of motion. Duration of preoperative symptoms was found to have no effect on postoperative range of motion. Table 62 presents authors' conclusions for the remaining prognostic factors examined in the studies.

Thirteen studies[71,74,83,86,92,101,104,105,115,121,125,141,147] assessed the role of prognostic factors on strength. The studies used subgroup analysis,[71,83,86,89,92,101,125,141,147,153] multiple regression analysis,[74,104,105,121] or analysis using non-parametric tests.[115] The patient factors that were examined include age,[74,83,105,121,153] sex,[74,83,86,105] tear size,[71,83,104,105,115,125,147,153] duration of preoperative symptoms,[92,121] biceps pathology,[92,105,121] preoperative strength,[74,105] preoperative shoulder stiffness,[141] number of tendons torn,[92] type of tendon,[101] tendon retraction,[105] location,[105] shape,[105] fatty infiltration[105] and muscle atrophy,[104] etiology of tear,[121] hand dominance,[105] general health status,[153] and WCB.[121] The majority of the 13 studies investigating strength concluded that tear size affected post operative strength; however, results varied. Three studies[92,105,125] found no significant effect between tear size and strength, whereas the remaining authors made no conclusions[71] or found that the greater the tear size, the poorer the result achieved for postoperative strength.[74,83,101,115,121,147] Authors' conclusions for the remaining factors are displayed in Table 62.

Table 62. Prognostic factors in operative studies

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Baker CL,[68] 1995 Retrospective cohort	**G1:** Open RCR **G2:** Mini-open RCR 3.3 yr	Subgroup analysis by tear size (post hoc)	UCLA cuff integrity	All small tears had good-to-excellent results. With large tears, more patients had good-to-excellent results in open than mini-open repair group. Cuff was more likely to be intact for smaller size tear.

AC joint = acromioclavicular joint; ASES = American Shoulder and Elbow Scale; BA = before-and-after; BMI = body mass index; CCT = controlled clinical trial; CMS = Constant-Murley score; DASH = Disabilities of the Arm, Shoulder and Hand; DM = diabetes mellitus; ER = external rotation; F = flexion; G = group; JOA = Japanese orthopaedic association; LHB = long head of biceps; mo = month; NR = not reported; PENN = University of Pennsylvania Shoulder Score; pre-op = preoperative; QOL = quality of life; RCR = rotator cuff repair; RCT = randomized controlled trial; ROM = range of motion; SF-12 = Short form-12; SF-36 = Short Form-36; SS = supraspinatus; SSI = shoulder strength index; SST = simple shoulder test; UCLA = University of California Los Angeles Scale; VAS = visual analogue scale; WCB = workers' compensation board; yr = year
*Scores are improvement measures

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Bennett WF,[62] 2003 BA	Open RCR 3.2 yr (2–4)	Subgroup analysis by tear orientation (a priori)	ASES CMS % function pain	There is no statistical difference between anterosuperior and posterosuperior tear types for any of the outcomes.
Bennett WF,[70] 2003 BA	Arthroscopic RCR NR (2–4 yr)	Subgroup analysis by age and sex (post hoc)	ASES CMS pain	Age or sex were not associated with outcomes.
Bennett WF,[64] 2003 Prospective cohort	**G1:** Bioabsorbable tacs **G2:** Suture tying NR (2–4 yr)	Subgroup analysis by sex (a priori)	ASES CMS pain	No significant impact of sex on outcomes.
Bigoni M,[71] 2009 RCT	**G1:** Side-to-side repair (25) **G2:** Tendon-to-bone fixation (25) 12 mo	Subgroup analysis by tear size (a priori)	CMS strength	No conclusions were made due to a small number of patients.
Bishop J,[72] 2006 Prospective cohort	**G1:** Open / mini-open RCR **G2:** Arthroscopic RCR 12 mo	Subgroup analysis by tear size (post hoc)	SF-36 ASES CMS ROM pain cuff integrity	In the open repair group, smaller tear size tended to have better, but non-significant, functional outcome scores including pain score, F and ER strength testing. In the arthroscopic group, smaller tears have significantly better outcomes except in pain which showed non-significant improvement. Tear size was associated with cuff integrity in the arthroscopic group but not in the open group.
Boehm TD,[73] 2005 RCT	**G1:** Nonabsorbable sutures (Mason-Allen technique) **G2:** Absorbable sutures (Kessler technique) 2.2 yr (2–2.5)	Regression analysis controlling for hand dominance, WCB status, age, sex, tear size, and type of suture (a priori)	CMS	No significant influence of hand dominance, WCB status, tear size, and suture type on outcome. Male gender and older patients had significantly worse outcomes.
Boileau P,[75] 2007 Retrospective cohort	**G1:** Biceps tenotomy **G2:** Biceps tenodesis 2.9±0.6 yr (2–6.3)	Regression analysis controlling for number of tendons torn, extension of tear, fatty infiltration, acromiohumeral distance, and atrophy of teres minor (post hoc)	CMS ROM	No significant effect of number of tendons torn or the extension of tear on functional outcomes. Fatty infiltration and acromiohumeral distance did not have a measurable effect on the outcome. Pre-op absence or atrophy of teres minor was associated with fatty infiltration of infraspinatus and significantly worse outcomes compared to patients with healthy teres minor.
Boileau P,[74] 2005 BA	Arthroscopic RCR 2.4 yr (2–3.8)	Multiple regression analysis controlling for age, sex, (a priori) tear size, duration of symptoms, WCB status, additional procedures (post hoc)	cuff integrity	Tendon healing was negatively associated with increasing age and delamination of the subscapularis or infraspinatus tendon. Small tear size was positively associated with tendon healing. No association between tendon healing and sex, duration of symptoms, previous injections, WCB status, or additional procedures.
Boszotta H,[76] 2004 BA	Mini-open RCR 2.9 yr (2.3–3.7)	Subgroup analysis by age, tear size, tear pattern, closure technique, number of sutures, quality and condition of long biceps tendon, acromion type, acromiohumeral distance, and immobilization (post hoc)	CMS UCLA	Larger tear size was associated with worse outcome. The quality and condition of long biceps tendon was associated with outcome. Patients with curved or hooked acromion types have significantly better outcomes than patients with flat-shaped acromion. There was no significant influence of age, pre-op acromiohumeral distance, tear configuration, closure technique, number of sutures or type and duration of immobilization on outcome.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Buess E,[77] 2005 Prospective cohort	**G1:** Open or mini-open RCR **G2:** Arthroscopic RCR 2 yr (15 mo–3.3 yr)	Subgroup analysis by tear size (a priori)	SST	No significant effect of tear size on outcome for both groups.
Charousset C,[80] 2008 BA	Arthroscopic RCR 2 yr (maximum)	Multiple regression analysis controlling for age, sex, dominant side affected, upper-limb heavy work, WCB status, duration of symptoms, mechanism of tearing, number of tendons torn, extension and retraction of lesion, tendon quality, bone quality, and tendon reducibility (a priori)	CMS	Women had significantly worse outcome than men. Upper-limb heavy work was negatively associated with outcome. Poor bone quality was found to be associated with poor functional recovery. No significant effect of age, dominant side, duration of symptoms, mechanism of tearing, type of job, involvement of multiple tendons, fatty degeneration, supraspinatus tear extent in sagittal or coronal planes, or AC joint involvement on functional outcome. Sex, age, tears involving 3 tendons and pre-op strength were predictive of post-op strength recovery in CMS subscale. No effect of WCB on functional outcome but time to recovery was longer.
Cofield RH,[83] 2001 BA	Open RCR 13.4 yr (2–22)	Subgroup analysis by age, sex, tear size, etiology of tear, side affected, hand dominance, duration of symptoms, shape of acromion, location of the tear, biceps tenodesis, and type of immobilization (post hoc)	pain active ROM strength	Patients with large or massive tears had lower active ROM and strength measures than patients with smaller tears. There was a trend for more pain with a larger tear size but this association was not significant. Men had significantly better active abduction and less pain than women. Older age was associated with lower active ROM and strength. Pre-op ROM and strength was associated with post-op ROM and strength. Etiology of tear, side of the repair, hand dominance, symptom duration, shape of acromion, location of the tear, biceps tenodesis, and type of immobilization did not influence outcome.
Cole BJ,[84] 2007 BA	Arthroscopic RCR 2.7 yr (2–3.8)	Subgroup analysis by age, sex, hand dominance, time to surgery, WCB status, biceps procedure, number of suture anchors and tear pattern (post hoc)	CMS Rowe score SST pain cuff integrity	Older patients had significantly more pain and less ER power. WCB status did not affect pain assessment, functional outcome scores, or ROM. Older age and pre-op extension of the tear into the infraspinatus were associated with recurrent tears. Concomitant biceps procedures, number of suture anchors used, time to surgery, gender, dominant or non dominant side, WCB status, and tear pattern were not associated with recurrent tears.
Cools A,[86] 2006 Prospective cohort as BA	Open RCR 18 mo (12–20)	Subgroup analysis by pre-op strength (post hoc)	CMS	Pre-op strength was positively correlated with functional outcome.
Davidson PA,[89] 2000 BA	Open _or_ arthroscopic RCR 2 yr (minimum)	Regression analysis controlling for repair tension (a priori)	CMS pain	Increased tension on RCR was significantly associated with worse outcomes.
DeFranco MJ,[90] 2007 BA	Arthroscopic RCR 22.3 mo (12 mo–3 yr)	Multiple regression analysis controlling for age (a priori)	cuff integrity	Younger patients had significantly better outcomes than older patients.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Deutsch A,[92] 2008 Prospective cohort as BA	Arthroscopic RCR 3.2 yr (2–5)	Subgroup analysis by number of tendons torn, tear size, tear pattern, presence of biceps tearing, and duration of pre-op symptoms (a priori)	ASES ROM strength pain cuff integrity	No significant effect of number of tendons torn or tear size on outcomes. Tear recurrence was significantly correlated with asymmetric retraction. No significant influence of biceps tears or duration of pre-op symptoms on tear recurrence.
Ellman H,[93] 1993 Prospective cohort as BA	Arthroscopic RCR 3.6 yr (2–7.3)	Subgroup analysis by tear size (a priori)	UCLA	Small tears associated with higher UCLA score than large tears.
Fuchs B,[99] 2006 BA	Open RCR & augmentation 3.2 yr (2–4.4)	Subgroup analysis by tear orientation, muscle atrophy (a priori).	CMS cuff integrity	There was no significant difference in the total CMS score between patient with supraspinatus tears and those with subscapularis tears. However, patients with subscapularis tears experienced significantly more pain at followup, as measured by the CMS pain subscale. Muscle atrophy approached significance as a predictor for retear.
Gartsman GM,[100] 1998 BA	Arthroscopic RCR 12.7 mo (11–21)	Subgroup analysis by age, sex, and tear size (a priori)	SF-36 ASES CMS	Older patients had significantly less improvement in SF-36. Female patients had significantly greater improvements in CMS and ASES than male patients. Tear with a greater length, width, and area had significantly less improvement in the strength score in CMS.
Gartsman GM,[101] 1997 BA	Open debridement & acromioplasty 5.3 yr (4–9.8)	Subgroup analysis by type and condition of tear (post hoc)	CMS UCLA SSI	All patients with severe superior migration of the humeral head had poor ROM, function, and strength. Poor outcomes were associated with irreparable tears of the subscapularis or teres minor, muscular atrophy of these two muscles, and moderate-to-severe superior migration of the humeral head.
Gazielly DF,[103] 1994 BA	Open RCR 4 yr (2–6)	Subgroup analysis by tear size, degree of occupational use, age (a priori)	cuff integrity	Age, size of tear, and occupational use was associated with tear recurrence.
Gladstone JN,[104] 2007 BA	Open _or_ mini-open _or_ arthroscopic RCR 12 mo (12–15)	Regression analysis controlling for fatty infiltration and muscle atrophy of supraspinatus and infraspinatus, and tear size (a priori)	ASES CMS strength cuff integrity	Patients with poor muscle quality had significantly less improvement in outcomes. Muscle atrophy and fatty infiltration have a strong negative effect on functional outcomes and strength. Pre-op tear size was the only significant predictor of cuff integrity, but it did not predict functional outcome or strength.
Grasso A,[105] 2009 RCT	**G1:** Arthroscopic single row repair (37) **G2:** Arthroscopic double row repair (35) 24.8±1.4 mo	Multiple regression analysis controlling for age, sex, dominance, location, shape, area of cuff tear, tendon retraction, fatty degeneration, treatment of the biceps tendon, preoperative strength (a priori)	DASH CMS Work-DASH strength	Age had a significant negative correlation with CMS. Sex was significantly correlated with DASH and strength. Preoperative strength was associated with postoperative strength. All other variables had no significant correlations with outcome in multivariate analysis.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Henn RF,[107] 2008 Prospective cohort as BA	Open _or_ mini-open _or_ arthroscopic RCR 12.3 ± 1.7 mo (7.4–20.2)	Subgroup analysis by WCB status. Multiple regression analysis controlling for multiple confounders (age, sex, smoking, expectations, number of comorbidities, education, marital status, work demands, and tear size) (a priori)	SF-36 DASH	Patients with WCB claims reported worse outcomes, after controlling for confounding factors. WCB patients were significantly younger, had greater work demands, and had lower marital rates, education levels, and pre-op expectations for the outcome.
Hsu SL,[108] 2007 BA	Open RCR 4.1 yr (2–7.1)	Subgroup analysis by presence of diabetes, and tear type (a priori). Non-parametric analysis for age (post hoc).	CMS	No statistical difference between patients with and without DM in total CMS. Patients with partial tears had significantly better total CMS scores than those with complete or large tears. Age was associated with strength score.
Iannotti JP,[109] 2006 RCT	**G1:** Porcine submucosa augmentation **G2:** No augment 14 mo (12 mo–2.2 yr)	Regression analysis controlling for tear size (a priori)	cuff integrity	Large tears were significantly more likely to heal than massive tear in both groups.
Iannotti JP,[60] 1996 BA	Open RCR NR	Subgroup analysis by WCB status, tear size, biceps tendon rupture, quality of remaining cuff tissue, and difficulty of repair (a priori)	CMS	WCB status and premorbid activity level did not influence functional outcome. Patients with larger tear sizes had significantly worse outcomes than patients with smaller tear sizes. Biceps tendon rupture, poor tissue quality, and difficulty of tendon mobilization were adversely associated with functional outcome.
Ide J,[110] 2007 BA	Arthroscopic RCR 3 yr (2–5)	Subgroup analysis by age, degree of tendon retraction, tear pattern and size (post hoc)	cuff integrity	Patients with severe tendon retraction had significantly more recurrences than those with minimal or moderate retraction. Significantly more failed repairs in older age than younger age. No significant effect of tear pattern and size on tear recurrence.
Ide J,[112] 2005 Prospective cohort	**G1:** Open RCR **G2:** Arthroscopic RCR 4.1 yr (2.1–6.9)	Subgroup analysis by tear size (post hoc)	UCLA JOA	Small tears had significantly better outcomes compared with large tears regardless of operative group.
Kim SH,[114] 2003 CCT	**G1:** Mini-open RCR **G2:** Arthroscopic RCR 3.3 yr (2.0–5.3)	Subgroup analysis by tear size, etiology of tear, acromial morphology, symptoms duration, and pre-op strength (a priori)	UCLA ASES pain	Larger tears had significantly worse scores on the UCLA, ASES, and function-VAS, but not pain-VAS. No other pre-op factors had a significant correlation with outcomes.
Kirschenbaum D,[115] 1993 BA	Open RCR 12 mo (maximum)	Non-parametric analysis of tear size (post hoc)	strength	Tear size was not significantly associated with strength; however, abduction and flexion strength was consistently less in patients with large or massive tears.
Klepps S,[116] 2004 BA	Open _or_ mini-open RCR 12 mo (minimum)	Subgroup analysis by tear size (post hoc)	ASES CMS UCLA pain cuff integrity	Larger or massive tear size was associated with worse, but non-significant, functional outcomes (CMS, UCLA, ASES) and pain score, and were more likely to retear than small or medium tears.

150

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Klinger HM,[65] 2005 BA	Arthroscopic debridement only 2.6 yr (2–3.8)	Subgroup by tear type, presence of subscapularis tear, superior migration of humeral head, decreased ROM, glenohumeral arthritis (post hoc)	CMS	The presence of two or more of these prognostic factors is correlated with poor outcome.
Ko S-H,[117] 2009 Prospective cohort	G1: Massive cuff stitch repair (35) G2: Simple stitch repair (36) 2.8 (2–3.4) yr	Non-parametric analysis by tear size and configuration (post hoc)	cuff integrity	No effect of tear size and configuration on cuff integrity.
Kose KC,[119] 2008 Retrospective cohort	G1: Mini-open RCR G2: Arthroscopic RCR 2.2 yr (12 mo–6.8 yr)	Subgroup analysis by age (post hoc)	CMS UCLA	There was a significant negative association between age and pain in the mini-open group. Age was not associated with the CMS score.
Kreuz PC,[120] 2005 BA	Arthroscopic RCR 3 yr (2–4)	Subgroup analysis by tear type (a priori)	CMS	Complete tears had significant improvement in outcomes compared to partial tears. Delay between trauma and outcome was inversely proportional.
Lafosse L,[121] 2007 BA	Arthroscopic RCR 3 yr (2–4.8)	Regression analysis controlling for etiology of tear, age, duration of symptoms, WCB status (a priori) and tear size (post hoc).	CMS pain active ROM strength	Etiology of tear, age, duration of symptoms, concomitant biceps procedures, pre-op status of the biceps tendon, degree of fatty infiltration, and WCB status did not affect outcomes. Large / massive tears were associated with more post-op weakness than small tears but no significant difference were found for pain, CMS score, or active ER or IR.
Lafosse L,[122] 2007 BA	Arthroscopic RCR 2.4 yr (2–3.3)	Multiple regression analysis controlling for age, mechanism of injury, duration of symptoms, and degree of fatty infiltration (a priori); WBC status, tear size and biceps pathology (post hoc)	CMS UCLA	No significant effect of age, duration of symptoms, WCB status, tear etiology, tear size, and biceps pathology on outcomes. The effect of rerupture and persistent fatty degeneration could not be determined.
Levy,[123] 2008 BA	Arthroscopic RCR 3.2 yr (2–6.1)	Subgroup analysis by tear size (a priori)	CMS	Small tears had significantly better outcomes than large tears.
Lichtenberg S,[124] 2006 BA	Arthroscopic RCR 2.2 yr	Subgroup analysis by age, tear size, grade of retraction, and biceps pathology (post hoc)	CMS cuff integrity	No significant effect of tear size, retraction, or biceps pathology on outcome measures. Age was a negative prognostic factor for retears.
Liem D,[125] 2007 Retrospective cohort	G1: Mini-open RCR G2: Arthroscopic RCR 12 mo (minimum)	Subgroup analysis by age and tear size (post hoc)	CMS ROM cuff integrity	No significant effect of tear size on outcomes. Age was a negative prognostic factor for retears.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Mallon WJ,[128] 2004 Retrospective cohort as BA	Open RCR 12 mo (minimum)	Subgroup analysis by smoking status and sex (a priori). Multiple regression analysis controlling for age, smoking status, tear size, and WBC status (a priori).	UCLA pain	Non-smokers had significantly greater improvement in UCLA and post-op pain scores than smokers. Women had greater improvement in the UCLA score between pre-op and post-op assessment, compared with men. Age, tear size and WCB status were not found to predict outcomes.
McBirnie JM,[130] 2005 BA	Arthroscopic RCR 2.4 yr (2–5)	Subgroup analysis by age, sex, WCB status (a priori), and tear size (post hoc)	CMS	No significant effects of WCB status, tear size, and additional procedures on outcome. No analysis of age and sex as planned.
McCallister WV,[131] 2005 BA	Open RCR 5.5±2.2 yr (2–10)	Subgroup analysis by age, sex, and number of tendons torn (post hoc)	SST	No significant effect of age and sex. Participants with a lower number of tendons torn had significantly better outcomes than patients with a higher number.
Milano G,[133] 2007 RCT	**G1:** Arthroscopic RCR & acromioplasty **G2:** Arthroscopic RCR 2 yr	Multiple regression analysis controlling for age, sex, dominance, location, shape, area, retraction, reducibility of cuff tear, fatty degeneration, involvement of subscapularis tendon, LHB treatment and type of acromion (a priori)	CMS DASH	Age was significantly positively associated with DASH scores. Gender and dominance did not significantly influence outcomes. There was no significant effect of location and area of tears on outcome. Tears that were U-shaped, retracted, partially reducible, involved the subcapularis, or had severe fatty degeneration had significantly worse outcomes.
Millar NL,[134] 2009 Retrospective cohort	**G1:** Open repair (20) **G2:** Arthroscopic knotted (29) **G3:** Arthroscopic knotless (38) 2 yr	Multiple regression analysis controlling for age, tear size, duration of symptoms, preoperative F and SS strength, preoperative stiffness, operative time, and surgical learning curve (a priori)	ASES cuff integrity	Preoperative SS strength was significantly associated with ASES score. There was no significant effect of stiffness, operative time, preoperative tear size, surgical learning curve on ASES score. Shorter operative time and smaller tear size was associated with lower retear rate. No significant association was found between age, duration of symptoms, preoperative F, SS strength, surgical learning curve, and the rate of cuff integrity.
Misamore GM,[135] 1995 Retrospective cohort as BA	Open RCR 3.8 yr (2–5.7)	Subgroup analysis by WCB status (a priori)	UCLA return to work	Patients without a WCB claim had significantly better outcomes as measured by the UCLA total score and individual subscores compared to those with a WCB claim. A significantly higher proportion of patients not receiving WCB returned to work compared to WCB patients.
Nam SC,[141] 2008 Prospective cohort as BA	Arthroscopic RCR 2.6 yr (16 mo–6.2 yr)	Subgroup analysis by pre-op shoulder stiffness (a priori)	CMS SST UCLA pain ROM strength	Pre-op shoulder stiffness was not associated with outcomes.
Nho SJ,[142] 2009 BA	Arthroscopic RCR 2.4 yr	Multiple regression analysis controlling for age, tear size and number of torn tendons (a priori)	ASES cuff integrity	Increased age, tear size and number of torn tendons were found to be significant predictors of tendon defect after repair. Patients without biceps or AC joint pathology and with normal tissue quality were significantly less likely to have a post-op tendon defect. Concomitant AC joint coplaning or distal clavicle excision was significantly negatively associated with ASES score.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Oh JH,[144] 2008 Prospective cohort as BA	Open _or_ arthroscopic RCR 15.1 mo (12 mo–2.7 yr)	Subgroup analysis by pre-op stiffness (a priori)	SF-36 ASES CMS SST	No significant effect of shoulder stiffness on outcomes.
Pai VS,[145] 2001 BA	Open RCR 2.8 yr	Subgroup analysis by age, duration of symptoms, pre-op range of motion and strength, tear size, and quality of tendon (a priori)	CMS UCLA	No significant effect of age and duration of symptoms on outcome. Patients with poor pre-op ROM and strength or poor tendon quality had worse outcomes. Patients with massive tears had significantly worse outcomes than patients with other tear sizes but there was no overall significant effect of tear size on outcome.
Park JY,[147] 2008 Prospective cohort	**G1:** Double-row anchor RCR **G2:** Single-row anchor RCR 2.1 yr (22 mo–2.5 yr)	Subgroup analysis by tear size (post hoc)	ASES CMS SSI	Large to massive tears had significantly poorer outcomes than small tears when treated with single-row repair fixation.
Pearsall AW,[148] 2007 Prospective cohort	**G1:** Mini-open RCR (25) **G2:** Arthroscopic RCR (27) 4.2 yr (2.3–7)	Subgroup analysis by age, sex, tear size, smoking, osteoarthritis, diabetes, biceps pathology, concomitant distal clavicle excision (a priori)	SST* UCLA pain (VAS)* ROM*	There was an inverse correlation between smoking and improvement in SST. Patients with larger tears had significantly less improvement in pain than patients with smaller tears. Presence of glenoid or humeral osteoarthritis had a significant effect on UCLA score. There was no significant effect of age, sex, presence of diabetes, biceps pathology, or concomitant distal clavicle excision on outcome improvements.
Pillay R,[149] 1994 Retrospective cohort as BA	Arthroscopic RCR 18.6 mo (6 mo–2.5 yr)	Subgroup analysis by tear type (a priori)	UCLA	There was no association between tear type and UCLA functional score.
Prasad N,[151] 2005 BA	Open RCR 2.2 yr (12 mo–4.2)	Subgroup analysis by age, sex, tear size, BMI, smoking status, and duration of symptoms (post hoc)	CMS pain	Older patients and patients with massive tears showed significantly less improvement in outcome compared to younger patients and patients with smaller tears. BMI, gender, smoking, and duration of symptoms did not affect the outcome.
Sauerbrey M,[154] 2005 Retrospective cohort	**G1:** Mini-open RCR **G2:** Arthroscopic RCR 2.1 yr (13 mo–4 yr)	Subgroup analysis by tear size (a priori)	Modified ASES	Surgical approaches were effective regardless of tear size.
Severud EL,[157] 2003 Retrospective cohort	**G1:** Mini-open RCR **G2:** Arthroscopic RCR 3.7 yr (2–6.8)	Subgroup analysis by tear size (post hoc)	ASES UCLA	No significant effect of tear size on outcomes.
Tashjian RZ,[160] 2006 BA	Open _or_ mini-open _or_ arthroscopic RCR 12 mo (maximum)	Multivariate regression analysis for number of comorbidities, with age, sex, WCB status, number of prior non-shoulder surgeries, smoking, tear size, symptom duration, and expectation as confounding variables (a priori).	SF-36 DASH SST VAS (pain, function, QOL)	Greater number of comorbidities was associated with significantly worse final scores on four SF-36 subsections (bodily pain, general health, role emotional, and vitality). Patients with more comorbidities showed significantly greater improvement on the VAS, DASH and SST than patients with fewer comorbidities.

Table 62. Prognostic factors in operative studies (continued)

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Tauro JC,[162] 2006 Retrospective cohort as BA	Arthroscopic RCR 2 yr	Subgroup analysis by tear size, pre-op stiffness (a priori)	Total passive ROM deficit (TROMD)	Tear size represented as a cuff tear index (CTI) was positively correlated with TROMD, where larger tear size was associated with more stiffness. Patients with pre-op stiffness were more likely to experience post-op stiffness.
Trenerry K,[164] 2005 Case-control as BA	Open RCR 17.3 mo (15.5–19)	Subgroup analysis by age, sex, hand dominance, affected side, symptom duration, mechanism of onset, WCB status, tear size, tear type, shoulder comorbidities, pre-op ROM (a priori)	ROM	There were no significant effects of any factors, with the exception of pre-op ROM restriction of hand behind the back, which was a significant predictor of post-op shoulder stiffness.
Vaz S,[166] 2000 BA	Arthroscopic debridement only 3.1 yr (12 mo–4 yr)	Subgroup analysis by age, sex, side of tear, nature of job, pre-op latency, acromion morphology and condition of cuff (post hoc)	CMS	There was no significant impact of any of the factors on outcome, except that patients with sedentary jobs returned to work significantly sooner than manual laborers.
Youm T,[173] 2005 Retrospective cohort	**G1:** Mini-open RCR **G2:** Arthroscopic RCR 3.0 yr (2.0–5.8)	Subgroup analysis by tear size (post hoc)	ASES UCLA	No significant effect of tear size within or between operative groups.
Zumstein MA,[174] 2008 BA	Open RCR & augmentation 9.9 yr (6.7–12.8)	Subgroup analysis by number of tendons torn and tear orientation (post hoc)	CMS	Number of tendons torn and tear type had no impact on post-op functional scores. However, patients with anterosuperior tears and those with three-tendon tears showed significantly greater gain compared to their pre-op state than did the two-tendon tears and posterosuperior tears.

Postoperative Rehabilitation Studies

Of the eleven studies evaluating the effectiveness of postoperative rehabilitation treatments, four studies (two RCTs,[180,184] one retrospective cohort study[181] and one BA study[175]) explored the role of various patient or clinical factors as prognostic factors (Table 63). The prognostic factors were examined using subgroup analysis in two studies,[175,184] regression analysis in one study,[180] correlation analysis in one study,[181] and both subgroup and regression analysis in the remaining study.[175] All studies planned the analyses a priori. Patient variables examined in the studies included age,[175,180,181,184] sex,[175,180,181,184] tear size,[175,180,181,184] biceps pathology,[181] number of comorbidities,[175] smoking,[175] and type of preoperative treatment.[175] The role of prognostic factors was evaluated for functional outcomes in all of the studies, as well as for health-related quality of life,[175] pain, range of motion, and strength.[180] In one study,[175] a greater number of comorbidities was found to be correlated with significantly worse health-related quality of life scores, but not with functional outcome scores. Three studies found that age, sex, and tear size were not associated with outcomes, with the exception that women had greater improvement in pain subscales,[180,184] while men had greater improvement in range of motion.[180] Authors' conclusions for the remaining factors are displayed in Table 63.

Table 63. Prognostic factors in postoperative rehabilitation studies

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Boissonnault WG,[175] 2007 BA	Rehabilitation protocol 13 wk (3–28)	Subgroup analysis by number of comorbidities. Multiple regression analysis controlling for age, sex, smoking, tear size, pre-op treatment. (a priori)	SF-36 DASH	A greater number of comorbidities was associated with significantly worse SF-36 scores, but not with DASH scores.
LaStayo PC,[180] 1998 RCT	**G1:** CPM **G2:** Manual passive ROM exercises 22 mo (6 mo–3.8 yr)	Regression analysis controlling for age, sex, and tear size (a priori).	SPADI pain ROM strength	No significant effect of age, sex, or size of tear on outcomes, except that women indicated significantly less pain than men.
Marc T,[181] 2009 Retrospective cohort	**G1:** Inpatient in rehab centre (26) **G2:** Private practice specializing in 'CGE' (38) **G3:** Inpatient and outpatient (16) 2 yr (minimum)	Correlation analysis controlling for age, tear size, sex biceps pathology (a priori)	CMS	Gain in CMS is not influenced by age, sex, tear size or state of biceps.
Raab MG,[184] 1996 RCT	**G1:** CPM & PT **G2:** PT only 3 mo	Subgroup analysis by age, sex, and tear size (a priori)	Shoulder score	Age, sex, and tear size were not associated with the overall shoulder score. For the subscores, women showed a significant improvement in the pain and men showed significant improvement in the ROM.

BA = before-and-after; CGE = Concept Global d'Epaule; CPM = continuous passive motion; DASH = Disabilities of the Arm, Shoulder and Hand; G = group; mo = month; PT = physical therapy; RCT = randomized controlled trial; ROM = range of motion; SF-36 = Short Form-36; SPADI = Shoulder Pain and Disability Index; wk = week; yr = year

Nonoperative Studies

Of the 10 studies examining the effectiveness of nonoperative interventions, two studies (one prospective cohort with before-and-after data[188] and one BA study[187]) explored the role of various patient or clinical factors as prognostic factors (Table 64). The analysis of prognostic factors was specified a priori in one study[188] and post hoc the other study.[187] The studies used subgroup analysis to examine the effect of tear type,[188] cause of tear,[187] duration of symptoms,[187] pain,[187] sleep loss,[187] and WCB status[187] on functional outcome scores.[187,188] Functional scores were found to be negatively correlated with preoperative sleep loss and WCB claim in one study.[187] In contrast, functional improvement was shown to be independent of tear type,[188] duration of symptoms, degree of pain, and cause of tear.[187]

Table 64. Prognostic factors in nonoperative studies

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Hawkins RH,[187] 1995 BA	Exercise protocol 3.8 yr (2.6–4.6)	Subgroup analysis by WCB status, sleep loss, duration of symptoms, degree of pain, and cause of tear (post hoc)	ASES CMS	WCB claim and preoperative sleep loss was associated with unsatisfactory functional outcome. None of the other patient variables were found to predict treatment outcome.
Heers G,[188] 2005 Prospective cohort as BA	Home exercise program 2.7 mo (maximum)	Subgroup by tear type (a priori)	CMS	Patients showed significant functional improvement regardless of type of tear.

ASES = American Shoulder and Elbow Scale; BA = before-and-after; CMS = Constant-Murley score; mo = month; WCB = workers' compensation board; yr = year

Operative vs. Nonoperative Studies

Of the five studies that examined the effectiveness of nonoperative vs. operative interventions, one retrospective cohort study[197] conducted a post hoc subgroup analysis to explore the effect of age and timing of surgery on functional outcomes (Table 65). The authors found that age had no significant effect on function, as measured by the JOA scale. Time between symptom onset and surgery affected outcomes, where intervals longer than 12 months were associated with postoperative difficulties.

Table 65. Prognostic factors in operative vs. nonoperative studies

Author, year Study design	Intervention Followup, mean (range)	Type of analysis	Outcome variable	Authors' conclusions
Yamada N,[197] 2000 Retrospective cohort	**G1:** Steroid injection, stretching, strengthening **G2:** Open RCR 4 yr (12 mo–23 yr)	Subgroup analysis by age and timing of surgery (post hoc)	JOA	Age had no significant effect on function, as assessed by the JOA scale. Time between symptom onset and surgery was associated with outcomes, where intervals longer than 12 months were associated with postoperative difficulties.

G = group; JOA = Japanese orthopaedic association; mo = month; RCR = rotator cuff repair; yr = year

Chapter 4. Discussion

Summary of Findings

This report provides a comprehensive synthesis of the evidence on the comparative effectiveness of nonoperative and operative interventions for RC tears. The findings and strength of evidence for comparative studies are summarized in Table 66. The variability in the studies in the table illustrates the numerous comparisons that have been made across the studies in this area. Uncontrolled studies were not included in the table, as they represent an extremely low grade on the hierarchy of evidence. The result is that there is sparse data available for most interventions. This precludes firm conclusions for any single approach or for the optimal overall management of this condition. The majority of the data is derived from studies of low methodological quality or lower in the hierarchies of evidence. Sample sizes were generally moderate and varied considerably from study to study, with an overall median of 53 patients per study (IQR 30 to 85). Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. The following is a summary of the evidence for the different types of interventions.

KQ1: Early vs. late repair. Only one study comparing early surgical repair vs. late surgical repair after failed nonoperative treatment was identified. There was low evidence in favor of early repair for function and no difference between groups for cuff integrity. The paucity of evidence related to this question is of particular concern, as primary care providers are frequently faced with the dilemma of whether to refer patients to surgery immediately or delay surgery by opting for initial nonoperative treatment.

KQ2a: Comparative effectiveness of operative approaches. The most frequent comparison was mini-open vs. arthroscopic rotator cuff repair; this comparison provided moderate evidence for no difference in function or cuff integrity between the two approaches. There was also moderate evidence showing no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. There was moderate evidence for no difference in function between open or mini-open vs. arthroscopic repairs and arthroscopic repairs with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared to debridement only. The strength of evidence was low for the remaining comparisons and outcomes; hence, the evidence was too limited to make a conclusion.

KQ2b: Comparative effectiveness of operative techniques. The most frequent comparison was single-row vs. double-row fixation. There was moderate evidence in favour of double-row fixation for function, yet the clinical significance of the difference is questionable, and no difference for cuff integrity. Moderate evidence showed no difference between mattress stitch and simple stitch for cuff integrity. The evidence was too limited to make conclusions for the other techniques studied.

KQ2c: Comparative effectiveness of operative augmentation. Three relatively small studies evaluated two different augmentation techniques, and no overall conclusions were possible.

KQ2d: Comparative effectiveness of postoperative rehabilitation. The most frequent comparison was continuous passive motion with physical therapy vs. physical therapy alone. This resulted in moderate evidence showing no clinical or statistical difference in function but low evidence for earlier return to work with continuous passive motion. The evidence for other aspects of postoperative rehabilitation was too limited to make conclusions.

KQ3: Comparative effectiveness of nonoperative interventions. Three studies compared different nonoperative interventions; hence, no overall conclusions were possible regarding any single approach.

KQ4: Comparative effectiveness of nonoperative vs. operative treatment. Five studies compared different nonoperative and operative interventions. Because the interventions and comparisons differed across the studies, the evidence was too limited to make conclusions regarding the relative effectiveness of the individual modalities.

KQ5: Complications. A total of 34 different complications were reported in 85 studies. The incidence of complications was generally low, yet studies varied considerably in their risk estimates. In 21 studies, it was reported that no complication occurred during the course of the study. Generally, the benefit of receiving treatment for RC tears appears to outweigh the risk of associated harms.

KQ6: Prognostic factors. The variety of prognostic factors examined across many different outcomes and the inconsistency among authors' conclusions make it difficult to identify predictors of good outcome for nonoperative and operative treatments. However, older age, increasing tear size and extent of preoperative symptoms were repeatedly found to be associated with recurrent tears. Sex, WCB status, and duration of symptoms were not found to be associated with poorer outcomes in the majority of studies that examined these variables.

Table 66. Summary of strength of evidence for nonoperative and operative interventions

Comparison (number of studies)	Strength of evidence	Summary
Early vs. late repair		
Early RCR vs. late RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Operative approaches		
Open RCR vs. mini-open RCR (n=3)	Moderate	No statistically significant or clinically important difference for function. Some evidence for earlier return to work or sports (by approximately 1 month) with mini-open repairs.
	Low	The evidence was too limited to make a conclusion for health-related quality of life.
Mini-open RCR vs. arthroscopic RCR (n=10)	Moderate	No difference in function or cuff integrity.
Open RCR vs. arthroscopic RCR (n=3)	Low	The evidence was too limited to make a conclusion.
Open or mini-open RCR vs. arthroscopic RCR (n=2)	Moderate	No difference in function.
	Low	The evidence was too limited to make a conclusion for cuff integrity.
Open RCR vs. open or arthroscopic debridement (n=4)	Moderate	Some evidence for greater improvement in function for open RCR.
Arthroscopic RCR with acromioplasty vs. without acromioplasty (n=3)	Moderate	No difference in function.
Arthroscopic RCR vs. acromioplasty alone	Low	The evidence was too limited to make a conclusion.
Biceps tenotomy vs. tenodesis (n=1)	Low	The evidence was too limited to make a conclusion.
RCR vs. palliative treatment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Mini-open RCR plus tenodesis with detachment vs. without detachment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic debridement with biceps tenotomy vs. without tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Complete open RCR vs. partial open RCR vs. debridement (n=1)	Low	The evidence was too limited to make a conclusion.
Open RCR with classic open acromioplasty vs. open RCR with modified open acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.

CGE = Concept Global d'Epaule; PT = physical therapy; RCR = rotator cuff repair; SLAP = superior labral from anterior to posterior

Table 66. Summary of strength of evidence for nonoperative and operative interventions (continued)

Comparison (number of studies)	Strength of evidence	Summary
Operative techniques		
Single-row vs. double-row suture anchor fixation (n=6)	Moderate	No clinically important difference for function and no difference for cuff integrity.
Bioabsorbable tacs vs. suture tying (n=1)	Low	The evidence was too limited to make a conclusion.
Side-to-side vs. tendon-to-bone fixation (n=1)	Low	The evidence was too limited to make a conclusion.
Nonabsorbable vs. absorbable sutures (n=1)	Low	The evidence was too limited to make a conclusion.
Bioabsorbable corkscrews vs. metal suture anchor (n=1)	Low	The evidence was too limited to make a conclusion.
Mattress locking vs. simple stitch (n=2)	Moderate	No difference in cuff integrity.
	Low	The evidence was too limited to make a conclusion for function.
Mattress vs. transosseous suture (n=1)	Low	The evidence was too limited to make a conclusion.
Ultrasonic welding vs. hand-tied knots (n=1)	Low	The evidence was too limited to make a conclusion.
Staple fixation vs. side-to-side suture (n=1)	Low	The evidence was too limited to make a conclusion.
Operative augmentation		
Porcine small intestine submucosa vs. no augmentation (n=2)	Low	The evidence was too limited to make a conclusion.
Patch graft vs. no augmentation (n=1)	Low	The evidence was too limited to make a conclusion.
Postoperative rehabilitation		
Continuous passive motion with PT treatment vs. PT treatment (n=3)	Moderate	No clinical or statistical difference in function. Some evidence for earlier return to work with continuous passive motion.
Aquatic therapy with land-based therapy vs. land-based therapy (n=1)	Low	The evidence was too limited to make a conclusion.
Postoperative rehabilitation (continued)		
Inpatient vs. day patient rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Individualized PT program with home exercise vs. home exercise (n=1)	Low	The evidence was too limited to make a conclusion.
Progressive vs. traditional loading (n=1)	Low	The evidence was too limited to make a conclusion.
Inpatient rehabilitation vs. outpatient CGE (n=1)	Low	The evidence was too limited to make a conclusion.
Standardized vs. non-standardized PT program (n=1)	Low	The evidence was too limited to make a conclusion.
Videotape vs. PT home exercise instruction (n=1)	Low	The evidence was too limited to make a conclusion.

Table 66. Summary of strength of evidence for nonoperative and operative interventions (continued)

Comparison (number of studies)	Strength of evidence	Summary
Nonoperative interventions		
Sodium hyaluraonate vs. dexamethasone (n=1)	Low	The evidence was too limited to make a conclusion.
Rehabilitation vs. no rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy, oral medications and steroid injection vs. physical therapy, oral medications and no steroid injection (n=1)	Low	The evidence was too limited to make a conclusion.
Nonoperative vs. operative treatment		
Shock-wave therapy vs. mini-open RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Steroid injection, physical therapy, and activity modification vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy vs. open or mini-open RCR	Low	The evidence was too limited to make a conclusion.
Physical therapy treatment, oral medication, and steroid injection vs. arthroscopic debridement vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.
Passive stretching, strengthening, and corticosteroid injection vs. open repair with acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.

Applicability

The study populations in this body of evidence were relatively homogeneous. The vast majority included only patients with full-thickness tears. There was more variation in the number of tendons involved with many studies including patients with only one torn tendon (e.g., supraspinatus) while others included any tendon and tendon combination (e.g., supraspinatus plus infraspinatus, supraspinatis plus infraspinatus plus subscupularis). Studies similarly differed in the number and types of comorbidities permitted for enrollement of study patients. The mean age was clustered between 50 and 65 years, with males comprising an average slightly more than half of the study participants. The duration since symptom onset was not reported in the majority of studies, but when reported was generally between 12 and 18 months.

The other issue regarding applicability for this body of evidence relates to the practitioners administering the interventions (e.g., surgeons, physical therapists, or other healthcare providers). Outcome effects may differ between the trials and real life practice based on practitioners' skills and experience, volume of surgery, and variations or rigor surrounding cointerventions or procedural protocols.

Limitations of the Existing Evidence

The strength of evidence was low for the majority of interventions that were evaluated and compared in the management of RC tears. The low grade was driven by the high risk of bias within individual studies and the lack of consistency and precision across studies. The majority of studies in this field are lower in the hierarchies of evidence, with most studies lacking an independent comparison or control group.

Overall, there were 21 RCTs and 6 CCTs; however, all of these were assessed as high risk of bias based on an empirically derived tool for assessing risk of bias developed by The Cochrane Collaboration. The trial features that were most problematic were inadequate blinding, inadequate allocation concealment, and incomplete outcome data. Inadequate blinding is an important limitation in this body of research due to the nature of the intervention and can lead to exaggerated effect estimates. Methodological approaches to adequately prevent knowledge of the intervention should be employed, such as blinding outcome assessors to treatment status. While blinding is not always feasible, adequate allocation concealment is always possible in an RCT and should be routinely employed. Incomplete outcome data or missing data was a problem in a number of trials due to loss to followup and inadequate handling of missing data in the reporting and/or analysis. Loss to followup was more problematic in studies that extended over a longer period of time. While attrition might be expected when the followup is over a number of years, it can exaggerate treatment effects and the potential for this bias should be considered when designing, conducting, and interpreting research.

One of the values of randomization is that all potential confounders, both known and unknown, are accounted for; hence, the results observed can be more closely attributed to the treatment under study. The majority of studies that were included in this report were not randomized; therefore, they are particularly vulnerable to bias resulting from lack of comparability between the groups under study. Moreover, the majority of studies did not control for important potential confounders in their design or analysis.

The strength of evidence was also rated low due to the lack of consistency and precision of results across studies. This is primarily due to the varied comparisons made across this body of literature with relatively few studies comparing the same interventions. Lack of consistency across studies may also be attributable to the variation in pathological presentation of rotator cuff disease. While the majority of patients had full-thickness tears, the size and configuration of the tears, degree of fatty infiltration, and number and type of comorbidities varied widely across the studies included in the review. Also contributing to the lack of consistency and precision was the variability in outcomes assessed across the studies.

The choice of outcomes and measurement tools needs attention in this area of research. The most common outcome assessed was function; however, 21 different tools were used for this purpose and often multiple tools were used within the same study. This makes comparisons across studies challenging. Moreover, it is unclear whether these functional scores are measuring the same construct to allow comparisons across studies that use different tools. There was also inconsistency in which ranges of motion were assessed in the studies and the vast majority of studies failed to report whether measurements were obtained actively or passively. Contributing to the inconsistency was the varied time points at which outcomes were assessed.

There was a paucity of evidence for some key questions that were considered clinically important. In particular, there was only one study that addressed whether early vs. late surgical repair results in better patient outcomes (Question 1). This question was identified as a critical issue by our technical expert panel, as there is uncertainty regarding whether, for what duration, and for which patients nonoperative treatment should be attempted prior to surgery. In addition, only three studies were identified that compared the effectiveness of nonoperative with operative treatment. Thus, firm conclusions on the optimal management of RC tears could not be made.

The body of evidence was insufficient for many outcomes that were considered by our review team to be clinically important a priori. These included health-related quality of life, function, return to work, and tendon healing. Consensus on clinically and patient-important

outcomes is needed. Many studies only reported results for one or two outcomes which may suggest selective outcome reporting or may simply reflect the retrospective nature of the studies.

Discussion and consensus is required regarding what differences are clinically important when comparing interventions. In some meta-analyses, a statistically significant difference was observed but the difference on the measurement scale was not deemed to be clinically important (e.g., less than 10 points on a 100-point scale). Such information is critical for designing future research (e.g., planning for adequate sample sizes) and interpreting the findings.

A further limitation of this body of evidence was the limited or inconsistent reporting with respect to a number of variables and design considerations. For instance, some of the interventions were inadequately described to allow for replication in practice or determining applicability. This was more problematic for the nonoperative interventions. Specifically, studies often reported using physical therapy as an intervention, without further description of treatment components or delivery. Sufficient detail should be reported regarding the specific components of the interventions; timing, and frequency of each component; training and experience of the individuals implementing the interventions; and, cointerventions. As another example, lack of comprehensive assessment and reporting across studies for complications resulted in challenges for interpreting these data. For instance, some studies reported no complications while others did not comment on complications. It is not known whether these investigators looked for complications systematically or which complications they looked for. Further, definitions of the same complications and assessment of complications (e.g., clinical vs. imaging) may have varied across studies.

Future Research

The following general recommendations for future research are based on the preceding discussion regarding the limitations of the current evidence base:

- All future studies should employ a comparison or control group and ensure comparability of treatment groups, optimally through the use of randomization.
- Future research should seek to minimize bias by blinding outcome assessors, using validated and standardized outcome assessment instruments, adequately concealing allocation (where applicable), and handling and reporting missing data appropriately.
- Studies examining the long-term effectiveness of treatments over the course of several years are needed; at the very least, studies should follow patients for a minimum of 12 months.
- Interventions and comparisons chosen for study should be guided by consensus regarding the most promising and/or controversial interventions in order to avoid numerous studies on disparate interventions.
- Consensus on clinically and patient-important outcomes is needed to ensure consistency and comparability across future studies. Moreover, consensus on minimal clinically important differences is needed to guide study design and interpretation of results.
- Future research needs to be reported in a consistent and comprehensive manner to allow for appropriate interpretation of results.

This review identified numerous comparators for which the evidence base is sparse and which are priorities for future research. There is a need for primary research comparing the effectiveness of early vs. delayed surgery, as much uncertainly remains regarding the appropriate timing of treatment. Currently, patients generally undergo surgery after several months of failed

conservative treatment, however evidence is needed to determine whether, for how long, and for which types of patients surgery should be delayed. Further, evidence comparing the relative effectiveness of operative vs. nonoperative treatments, and among the various nonoperative treatment options, was extremely sparse. Future research examining these comparisons should ensure that the diagnosis of rotator cuff tears is confirmed using imaging and that the interventions are described in sufficient detail to allow for adequate assessment and replication of treatments. Although the majority of studies identified in this review focused on the comparative effectiveness of operative treatments, there was sparse evidence for most individual treatment comparisons, leaving many unanswered questions. Investigators should use a streamlined approach in evaluating operative treatments, beginning with broad treatment questions prior to focusing on detailed procedures. One main unanswered question is the relative effectiveness among the approaches to repair (open, mini-open or arthroscopic). There is currently much enthusiasm for the use of arthroscopic procedures, however evidence of superior outcomes compared to open repair should be established prior to investing resources into this costly and technically difficult procedure.

Investigators should select the highest level of evidence appropriate of their research questions when designing future studies. Authors may find tools such as the CONSORT[198] and the STROBE[199] statements helpful in designing and reporting on randomized controlled trials and cohort studies, respectively. In addition, the trial comparing early vs. delayed repair by Moosmayer et al.[66] provides a good example of a well-designed and conducted study in this field.

Conclusions

Numerous interventions and comparisons have been studied for the nonoperative and operative management of RC tears. The data are sparse for most interventions which prevents making firm conclusions for any single approach or for the optimal overall management of this condition. Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. The majority of the data were derived from studies of low methodological quality or lower in the hierarchies of evidence.

In terms of operative approaches, there is moderate evidence demonstrating no difference in function between mini-open and arthroscopic repairs, open and mini-open repairs, open or mini-open and arthroscopic repairs, and arthroscopic repairs with and without acromioplasty. There is some evidence suggesting an earlier return to work for mini-open as compared with open repairs and greater improvement in function for open repairs compared with arthroscopic debridement. For operative techniques, there is moderate evidence for no clinically important difference in function or cuff integrity between single-row and double-row fixation, and no difference for cuff integrity between mattress locking and simple stitch. The evidence was too limited to make conclusions regarding comparative effectiveness for the other surgical approaches and techniques studied. In terms of postoperative rehabilitation, there is moderate evidence demonstrating no difference in function but earlier return to work for continuous passive motion with physical therapy compared with physical therapy alone. No conclusions were possible for studies evaluating operative augmentation, nonoperative interventions, and those comparing nonoperative and operative treatments. In general the rates of complications were low across all interventions. There is some evidence that tear size and age may modify

outcomes; while, WCB status, sex, and duration of symptoms generally showed no significant impact.

Future research should incorporate design elements to minimize bias in treatment effects including randomization where possible, blinding of outcome assessors, comparability of study groups, and appropriate handling and reporting of missing data. Consensus is needed on clinically and patient-important outcomes, as well as minimum clinically-important differences. Consistency across studies is needed in choice of outcomes and measurement tools. Comprehensive and consistent reporting in future studies will allow for more accurate comparisons and the interpretation of findings across studies as well as greater understanding with respect to the applicability of the findings.

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Abbreviations

Abbreviation	Description
AHRQ	Agency of Healthcare Research and Quality
ASES	American Shoulder and Elbow Surgeons
BA	Before-and-after
EPC	Evidence-based Practice Center
CI	Confidence interval
CCT	Controlled clinical trial
CMS	Constant-Murley Score
CT	Computed tomography
DASH	Disabilities of the Arm, Shoulder, and Hand
FSET	Shoulder Elevation Test
IQR	Inter-quartile range
JOA	Japanese Orthopaedic Association
LHB	Long head of biceps
MMLS	Modified mattress locking stitch
MRI	Magnetic resonance imaging
NOQAS	Newcastle-Ottawa Quality Assessment Scales
NSAID	Non-steroidal anti-inflammatory drugs
RC	Rotator cuff
RC-QOL	Rotator Cuff Quality of Life scale
RCR	Rotator cuff repair
RCT	Randomized controlled trial
SF-36	Short Form (36) Health Survey
SLAP	Superior labral from anterior to posterior
SMD	Standardized mean difference
SPADI	Shoulder Pain and Disability Index
SRQ	Shoulder Rating Questionnaire
SSI	Shoulder Strength Index
SSQ	Shoulder Service Questionnaire
SST	Simple Shoulder Test
TEP	Technical expert panel
UAEPC	University of Alberta Evidence-based Practice Center
UCLA	University of California, Los Angeles
PENN	University of Pennsylvania Shoulder Score
VAS	Visual analogue scale
WCB	Workers' compensation board
WMD	Weighted mean difference
WORC	Western Ontario Rotator Cuff Index