Comparative Effectiveness of Core-Needle and Open Surgical Biopsy for the Diagnosis of Breast Lesions

Appendixes

Appendix A. Technical Experts and Peer Reviewers

Table A1. Technical expert panel

Name	Title	Specialty	Organization
Wendie Berg, MD, PhD	American Radiology Services Johns Hopkins at Greenspring Lutherville, Maryland	Radiology	American College of Radiology representative
R. James Brenner, MD, JD, FACR, FCLM	Professor, Clinical Radiology and Chief, Breast Imaging, UCSF	Radiology	UCSF
Patty Carney, PhD	Professor of Family Medicine, and Associate Director for Population Studies at the OHSU Cancer Institute	Family Medicine	OHSU
Joanne Elmore, MD, MPH	Section Head, Division of General Internal Medicine Professor of Medicine Adjunct Associate Professor of Epidemiology Associate Director UW Robert Wood Johnson Clinical Scholars Program	Internal Medicine/ Epidemiology	University of Washington
Richard E. Fine, MD, FACS	Director Advanced Breast Care of Georgia	Surgery	Surgeon-Oncology
Carol Lee, MD	Yale University School of Medicine Chair of the American College of Radiology Breast Commission	Radiology	Yale University School of Medicine
Bev Parker, PhD	Research Analyst	Consumer	Y-ME National Breast Cancer Organiation
Elizabeth Steiner, MD	Assistant Professor of Family Medicine	Family Medicine	OHSU
Maria Wetzel, BS	Clinical Laboratory Scientist	Consumer	National Breast Cancer Coalition
Pamela Wilcox	Assistant Exec. Dir. of ACR	Radiology	American College of Radiology representative
Bonnie Yankaskas, PhD, MPH	Professor of Radiology, Adjunct Professor of Epidemiology, Principal Investigator for the Carolina Mammography Registry (CMR)	Radiology	University of North Carolina

ECRI Institute Personnel

All ECRI Institute personnel involved in the preparation of this report may be contacted at:

ECRI Institute
5200 Butler Pike
Plymouth Meeting, PA 19462
Telephone: (610) 825-6000
Facsimile: (610) 834-1275

Karen Schoelles, M.D., S.M.
Medical Director

Jonathon Treadwell, Ph.D.
Associate Director, Evidence-based Practice Center

Wendy Bruening, Ph.D.
Senior Research Analyst

Jason Launders MSc
Senior Project Officer - Medical Physicist

Joann Fontanarosa, Ph.D.
Research Analyst

Kelley Tipton, MPH
Research Assistant

Appendix B. Methods of Identifying the Literature

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date Limits	Platform/Provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	1990 through October 30, 2008	OVID
The Cochrane Central Register of Controlled Trials (CENTRAL)	Through 2008, Issue 2	www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	Through 2008, Issue 2	www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	Through 2008, Issue 2	www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	Through 2008, Issue 2	www.thecochranelibrary.com
ECRI Institute Library Catalog	Through May 2008	ECRI Institute
EMBASE (Excerpta Medica)	1990 through September 11, 2009	OVID
Health Technology Assessment Database (HTA)	Through 2008, Issue 2	www.thecochranelibrary.com
Healthcare Standards	1990 through May 2008	ECRI
International Health Technology Assessment (IHTA)	Through May 2008	ECRI
MEDLINE	1990 through September 11, 2009	OVID
PreMEDLINE	Searched October 30, 2008	OVID
U.K. National Health Service Economic Evaluation Database (NHS EED)	Through 2008, Issue 2	www.thecochranelibrary.com
U.S. National Guideline Clearinghouse™ (NGC)	Searched May 2008	www.ngc.gov

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI Institute's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature.

Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), EMTREE, PsycINFO and Keywords

Conventions

OVID

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = Publication Type

[sb] = Subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = Text word

Topic-Specific Search Terms

Concept	Controlled Vocabulary	Keywords
Adverse events	Ae.fs. Co.fs. Cross infection Drainage Surgical wound infection	
Breast and breast diseases	Breast Breast cancer/di exp Breast disease/di exp Breast diseases/di Breast neoplasms/di	Breast$ Calcification$ Calcinosis Cancer Carcinoma$ Lesion$ Lump$ Mammar$ Papilloma Tum?or$
Breast biopsy	Biopsy Biopsy needle Breast biopsy Directional vaccum assisted biopsy Needle biopsy Percutaneous biopsy Stereotactic breast biopsy Tumor biopsy	Large core Mammatome Mammotome Needle Vacuum
Open biopsy	Breast/su Breast tumor/su Su.fs.	Excision$ Incision$ Open Surgical
Patient Satisfaction/QOL	Pain assessment Pain measurement Patient satisfaction Quality of life Visual analog scale	Preference$ QOL Satisf$
Seeding		seeding

CINAHL/Embase/Medline

English Language, Human

Set N	Concept	Search statement
1	Breast biopsy	(breast biopsy or stereotactic breast biopsy or directional vacuum assisted biopsy).de.
2	Breast	Breast
3	Breast diseases	Exp breast cancer/di or exp breast neoplasms/di or exp breast disease/di or exp breast diseases/di
4		(breast or mammar$) and (Papilloma or calcification$ or calcinosis or tum?or$ or lesion$ or cancer or carcinoma$ or lump$)
5	Combine sets	or/2-4
6	Biopsy	5 and ((Biopsy or tumor biopsy).de. or biops$)
7	Large core needle biopsy	6 and ((needle biopsy or biopsy needle or percutaneous biopsy).de. or (large core or needle or mammotome or mammatome or vacuum))
8	Open biopsy	6 and (breast/su or breast tumor/su)
9		6 and (su.fs. or open or excision$ or incision$ or surgical)
10	Combine sets	8 or 9
11	Combine sets	or/1,7,10
12	Limit by publication type	11 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.)

Set N	Concept	Search statement
13	Diagnostics filter	12 and (exp prediction and forecasting/ or (predictive value of tests or receiver operating characteristic or ROC curve or sensitivity and specificity or accuracy or diagnostic accuracy or precision or likelihood).de. or ((false or true) adj (positive or negative)))
14	Clinical trials filter	13 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebos or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or Case control studies/ or Cohort/ or Longitudinal studies/ or Evaluation studies/ or Follow-up studies/ or Prospective studies/ or Retrospective studies/ or Case control study/ or Cohort analysis/ or Longitudinal study/ or Follow up/ or Cohort analysis/ or Followup studies/ or random$.hw. or random$.ti. or placebo$.mp. or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham or mask)).mp. or latin square.mp. or (time adj series) or (case adj (study or studies) or ISRCTN$.mp. or ACTRN$.mp. or (NCT$ not nctc$)))
15	Combine sets	13 or 14
16	Eliminate overlap	
17	Seeding	12 and seeding.ti,ab.
18	Patient satisfaction/QOL	12 and ((patient satisfaction or pain measurement or pain assessment or visual analog scale or quality of life).de. or satisf$ or QOL or preference$)
19	Adverse events	12 and ((ae or co).fs. or (cross infection or drainage or surgical wound infection).de.)
20	Disfiguration	12 and (disfigur$ or deform$)
21	Combine sets	or/16-20

Appendix C. Excluded Studies

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2

Study	Primary Reason for Exclusion
Bukhari et al. 2009[1]	Patients were selected for core-needle biopsy on the basis of prior fine-needle aspiration results
Eliahou et al. 2009[2]	Enrolled a high-risk population
Peters et al. 2009[3]	Enrolled a high-risk population
Salem et al. 2009[4]	Enrolled a high-risk population
Tozaki et al. 2009[5]	Enrolled a high-risk population
Bernik et al. 2008[6]	Retrospective case study
Brem et al. 2008[7]	Retrospective case study
Carder et al. 2008[8]	Retrospective case study
Cheung et al. 2008[9]	Did not address Key Question 1
Choo et al. 2008[10]	Did not verify core-needle diagnoses
Doren et al. 2008[11]	Retrospective case study
Eby et al. 2008[12]	Retrospective case study
Eun et al. 2008[13]	Enrolled only patients with benign masses
Forgeard et al. 2008[14]	Retrospective case study
Hahn et al. 2008[15]	Enrolled only patients with benign masses
Hauth et al. 2008[16]	Enrolled a high-risk population
He et al. 2008[17]	Enrolled a high-risk population
Herti et al. 2008[18]	Did not address Key Question 1
Hemmer et al. 2008[19]	Did not address Key Question 1
Hukkinen et al. 2008[20]	Enrolled only patients with malignant masses
Hwang et al. 2008[21]	Retrospective case study
Jang et al. 2008[22]	Retrospective case study
Ji et al. 2008[23]	Duplicate report of Youk et al. 2008[24]
Kil et al. 2008[25]	Retrospective case study
Kim et al. 2008[26]	Did not verify benign diagnoses
Kim et al. 2008[27]	Retrospective case study
Kumaroswamay et al. 2008[28]	Did not verify benign diagnoses
Lee et al. 2008[29]	Did not verify benign diagnoses
Londero et al. 2008[30]	Retrospective case study
Mahoney et al. 2008[31]	Enrolled patients with a prior diagnosis of breast cancer
Menon et al. 2008[32]	Retrospective case study
Michalopoulos et al. 2008[33]	Did not address Key Question 1
Perretta et al. 2008[34]	Enrolled a high-risk population
Peter et al. 2008[35]	Fewer than 50% of enrolled patients completed the study
Resetkova et al. 2008[36]	Retrospective case study
Rizzo et al. 2008[37]	Retrospective case study
Salem et al. 2008[38]	Did not address Key Question 1
Shin et al. 2008[39]	Retrospective case study
Sigal-Zafrani et al. 2008[40]	Fewer than 50% of enrolled patients completed the study
Skandarajah et al. 2008[41]	Retrospective case study
Smetherman et al. 2008[42]	Retrospective case study
Sohn et al. 2008[43]	Retrospective case study
Somerville et al. 2008[44]	Did not address Key Question 1
Tagaya et al. 2008[45]	Enrolled only patients with benign masses
Taourel et al. 2008[46]	Did not verify benign diagnoses
Tozaki et al. 2008[47]	Enrolled a high-risk population
Tseng et al. 2008[48]	Retrospective case study
Zagouri et al. 2008[49]	Did not address Key Question 1
Zografos et al. 2008[50]	Enrolled a high-risk population
Zografos et al. 2008[51]	Did not verify benign diagnoses
Zografos et al. 2008[52]	Did not verify any core-needle diagnoses
Andreu et al. 2007[53]	Fewer than 50% of enrolled patients completed the study
Arora et al. 2007[54]	Retrospective case study
Ashkenazi et al. 2007[55]	Retrospective case study
Bode et al. 2007[56]	Retrospective case study

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Cassano et al. 2007[57]	Patients were selected for core-needle biopsy on the basis of prior fine-needle aspiration results
Ciatto et al. 2007[58]	Enrolled a high-risk population
Dillon et al. 2007[59]	Retrospective case study
Douglas-Jones et al. 2007[60]	Retrospective case study
Duchesne et al. 2007[61]	Fewer than 50% of enrolled patients completed the study
Duijm et al. 2007[62]	Fewer than 50% of enrolled patients completed the study
Easley et al. 2007[63]	Fewer than 50% of enrolled patients completed the study
Esserman et al. 2007[64]	Retrospective case study
Foxcroft et al. 2007[65]	Retrospective case study
Garg et al. 2007[66]	Patients were selected for core-needle biopsy on the basis of prior fine-needle aspiration results
Hollloway et al. 2007[67]	Did not verify benign diagnoses
Houssami et al. 2007[68]	Retrospective case study
Karabakhtsian et al. 2007[69]	Retrospective case study
Kikuchi et al. 2007[70]	Did not verify benign diagnoses
Kim et al. 2007[71]	Fewer than 50% of enrolled patients completed the study
Ko et al. 2007[72]	Retrospective case study
Krainick-Strobel et al. 2007[73]	Enrolled only patients with benign masses
Kumaraswamy and Carder 2007[74]	Fewer than 50% of enrolled patients completed the study
u and Kleer 2007[75]	Retrospective case study
Lavoue et al. 2007[76]	Retrospective case study
Lee et al. 2007[77]	Enrolled a high-risk population
Lee et al. 2007[78]	Enrolled a high-risk population
Leikola et al. 2007[79]	Retrospective case study
Liberman et al. 2007[80]	Enrolled a high-risk population
Londero et al. 2007[81]	Retrospective case study
Lourenco et al. 2007[82]	Retrospective case study
Luczynska et al. 2007[83]	Did not verify benign diagnoses
Martel et al. 2007[84]	Retrospective case study
Mathew et al. 2007[85]	Enrolled only patients with benign masses
Mendel et al. 2007[86]	Fewer than 10 patients enrolled
Murta De Lucena et al. 2007[87]	Did not verify benign diagnoses
Nakano et al. 2007[88]	Patients were selected for core-needle biopsy on the basis of prior fine-needle aspiration results
Popiela et al. 2007[89]	Enrolled a high-risk population
Povoski and Jimenez 2007[90]	Did not report sufficient data to address Key Question 1
Rustein et al. 2007[91]	Retrospective case study
Schaefer et al. 2007[92]	Did not address any of the Key Questions
Smitt and Horst 2007[93]	Enrolled only patients with malignant masses
Sohn et al. 2007[94]	Retrospective case study
Sydnor et al. 2007[95]	Retrospective case study
Uematsu and Kasami 2007[96]	Did not address Key Question 1
Uematsu et al. 2007[97]	Did not verify benign diagnoses
Usami et al. 2007[98]	Enrolled only patients with malignant masses
Zagouri et al. 2007[99]	Retrospective case study
Zografos et al. 2007[100]	Did not verify benign diagnoses
Zuiani et al. 2007[101]	Enrolled a high-risk population
Al-Attar et al. 2006[102]	Did not address Key Question 1
Becker et al. 2006[103]	Retrospective case study
Bedei et al. 2006[104]	Retrospective case study
Chrzan et al. 2006[105]	Retrospective case study
Cox et al. 2006[106]	Retrospective case study
Dillon et al. 2006[107]	Retrospective case study
Dillon et al. 2006[108]	Retrospective case study
Fine and Staren 2006[109]	Enrolled only patients with benign masses
Fitzal et al. 2006[110]	Did not address Key Question 1
Gebauer et al. 2006[111]	Less than 50% of enrolled patients completed the study
Ghate et al. 2006[112]	Did not verify benign diagnoses

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Govindarajulu et al. 2006[113]	Enrolled only patients with malignant masses
Hanley and Kessaram 2006[114]	Enrolled only patients with malignant masses
Hoffmann 2006[115]	Did not address Key Question 1
Huo et al. 2006[116]	Retrospective case study
Jackman and Rodriguez-Soto 2006[117]	Did not address Key Question 1
Jensen et al. 2006[118]	Fine-needle aspiration results were used in decisions about verification of results
Kamer et al. 2006[119]	Fewer than 10 patients enrolled
Killebrew and Oneson 2006[120]	Did not verify benign diagnoses
Koskela et al. 2006[121]	Did not report sufficient data to address Key Question 1
Lam et al. 2006[122]	Retrospective case study
Lannin et al. 2006[123]	Did not address Key Question 1
Liberman et al. 2006[124]	Retrospective case study
Lieske et al. 2006[125]	Fine-needle aspiration results were used in decisions about verification of results
Lim et al. 2006[126]	Retrospective case study
Lopez-Medina et al. 2006[127]	Retrospective case study
Margenthaler et al. 2006[128]	Enrolled a high-risk population
Mercado et al. 2006[129]	Retrospective case study
Newman et al. 2006[130]	Enrolled only patients with malignant masses
Orel et al. 2006[131]	Enrolled a high-risk population
Perlet et al. 2006[132]	Enrolled a high-risk population
Popiela et al. 2006[133]	Less than 50% of enrolled patients completed the study
Renshaw et al. 2006[134]	Retrospective case study
Renshaw et al. 2006[135]	Retrospective case study
Senn et al. 2006[136]	Did not verify benign diagnoses
Shin et al. 2006[137]	Did not address Key Question 1
Sie et al. 2006[138]	Retrospective case study
Uriburu et al. 2006[139]	Did not address Key Question 1
Valdes et al. 2006[140]	Retrospective case study
Vargas et al. 2006[141]	Did not address Key Question 1
Viehweg et al. 2006[142]	Enrolled a high-risk population
Wu et al. 2006[143]	Less than 50% of enrolled patients completed the study
Yazici et al. 2006[144]	Did not address Key Question 1
Altomare et al. 2005[145]	Did not verify benign diagnoses
Badoual et al. 2005[146]	Enrolled only patients with malignant masses
Bonifacino et al. 2005[147]	Fine-needle aspiration results were used in decisions about verification of results
Brem et al. 2005[148]	Retrospective case study
Caines et al. 2005[149]	Did not address Key Question 1
Cho et al. 2005[150]	Unresolvable multiple discrepancies in reported data
Costantini et al. 2005[151]	Did not verify benign diagnoses
Diebold et al. 2005[152]	Did not report sufficient data to address Key Question 1
Doridot et al. 2005[153]	Used a core-needle instrument that is no longer commercially available
Doyle et al. 2005[154]	Did not address Key Question 1
Elsheikh et al. 2005[155]	Retrospective case study
Gambos et al. 2005[156]	Retrospective case study
Grady et al. 2005[157]	Retrospective case study
Hanna et al. 2005[158]	Used a core-needle instrument that is no longer commercially available
Homesh et al. 2005[159]	Fine-needle aspiration results were used in decisions about verification of results
Lehman et al. 2005[160]	Did not verify benign diagnoses
Monticciolo 2005[161]	Enrolled only patients with malignant masses
Pilgrim and Ravichandran 2005[162]	Fine-needle aspiration results were used in decisions about verification of results
Qazi and Mohayuddin 2005[163]	Fine-needle aspiration results were used in decisions about verification of results
Riedl et al. 2005[164]	Did not address Key Question 1
Rulli et al. 2005[165]	Used a core-needle instrument that is no longer commercially available
Satchithananda et al. 2005[166]	Did not address Key Question 1
Schneider et al. 2005[167]	Used a core-needle instrument that is no longer commercially available
Soo et al. 2005[168]	Did not address Key Question 1
Wahner-Roedler et al. 2005[169]	Fewer than 10 patients enrolled
Wiratkapun et al. 2005[170]	Retrospective case study
Wong et al. 2005[171]	Did not verify benign diagnoses

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
You et al. 2005[172]	Retrospective case study
Zuiani et al. 2005[173]	Retrospective case study
Agoff et al. 2004[174]	Retrospective case study
Arpino et al. 2004[175]	Retrospective case study
Carmon et al. 2004[176]	Did not address Key Question 1
Chagpar et al. 2004[177]	Enrolled only patients with malignant masses
Chen et al. 2004[178]	Did not verify benign diagnoses
Collins et al. 2004[179]	Did not address Key Question 1
Docktor et al. 2004[180]	Did not address Key Question 1
Foster et al. 2004[181]	Retrospective case study
Gan et al. 2004[182]	Did not address Key Question 1
Geller et al. 2004[183]	Did not address Key Question 1
Gendler et al. 2004[184]	Retrospective case study
Georgina-Smith et al. 2004[185]	Retrospective case study
Golshan et al. 2004[186]	Enrolled only patients with malignant masses
Golub et al. 2004[187]	Did not address Key Question 1
Hansen et al. 2004[188]	Did not address Key Question 1
Hoorntje et al. 2004[189]	Did not address Key Question 1
Hoorntje et al. 2004[190]	Did not address Key Question 1
Ivan et al. 2004[191]	Retrospective case study
Margolin et al. 2004[192]	Did not address Key Question 1
Mendez et al. 2004[193]	Did not confirm benign diagnoses
O'Leary et al. 2004[194]	Did not address Key Question 1
Peters-Engl et al. 2004[195]	Enrolled only patients with malignant masses
Piana et al. 2004[196]	Enrolled only patients with malignant masses
Pijnappel et al. 2004[197]	Enrolled a high-risk population
Renshaw 2004[198]	Did not address Key Question 1
Renshaw et al. 2004[199]	Retrospective case study
Rotenberg et al. 2004[200]	Did not confirm benign diagnoses
Agarwal et al. 2003[201]	Enrolled only patients with malignant masses
Baez et al. 2003[202]	Enrolled only patients with benign masses
Bauer et al. 2003[203]	Retrospective case study
Berg et al. 2003[204]	Retrospective case study
Bonnett et al. 2003[205]	Retrospective case study
Brenner et al. 2003[206]	Retrospective case study
Carder and Liston 2003[207]	Enrolled patients with a benign mass
Cawson et al. 2003[208]	Retrospective case study
Charles et al. 2003[209]	Enrolled patients with a malignant mass
Chen et al. 2003[210]	Did not report sufficient data to address Key Question 1
Corn 2003[211]	Used a core-needle instrument that is no longer commercially available
Crisi et al. 2003[212]	Retrospective case study
Crowe et al. 2003[213]	Did not verify benign diagnoses
Dennison et al. 2003[214]	Fine-needle aspiration results were used in decisions about verification of results
Dmytrasz et al. 2003[215]	Retrospective case study
Farshid and Rush 2003[216]	Fine-needle aspiration results were used in decisions about verification of results
Fine et al. 2003[217]	Enrolled only patients with benign masses
Fures et al. 2003[218]	Did not verify benign diagnoses
Harris et al. 2003[219]	Enrolled patients with a malignant mass
Hoorntje et al. 2003[220]	Retrospective case study
Jackman and Marzoni 2003[221]	Did not address Key Question 1
Kneeshaw et al. 2003[222]	Retrospective case study
Komenaka et al. 2003[223]	Retrospective case study
Lee et al. 2003[224]	Enrolled only patients with malignant masses
Leifland et al. 2003[225]	Fine-needle aspiration results were used in decisions about verification of results
Leifland et al. 2003[226]	Fine-needle aspiration results were used in decisions about verification of results
Liberman et al. 2003[227]	Enrolled a high-risk population
Mariotti et al. 2003[228]	Did not verify benign diagnoses
Masood et al. 2003[229]	Retrospective case study
Middleton et al. 2003[230]	Retrospective case study

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Miller et al. 2003[231]	Retrospective case study
Puglisi et al. 2003[232]	Retrospective case study
Shah et al. 2003[233]	Retrospective case study
Sneige et al. 2003[234]	Retrospective case study
Sperber et al. 2003[235]	Enrolled only patients with benign masses
Tsang et al. 2003[236]	Used a core-needle instrument that is no longer commercially available
Verkooijen et al. 2003[237]	Did not address Key Question 1
Winchester et al. 2003[238]	Retrospective case study
Witt et al. 2003[239]	Did not address Key Question 1
Yeh et al. 2003[240]	Retrospective case study
Zhao et al. 2003[241]	Retrospective case study
Acheson et al. 2002[242]	Retrospective case study
Bonnett et al. 2002[243]	Retrospective case study
Chen et al. 2002[244]	Enrolled patients with recurrent breast cancer
Chun and Velanovich et al. 2002[245]	Did not address Key Question 1
Fine et al. 2002[246]	Enrolled only patients with benign masses
Gal-Gombos et al. 2002[247]	Retrospective case study
Giardina et al. 2002[248]	Did not verify benign diagnoses
Haj et al. 2002[249]	Used a core-needle instrument that is no longer commercially available
Harvey et al. 2002[250]	Retrospective case study
Hoorntje et al. 2002[251]	Did not verify benign diagnoses
Hui et al. 2002[252]	Did not address Key Question 1
Insausti et al. 2002[253]	Used a core-needle instrument that is no longer commercially available
Jackman et al. 2002[254]	Retrospective case study
Jan et al. 2002[255]	Fine-needle aspiration results were used in decisions about verification of results
Knight et al. 2002[256]	Did not address Key Question 1
Liberman et al. 2002[257]	Did not address Key Question 1
Lifrange et al. 2002[258]	Used a core-needle instrument that is no longer commercially available
Mainiero et al. 2002[259]	Did not address Key Question 1
McKee et al. 2002[260]	Did not address Key Question 1
Perlet et al. 2002[261]	Not published in English
Pijnappel et al. 2002[262]	Enrolled a high-risk population
Popiela et al. 2002[263]	Did not verify benign diagnoses
Rao et al. 2002[264]	Retrospective case study
Renshaw 2002[265]	Retrospective case study
Renshaw et al. 2002[266]	Retrospective case study
Rosen et al. 2002[267]	Retrospective case study
Schneider et al. 2002[268]	Enrolled a high-risk population
Shin and Rosen 2002[269]	Retrospective case study
Smyczek-Gargya et al. 2002[270]	Did not verify benign diagnoses
Soo et al. 2002[271]	Did not verify benign diagnoses
Tan et al. 2002[272]	Fine-needle aspiration results were used in decisions about verification of results
Tse et al. 2002[273]	Retrospective case study
Verkooijen and Peeters 2002[274]	Enrolled a high-risk population
Verkooijen et al. 2002[275]	Did not address Key Question 1
Watermann et al. 2002[276]	Used a core-needle instrument that is no longer commercially available
Wunderbaldinger et al. 2002[277]	Enrolled only patients with malignant masses
Bagnall et al. 2001[278]	Enrolled only patients with malignant masses
Berg et al. 2001[279]	Enrolled a high-risk population
Berg et al. 2001[280]	Retrospective case study
Brem et al. 2001[281]	Did not verify benign diagnoses
Chao et al. 2001[282]	Not published in English
Clarke et al. 2001[283]	Fine-needle aspiration results were used in decisions about verification of results
Daniel et al. 2001[284]	Did not verify benign diagnoses
Deurloo et al. 2001[285]	Did not address Key Question 1
Ely et al. 2001[286]	Retrospective case study
Fine et al. 2001[287]	Did not address Key Question 1
Grimes et al. 2001[288]	Did not address Key Question 1
Hung et al. 2001[289]	Fine-needle aspiration results were used in decisions about verification of results

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Ibrahim et al. 2001[290]	Fine-needle aspiration results were used in decisions about verification of results
Jackman et al. 2001[291]	Retrospective case study
Jacobs et al. 2001[292]	Core-needle biopsies were performed with a device no longer commercially available
Joshi et al. 2001[293]	Did not verify benign diagnoses
Kaufman et al. 2001[294]	Did not address Key Question 1
King et al. 2001[295]	Did not address Key Question 1
Kuhl et al. 2001[296]	Enrolled high-risk patients
Liberman et al. 2001[297]	Did not address Key Question 1
Liberman et al. 2001[298]	Did not address Key Question 1
Lifrange et al. 2001[299]	Used a core-needle instrument that is no longer commercially available
Maganini et al. 2001[300]	Retrospective case study
Marti et al. 2001[301]	Used a core-needle instrument that is no longer commercially available
Meloni et al. 2001[302]	Fine-needle aspiration results were used in decisions about verification of results
Mendez et al. 2001[303]	Retrospective case study
Mercado et al. 2001[304]	Retrospective case study
Morrow et al. 2001[305]	Did not address Key Question 1
O'Driscoll et al. 2001[306]	Fewer than 10 patients enrolled
Parker et al. 2001[307]	Less than 50% of enrolled patients completed the study
Parker et al. 2001[308]	Did not address Key Question 1
Renshaw 2001[309]	Retrospective case study
Renshaw et al. 2001[310]	Retrospective case study
Saarenmaa et al. 2001[311]	Enrolled only patients with malignant masses
Schneider et al. 2001[312]	Did not verify benign diagnoses
Schoonjans and Brem 2001[313]	Less than 50% of enrolled patients completed the study
Shannon et al. 2001[314]	Fine-needle aspiration results were used in decisions about verification of results
Sklair-Levy et al. 2001[315]	Retrospective case study
Smith et al. 2001[316]	Enrolled patients at high risk
Sun et al. 2001[317]	Fine-needle aspiration results were used in decisions about verification of results
Verkooijen et al. 2001[318]	Did not address Key Question 1
Westenend et al. 2001[319]	Fine-needle aspiration results were used in decisions about verification of results
Adrales et al. 2000[320]	Did not verify benign diagnoses
Bagnall et al. 2000[321]	Enrolled only patients with malignant masses
Burns et al. 2000[322]	Did not verify benign diagnoses
Darling et al. 2000[323]	Retrospective case study
Cangiarella et al. 2000[324]	Fine-needle aspiration results were used in decisions about verification of results
Cangiarella et al. 2000[325]	Did not address Key Question 1
Gukas et al. 2000[326]	Less than 50% of enrolled patients completed the study
Hatada et al. 2000[327]	Fine-needle aspiration results were used in decisions about verification of results
Lamm et al. 2000[328]	Did not address Key Question 1
Lee et al. 2000[329]	Retrospective case study
Liberman et al. 2000[330]	Retrospective case study
Melotti et al. 2000[331]	Did not address Key Question 1
Mok and Keepin 2000[332]	Enrolled a high-risk population
Moritz et al. 2000[333]	Did not address any of the Key Questions
Nisbet et al. 2000[334]	Did not verify diagnoses
O'hea and Tornos 2000[335]	Retrospective case study
Philpotts et al. 2000[336]	Retrospective case study
Philpotts et al. 2000[337]	Retrospective case study
Portincasa et al. 2000[338]	Used a core-needle instrument that is no longer commercially available
Schwatzberg et al. 2000[339]	Used a core-needle instrument that is no longer commercially available
Simon et al. 2000[340]	Less than 50% of enrolled patients completed the study
Sneige and Tulbah 2000[341]	Did not address Key Question 1
Stolier et al. 2000[342]	Did not address Key Question 1
Teh et al. 2000[343]	Did not verify benign diagnoses
Whitlock et al. 2000[344]	Less than 50% of enrolled patients completed the study
Yang et al. 2000[345]	Used a core-needle instrument that is no longer commercially available
Al-Sobhi et al. 1999[346]	Did not address Key Question 1
Baker et al. 1999[347]	Fewer than 10 patients enrolled
Bloomston et al. 1999[348]	Used a core-needle instrument that is no longer commercially available

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Bokran et al. 1999[349]	Retrospective case study
Brem et al. 1999[350]	Retrospective case study
Britton and McCann 1999[351]	Did not address Key Question 1
Damascelli et al. 1999[352]	Used a core-needle instrument that is no longer commercially available
Deschryver et al. 1999[353]	Retrospective case study
Diaz et al. 1999[354]	Did not address Key Question 1
DiPiro et al. 1999[355]	Retrospective case study
El-Tamer et al. 1999[356]	Enrolled only patients with malignant masses
Evans et al. 1999[357]	Did not verify benign diagnoses
Ferzli et al. 1999[358]	Used a core-needle instrument that is no longer commercially available
Fraser et al. 1999[359]	Fine-needle aspiration results were used in decisions about verification of results
Gajdos et al. 1999[360]	Did not address Key Question 1
Gentry and Henry 1999[361]	Did not address Key Question 1
Gray et al. 1999[362]	Did not address Key Question 1
Harlow et al. 1999[363]	Did not address Key Question 1
Harvey et al. 1999[364]	Retrospective case study
Johnson et al. 1999[365]	Retrospective case study
Klem et al. 1999[366]	Did not verify benign diagnoses
LaRaja et al. 1999[367]	Used a core-needle instrument that is no longer commercially available
Lee et al. 1999[365]	Enrolled only patients with benign masses
Liberman et al. 1999[368]	Retrospective case study
Liberman et al. 1999[369]	Retrospective case study
Liberman et al. 1999[370]	Did not address Key Question 1
Matthews and Williams 1999[371]	Used a core-needle instrument that is no longer commercially available
Mitnick et al. 1999[372]	Retrospective case study
Philpotts et al. 1999[373]	Did not address Key Question 1
Rebner et al. 1999[374]	Used a core-needle instrument that is no longer commercially available
Rich et al. 1999[375]	Did not verify benign diagnoses
Rosen et al. 1999[376]	Retrospective case study
Roth et al. 1999[377]	Enrolled only patients with malignant masses
Sharifi et al. 1999[378]	Did not address Key Question 1
Sheth et al. 1999[379]	Used a core-needle instrument that is no longer commercially available
Shin et al. 1999[380]	Results of fine-needle aspiration were used to decide who underwent core-needle biopsy
Staren et al. 1999[381]	Fine-needle aspiration results were used in decisions about verification of results
Tran et al. 1999[382]	Does not address any of the Key Questions
Velanovich et al. 1999[383]	Did not verify benign diagnoses
Williams et al. 1999[384]	Did not verify benign diagnoses
Won et al. 1999[385]	Retrospective case study
Yong et al. 1999[386]	Fine-needle aspiration results were used in decisions about verification of results
Andreu et al. 1998[387]	Fine-needle aspiration results were used in decisions about verification of results
Antley et al. 1998[388]	Did not report sufficient data to address Key Question 1
Bleznak et al. 1998[389]	Did not address Key Question 1
Damascelli et al. 1998[390]	Used a core-needle instrument that is no longer commercially available
Doyle et al. 1998[391]	Fine-needle aspiration results were used in decisions about verification of results
Goodman et al. 1998[392]	Did not address Key Question 1
Helbich et al. 1998[393]	Did not address Key Question 1
Jackman et al. 1998[394]	Enrolled only patients with benign masses
Johnson et al. 1998[395]	Did not verify benign diagnoses
Kaufman et al. 1998[396]	Did not address Key Question 1
Kelley et al. 1998[397]	Used a core-needle instrument that is no longer commercially available
King et al. 1998[398]	Retrospective case study
Liberman et al. 1998[399]	Enrolled only patients with malignant masses
Liberman et al. 1998[400]	Did not address Key Question 1
Lin et al. 1998[401]	Retrospective case study
Lind et al. 1998[402]	Enrolled only patients with benign masses
Meyer et al. 1998[403]	Enrolled only patients with benign masses
Mitnick et al. 1998[404]	Retrospective case study
Seoudi et al. 1998[405]	Did not verify benign diagnoses

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Slanetz et al. 1998[406]	Did not address Key Question 1
Soo et al. 1998[407]	Fewer than 10 patients enrolled
Woodcock et al. 1998[408]	Did not verify benign diagnoses
Zardawi 1998[409]	Did not verify benign diagnoses
Zonderland et al. 1998[410]	Fine-needle aspiration results were used in decisions about verification of results
Acheson et a. 1997[411]	Less than 50% of enrolled patients completed the study
Anania et al. 1997[412]	Did not address Key Question 1
Burbank 1997[413]	Retrospective case study
Burbank 1997[414]	Did not address Key Question 1
Burbank 1997[415]	Enrolled only patients with benign masses
Cerwenka et al. 1997[416]	Did not verify benign diagnoses
D'Angelo et al. 1997[417]	Used a core-needle instrument that is no longer commercially available
Devia et al. 1997[418]	Did not address Key Question 1
Fenoglio et al. 1997[419]	Did not address Key Question 1
Ferzli et al. 1997[420]	Used a core-needle instrument that is no longer commercially available
Florentine et al. 1997[421]	Fine-needle aspiration results were used in decisions about verification of results
Gadzala et al. 1997[422]	Retrospective case study
Hirst and Davis 1997[423]	Did not verify benign diagnoses
Howisey et al. 1997[424]	Did not address Key Question 1
Jackman and Marzoni 1997[425]	Did not address Key Question 1
Jackman et al. 1997[426]	Retrospective case study
Liberman et al. 1997[427]	Did not address Key Question 1
Liberman et al. 1997[428]	Did not address Key Question 1
Lifrange et al. 1997[429]	Fine-needle aspiration results were used in decisions about verification of results
Meyer et al. 1997[430]	Did not address Key Question 1
Pijnappel et al. 1997[431]	Fine-needle aspiration results were used in decisions about verification of results
Roe et al. 1997[432]	Did not report sufficient data to address Key Question 1
Smith et al. 1997[433]	Did not address Key Question 1
Stolier et al. 1997[434]	Did not address Key Question 1
Whitten et al. 1997[435]	Did not address Key Question 1
Written et al. 1997[436]	Did not address Key Question 1
Ballo and Sneige 1996[437]	Fine-needle aspiration results were used in decisions about verification of results
Burbank et al. 1996[438]	Did not address Key Question 1
Caines et al. 1996[439]	Did not verify benign diagnoses
Chare et al. 1996[440]	Fine-needle aspiration results were used in decisions about verification of results
Crotch-Harvey and Loughran 1996[441]	Fine-needle aspiration results were used in decisions about verification of results
Dershaw et al. 1996[442]	Did not address Key Question 1
Di et al. 1996[443]	Enrolled only patients with malignant masses
Frayne et al. 1996[444]	Fine-needle aspiration results were used in decisions about verification of results
Handy et al. 1996[445]	Did not address Key Question 1
Hillhouse et al. 1996[446]	Did not address Key Question 1
Hunter et al. 1996[447]	Did not address Key Question 1
Liberman et al. 1996[448]	Did not address Key Question 1
Pillsbury et al. 1996[449]	Did not verify benign diagnoses
Poole et al. 1996[450]	Fine-needle aspiration results were used in decisions about verification of results
Taft et al. 1996[451]	Did not verify benign diagnoses
Tocino et al. 1996[452]	Retrospective case study
Wallace et al. 1996[453]	Did not verify benign diagnoses
Yim et al. 1996[454]	Did not address Key Question 1
Hann et al. 1995[455]	Did not address Key Question 1
Israel and Fine1995[456]	Did not verify benign diagnoses
Liberman et al. 1995[457]	Retrospective case study
Liberman et al. 1995[458]	Retrospective case study
Liberman et al. 1995[459]	Enrolled patients with recurrent breast cancer
McCombs et al. 1995[460]	Did not verify benign diagnoses
Nath et al. 1995[461]	Fewer than 10 patients enrolled
Rubin et al. 1995[462]	Did not address Key Question 1
Strong et al. 1995[463]	Did not verify benign diagnoses
Vega et al. 1995[464]	Enrolled high-risk patients

Table C2. Studies that did not meet the inclusion criteria for Key Questions 1 and 2 (continued)

Study	Primary Reason for Exclusion
Vega et al. 1995[465]	Did not verify benign diagnoses
Youngson et al. 1995[466]	Did not address Key Question 1
Caines et al. 1994[467]	Did not verify benign diagnoses
Jackman et al. 1994[468]	Did not verify benign diagnoses
Janes and Bouton 1994[469]	Did not verify benign diagnoses
Kaye et al. 1994[470]	Did not address Key Question 1
Liberman et al. 1994[471]	Did not address Key Question 1
Liberman et al. 1994[472]	Did not address Key Question 1
Mikhail et al. 1994[473]	Enrolled a high-risk population
Morrow et al. 1994[474]	Did not verify benign diagnoses
Sadler et al. 1994[475]	Fine-needle aspiration results were used in decisions about verification of results
Youngson et al. 1994[476]	Did not address Key Question 1
Rotten et al. 1993[477]	Fine-needle aspiration results were used in decisions about verification of results
Dronkers 1992[478]	Did not verify benign diagnoses
Elliot et al. 1992[479]	Did not verify benign diagnoses
Harter et al. 1992[480]	Fewer than 10 patients enrolled
Pezner et al. 1992[481]	Did not address any of the Key Questions
Khanna et al. 1991[482]	Fine-needle aspiration results were used in decisions about verification of results

Appendix D. Data Abstraction Forms

Quality Assessment

- Was patient recruitment either consecutive or random?
- Were at least 85% of the patients recruited for enrollment actually enrolled?
- Were the patient inclusion/ exclusion criteria consistently applied to all patients?
- Was the study free from obvious spectrum bias? Obvious spectrum bias was defined as more than 40% or less than 10% of the breast lesions were diagnosed as malignant; and/or the mean or median age of the enrolled population was less than 50 or greater than 70.
- Was the study prospective in design?
- Was a complete set of data reported for at least 85% of enrolled lesions?
- Were the patients assessed by the gold standard (open surgical procedure) regardless of the initial biopsy results?
- Were patients assessed by a reference standard regardless of the biopsy results?
- Was funding for this study provided by a source that doesn't have an obvious financial interest in the findings of the study?
- Did the study account for inter-reader/score differences?
- Were the reader(s) of the biopsies blinded to the results of the reference standard?
- Were readers of the reference standard blinded to the results of the biopsy?
- Were the readers of the biopsy blinded to all other clinical information?
- Were readers of the reference standard blinded to all other clinical information?

Study Design

- Design of study
- Study was prospective or retrospective?
- Number of centers
- Care setting
- Country study conducted in
- Study funded by
- How many different people performed core-needle biopsies during the course of the study?
- What is the training of the persons performing the core-needle biopsies?
- What is the experience of the persons performing the core-needle biopsies?
- Describe in detail the methods used to perform the biopsies
- Who is interpreting the biopsy specimens, and what kind of training do they have?
- Biopsy results confirmed by comparing them to what?

- Describe in detail the reference standard

Patient Details

- Describe the inclusion criteria
- Describe the exclusion criteria
- Number of patients recruited/approached about enrollment
- Number of patients and lesions enrolled
- Number of lesions completing the study
- Age, median or mean, range
- Other reported age discriptors such as % post-menopausal
- Ethnicity
- Types of lesions enrolled and number of each

Accuracy Data

- Enter the type of biopsy being used for the following set of data
- How many lesions were biopsied?
- How many technical failures/ inadequate biopsies occurred?
- How many were lost to followup?
- How many lesions were diagnosed as benign and what was the final diagnosis for each
- How many lesions were diagnosed as invasive and what was the final diagnosis for each
- How many lesions were diagnosed as DCIS and what was the final diagnosis for each
- How many lesions were diagnosed as Atypical, Suspicious, or High Risk, and what was the final diagnosis for each
- Where there any other diagnoses on core-needle biopsy and if so what were they and what was the final diagnosis for each
- Enter information about accuracy by lesion characteristics
- Enter information about accuracy by patient characteristics
- Enter information about accuracy by biopsy methodology characteristics
- Enter any other reported information affected biopsy accuracy

Harms Data

- Requirement for a repeated biopsy procedure, rate
- Complications of the biopsy procedure, types and rates of
- Time to recovery or time to return to work
- Use of pain medications
- Patient satisfaction, quality of life data

- Impact of biopsy procedure on accuracy of subsequent mammography procedures
- Any other harms info reported by the study

Appendix E. Evidence Tables

Table E3. Previously published systematic reviews: design

Study	Search Dates	Types of Biopsy Evaluated	Types of Breast Abnormalities Evaluated	Reference Standard Required	Other Inclusion Criteria	Method of Rating the Quality	Statistical Methods
Fahrbach et al. 2006[483]	1996 to June 2004	Stereotactic vacuum-assisted core-needle biopsy and stereotactic core-needle biopsy	All-comer populations referred after screening mammography	Surgical biopsy or patient followup	English language; ten or more patients; conducted in North America, Europe, Australia, or New Zealand; reported absolute numbers of each lesion type on biopsy; studies of devices no longer on the market- SiteSelect, MIBB device, ABBI device were excluded	Narrative discussion, no overall rating given	Random-effects models in SAS and SPSS, multivariate regression models
Verkooijen et al. 2000[484]	1975 to May 1999	Large-core needle biopsy under stereotactic or ultrasound guidance	Non-palpable lesions detected on mammography	Surgical biopsy or a minimum of 2 years of followup in at least 90% of patients	The absolute number of benign and malignant lesions had to be derivable; a minimum of five large-core biopsy specimens per lesion had to be obtained; studies of fine-needle aspiration were excluded.	Not rated	Pooled by meta-analysis using SPSS. No further details provided.

Table E4. Previously published systematic reviews: quality rating

Study	Was an 'a priori' design provided?	Was there duplicate study selection and data extraction?	Was a comprehensive literature search performed?	Was the status of publication (i.e., grey literature) used as an inclusion criterion?	Was a list of studies (included/excluded) provided?	Were the characteristics of the included studies provided?	Was the scientific quality of the included studies used appropriately in formulating conclusions?	Was the quality of the studies assessed and documented?	Were the methods used to combine the finding of studies appropriate?	Was the likelihood of publication bias assessed?	Was the conflict of interest stated?	Quality Rating
Fahrbach et al. 2006[483]	Can't tell	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No	Moderate
Verkooijen et al. 2000[484]	Can't tell	Yes	Yes	Yes	Yes	No	No	No	Can't tell	No	No	Moderate

Table E5. Previously published systematic reviews: results

Study	N Studies	N Patients	Accuracy	Accuracy Affected by Patient Type/ Breast Abnormality Types	Accuracy Affected by Procedure-related Factors	Accuracy Affected by Personnel/ Facility Factors	Harms	Conclusion
Fahrbach et al. 2006[483]	12 of vacuum-assisted biopsy and 25 of core-needle biopsy	11,355 patients, 5,119 with vacuum-assisted biopsy and 6,236 patients with automated gun core-needle biopsy	Overall agreement between vacuum-assisted and reference standard was 97.3%; overall agreement between core-needle and reference standard was 93.5%. Rate of benign lesions turning out to be malignant: vacuum-assisted: 2.02% (95% CI: 0.00 to 4.35), core-needle: 2.36% (95% CI: 1.15 to 3.58). Rate of atypia lesions turning out to be malignant: vacuum-assisted: 20.38% (15.25 to 25.52), core-needle: 36.69% (26.53 to 46.84)	For atypia to malignant upgrades the type of procedure was a significant predictor, with more underestimations occurring with core-needle as compared to vacuum-assisted	Reference standard and patient position did not influence accuracy	For benign to malignant upgrades, more benign to malignant upgrades occurred in non-North American locations than in North American locations	Frequency of technical failures: 5.7% for core-needle, 1.5% for vacuum-assisted	Vacuum-assisted biopsy may provide lower miss and underestimation rates than automated gun core-needle biopsy.

Table E5. Previously published systematic reviews: results (continued)

Study	N Studies	N Patients	Accuracy	Accuracy Affected by Patient Type/ Breast Abnormality Types	Accuracy Affected by Procedure-related Factors	Accuracy Affected by Personnel/ Facility Factors	Harms	Conclusion
Verkooijen et al. 2000[484]	5	865 biopsies performed	DCIS on needle biopsy upgraded to invasive cancer: 15% (95% CI: 8.0 to 26); ADH on needle biopsy upgraded to invasive cancer: 40% (95% CI: 26 to 56); sensitivity of core-needle for detecting malignancies: 97% (95% CI: 95 to 99)	Not performed	Not performed	Not performed	2 complications reported: 1 hematoma 1 infection	In a setting such as the U.S. where about 20% of cases referred for biopsy are malignant, the risk of breast cancer despite a benign diagnosis on core-needle biopsy is less than 1%. However, in a setting such as Europe where about 60% of cases referred for biopsy are malignant, the risk of breast cancer despite a benign diagnosis on core-needle biopsy is 4%.

Table E6. Studies included to address Key Questions 1 and 2: design details

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Jackman et al. 2009[485]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	Biopsys Medical, Inc. and Ethicon Endo-Surgery	Stereotactic guidance vacuum-assisted 11G and 14G	Combination of surgery and patient followup	1,280	2 years	10.6%
Peters et al. 2008[486]	Single group (cohort or case series study)	Retrospective	4	General hospital	Netherlands	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	948	2 years	5%
Schueller et al. 2008[487]	Single group (cohort or case series study)	Retrospective	1	General hospital	Austria	Authors stated no financial relationship to disclose	Ultrasound guidance automated gun 14G	Combination of surgery and patient followup	1438	2 years	5.7%
Sim and Kei 2008[488]	Single group (cohort or case series study)	Retrospective	1	General hospital	Singapore	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient folowup	105	2 years	12.4%
Tonegutti and Girardi 2008[489]	Single group (cohort or case series study)	Retrospective	1	General hospital	Italy	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	268	2 years	0%
Youk et al. 2008[24]	Single group (cohort or case series study)	Retrospective	1	General hospital	South Korea	NR	US guidance automated gun 14G	Combination of surgery and patient followup	4,359	2 years	44%
Ciatto et al. 2007[490]	Single group (cohort or case series study)	Retrospective	1	Dedicated breast cancer center	Italy	Funded in part by a National Helath and Medical Research Council (NHMRC) grant	Multiple methods	Combination of surgery and patient followup	4,035	1 year	26%
de Lucena et al. 2007[491]	Single group (cohort or case series study)	Prospective	1	General hospital	Brazil	NR	US guidance automated gun 14G	Open surgery or surgical biopsy only	150	Immediate surgery	0%
Uematsu et al. 2007[492]	Single group (cohort or case series study)	Prospective	1	General cancer center	Japan	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	100	Mean: 26 months Range: 5 to 44 months	0%
Vag et al. 2007[493]	Single group (cohort or case series study)	Prospective	1	General hospital	Germany	NR	US guidance vacuum-assisted 10G	Combination of surgery and patient followup	70	2 years	0%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Chapellier et al. 2006[494]	Single group (cohort or case series study)	Prospective	1	General cancer center	France	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	318	Range: 4 to 16 months	0%
Cipolla et al. 2006[495]	Single group (cohort or case series study)	NR	1	General hospital	Italy	NR	Multiple methods	Combination of surgery and patient followup	426	1 year	0%
Dhillon et al. 2006[496]	Single group (cohort or case series study)	Prospective	1	General hospital	UK	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	150	Median: 48 months	0%
Bolivar et al. 2005[497]	Single group (cohort or case series study)	Prospective	1	General hospital	Spain	NR	US guidance automated gun 14G	Combination of surgery and patient followup	214	2 years	5%
Crystal et al. 2005[498]	Single group (cohort or case series study)	NR	1	General hospital	Israel	NR	US guidance automated gun 14G	Combination of surgery and patient followup	715	Median: 39 months Range: 27 to 60 months	0%
Dillon et al. 2005[499]	Single group (cohort or case series study)	Retrospective	1	General hospital	Ireland	NR	Multiple methods	Combination of surgery and patient followup	2,427	Median: 24 months Range: 3 to 67 months	19%
Koskela et al. 2005[500]	Single group (cohort or case series study)	Prospective	1	General hospital	Finland	Kuopio University Hospital (the center it was conducted in)	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	213	Mean: 24 months Range: 6 to 39 months	4%
Sauer et al. 2005[501]	Single group (cohort or case series study)	Retrospective	1	General hospital	Germany	NR	US guidance automated gun 14G	Combination of surgery and patient followup	962	Mean: 22.2 months Median: 21 months Range : 8 to 36 months	13%
Weber et al. 2005[502]	Non-randomized multiple groups study	Prospective	1	General hospital	Switzerland	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	225	Median: 2.1 years Range: 0.5 to 4.4 years	15%
Wu et al. 2005[503]	Single group (cohort or case series study)	NR	1	General hospital	Taiwan	NR	US guidance vacuum-assisted 11G	Combination of surgery and patient followup	113	1 year	0%
Alonso-Bartolome et al. 2004[504]	Single group (cohort or case series study)	Prospective	2	General hospital	Spain	NR	US guidance vacuum-assisted 11G	Combination of surgery and patient followup	102	6 to 12 months	0%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Delle and Terinde 2004[505]	Single group (cohort or case series study)	NR	1	General hospital	Germany	NR	US guidance automated gun 14G	Combination of surgery and patient followup	169	2 years	0%
Fajardo et al. 2004[506]	Some patients were randomized to stereotactic or US guidance but data were reported as if the study was a single-group cohort study	Prospective	22	Academic and community practice clinical sites	USA	National Cancer Institute	Multiple methods	Combination of surgery and patient followup	2,403	2 years	30%
Kettritz et al. 2004[507]	Single group (cohort or case series study)	Prospective	5	General hospital	Germany	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	2,893	Mean: 25 months Range: 6 to 67 months	22%
Lomoschitz et al. 2004[508]	Non-randomized multiple groups study	Prospective	1	General hospital	Austria	One author partially supported by both Ethicon Edonsurgery and Biopsys Medical	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	100	2 years	0%
Abdsaleh et al. 2003[509]	Single group (cohort or case series study)	Prospective	1	General hospital	Sweden	NR	Multiple methods	Combination of surgery and patient followup	180	1 year	21%
Ambrogetti et al. 2003[510]	Single group (cohort or case series study)	Retrospective	1	General hospital	France	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	364	Mean: 15.8 months Range: 6 to 36 months	35%
Fishman et al. 2003[511]	Single group (cohort or case series study)	Prospective	1	General hospital	USA	NR	US guidance automated gun 14G	Combination of surgery and patient followup	73	Mammographic and US followup Median: 21 months Range: 4 to 30 months	33%
Han et al. 2003[512]	Single group (cohort or case series study)	Retrospective	1	General hospital	Korea	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	271	At least 6 months	27%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Kirshenbaum et al. 2003[513]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	506	Mean: 2.1 years Range: 3 months to 5 years	23%
March et al. 2003[514]	Single group (cohort or case series study)	Prospective	2	Dedicated breast cancer center	USA	RSNA Seed Grant and the Rays of Hope charitable fund	US guidance vacuum-assisted 11G	Combination of surgery and patient followup	34	6 months	9%
Pfleiderer et al. 2003[515]	Single group (cohort or case series study)	Prospective	1	General hospital	Germany	NR	MRI guidance automated gun 14G	Combination of surgery and patient followup	14	2 years	0%
Philpotts et al. 2003[516]	Non-randomized multiple groups study	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	281	Mean: 19 months Range: 3 to 53 months for 14G Mean: 13 months Range: 1 to 24 for 11G	24%
Wong and Hisham 2003[517]	Single group (cohort or case series study)	Prospective	1	General hospital	Malaysia	NR	Freehand automated gun 14 or 16G	Combination of surgery and patient followup	150	Range: 6 to 13 months	0%
Apesteguia et al. 2002[518]	Single group (cohort or case series study)	Prospective	1	General hospital	Spain	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	132	1 year	0%
Georgian-Smith et al. 2002[519]	Single group (cohort or case series study)	Retrospective	4	General hospital	USA	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	185	Range: 6 to 12 months	21%
Jackman and Lamm 2002[520]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	Funded in part by Biopsys Medical	Multiple methods	Combination of surgery and patient followup	31	At least 6 months	0%
Johnson et al. 2002[521]	Single group (cohort or case series study)	NR	1	General hospital	USA	Fashion Footwear of NY	US guidance vacuum-assisted 11 or 8G	Combination of surgery and patient followup	101	Mean: 9.5 months	24%
Liberman et al. 2002[522]	Single group (cohort or case series study)	Retrospective	1	General cancer center	USA	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	800	At least 1 year	29%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Meloni et al. 2002[523]	Single group (cohort or case series study)	Retrospective	1	General hospital	Italy	NR	Stereotactic guidance vacuum-assisted	Combination of surgery and patient followup	129	Mean: 18.7 months Range: 14 to 26 months	0%
Morris et al. 2002[524]	Single group (cohort or case series study)	Prospective	1	Dedicated breast cancer center	USA	NR	Stereotactic guidance vacuum-assisted 14G	Combination of surgery and patient followup	21	Median: 46 months Range: 40-54 months	10%
Pfarl et al. 2002[525]	Single group (cohort or case series study)	Retrospective	1	General hospital	Austria	NR	Stereotactic guidance vacuum-assisted 11G	Open surgery or surgical biopsy only	332	Immediate surgery	4%
Verkooijen et al. COBRA 2002[526]	Single group (cohort or case series study)	Prospective	5	General hospital	Netherlands	Dutch National Health Insurance Fund Council	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	984	Immediate surgery	11%
Becker et al. 2001[527]	Single group (cohort or case series study)	Retrospective	1	General hospital	Canada	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	232	Range: 6 to 12 months	27%
Brenner et al. 2001[528]	Single group (cohort or case series study)	Prospective	7	Cancer centers and hospitals	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	1,003	Mean: 19.3 months Range: 0 to 36 months	1%
Cangiarella et al. 2001[529]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	160	Mean: 20.5 months Range: 6 to 35 months	38%
Dahlstrom and Jain 2001[530]	Single group (cohort or case series study)	NR	1	General hospital	Australia	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	301	Range: 2.4 to 7.5 years	0%
Lai et al. 2001[531]	Single group (cohort or case series study)	NR	1	General hospital	Canada	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	673	Mean: 6.7 months Range: 6 to 24 months	29%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Levin et al. 2001[532]	Single group (cohort or case series study)	Prospective	1	General hospital	Canada	Physician's Services Incorporated Foundation	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	70	Immediate surgery	0%
Margolin et al. 2001[533]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	1,333	Mean: 14 months Range: 6 to 24 months; missing data were collected from SEER database; at the time of accession of SEER data followup ranged from 15 to 75 months	3%
Perez-Fuentes et al. 2001[534]	Single group (cohort or case series study)	NR	1	Dedicated breast cancer center	Venezuela	NR	US guidance vacuum-assisted 11G	Combination of surgery and patient followup	88	Median: 11.1 months Range: 4 to 24 months	33%
Smith et al. 2001[535]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	US guidance automated gun 14G	Combination of surgery and patient followup	500	Mean: 22 months Median: 14 months Range: 12 to 60 months	21%
White et al. 2001[536]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	1,042	Median: 29 months, minimum of one year	29%
Wunderbaldinger et al. 2001[537]	Single group (cohort or case series study)	Prospective	1	General hospital	Austria	author supported by Erwin Schroedinger Auslandsstipenium of the Austrian Science Fund	US guidance automated gun 14G	Open surgery or surgical biopsy only	45	Immediate surgery	0%
Yeow et al. 2001[538]	Single group (cohort or case series study)	Prospective	1	General hospital	China	NR	US guidance automated gun 14 or 16G	Combination of surgery and patient followup	98	Mean: 4 years Range: 3 to 5 years	0%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Beck et al. 2000[539]	Single group (cohort or case series study)	NR	1	General hospital	Germany	NR	Stereotactic guidance vacuum-assisted 11G	Combination of surgery and patient followup	594	1 year	0%
Kirwan et al. 2000[540]	Single group (cohort or case series study)	Retrospective	1	General hospital	UK	NR	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	72	Immediate surgery	13%
Latosinsky et al. 2000[541]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NIH grant	Multiple methods	Combination of surgery and patient followup	692	Median: 17.2 months Range: 2.8 to 43 months	42%
Liberman et al. 2000[542]	Single group (cohort or case series study)	Retrospective	1	General cancer center	USA	NR	Multiple methods	Combination of surgery and patient followup	155	Median: 53 months Range: 24 to 69 months	32%
Makoske et al. 2000[543]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	817	Mean: 1.7 years	30%
Ward et al. 2000[544]	Single group (cohort or case series study)	NR	1	General hospital	Canada	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	121	Mean: 16 months Range: 4 to 36 months	7%
Welle et al. 2000[545]	Single group (cohort or case series study)	Retrospective	3	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	225	Range: 6 to 24 months	20%
Helbich et al. 1999[546]	Randomized controlled trial	Prospective	1	General hospital	Austria	Ludwig-Boltzmann Institute for Radiologic Tumor Research; one author was supported by a grant from the Max Kade Foundation	Multiple methods	Open surgery or surgical biopsy only	44	Immediate surgery	0%
Jackman et al. 1999[547]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	483	Median: 55 months	1%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Meyer et al. 1999[548]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	1,836	At least 1 year	25%
Puglisi et al. 1999[549]	Single group (cohort or case series study)	Retrospective	1	General hospital	Italy	NR	Perforated compression grid automated gun 14G	Combination of surgery and patient followup	106	At least 6 months	1%
Soo et al. 1999[550]	Non-randomized multiple groups study	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	116	Mean: 16 months Range: 5 to 31 months	19%
Caruso et al. 1998[551]	Single group (cohort or case series study)	Prospective	1	General hospital	Italy	NR	Multiple methods	Open surgery or surgical biopsy only	92	Immediate surgery	13%
Doyle et al. 1998[552]	Single group (cohort or case series study)	Retrospective	1	Dedicated breast cancer center	New Zealand	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	151	Range: 6 to 36 months	11%
Fuhrman et al. 1998[553]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	1,440	At least 6 months	18%
Heywang-Kobrunner et al. 1998[554]	Single group (cohort or case series study)	NR	1	General hospital	Germany	NR	Stereotactic guidance vacuum-assisted 11 or 14G	Combination of surgery and patient followup	261	6 months	31%
Ioffe et al. 1998[555]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	224	Range: 6 to 12 months	14%
Liberman et al. 1998[556]	Single group (cohort or case series study)	NR	1	General cancer center	USA	NR	US guidance automated gun 14G	Combination of surgery and patient followup	151	Median: 20 months Range: 6 to 48 months	23%
Schulz-Wendtland et al. 1998[557]	Single group (cohort or case series study)	NR	1	General hospital	Germany	NR	US guidance automated gun 14G	Combination of surgery and patient followup	307	2 years	0%
Vega-Bolivar et al. 1998[558]	Single group (cohort or case series study)	Retrospective	1	General hospital	Spain	NR	Stereotactic guidance Surecut 15G	Combination of surgery and patient followup	182	Mean: 27 months Range: 6 to 47 months	6%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Whitman et al. 1998[559]	Single group (cohort or case series study)	Retrospective	2	General hospital	USA	NR	Stereotactic guidance automated gun 16G	Open surgery or surgical biopsy only	12	Immediate surgery	0%
Zannis and AliaNo 1998[560]	Non-randomized multiple groups study	Retrospective	1	Ambulatory surgical center	USA	NR	Multiple methods	Combination of surgery and patient followup	424	At least 6 months	31%
Bauer et al. 1997[561]	Single group (cohort or case series study)	Retrospective	NR	NR	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	799	Mean: 9 months	0%
Britton et al. 1997[562]	Single group (cohort or case series study)	NR	1	General hospital	UK	NR	Multiple methods	Combination of surgery and patient followup	202	Mean: 20.1 months Range: 5.3 to 30.8 months	2%
Helbich et al. 1997[563]	Single group (cohort or case series study)	Prospective	1	General hospital	Austria	NR	Multiple methods	Open surgery or surgical biopsy only	210	Immediate surgery	0%
Khattar et al. 1997[564]	Single group (cohort or case series study)	Prospective	1	General hospital	Denmark	NR	US guidance automated gun	Open surgery or surgical biopsy only	106	Immediate surgery	43%
Liberman et al. 1997[565]	Single group (cohort or case series study)	Retrospective	1	General cancer center	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	442	Median: 18 months Range: 6 to 46 months	34%
Pitre et al. 1997[566]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Stereotactic guidance automated gun	Combination of surgery and patient followup	128	1 year	8%
Stolier et al. 1997[567]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	244	Mean: 12.8 months Range: 6 to 39 months	NR
Sutton, et al. 1997[568]	Single group (cohort or case series study)	Retrospective	1	Screening clinic	Australia	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	206	1 year	32%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Walker et al. 1997[569]	Single group (cohort or case series study)	NR	1	General hospital	UK	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	200	Range: 6 to 36 months	10%
Frazee et al. 1996[570]	Non-randomized multiple groups study	Prospective	1	General hospital	USA	NR	Stereotactic guidance automated gun	Combination of surgery and patient followup	103	At least 6 months	0%
Fuhrman et al. 1996[571]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	451	1 year	22%
Head and Haynes 1996[572]	Single group (cohort or case series study)	Prospective	1	Dedicated breast cancer center	USA	NR	Stereotactic guidance automated gun 18G	Combination of surgery and patient followup	115	2 years	8%
Mainiero et al. 1996[573]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	138	At least 6 months	14%
Meyer et al. 1996[574]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	388	1 year	30%
Nguyen et al. 1996[575]	Single group (cohort or case series study)	NR	1	General hospital	USA	American Cancer Society, UCLA Jonsson Comprehensive Cancer Center, and the Stein-Oppenheim Foundation	Multiple methods	Combination of surgery and patient followup	431	At least 6 months	10%
Pettine et al. 1996[576]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	25	6 month repeat mammography for benign	0%
Rosenblatt et al. 1996[577]	Single group (cohort or case series study)	Retrospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	25	1 year	16%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
Scopa et al. 1996[578]	Non-randomized multiple groups study	NR	1	General hospital	Greece	NR	Freehand TruCut	Open surgery or surgical biopsy only	120	Immediate surgery	0%
Cross et al. 1995[579]	Single group (cohort or case series study)	NR	1	Dedicated breast cancer center	USA	NR	Stereotactic guidance automated gun 14G	Combination of surgery and patient followup	250	1 year	12%
Doyle et al. 1995[580]	Non-randomized multiple groups study	Prospective	1	General Hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	150	Range: 6 to 24 months	3%
Hamed et al. 1995[581]	Randomized controlled trial	Prospective	1	General hospital	UK	NR	Freehand Biopty-cut	Open surgery or surgical biopsy only	122	Immediate surgery	0%
Burbank et al. 1994[582]	Non-randomized multiple groups study	NR	1	General hospital	USA	NR	Multiple methods	Combination of surgery and patient followup	105	At least 6 months	0%
Gisvold et al. 1994[583]	Single group (cohort or case series study)	Prospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	160	Immediate surgery	0%
Parker et al. 1994[584]	Non-randomized multiple groups study	Retrospective	20	Various hospitals, breast care centers, clinics	USA	NR	Multiple methods	Combination of surgery and patient followup	6,152	At least 6 months	39%
Smyth and Cederbom 1994[585]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	58	Immediate surgery	0%
Elvecrog et al. 1993[586]	Non-randomized multiple groups study	Prospective	1	General hospital	USA	NR	Stereotactic guidance automated gun 14G	Open surgery or surgical biopsy only	100	Immediate surgery	0%
Parker et al. 1993[587]	Single group (cohort or case series study)	NR	1	Specialized imaging center	USA	NR	US guidance automated gun 14G	Combination of surgery and patient followup	181	Range: 12 to 36 months	0%

Table E6. Studies included to address Key Questions 1 and 2: design details (continued)

Study	Design of Study	Type of Study	Number of Centers	Care Setting	Country Conducted in	Funded by	Type(s) Core Biopsy	Core Biopsy Results Confirmed by	Number of Lesions Enrolled	Followup	% Attrition
McMahon et al. 1992[588]	Randomized controlled trial	Prospective	1	General hospital	UK	NR	Multiple methods	Combination of surgery and patient followup	151	Median: 11 months Range: 1 to 24 months	0%
Barreto et al. 1991[589]	Single group (cohort or case series study)	NR	1	General hospital	UK	NR	Freehand automated gun 18G	Open surgery or surgical biopsy only	107	Immediate surgery	0%
Cusick et al. 1990[590]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Freehand	Open surgery or surgical biopsy only	96	Immediate surgery	0%
Parker et al. 1990[591]	Single group (cohort or case series study)	NR	1	General hospital	USA	NR	Stereotactic guidance automated gun	Open surgery or surgical biopsy only	103	Immediate surgery	0%

NR = Not Reported
US = Ultrasound
UK = United Kingdom
USA = United States of America

Table E7. Quality assessment instrument

1. Was patient recruitment either consecutive or random?
2. Were more than 85% of the patients approached for recruitment enrolled in the study?
3. Were the patient inclusion/ exclusion criteria consistently applied to all patients?
4. Was the study free from obvious spectrum bias? Obvious spectrum bias was defined as more than 40% or less than 10% of the breast lesions were diagnosed as malignant; and/or the mean or median age of the enrolled population was less than 50 or greater than 70.
5. Was the study prospective in design?
6. Was a complete set of data reported for at least 85% of enrolled lesions?
7. Were the patients assessed by the gold standard (open surgical procedure) regardless of the initial biopsy results?
8. Were patients assessed by a reference standard regardless of the biopsy results?
9. Was funding for this study provided by a source that doesn't have an obvious financial interest in the findings of the study?
10. Did the study account for inter-reader/scorer differences?
11. Were the reader(s) of the biopsies blinded to the results of the reference standard?
12. Were readers of the reference standard blinded to the results of the biopsy?
13. Were the readers of the biopsy blinded to all other clinical information?
14. Were readers of the reference standard blinded to all other clinical information?

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Jackman et al. 2009[485]	Yes	Yes	Yes	NR	No	Yes	No	Yes	No	No	Yes	NR	No	NR	1	5.4
Peters et al. 2008[486]	Yes	NR	Yes	No: over 40% malignant	No	Yes	No	Yes	NR	No	Yes	No	No	No	-1	4.6
Schueller et al. 2008[487]	Yes	Yes	Yes	No: over 40% malignant	No	Yes	No	Yes	Yes	NR	Yes	No	No	No	1	5.4
Sim and Kei 2008[488]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	NR	Yes	No	NR	No	3	6.1
Tonegutti and Girardi 2008[489]	Yes	Yes	Yes	No: 41.6% malignant	No	Yes	No	Yes	NR	NR	NR	NR	NR	NR	3	6.1
Youk et al. 2008[24]	Yes	Yes	Yes	No: mean 45.3 years of age	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6
Ciatto et al. 2007[490]	Yes	Yes	Yes	NR	No	No	No	Yes	Yes	No	Yes	No	No	No	-1	4.6
de Lucena et al. 2007[491]	NR	NR	NR	No: 67% malignant	Yes	Yes	Yes	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Uematsu et al. 2007[492]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	No	Yes	NR	NR	NR	6	7.1
Vag et al. 2007[493]	NR	NR	NR	No: 41.4% malignant	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	3	6.1
Chapellier et al. 2006[494]	NR	NR	NR	Yes	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	4	6.4
Cipolla et al. 2006[495]	Yes	Yes	Yes	No: 43% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Dhillon et al. 2006[496]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	7	7.5
Bolivar et al. 2005[497]	Yes	Yes	Yes	No: 58% malignant	Yes	Yes	No	Yes	NR	No	Yes	NR	NR	NR	5	6.8
Crystal et al. 2005[498]	Yes	Yes	Yes	No: 45% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Dillon et al. 2005[499]	Yes	Yes	Yes	No: 57% malignant	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Koskela et al. 2005[500]	Yes	Yes	Yes	No: 42% malignant	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	3	6.1
Sauer et al. 2005[501]	Yes	Yes	Yes	No: 64.2% malignant	No	Yes	No	Yes	NR	No	Yes	No	No	No	0	5.0
Weber et al. 2005[502]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	Yes	Yes	NR	NR	NR	8	7.9
Wu et al. 2005[503]	Yes	Yes	Yes	No: 0% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Alonso-Bartolome et al. 2004[504]	NR	Yes	Yes	No: 0.9% malignant, mean age 42	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Delle and Terinde 2004[505]	Yes	Yes	Yes	No: 77% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Fajardo et al. 2004[506]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	NR	NR	NR	9	8.2
Kettritz et al. 2004[507]	NR	NR	No	NR	Yes	No	No	Yes	NR	NR	Yes	NR	No	NR	-1	4.6
Lomoschitz et al. 2004[508]	Yes	Yes	Yes	No: 47% malignant	Yes	Yes	No	Yes	No	No	NR	NR	NR	NR	3	6.1
Abdsaleh et al. 2003[509]	Yes	Yes	Yes	No: 74% malignant	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	6	7.1
Ambrogetti et al. 2003[510]	Yes	Yes	Yes	No: 43.4% malignant	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6
Fishman et al. 2003[511]	Yes	Yes	No	NR	Yes	No	No	Yes	NR	No	Yes	NR	Yes	NR	2	5.7
Han et al. 2003[512]	Yes	Yes	Yes	No: mean age 47 years	No	No	No	Yes	NR	NR	NR	NR	NR	NR	1	5.4
Kirshenbaum et al. 2003[513]	Yes	Yes	Yes	Yes	No	No	No	Yes	NR	NR	Yes	No	No	No	0	5.0
March et al. 2003[514]	Yes	No: 67%	Yes	NR	Yes	Yes	No	Yes	Yes	No	Yes	No	No	No	2	5.7
Pfleiderer et al. 2003[515]	No	NR	Yes	No: 42% malignant	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	4	6.4

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Philpotts et al. 2003[516]	Yes	Yes	Yes	NR	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6
Wong and Hisham 2003[517]	Yes	Yes	Yes	No: 46% malignant	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	6	7.1
Apesteguia et al. 2002[518]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	NR	NR	NR	NR	NR	6	7.1
Georgian-Smith et al. 2002[519]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	NR	Yes	No	No	No	2	5.7
Jackman and Lamm 2002[520]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	NR	Yes	No	No	No	1	5.4
Johnson et al. 2002[521]	Yes	Yes	Yes	No: 5% malignant	NR	No	No	Yes	Yes	NR	Yes	NR	NR	NR	4	6.4
Liberman et al. 2002[522]	Yes	Yes	Yes	No	No	No	No	Yes	NR	NR	Yes	No	No	No	-2	4.3
Meloni et al. 2002[523]	Yes	Yes	Yes	NR	Yes	Yes	No	Yes	NR	NR	Yes	No	No	No	3	6.1
Morris et al. 2002[524]	NR	NR	Yes	Yes	Yes	Yes	No	Yes	NR	No	Yes	NR	NR	NR	4	6.4
Pfarl et al. 2002[525]	Yes	Yes	Yes	No: 65% malignant	No	Yes	Yes	Yes	NR	NR	Yes	No	No	No	3	6.1
Verkooijen et al. COBRA 2002[526]	Yes	NR	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	NR	NR	8	7.9
Becker et al. 2001[527]	Yes	Yes	Yes	Yes	No	No	No	Yes	NR	NR	Yes	No	No	No	0	5.0
Brenner et al. 2001[528]	NR	NR	NR	NR	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	3	6.1
Cangiarella et al. 2001[529]	Yes	Yes	Yes	No: 9% malignant	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	3	6.1
Dahlstrom and Jain 2001[530]	Yes	Yes	Yes	NR	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Lai et al. 2001[531]	Yes	Yes	Yes	Yes	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	4	6.4

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Levin et al. 2001[532]	NR	NR	Yes	NR	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	NR	NR	6	7.1
Margolin et al. 2001[533]	Yes	Yes	Yes	No: mean age less than 50	No	Yes	No	Yes	NR	NR	Yes	No	No	No	1	5.4
Perez-Fuentes et al. 2001[534]	No	NR	No	No: mean age 48	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	-1	4.6
Smith et al. 2001[535]	Yes	Yes	Yes	No: mean age 47	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	3	6.1
White et al. 2001[536]	Yes	Yes	Yes	Yes	No	No	No	Yes	NR	No	Yes	No	No	No	-1	4.6
Wunderbaldinger et al. 2001[537]	No	NR	Yes	No: 49% malignant	Yes	Yes	Yes	Yes	Yes	No	No	No	NR	NR	3	6.1
Yeow et al. 2001[538]	Yes	Yes	Yes	No: mean age 46	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	6	7.1
Beck et al. 2000[539]	Yes	Yes	Yes	NR	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Kirwan et al. 2000[540]	NR	NR	NR	NR	No	Yes	Yes	Yes	NR	NR	Yes	No	No	No	0	5.0
Latosinsky et al. 2000[541]	Yes	Yes	Yes	NR	No	No	No	Yes	Yes	NR	NR	Yes	No	No	1	5.4
Liberman et al. 2000[542]	Yes	Yes	Yes	No: median age 47 years	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6
Makoske et al. 2000[543]	Yes	Yes	Yes	NR	Yes	No	No	Yes	NR	NR	Yes	No	No	No	1	5.4
Ward et al. 2000[544]	Yes	Yes	Yes	Yes	NR	Yes	No	Yes	NR	NR	Yes	No	No	No	3	6.1
Welle et al. 2000[545]	NR	NR	NR	NR	No	No	No	Yes	NR	NR	Yes	No	No	No	-4	3.6
Helbich et al. 1999[546]	Yes	NR	Yes	No: 86% malignant	Yes	Yes	Yes	No	NR	No	Yes	NR	No	NR	3	6.1
Jackman et al. 1999[547]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	Yes	No	No	No	No	0	5.0
Meyer et al. 1999[548]	Yes	Yes	Yes	Yes	No	No	No	Yes	NR	No	Yes	No	No	No	-1	4.6

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Puglisi et al. 1999[549]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	No	Yes	No	No	No	1	5.4
Soo et al. 1999[550]	Yes	Yes	Yes	NR	No	No	No	Yes	NR	Yes	Yes	No	No	No	0	5.0
Caruso et al. 1998[551]	Yes	NR	Yes	No: 85% malignant	Yes	Yes	Yes	Yes	NR	No	Yes	NR	No	NR	5	6.8
Doyle et al. 1998[552]	Yes	Yes	Yes	NR	No	Yes	No	Yes	NR	No	Yes	No	No	No	0	5.0
Fuhrman et al. 1998[553]	Yes	Yes	Yes	Yes	No	No	No	Yes	NR	No	Yes	No	No	No	-1	4.6
Heywang-Kobrunner et al. 1998[554]	Yes	Yes	Yes	NR	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	3	6.1
Ioffe et al. 1998[555]	Yes	NR	Yes	Yes	NR	NR	No	Yes	NR	NR	NR	NR	NR	NR	3	6.1
Liberman et al. 1998[556]	Yes	Yes	Yes	Yes	NR	No	No	Yes	NR	NR	Yes	NR	NR	NR	4	6.4
Schulz-Wendtland et al. 1998[557]	Yes	Yes	Yes	No: 52% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Vega-Bolivar et al. 1998[558]	Yes	NR	Yes	No: over 40% were malignant	No	Yes	No	Yes	NR	No	Yes	No	No	No	-1	4.6
Whitman et al. 1998[559]	NR	Yes	NR	No: 50% malignant	No	Yes	No	Yes	NR	NR	NR	NR	NR	NR	1	5.4
Zannis and AliaNo 1998[560]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	NR	Yes	No	No	No	2	5.7
Bauer et al. 1997[561]	Yes	Yes	Yes	Yes	No	Yes	No	Yes	NR	Yes	Yes	No	No	No	2	5.7
Britton et al. 1997[562]	Yes	Yes	Yes	No: 50% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Helbich et al. 1997[563]	Yes	Yes	Yes	No: 47% malignant	Yes	Yes	Yes	Yes	NR	No	Yes	No	NR	NR	6	7.1
Khattar et al. 1997[564]	NR	NR	Yes	No: 44% malignant	Yes	No	Yes	Yes	NR	NR	Yes	NR	NR	NR	4	6.4

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Liberman et al. 1997[565]	Yes	NR	Yes	NR	No	No	No	Yes	NR	NR	Yes	No	No	No	-2	4.3
Pitre et al. 1997[566]	Yes	Yes	Yes	No: 8.6% malignant	No	Yes	No	Yes	NR	NR	Yes	No	No	No	1	5.4
Stolier et al. 1997[567]	Yes	Yes	Yes	NR	No	Yes	No	Yes	NR	NR	Yes	No	No	No	1	5.4
Sutton, et al. 1997[568]	NR	NR	No	Yes	No	No	No	Yes	NR	NR	Yes	No	No	No	-4	3.6
Walker et al. 1997[569]	Yes	Yes	Yes	No: 54% malignant	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Frazee et al. 1996[570]	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	NR	NR	NR	NR	NR	NR	6	7.1
Fuhrman et al. 1996[571]	NR	Yes	Yes	NR	NR	No	No	Yes	NR	NR	NR	NR	NR	NR	1	5.4
Head and Haynes 1996[572]	NR	NR	NR	Yes	Yes	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	4	6.4
Mainiero et al. 1996[573]	NR	Yes	Yes	Yes	No	Yes	No	Yes	NR	NR	NR	NR	NR	NR	3	6.1
Meyer et al. 1996[574]	Yes	No: 67.7%	Yes	No: median age 49	NR	No	No	Yes	NR	NR	NR	NR	NR	NR	1	5.4
Nguyen et al. 1996[575]	NR	NR	Yes	No: 43% malignant	NR	Yes	No	Yes	Yes	NR	Yes	NR	NR	NR	4	6.4
Pettine et al. 1996[576]	NR	Yes	Yes	NR	No	Yes	Yes	NR	NR	NR	NR	NR	NR	NR	3	6.1
Rosenblatt et al. 1996[577]	Yes	Yes	Yes	No: 52% malignant	No	No	No	Yes	NR	NR	Yes	No	No	No	-1	4.6
Scopa et al. 1996[578]	NR	Yes	Yes	No: 65% malignant	NR	Yes	Yes	Yes	NR	NR	NR	NR	NR	NR	5	6.8
Cross et al. 1995[579]	NR	NR	NR	Yes	NR	Yes	No	Yes	NR	NR	Yes	No	No	No	0	5.0
Doyle et al. 1995[580]	Yes	Yes	Yes	Yes	Yes	No	No	Yes	NR	NR	NR	NR	NR	NR	4	6.4

Table E8. Quality of studies addressing Key Questions 1 and 2 (see Table E7 for the wording of the questions) (continued)

Study	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Raw Score	Standardize
Hamed et al. 1995[581]	Yes	Yes	Yes	No: 88% malignant	Yes	Yes	No	No	NR	NR	NR	NR	NR	NR	3	6.1
Burbank et al. 1994[582]	NR	Yes	NR	NR	NR	Yes	No	Yes	NR	NR	NR	NR	NR	NR	2	5.7
Gisvold et al. 1994[583]	Yes	No: 33.6%	No	No: 42% malignant	Yes	Yes	Yes	Yes	NR	No	Yes	NR	NR	NR	4	6.4
Parker et al. 1994[584]	NR	NR	Yes	NR	No	No	No	Yes	NR	NR	No	No	NR	NR	-3	3.9
Smyth and Cederbom 1994[585]	NR	NR	NR	Yes	NR	Yes	Yes	No	NR	No	No	No	NR	NR	-1	4.6
Elvecrog et al. 1993[586]	Yes	Yes	Yes	NR	Yes	Yes	Yes	Yes	Yes	NR	NR	NR	NR	NR	8	7.9
Parker et al. 1993[587]	Yes	Yes	Yes	NR	NR	Yes	No	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
McMahon et al. 1992[588]	Yes	Yes	Yes	NR	Yes	Yes	No	Yes	NR	No	Yes	NR	NR	NR	5	6.8
Barreto et al. 1991[589]	NR	NR	Yes	No: 90% malignant	NR	Yes	Yes	Yes	NR	NR	Yes	NR	NR	NR	5	6.8
Cusick et al. 1990[590]	NR	Yes	Yes	No: 81.3% malignant	NR	Yes	Yes	No	NR	NR	NR	NR	NR	NR	3	6.1
Parker et al. 1990[591]	Yes	No	Yes	NR	NR	Yes	Yes	No	NR	NR	NR	NR	NR	NR	2	5.7

NR = Not Reported

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Jackman et al. 2009[485]	4	Radiologists	0.25 to 3.75 years of experience performing stereotactic biopsies but no experience with vacuum-assisted biopsies before the study began	Stereotactic	Prone	Mammotome 11G or 14G	12 or more
Peters et al. 2008[486]	NR	NR	NR	Stereotactic	Prone	Biopty automated gun 14G	Range: 5 to 8
Schueller et al. 2008[487]	2	Radiologists	Performed 100 or more biopsies before the study period began	US	Supine or decubitus	Bard automated gun 14G	Mean: 5.9 Range: 5 to 10
Sim and Kei 2008[488]	1	Radiologist	NR	Stereotactic	Seated	Mammotome 11G	Mean: 13.5 Range: 2 to 36
Tonegutti and Girardi 2008[489]	1	Radiologists	Short training period with 30 patients	Stereotactic	Prone	Mammotome 11G	20
Youk et al. 2008[24]	9	Radiologists	7 had fellowship training, 2 had extensive clinical experience in breast imaging and biopsy	US	Supine	Pro-Mag automated gun, 14G	Mean: 5.4 cores Range: 3 to 8
Ciatto et al. 2007[490]	13	Radiologists	NR	US or stereotactic guidance	NR	Automated gun 14G or Mammotome 11G	2 to 4
de Lucena et al. 2007[491]	1	NR	NR	US	NR	Pro-Mag automated gun 14G	6
Uematsu et al. 2007[492]	1	Radiologists	1 year of prior experience with the procedure	Stereotactic	Prone	Mammotome 11G	NR
Vag et al. 2007[493]	NR	Radiologists	reports the device is new and they are trying it out, but the radiologist was highly experienced in breast interventions	US	NR	VACORA 10G	NR
Chapellier et al. 2006[494]	NR	Radiologists	Device was newly acquired at start of the study	Stereotactic	NR	Mammotome	NR
Cipolla et al. 2006[495]	NR	NR	NR	Stereotactic or US	NR	14G needle	Mean: 3 Range: 2 to 5

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Dhillon et al. 2006[496]	NR	NR	NR	Stereotactic	Prone	Mammotome 11G	Mean: 12 Range: 6 to 18
Bolivar et al. 2005[497]	NR	NR	NR	US	Supine	Automated gun 14G	Mean: 3.5 cores Range: 1 to 7
Crystal et al. 2005[498]	NR	NR	NR	US	NR	Biopty automated gun 14G	Median: 4 cores Range: 1 to 8
Dillon et al. 2005[499]	NR	NR	NR	US or stereotactic guidance or freehand	Supine or seated	Automated 14G or 16G needles	NR
Koskela et al. 2005[500]	5	Radiologists	4 to 6 years of experience	Stereotactic	Seated	Biopty automated gun 14G	Mean: 7 cores Range: 4 to 15
Sauer et al. 2005[501]	3	NR	Undergone dedicated training in the biopsy method	US	NR	Biopty automated gun 14G	Mean: 2
Weber et al. 2005[502]	NR	Surgeons	5 month training period with the device before the study commenced	Stereotactic	Prone	Mammotome 11G	NR
Wu et al. 2005[503]	1	Surgeons	Reported to be “skilled”	US	NR	Mammotome 11G	NR
Alonso-Bartolome et al. 2004[504]	NR	NR	NR	US	Supine	NR	NR
Delle and Terinde 2004[505]	NR	NR	NR	US	NR	Automated gun	Median: 2 Range: 1 to 4
Fajardo et al. 2004[506]	NR	Radiologists	Radiologists at each participating site performed at least 50 procedures before enrolling patients into the trial	Stereotactic	NR	14G needle	Minimum: 5
Kettritz et al. 2004[507]	NR	Radiologists	NR	Stereotactic	Prone	Mammotome 11G	At least 20 or remove entire lesion
Lomoschitz et al. 2004[508]	4	Radiologists	Two were highly experienced with the procedure, two were not	Stereotactic	Prone	Mammotome 11G	20
Abdsaleh et al. 2003[509]	1	Radiologists	NR	Stereotactic or US	NR	Semi-automated 14G	NR
Ambrogetti et al. 2003[510]	1	NR	NR	Stereotactic	Prone	NR	Mean: 10.2 Range: 4 to 25

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Fishman et al. 2003[511]	1	Radiologists	Person performing procedure was a resident supervised by an attending radiologist	US	NR	Bard automated gun 14G	5
Han et al. 2003[512]	2	Radiologists	NR	Stereotactic	Prone	Biopty automated gun 14G	Mean: 7 Range: 5 to 20
Kirshenbaum et al. 2003[513]	3	Radiologists	NR	Stereotactic	72% seated	Bard automated gun 14G or Mammotome 11G	Bard gun Mean: 5.9 Range: 1 to 11 Mammotome Mean: 5.1 Range: 4 to 8
March et al. 2003[514]	3	Radiologists	Reports the procedure is not their usual practice	US	NR	Mammotome 11G	Mean: 29 Range: 10 to 70
Pfleiderer et al. 2003[515]	NR	NR	NR	MRI	Prone	Magnum automated gun 14G	Range: 3 to 6
Philpotts et al. 2003[516]	More than 5	Radiologists	Majority of the procedures appear to have been performed by fellows and residents under the supervision of 5 experienced breast radiologists	US	Supine	US Biopty automated gun 14G or Mammotome 11G	Biopty Mean: 4.7 Range: 1 to 17 Mammotome Mean: 5.8 Range: 1 to 12
Wong and Hisham 2003[517]	NR	NR	NR	Freehand	NR	Bard automated gun 14 or 16G	NR
Apesteguia et al. 2002[518]	NR	Radiologists	NR	Stereotactic	Prone	Mammotome 11G	Mean: 10.7 Range: 1 to 26
Georgian-Smith et al. 2002[519]	NR	Radiologists	NR	Stereotactic	Most seated	Mammotome 11G	Mean: 9.5 Range: 5 to 26
Jackman and Lamm 2002[520]	NR	Radiologists	NR	Stereotactic	Prone	Biopty automated gun 14G or Mammotome 11G or 14G	Median 14 Range: 5 to 30

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Johnson et al. 2002[521]	NR	NR	No experience at the beginning of the study	US	Supine	Mammotome 11G or 8G	Attempt to completely remove lesion
Liberman et al. 2002[522]	NR	NR	NR	Stereotactic	Prone	Mammotome 11G	Median: 15 Range: 4 to 47
Meloni et al. 2002[523]	NR	NR	NR	Stereotactic	Seated	Vacuum-assisted	Mean: 12 Range: 3 to 14
Morris et al. 2002[524]	NR	NR	NR	Stereotactic	Prone	Mammotome 14G	NR
Pfarl et al. 2002[525]	More than 7	Radiologists	7 had an average of 2.6 (Range: 0 to 18) procedures before the study commenced; non specified number of residents in training had no experience before the study commenced	Stereotactic	Prone	Mammotome 11G	15 to 20
Verkooijen et al. COBRA 2002[526]	More than 5	Radiologists	radiologists first attended 10 biopsy procedures and subsequently they performed another 10 under the supervision of a radiologist with considerable experience	Stereotactic	Prone	Bard automated gun 14G	NR
Becker et al. 2001[527]	4	Radiologists	NR	Stereotactic	Seated	14G needle	NR
Brenner et al. 2001[528]	NR	NR	All took a two-day course	Stereotactic	Prone	Automated gun 14G	5 or more
Cangiarella et al. 2001[529]	NR	Radiologists	NR	Stereotactic	Prone	Mammotome 11G	Mean: 11 Range: 7 to 15

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Dahlstrom and Jain 2001[530]	NR	NR	NR	Stereotactic	NR	Biopty automated gun 14G	5
Lai et al. 2001[531]	NR	NR	NR	Stereotactic	Prone	Mammotome 11G	Mean: 17.2
Levin et al. 2001[532]	3	Radiologists	2 of 3 radiologists had prior training in stereotactic core biopsy and attended a two-day course on use of the add-on unit; these two taught the third radiologist	Stereotactic	Seated	BIP automated gun 14G	5
Margolin et al. 2001[533]	3	Radiologists	NR	Stereotactic or US	Prone	Automated 14G, 16G, or 18G gun or Mammotome 11G or 14G	NR
Perez-Fuentes et al. 2001[534]	NR	NR	NR	US	Supine	Mammotome 11G	Median: 17 Range: 8 to 40
Smith et al. 2001[535]	NR	NR	NR	US	NR	Automated 14G gun	NR
White et al. 2001[536]	NR	Radiologists	NR	Stereotactic or US	Prone or supine	Automated 14G gun or Mammotome 11G or 14G	NR
Wunderbaldinger et al. 2001[537]	1	Radiologists	Performed 30 procedures on phantoms prior to the study	US	Seated	Magnum automated gun 14G	Mean: 6 Range: 3 to 10
Yeow et al. 2001[538]	1	Radiologists	NR	US	NR	Automated gun 14G or 16G	Mean: 3.4 Range: 1 to 7
Beck et al. 2000[539]	NR	NR	NR	Stereotactic	Prone	Mammotome 11G	NR
Kirwan et al. 2000[540]	NR	NR	NR	Stereotactic	Prone	Automated gun 14G	NR

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Latosinsky et al. 2000[541]	NR	NR	NR	Stereotactic or US	Prone for stereotactic	Automated gun or vacuum-assisted 14G	NR
Liberman et al. 2000[542]	NR	NR	NR	US or stereotactic	NR	Automated 14G gun	Median: 4 Range: 1 to 7
Makoske et al. 2000[543]	More than 1	Radiologists and surgeons	No experience in the procedure at the beginning of study; they were, however, trained and credentialed.	Stereotactic	NR	Automated gun or Mammotome	Minimum: 5
Ward et al. 2000[544]	2	Radiologists	Radiologists described as “specialize in breast imaging and diagnosis”	Stereotactic	NR	Bard automated gun 14G or 16G	Mean: 11 Range: 4 to 18
Welle et al. 2000[545]	NR	NR	NR	Stereotactic	Most decubitus	Bard automated gun 14G or Mammotome 11G	3 to 16
Helbich et al. 1999[546]	1	Radiologists	NR	Stereotactic	Seated	Patients randomized to various automated biopsy guns with different needle G	NR
Jackman et al. 1999[547]	NR	NR	NR	Stereotactic	Prone	Biopty automated gun 14G	Mean: 8.1 Range: 2 to 20
Meyer et al. 1999[548]	NR	NR	NR	Stereotactic	Prone	Automated gun 14G or Mammotome 11G or 14G	Mean: 5 to 8
Puglisi et al. 1999[549]	NR	NR	NR	Perforated compression grid	NR	Automated gun 14G	Median: 5
Soo et al. 1999[550]	4	Radiologists	NR	Stereotactic	Prone	Magnum automated gun 14G or Mammotome 14G	Automated gun Mean: 5.8 Mammotome Mean: 15.8
Caruso et al. 1998[551]	1	Surgeons	Reports “experienced surgeon”	Freehand	NR	Trucut 18G	NR

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Doyle et al. 1998[552]	NR	NR	No experience with the procedure at the beginning of the study	Stereotactic	Decubitus	Pro-Mag automated gun 14G	NR
Fuhrman et al. 1998[553]	3	Radiologists	Reports "radiologists with expertise in breast imaging"	Stereotactic or US	Stereotactic prone, US supine	Automated gun 14G	At least 5
Heywang-Kobrunner et al. 1998[554]	NR	NR	NR	Stereotactic	Prone	Mammotome 11G or 14G	NR
Ioffe et al. 1998[555]	NR	NR	NR	Stereotactic or US	NR	Bard automated gun 14G	At least 5
Liberman et al. 1998[556]	NR	NR	NR	US	Supine	Pro-Mag automated gun 14G	Median: 4 Range: 2 to 7
Schulz-Wendtland et al. 1998[557]	NR	NR	NR	US	NR	14G needle	1 to 3
Vega-Bolivar et al. 1998[558]	1	Radiologists	NR	Stereotactic	NR	Surecut 15G	At least 2
Whitman et al. 1998[559]	NR	NR	NR	Stereotactic	NR	Monopty 16G	NR
Zannis and AliaNo 1998[560]	1	Surgeons	NR	Stereotactic	Prone	Trucut 14G or Mammotome 14G or 11G	Trucut Mean: 4.8 cores Range: 1 to 7 Mammotome at least 16
Bauer et al. 1997[561]	NR	NR	NR	Stereotactic	Prone or seated	BIP automated gun 14G	Mean: 9 Range: 1 to 13
Britton et al. 1997[562]	4	Radiologists	NR	Stereotactic or US	Supine for US	Automated gun 14, 16, or 18G	Mean: 5

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Helbich et al. 1997[563]	1	Radiologists	Described as an "expert"	Stereotactic or US	Prone or supine or seated	Automated gun 14G	NR
Khattar et al. 1997[564]	NR	Surgeons	NR	US	Supine	Pro-Mag automated gun	2 or 3
Liberman et al. 1997[565]	NR	NR	NR	Stereotactic	Prone	Biopty-cut 14G	Mean: 6 Range: 1 to 22
Pitre et al. 1997[566]	NR	NR	NR	Stereotactic	Prone	Pro-Mag automated gun	Mean: 5
Stolier et al. 1997[567]	1	Surgeons	No experience in the procedure at the beginning of study	Stereotactic	Prone	Automated gun 14G or Mammotome	Minimum: 5
Sutton, et al. 1997[568]	5	Radiologists	All involved radiologists have experience in mammography and interventional techniques in breast disease diagnosis	Stereotactic	Prone	Biopty automated gun 14G	NR
Walker et al. 1997[569]	NR	NR	NR	Stereotactic	NR	Automated gun 14G	Minimum: 5
Frazee et al. 1996[570]	NR	Radiologists	NR	Stereotactic	Prone	NR	Minimum: 5
Fuhrman et al. 1996[571]	NR	NR	NR	Stereotactic	Prone	Automated gun 14G	Minimum: 5
Head and Haynes 1996[572]	NR	NR	NR	Stereotactic	Prone	Biopty automated gun 18G	NR
Mainiero et al. 1996[573]	NR	NR	NR	Stereotactic	Prone	Biopty automated gun 14G	NR
Meyer et al. 1996[574]	NR	Radiologists	NR	Stereotactic	Prone	Biopty automated gun 14G	NR

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Nguyen et al. 1996[575]	NR	NR	NR	Stereotactic or US	Prone	Automated gun 14G	5 to 10
Pettine et al. 1996[576]	NR	NR	NR	Stereotactic	Prone	Biopty automated 14G gun	5 to 9
Rosenblatt et al. 1996[577]	NR	NR	NR	Stereotactic	Prone	Biopty automated gun 14G	NR
Scopa et al. 1996[578]	NR	NR	NR	Freehand	NR	TruCut	NR
Cross et al. 1995[579]	NR	NR	NR	Stereotactic	Prone	Bard automated gun 14G	Mean: 3.4 Range: 1 to 8
Doyle et al. 1995[580]	NR	NR	NR	Stereotactic or US	Prone	Automated gun 14G or 15G	NR
Hamed et al. 1995[581]	NR	NR	NR	Freehand	NR	Biopty automated gun 14G or 18G	Mean: 3
Burbank et al. 1994[582]	NR	NR	NR	Stereotactic or US	NR	NR	NR
Gisvold et al. 1994[583]	7	Radiologists	All attended a training session before performing any procedures	Stereotactic	Prone	Biopty automated gun 14G	Minimum: 5
Parker et al. 1994[584]	NR	Radiologists	The radiologists participated in a two-day training session before the study commenced	Freehand	NR	Biopty automated gun 14G	NR
Smyth and Cederbom 1994[585]	NR	NR	NR	Stereotactic	Prone	Automated gun	NR
Elvecrog et al. 1993[586]	2	Radiologists	NR	Stereotactic	Prone	Biopty automated gun 14G	Minimum: 5

Table E9. Details of the core-needle biopsies performed in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Different People Performing Biopsies	Training of Persons Performing Biopsies	Experience of Persons Performing Biopsies	Method of Imaging Guidance	Patient Position	Biopsy Device	Number of Cores
Parker et al. 1993[587]	NR	Radiologists	NR	US	Supine	Biopty automated gun 14G	4 to 5
McMahon et al. 1992[588]	More than 8	Surgeons	NR	Freehand	NR	Various 14 to 18G devices	1
Barreto et al. 1991[589]	NR	NR	No experience at the beginning of the study	Freehand	NR	Biopty automated gun 18G	1
Cusick et al. 1990[590]	NR	NR	NR	Freehand	NR	NR	NR
Parker et al. 1990[591]	4	Radiologists	NR	Stereotactic	NR	Biopty automated gun 14, 16, or 18G	NR

NR = Not Reported

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Jackman et al. 2009[485]	Consecutive patients referred for core-needle biopsy between March 1995 through December 2001	Weighed more than 300 lbs; had bleeding diathesis; use of anti-coagulants that could not be discontinued (but no patients had these conditions during the study period).
Peters et al. 2008[486]	All patients with nonpalpable lesions referred for core-needle biopsy between February 2000 and June 2002	Coagulopathies or the use of anti-coagulants that could not be discontinued and an inability to stay in the prone position for one hour
Schueller et al. 2008[487]	All patients referred to the center for core-needle biopsy between January 1995 and February 2004	Patients unable to cooperate with the procedure or had a bleeding diathesis
Sim and Kei et al. 2008[488]	All patients with microcalcifications referred for core-needle biopsy between November 2002 and August 2005	NR
Tonegutti and Girardi 2008[489]	Women with suspicious nonpalpable mammographic lesions (microcalcifications, mass with or without microcalcifications, architectural distortion) not recognisable by ultrasound	NR
Youk et al. 2008[24]	All patients undergoing US-guided core-needle biopsy between February 2000 and June 2005	NR
Ciatto et al. 2007[490]	All consecutive core-needle biopsies performed at the study center between January 1996 and March 2005	NR
de Lucena et al. 2007[491]	NR	NR
Uematsu et al. 2007[492]	Consecutive patients with mammographically-detected microcalcifications BIRADS 3, 4, or 5 whose lesions were not visible on US	Unable to provide consent or undergo MRI imaging due to pacemaker, claustrophobia, or metallic clip; blood coagulation disorder; currently being treated with anti-coagulants; unable to cooperate with the biopsy procedure
Vag et al. 2007[493]	NR	NR
Chapellier et al. 2006[494]	Core-needle biopsies performed between January 2001 to November 2002	NR
Cipolla et al. 2006[495]	Consecutive patients undergoing core-needle biopsy at the center between September 1999 to February 2004	NR
Dhillon et al. 2006[496]	The first 150 consecutive patients who met these criteria: all indeterminate calcifications; distortions or masses not seen on US; a non-diagnostic biopsy on US; problem cases referred from other units	NR
Bolivar et al. 2005[497]	All patients with suspicious non-palpable breast lumps who underwent US-guided biopsy between August 1997 to April 2001	NR
Crystal et al. 2005[498]	Patients with US visible solid breast lesions referred for biopsy between October 1, 1998 and September 1, 2001	Lesions that appeared to be radial scars were excluded
Dillon et al. 2005[499]	All women who underwent biopsy at the center between January 1999 to September 2003	NR
Koskela et al. 2005[500]	Between June 1998 and January 2001, all patients with lesions not visible on US who were scheduled for core-needle stereotactic biopsy	Lesions located too high or too close to the chest wall such that it could not be reached by the stereotactic equipment
Sauer et al. 2005[501]	All patients undergoing US biopsy of lesions detected on routine screening over a 28 month period	NR

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Weber et al. 2005[502]	All patients between October 1999 to August 2003 with mammographically suspicious but nonpalpable lesions	Breast too small, lesion too close to the chest wall, lesion not evident on image
Wu et al. 2005[503]	Patients suspected of having benign lesions who underwent vacuum-assisted biopsy between July 2000 and July 2003	NR
Alonso-Bartolome et al. 2004[504]	Patients with "probably benign" lesions	NR
Delle and Terinde 2004[505]	Patients referred to the clinic because of palpable or non-palpable lesions or because of suspicion of cancer on mammography between September 2000 and September 2001	NR
Fajardo et al. 2004[506]	NR	Lesions located in prior lumpectomy or radiation therapy site, known bleeding disorder or anticoagulant therapy, pregnancy, allergy to local anesthesia, breast implants, psychiatric or neurologic conditions limiting patient's ability to cooperate during biopsy and/or provide informed consent
Kettritz et al. 2004[507]	NR	NR
Lomoschitz et al. 2004[508]	Consecutive women with solitary non-palpable lesions referred for 11G mammotome between February 1999 and July 2000, consecutive until 50 women with mammographic masses and 50 women with microcalcifications were enrolled	NR
Abdsaleh et al. 2003[509]	Consecutive patients between August 2000 and December 2001	NR
Ambrogetti et al. 2003[510]	Consecutive nonpalpable isolated microcalcifications detected in routine screening considered suspicious enough to warrant investigation between February 1999 and June 2002	NR
Fishman et al. 2003[511]	Consecutive patients referred for an US-guided biopsy over a 7-month period	Lesion turned out to be a cyst, pathological material was lost in one case, and in two cases ad hoc exclusion because the pathologist involved in the study had come to a different diagnosis than the "routine" pathology reading
Han et al. 2003[512]	Nonpalpable calcifications referred between April 1997- March 2002	NR
Kirshenbaum et al. 2003[513]	All patients undergoing stereotactic core-needle biopsy between October 1994 and February 2001 with nonpalpable lesions.	NR
March et al. 2003[514]	Patients referred to two outpatient centers between August 2000 and October 2001 for US-guided biopsy of a single breast lesion well-visualized on US and located at least 0.5 cm from the skin and pectoralis margin and at least 2 cm from the nipple with the lesion measuring 1.2 cm or less in diameter	Lesion turned out to be a cyst
Pfleiderer et al. 2003[515]	Women were invited after an MRI exam that found lesions with suspicious contrast enhancement, reasons why they had the MRI exam not reported	Pregnancy or lactation, coagulation abnormalities, allergies to local anesthetics or MRI contrast agents, compressed breast thickness less than 25 mm
Philpotts et al. 2003[516]	All patients who underwent US-guided biopsy between January 1997 and August 2001	NR
Wong and Hisham 2003[517]	Consecutive biopsies of palpable breast lesions from May 2000 to May 2001	Nonpalpable lesion, less than 6 months followup

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Apesteguia et al. 2002[518]	All cases detected between April and December 1999 with suspicious non-palpable lesion which could not be reliably detected by US	NR
Georgian-Smith et al. 2002[519]	Consecutive patients between June 1999 and August 2000	NR
Jackman and Lamm 2002[520]	All patients who underwent core-needle biopsy between July 1991 and December 1999 who had breast implants	NR
Johnson et al. 2002[521]	All patients with probably benign lesions scheduled for US-guided mammotome excisional attempt between April 2000 to January 2002	NR
Liberman et al. 2002[522]	Consecutive lesions undergoing stereotactic biopsy between October 31, 1996 to March 8, 2001. Indications for biopsy were nonpalpable lesions suspicious of malignancy, calcifications or masses 0.5 cm or less or masses that could not be viewed on US	Bleeding diathesis, patient unable to cooperate, lesion could not be targeted
Meloni et al. 2002[523]	All cases of non-palpable mammographically detected lesions undergoing vacuum-assisted core-needle biopsy at the center between December 1999 and November 2000	NR
Morris et al. 2002[524]	Twenty-one nonpalpable masses seen on mammography in 19 women who gave informed consent.The masses on mammography had no associated calcifications and were classified as either BI-RADS 4 (n = 17) or 5 (n = 4) lesions.	NR
Pfarl et al. 2002[525]	All patients undergoing 11G Mammotome biopsy from September 1997 to December 2001	Unable to cooperate with the procedure, had a bleeding diathesis
Verkooijen et al. COBRA 2002[526]	Nonpalpable breast lesions requiring histologic exam enrolled in 19 Dutch hospitals	Coagulotherapies or use of anticoagulants that could not be discontinued, inability to maintain prone position for one hour, inability to comprehend study protocol
Becker et al. 2001[527]	Biopsies performed for microcalcifications at the center between November 1993 and January 1997	NR
Brenner et al. 2001[528]	NR	NR
Cangiarella et al. 2001[529]	Patients with indeterminate microcalcifications that had been detected by routine screening and had no evidence of a mammographic density or mass biopsied between January 1997 and December 1997	NR
Dahlstrom and Jain 2001[530]	Women with suspicious calcifications detected on routine screening between July 1993 and August 1998	NR
Lai et al. 2001[531]	Consecutive patients who underwent biopsy between September 1997 and March 2000	NR
Levin et al. 2001[532]	Women with a single non-palpable lesion detected during a routine mammography and scheduled for a lumpectomy. Spiculated lesions, indeterminate nodules, indeterminate calcifications, and localized asymmetric density were eligible.	Palpable lesion, radial scar, bleeding diathesis, lesion not well visualized, in a difficult location
Margolin et al. 2001[533]	All patients who underwent core biopsy between January 1994 and December 1998	NR

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Perez-Fuentes et al. 2001[534]	All patients who underwent US-guided vacuum-assisted core needle biopsies at the center between August 1998 to December 2000. Criteria for deciding who got this type of core biopsy rather than another type seemed vague and inconsistently applied. Listed below: palpable or nonpalpable masses that could be seen with US and that were suspicious or highly suggestive of malignancy. Also used for occasional lesions that appeared to probably be benign. Selectively used for solid lesions that were suspicious and measured 2 cm or less. Solid lesions that were suggestive of malignancy and measured 1 cm or less. Complex lesions, intraductal lesions, subtle lesions, cysts with mural thickening, intramural nodules, or thick septations regardless of size; lesions suspected of being radial scars or papillomas; other lesions; occasional probably benign lesions 2 cm or less.	Bleeding diathesis or unable to cooperate with the procedure.
Smith et al. 2001[535]	Betweeen August 1991 and February 1998, women referred for US-guided biopsy because of non-calcificied US visible masses	NR
White et al. 2001[536]	All patients who had image-guided core-needle biopsy at the center between August 1992 and February 1999	NR
Wunderbaldinger et al. 2001[537]	Patients scheduled to undergo open biopsy for non-palpable breast lesions	NR
Yeow et al. 2001[538]	Consecutive patients referred for needle biopsy January 1995 to October 1997 with palpable breast masses	Lesion was identified as a cyst
Beck et al. 2000[539]	Until April 1999 patients with indeterminate lesions who were sent for biopsy	NR
Kirwan et al. 2000[540]	Women with mammographically-detected stellate lesions with or without microcalcifications	NR
Latosinsky et al. 2000[541]	Between November 1994 to May 1998, all patients who underwent core biopsy	NR
Liberman et al. 2000[542]	Patients with palpable lesions who underwent core-needle biopsy betweeen August 1992 and May 1998	NR
Makoske et al. 2000[543]	All eligible patients from 1993 through 1998, those with nonpalpable lesions found on mammography who were sent for biopsy	NR
Ward et al. 2000[544]	Patients with indeterminate microcalcifications sent for core biopsy between November 1993 and January 1997	Cases with associated mass, distortion, or palpable lesion were excluded
Welle et al. 2000[545]	Patients with stereotactic core-needle biopies performed between September 1995 trhough March 1999	NR
Helbich et al. 1999[546]	NR	NR
Jackman et al. 1999[547]	Consecutive patients with nonpalpable lesions who had stereotactic core-needle biopsy between July 1991 and December 1993	NR
Meyer et al. 1999[548]	Patients seen between August 1991 and December 31, 1997 for suspicious nonpalpable breast abnormalities	NR
Puglisi et al. 1999[549]	Consecutive patients seen from July 1992-December 1997	US-guided procedures

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Soo et al. 1999[550]	Patients with noncalcified, nonpalpable, mammographically-detected lesions referred for biopsy between October 1995 and August 1997	NR
Caruso et al. 1998[551]	From 1990 to 1995, a consecutive series of 91 patients	NR
Doyle et al. 1998[552]	Patients who underwent stereotactic core-needle biopsy between September 1994 and March 1998	NR
Fuhrman et al. 1998[553]	All nonpalpable breast lesions from July 1993-February 1997 that underwent image-guided core needle breast biopsy.	Palpable masses, lesions not clearly visualized in the stereotactic unit (usually lesions deep in the breast along the chest wall), lesions found in small breasts which compress to <2 cm in the stereotactic unit, asymmetric dense breast tissue, unable to tolerate the prone position for 30 minutes.
Heywang-Kobrunner et al. 1998[554]	Patients referred for biopsy up to March 1997	NR
Ioffe et al. 1998[555]	Consecutive core-needle biopsies between July 1995 and January 1997	NR
Liberman et al. 1998[556]	Patients with a solitary, nonpalpable mass who underwent US-guided biopsy between May 1993 and June 1997	The parenchyma was too thin to support the excursion of the needle, a hemorrhagic diathesis, unable to cooperate, or the lesion was less than 5 mm
Schulz-Wendtland et al. 1998[557]	Patients who underwent US-guided biopsies between May 1992 and April 1993	NR
Vega-Bolivar et al. 1998[558]	Patients seen between October 1993-October 1996 for nonpalpable breast lesions	NR
Whitman et al. 1998[559]	Mammographically-guided coaxial core-needle biopsy procedures performed with a fenestrated alphanumeric compression device between 1995-1997	NR
Zannis and AliaNo 1998[560]	Consecutive records of patients undergoing a stereotactic procedure and biopsy by the same surgeon for a non-palpable, mammographically-detected lesion between January 1993 and August 1997	NR
Bauer et al. 1997[561]	Mammographically-detected breast lesions considered worrisome enough to require biopsy, such as clustered microcalcifications, a spiculated mass, or an area of architectural distortion during the 30 months from July 1, 1993 to January 1, 1996.	NR
Britton et al. 1997[562]	All patients after April 1994 who were recalled for core-needle biopsy after routine mammographic screening	NR
Helbich et al. 1997[563]	Consecutive patients with solid breast lesions over 20 months	NR
Khattar et al. 1997[564]	Between February 1993 and March 1995, patients over 18 years of age with a palpable mass scheduled for surgical excision	Lesion was revealed to be a simple cyst on US

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Liberman et al. 1997[565]	Patients who underwent stereotactic core biopsy between August 7, 1992 and December 14, 1995	Thickness of compressed breast was inadequate to accommodate the needle; the lesion measured less than 5 mm in diameter; the lesion could not be targeted accurately; the patient had a bleeding diathesis; the patient was on anticoagulants; the patient was unable to cooperate with the procedure.
Pitre et al. 1997[566]	Patients who had stereotactic core-needle biopsy for a nonpalpable unicentric mammographically-detected breast lesion between January 1994 and February 1995	NR
Stolier et al. 1997[567]	All patients who underwent core-needle biopsy at the center by the study author from August 1993 through May 1996	NR
Sutton, et al. 1997[568]	Women who elected to have stereotactic-guided large-gauge core biopsy between July 1993 and June 1995 after detection of suspicious non-palpable abnormalities at a mammographic screening clinic	Initially, women with abnormalities considered to be obviously malignant were excluded from the series (from July to December 1993) but after the first 70 patients, these highly suspicious lesions were offered core biopsy
Walker et al. 1997[569]	All patients who had stereotactic core-needle for a nonpalpable lesion since 1993	NR
Frazee et al. 1996[570]	Patients with nonpalpable mammographic abnormality between July 1994 to June 1995	NR
Fuhrman et al. 1996[571]	All non-palpable suspicious masses and calcifications noted on mammography from July 1993 - January 1995	Lesions not clearly visualized in the stereotactic unit, usually lesions deep within the breast along the chest wall, lesions found in small breasts which compress to less than 2cm in the stereotactic unit, asymmetric dense breast tissue, and patients unable to tolerate the prone position for 30 minutes
Head and Haynes 1996[572]	Patients with nonpalpable breast lesions discovered during routine mammography	NR
Mainiero et al. 1996[573]	Patients with microcalcifications were considered indeterminate or suspicious for malignancy	Lesions in which calcifications were within a mass or an area of architectural distortion
Meyer et al. 1996[574]	Clinically occult suspicious mammographic abnormalities. The mass must be at least 6mm in diameter and be clearly visible on mammography	NR
Nguyen et al. 1996[575]	All core-needle biopsies performed between December 1992 and June 1995	NR
Pettine et al. 1996[576]	Patients with nonpalable lesions discovered on mammogram followed immediately by wire localized biopsy	NR
Rosenblatt et al. 1996[577]	All patients who underwent biopsy of multiple unilateral lesions between January 1994 and September 1995	NR
Scopa et al. 1996[578]	Patients undergoing Tru-Cut biopsies who had not been previously investigated with fine-needle aspiration	NR
Cross et al. 1995[579]	Patients who were referred to the center for stereotactic biopsy of a nonpalpable mammographic abnormality	NR.

Table E10. Patient inclusion/exclusion criteria for studies addressing Key Questions 1 and 2 (continued)

Study	Patient Inclusion Criteria	Patient Exclusion Criteria
Doyle et al. 1995[580]	Mammographically-detected impalpable breast lesions, completely well-circumscribed masses less than 8mm in diameter with smooth borders. Opacities containing fat or with concave margins, clusters or uniform tiny rounded calcifications, scattered calcifications, and scattered nodules. Lesions considered strongly suggestive of cancer included new spiculated masses, new clustered pleomorphic calcifications, or both.	Inability to provide informed consent and irreversible bleeding diathesis
Hamed et al. 1995[581]	Female patients with clinically suspected breast carcinoma	Patients with locally advanced breast carcinoma
Burbank et al. 1994[582]	NR	Patients who underwent bone biopsies
Gisvold et al. 1994[583]	All patients referred for wire-localized open surgery between October 19, 1991 and January 15, 1993 were considered for the study. The inclusion criteria are: If it appeared the lesion and patient were suitable (patient could lie prone for an hour, no bleeding problems, and no allergy to local anesthesia; lesions thought to be visualizable and were not too superficial or close to the nipple).	Equipment or radiologist not available, lesion visualizable only on US
Parker et al. 1994[584]	Core-needle biopsies performed at sites at which the radiologists and assisting technologists had undergone dedicated training in larger core breast biopsy and had followed a standard protocol	NR
Smyth and Cederbom 1994[585]	Patients with mammographically suspicious non palpable lesions	NR
Elvecrog et al. 1993[586]	Patients with single non-palpable mammographic lesion; study restricted to patients who would have undergone open biopsy if core biopsy wasn't available	Lesions less than 5 mm in diameter
Parker et al. 1993[587]	Consecutive patients with solid or indeterminate breast lesions visualized by US between August 1989 and July 1991	NR
McMahon et al. 1992[588]	Consecutive patients with palpable breast lumps between September 1989 and August 1991	NR
Barreto et al. 1991[589]	Symptomatic patients with palpable breast lumps suspected of having early breast cancer who were scheduled for open surgical excision	NR
Cusick et al. 1990[590]	Patients with suggestive mammary lumps seen at the surgery clinic of San Bernardino County Medical Center	NR
Parker et al. 1990[591]	During a 13-month period, consecutive patients who underwent stereotactic-needle core breast biopsies	NR

NR = Not Reported

Table E11. Characteristics of patients enrolled in studies addressing Key Questions 1 and 2

Study	Number of Patients Recruited for Enrollment	Number of Patients Enrolled	Number of Lesions Enrolled	Age	Age Dispersion	Ethnicity
Jackman et al. 2009[485]	1,152	1,152	1,280	NR	NR	NR
Peters et al. 2008[486]	955	948	948	NR	NR	NR
Schueller et al. 2008[487]	1390	1390	1438	Median: 51	Range: 15 to 93	NR
Sim and Kei et al. 2008[488]	106	97	105	Mean: 53.2	Range: 36 to 81	Asian: 100%
Tonegutti and Girardi 2008[489]	268	268	268	Mean: 52	Range: 22-79	NR
Youk et al. 2008[24]	4,359	4,359	4,359	Median: 45 Mean: 45.3	Range: 12 to 88	NR
Ciatto et al. 2007[490]	4,035	4,035	4,035	NR	NR	NR
de Lucena et al. 2007[491]	NR	144	150	Mean: 50	Range: 15 to 89 Standard deviation: 16	NR
Uematsu et al. 2007[492]	NR	96	100	Mean: 49.4	Range: 28 to 85	NR
Vag et al. 2007[493]	NR	65	70	Median: 57	Range: 31 to 82	NR
Chapellier et al. 2006[494]	NR	301	318	Mean: 56	Range: 35 to 78, 64% postmenopausal	NR
Cipolla et al. 2006[495]	426	426	426	64% post-menopausal	NR	NR
Dhillon et al. 2006[496]	150	150	150	Median: 56	Range: 37 to 77	NR
Bolivar et al. 2005[497]	208	208	214	Mean: 55	Range: 32 to 87	NR
Crystal et al. 2005[498]	652	652	715	NR	NR	NR
Dillon et al. 2005[499]	2,427 (lesions)	NR	2,427	NR	NR	NR
Koskela et al. 2005[500]	212	205	213	Mean: 56	Range: 32 to 88	NR
Sauer et al. 2005[501]	906	906	962	NR	NR	NR
Weber et al. 2005[502]	239	225	225	Median: 56.1	Range: 30 to 84	NR
Wu et al. 2005[503]	113	113	113	Median: 31	Range: 18 to 35	NR
Alonso-Bartolome et al. 2004[504]	97	97	102	Mean: 42	Range: 18 to 77	NR
Delle and Terinde 2004[505]	146	146	169	NR	NR	NR

Table E11. Characteristics of patients enrolled in studies addressing Key Questions 1 and 2 (continued)

Study	Number of Patients Recruited for Enrollment	Number of Patients Enrolled	Number of Lesions Enrolled	Age	Age Dispersion	Ethnicity
Fajardo et al. 2004[506]	2,403	2,403	2,403	Mean: 54.6	Range: 25 to 89	% White European descent: 1,313 (78.1%) % Black African descent: 265 (15.8%) % Asian descent: 27 (1.6%) % Hispanic descent: 62 (3.7%) % other, please specify: 6 Native American (0.4%), 8 another race (0.5%)
Kettritz et al. 2004[507]	2,939	NR	2,893	NR	NR	NR
Lomoschitz et al. 2004[508]	100	100	100	Median: 55	Range: 31 to 81	NR
Abdsaleh et al. 2003[509]	180	180	180	NR	Range: 35 to 93	NR
Ambrogetti et al. 2003[510]	364	364	364	Mean: 54.9	Range: 33 to 81	NR
Fishman et al. 2003[511]	75	70	73	NR	NR	NR
Han et al. 2003[512]	284 (lesions)	267	271	Mean: 47 yrs	Range: 23 to 72	NR
Kirshenbaum et al. 2003[513]	492	492	506	Mean: 59.1	Range: 27 to 78	NR
March et al. 2003[514]	57	34	34	NR	NR	NR
Pfleiderer et al. 2003[515]	NR	14	14	Mean: 47.9	Standard deviation: 13.1	NR
Philpotts et al. 2003[516]	271	271	281	NR	NR	NR
Wong and Hisham 2003[517]	NR	145	150	NR	Range: 20 to 80	% Asian descent: 80% % other, please specify: 18% Indian 2% “other”
Apesteguia et al. 2002[518]	126	126	132	Mean: 50.5	Range: 29 to 81 Standard deviation: 10.2	NR
Georgian-Smith et al. 2002[519]	179	179	185	Mean: 54.6	Range: 35 to 85	NR
Jackman and Lamm 2002[520]	25	25	31	Median: 58	Range: 35 to 75	NR
Johnson et al. 2002[521]	81	81	101	Mean: 46.8	Range: 21 to 72	NR

Table E11. Characteristics of patients enrolled in studies addressing Key Questions 1 and 2 (continued)

Study	Number of Patients Recruited for Enrollment	Number of Patients Enrolled	Number of Lesions Enrolled	Age	Age Dispersion	Ethnicity
Liberman et al. 2002[522]	797	797	800	Median: 57	Range: 28 to 88	NR
Meloni et al. 2002[523]	138	129	129	NR	NR	NR
Morris et al. 2002[524]	NR	19	21	Mean: 57	Range: 36 to 75	NR
Pfarl et al. 2002[525]	332 (lesions)	325	332	Median: 56	Range: 28 to 83	NR
Verkooijen et al. COBRA 2002[526]	973	928	984	Mean: 58	Range: 29 to 85	NR
Becker et al. 2001[527]	218	218	232	Mean: 57.3	Range: 33 to 84	NR
Brenner et al. 2001[528]	NR	1003	1003	NR	NR	NR
Cangiarella et al. 2001[529]	142	142	160	Mean: 53.5	Range: 34 to 79	NR
Dahlstrom and Jain 2001[530]	266	discrepancy: study reports data for 301 core biopsies but states in methods that 266 women with 274 lesions were enrolled	310	NR	NR	NR
Lai et al. 2001[531]	650	650	673	Mean: 54.7	Range: 22 to 89 Standard deviation: 11.6	NR
Levin et al. 2001[532]	NR	70	70	NR	Range: 39 to 80	NR
Margolin et al. 2001[533]	1,183	1,183	1,333	Mean: split into three groups 55, 52, 40	Range: 17 to 93	NR
Perez-Fuentes et al. 2001[534]	88 (lesions)	83	88	Median: 48	Range: 25 to 78	NR
Smith et al. 2001[535]	446	446	500	Median: 46 Mean: 47	Range: 18 to 89	NR
White et al. 2001[536]	939	939	1042	Median: 60	Range: 32 to 85	NR
Wunderbaldinger et al. 2001[537]	NR	45	45	Mean: 50	Range: 20 to 77	NR
Yeow et al. 2001[538]	104	98	98	Mean: 46.5	Range: 23 to 85 Standard deviation: 12.3	NR
Beck et al. 2000[539]	560	560	594	NR	NR	NR
Kirwan et al. 2000[540]	NR	72	72	NR	NR	NR
Latosinsky et al. 2000[541]	607	607	692	NR	NR	NR

Table E11. Characteristics of patients enrolled in studies addressing Key Questions 1 and 2 (continued)

Study	Number of Patients Recruited for Enrollment	Number of Patients Enrolled	Number of Lesions Enrolled	Age	Age Dispersion	Ethnicity
Liberman et al. 2000[542]	155 (lesions)	NR	155	Median: 47	Range: 19 to 88	NR
Makoske et al. 2000[543]	817	817	887	NR	NR	NR
Ward et al. 2000[544]	161	NR	121	Mean: 58	Range: 33 to 83	NR
Welle et al. 2000[545]	NR	225	225	NR	NR	NR
Helbich et al. 1999[546]	NR	44	44	NR	Range: 20 to 77	NR
Jackman et al. 1999[547]	410	410	483	Median: 55	Range: 29 to 89	NR
Meyer et al. 1999[548]	NR	1,643	1,836	Mean: 50	Range: 20 to 85	NR
Puglisi et al. 1999[549]	NR	99	106	Median: 57	Range: 33 to 84	NR
Soo et al. 1999[550]	110	110	116	NR	NR	NR
Caruso et al. 1998[551]	NR	91	92	Median: 65	Range: 29 to 81	NR
Doyle et al. 1998[552]	151 (lesions)	NR	151	NR	NR	NR
Fuhrman et al. 1998[553]	1,440	1,440	1,440	NR	NR	NR
Heywang-Kobrunner et al. 1998[554]	238	238	261	NR	NR	NR
Ioffe et al. 1998[555]	NR	198	224	Mean: 51	Range: 14 to 87	NR
Liberman et al. 1998[556]	179	151	151	Median: 50	Range: 23 to 80	NR
Schulz-Wendtland et al. 1998[557]	307	307	2,307	NR	NR	NR
Vega-Bolivar et al. 1998[558]	180	180	182	Mean: 55	Range: 30 to 79	NR
Whitman et al. 1998[559]	11	11	12	Mean: 55	Range: 31 to 75, 8.3% older than age 65	NR
Zannis and AliaNo 1998[560]	372	372	424	Mean: 57.7	Range: 25 to 90	NR
Bauer et al. 1997[561]	799 (lesions)	NR	799	Mean: 61	Range: 38 to 87	NR
Britton et al. 1997[562]	202	202	202	NR	NR	NR
Helbich et al. 1997[563]	205	205	210	Mean: 52.2	Range: 23 to 88	NR
Khattar et al. 1997[564]	117	106	106	Median: 52	Range: 19 to 85	NR
Liberman et al. 1997[565]	NR	NR	442	NR	NR	NR
Pitre et al. 1997[566]	128	128	128	Mean: 56.4	NR	NR
Stolier et al. 1997[567]	242	242	244	NR	NR	NR
Sutton, et al. 1997[568]	200	200	206	Mean: 59	Range: 41 to 85	NR
Walker et al. 1997[569]	200	200	200	NR	Range: 35 to 86	NR

Table E11. Characteristics of patients enrolled in studies addressing Key Questions 1 and 2 (continued)

Study	Number of Patients Recruited for Enrollment	Number of Patients Enrolled	Number of Lesions Enrolled	Age	Age Dispersion	Ethnicity
Frazee et al. 1996[570]	103	103	103	Mean: 60	NR	NR
Fuhrman et al. 1996[571]	451 (lesions)	NR	451	NR	NR	NR
Head and Haynes 1996[572]	115	115	115	NR	NR	NR
Mainiero et al. 1996[573]	128	124	138	Mean: 56.2	Range: 30 to 87	NR
Meyer et al. 1996[574]	545 (lesions)	369	388	Median: 49 yrs Mean: 51 yrs	Range: 24 to 81	NR
Nguyen et al. 1996[575]	NR	408	431	NR	NR	NR
Pettine et al. 1996[576]	25	25	25	NR	NR	NR
Rosenblatt et al. 1996[577]	156	25	58	NR	NR	NR
Scopa et al. 1996[578]	109	109	120	Mean: 51.2	Range: 21 to 85	NR
Cross et al. 1995[579]	NR	225	250	Mean: 54	Range: 26 to 89	NR
Doyle et al. 1995[580]	366	365	365	Mean: 57 years	NR	NR
Hamed et al. 1995[581]	122	122	122	NR	NR	NR
Burbank et al. 1994[582]	105 (lesions)	NR	105	NR	NR	NR
Gisvold et al. 1994[583]	471	158	160	NR	NR	NR
Parker et al. 1994[584]	6,152 (lesions)	NR	6,152	NR	NR	NR
Smyth and Cederbom 1994[585]	52	52	58	Mean: 57	NR	NR
Elvecrog et al. 1993[586]	107	100	100	NR	NR	NR
Parker et al. 1993[587]	164	164	181	NR	NR	NR
McMahon et al. 1992[588]	151	152	151	Median: 57 Trucut 50 Bipopty 14G 56 Biopty 18G	Range: 24 to 87	NR
Barreto et al. 1991[589]	NR	107	107	Mean: 60.5 one group, 57.9 other group	SE 1.3 one group, 2.4 other group	NR
Cusick et al. 1990[590]	95	95	96	Mean: 52 years	Range: 24 to 78	NR
Parker et al. 1990[591]	103	103	103	NR	NR	NR
	Sum		**55,936**			

NR = Not Reported

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Jackman et al. 2009[485]	1,280	NR	NR	NR	NR	NR	NR	NR	NR	NR
Peters et al. 2008[486]	948	100%	948	NR	NR	NR	NR	NR	NR	NR
Schueller et al. 2008[487]	1438	100%	0	NR	NR	NR	Median: 17 mm Range: 5 to 55 mm	36.0%	50.6%	13.4%
Sim and Kei et al. 2008[488]	105	NR	NR	105	NR	NR	NR	0%	89%	1.9%
Tonegutti and Girardi 2008[489]	268	100%	268	186	36	18	67% were 10 mm or less	7%	40%	19%
Youk et al. 2008[24]	4,359	NR	NR	NR	NR	NR	NR	NR	NR	NR
Ciatto et al. 2007[490]	4,035	67%	2,714	1,887	NR	NR	NR	NR	NR	NR
de Lucena et al. 2007[491]	150	NR	NR	NR	NR	NR	44% were 2 cm or less 52% were 2 to 5 cm	NR	NR	NR
Uematsu et al. 2007[492]	100	NR	NR	100	NR	NR	NR	18%	27%	55%
Vag et al. 2007[493]	70	63%	44	NR	NR	NR	Median: 12 mm Range: 5 to 35 mm	15.70%	33%	51.40%
Chapellier et al. 2006[494]	318	NR	NR	288	30	NR	NR	11%	53.50%	34.90%
Cipolla et al. 2006[495]	426	71%	302	NR	NR	NR	NR	10.10%	10.60%	50.20%
Dhillon et al. 2006[496]	150	NR	NR	130	12	8	NR	NR	NR	NR

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Bolivar et al. 2005[497]	214	95%	204	9	152	34	53 lesions 1 to 10 mm 119 lesions 11 to 20 mm 32 lesions larger than 20 mm	NR	NR	NR
Crystal et al. 2005[498]	715	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dillon et al. 2005[499]	2,427	NR	NR	NR	NR	NR	NR	NR	NR	NR
Koskela et al. 2005[500]	213	NR	NR	108	NR	NR	NR	22.10%	56.80%	16.40%
Sauer et al. 2005[501]	962	75%	726	NR	NR	NR	Mean: 2.5 cm Range: 0.2 to 11 cm	NR	NR	NR
Weber et al. 2005[502]	225	100%	225	NR	NR	NR	NR	NR	NR	NR
Wu et al. 2005[503]	113	27%	30	NR	NR	NR	Median size: 1.4 cm Range: 0.5 to 2.0 cm	NR	NR	NR
Alonso-Bartolome et al. 2004[504]	102	61%	62	NR	NR	NR	Mean: 14.7 mm Range: 6-30 mm	NR	NR	100%
Delle and Terinde 2004[505]	169	NR	NR	NR	NR	NR	Mean 1.5 cm	NR	NR	NR
Fajardo et al. 2004[506]	2,403	70%	1,681	NR	NR	NR	NR	NR	NR	NR
Kettritz et al. 2004[507]	2,893	NR	NR	2,013	NR	61	1,677 were less than 10 mm, 809 were 11 to 20 mm, and 388 were larger	5.90%	84.30%	9.80%

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Lomoschitz et al. 2004[508]	100	100%	100	50	50	NR	NR	NR	NR	NR
Abdsaleh et al. 2003[509]	180	NR	NR	15	130	NR	6 to 80 mm	NR	NR	NR
Ambrogetti et al. 2003[510]	364	100%	364	326	NR	NR	NR	NR	NR	NR
Fishman et al. 2003[511]	73	78%	57	NR	NR	NR	Mean: 1.7 cm Range: 0.6 to 6 cm	NR	NR	NR
Han et al. 2003[512]	271	100%	271	228	NR	NR	NR	NR	NR	NR
Kirshenbaum et al. 2003[513]	506	100%	506	228	212	75	Mean: 0.8 cm Range: 0.3 to 2.3 cm	NR	NR	NR
March et al. 2003[514]	34	71%	24	3	NR	NR	Mean: 0.7 cm Range: 0.4 to 1.2 cm	NR	NR	NR
Pfleiderer et al. 2003[515]	14	NR	NR	NR	NR	NR	NR	28.60%	64.30%	NR
Philpotts et al. 2003[516]	281	NR	NR	NR	NR	NR	NR	NR	NR	NR
Wong and Hisham 2003[517]	150	0%	0	NR	NR	NR	NR	NR	NR	NR
Apesteguia et al. 2002[518]	132	100%	132	82	NR	24	NR	NR	NR	NR
Georgian-Smith et al. 2002[519]	185	NR	NR	159	16	5	NR	NR	NR	NR
Jackman and Lamm 2002[520]	31	97%	30	21	10	NR	NR	9.70%	90.30%	0%
Johnson et al. 2002[521]	101	27%	27	NR	NR	NR	Mean: 1.15 cm	NR	NR	NR

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Liberman et al. 2002[522]	800	100%	800	606	194	NR	Median: 0.8 cm Range: 0.2 to 10 cm	NR	NR	NR
Meloni et al. 2002[523]	129	100%	129	NR	NR	NR	NR	NR	NR	NR
Morris et al. 2002[524]	21	100%	21	NR	21	NR	Mean: 1.8 cm Range: 0.8 to 5.5 cm	NR	NR	NR
Pfarl et al. 2002[525]	332	NR	NR	166	152	NR	NR	NR	NR	NR
Verkooijen et al. COBRA 2002[526]	984	100%	984	533	310	26	NR	NR	NR	NR
Becker et al. 2001[527]	232	NR	NR	232	NR	NR	NR	NR	NR	NR
Brenner et al. 2001[528]	1,003	100%	1003	355	630	92	NR	11.10%	39.10%	35.70%
Cangiarella et al. 2001[529]	160	NR	NR	160	NR	NR	NR	NR	NR	NR
Dahlstrom and Jain 2001[530]	310	NR	NR	301	NR	NR	NR	NR	NR	NR
Lai et al. 2001[531]	673	NR	NR	NR	NR	NR	NR	NR	NR	NR
Levin et al. 2001[532]	70	100%	70	27	NR	NR	NR	NR	NR	NR
Margolin et al. 2001[533]	1,333	NR	NR	NR	NR	NR	NR	NR	94%	NR
Perez-Fuentes et al. 2001[534]	88	73%	64	NR	NR	NR	NR	9.10%	81.80%	8.00%
Smith et al. 2001[535]	500	95%	475	0	NR	NR	Mean: 15 mm Range: 4 to 60 mm	NR	NR	NR
White et al. 2001[536]	1,042	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Wunderbaldinger et al. 2001[537]	45	100%	45	4	41	NR	Mean: 18 mm Range: 8 to 41 mm	NR	NR	NR
Yeow et al. 2001[538]	98	0%	0	NR	NR	NR	Mean: 2.6 cm Range: 0.9 to 10 cm	NR	NR	NR
Beck et al. 2000[539]	594	NR	NR	NR	NR	NR	NR	16.50%	83.50%	NR
Kirwan et al. 2000[540]	72	NR	NR	NR	NR	NR	NR	NR	NR	NR
Latosinsky et al. 2000[541]	692	NR	NR	313	426	4	NR	NR	NR	NR
Liberman et al. 2000[542]	155	0%	0	NR	NR	NR	Median: 1.7 cm Range: 0.5 to 15 cm	NR	NR	NR
Makoske et al. 2000[543]	887	100%	887	NR	NR	NR	NR	NR	NR	NR
Ward et al. 2000[544]	121	100%	121	121	NR	NR	NR	NR	NR	NR
Welle et al. 2000[545]	225	NR	NR	90	135	NR	NR	NR	NR	NR
Helbich et al. 1999[546]	44	NR	NR	24	5	5	Mean 12.9 mm Range: 8 to 27 mm	NR	NR	NR
Jackman et al. 1999[547]	483	100%	483	234	249	NR	NR	NR	NR	NR
Meyer et al. 1999[548]	1,836	100%	1,836	643	1,194	NR	NR	NR	NR	NR
Puglisi et al. 1999[549]	106	75%	79	66	59	NR	NR	NR	NR	NR
Soo et al. 1999[550]	116	100%	116	0	NR	NR	NR	NR	NR	NR
Caruso et al. 1998[551]	92	0%	0	11	92	NR	NR	NR	NR	NR

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Doyle et al. 1998[552]	151	100%	151	88	71	5	NR	NR	NR	NR
Fuhrman et al. 1998[553]	1,440	100%	1,440	749	691	NR	NR	NR	NR	NR
Heywang-Kobrunner et al. 1998[554]	261	NR	NR	134	127	NR	NR	1.90%	10.00%	88.10%
Ioffe et al. 1998[555]	224	NR	NR	51	173	NR	NR	NR	NR	NR
Liberman et al. 1998[556]	151	100%	151	NR	NR	NR	NR	NR	NR	NR
Schulz-Wendtland et al. 1998[557]	2,307	NR	NR	NR	NR	NR	NR	NR	NR	NR
Vega-Bolivar et al. 1998[558]	182	100%	182	75	33	24	NR	NR	NR	NR
Whitman et al. 1998[559]	12	NR	NR	NR	NR	NR	NR	NR	NR	NR
Zannis and AliaNo 1998[560]	424	100%	424	NR	424	NR	NR	NR	NR	NR
Bauer et al. 1997[561]	799	NR	NR	NR	NR	NR	NR	NR	NR	NR
Britton et al. 1997[562]	202	NR	NR	NR	NR	NR	NR	NR	NR	NR
Helbich et al. 1997[563]	210	NR	NR	NR	NR	NR	Mean: 14 mm Range: 7 to 30 mm	NR	NR	NR
Khattar et al. 1997[564]	106	0%	0	NR	NR	NR	NR	NR	NR	NR
Liberman et al. 1997[565]	442	NR	NR	196	246	NR	NR	NR	NR	NR
Pitre et al. 1997[566]	128	100%	128	NR	NR	NR	NR	3.90%	NR	NR
Stolier et al. 1997[567]	244	NR	NR	65	173	4	NR	NR	NR	44.70%

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Sutton, et al. 1997[568]	206	100%	206	81	125	NR	Mean: 14 mm Range: 2 mm to 30 mm	NR	NR	NR
Walker et al. 1997[569]	200	100%	200	136	28	36	NR	NR	NR	NR
Frazee et al. 1996[570]	103	100%	103	NR	NR	NR	NR	NR	NR	NR
Fuhrman et al. 1996[571]	451	NR	NR	NR	NR	NR	NR	NR	NR	NR
Head and Haynes 1996[572]	115	100%	115	22	85	NR	NR	NR	NR	NR
Mainiero et al. 1996[573]	138	NR	NR	138	NR	NR	NR	NR	NR	NR
Meyer et al. 1996[574]	388	100%	388	NR	NR	NR	NR	NR	NR	NR
Nguyen et al. 1996[575]	431	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pettine et al. 1996[576]	25	100%	25	NR	NR	NR	NR	NR	NR	NR
Rosenblatt et al. 1996[577]	58	NR	NR	22	14	NR	Median: 1.5 cm Range: 0.8 to 3.0 cm	NR	NR	NR
Scopa et al. 1996[578]	120	NR	NR	NR	NR	NR	Range: 0.7 to 5 cm	NR	NR	NR
Cross et al. 1995[579]	250	100%	250	NR	NR	NR	NR	NR	NR	NR
Doyle et al. 1995[580]	365	62%	225	59	225		Larger than 5 mm	NR	NR	NR
Hamed et al. 1995[581]	122	NR	NR	NR	NR	NR	NR	NR	NR	NR
Burbank et al. 1994[582]	105	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gisvold et al. 1994[583]	160	NR	NR	NR	NR	NR	Range: 3 to 70 mm	NR	NR	NR

Table E12. Characteristics of the breast lesions in the studies addressing Key Questions 1 and 2 (continued)

Study	Number of Lesions Enrolled	% Non-palpable Lesions	Number of Non-palpable Lesions	Number of Microcalcifi-cations	Number with Mammo-graphic Masses	Number with Mammo-graphic Distortions	Lesion Size	BIRADS 5	BIRADS 4	BIRADS 3
Parker et al. 1994[584]	6,152	93%	5,702	1,637	4,515		NR	NR	NR	NR
Smyth and Cederbom 1994[585]	58	100%	58	NR	NR	NR	NR	NR	NR	NR
Elvecrog et al. 1993[586]	100	100%	100	26	100		NR	NR	NR	NR
Parker et al. 1993[587]	181	46%	84	NR	NR	NR	NR	NR	NR	NR
McMahon et al. 1992[588]	151	0%	0	NR	NR	NR	NR	NR	NR	NR
Barreto et al. 1991[589]	107	0%	0	NR	NR	NR	NR	NR	NR	NR
Cusick et al. 1990[590]	96	NR	NR	NR	NR	NR	NR	NR	NR	NR
Parker et al. 1990[591]	103	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sum	**55,936**		**25,760**	**13,303**	**11,186**	**421**				

NR = Not Reported

Table E13. Studies of the dissemination of cancerous cells during biopsy procedures

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Michalopoulos et al. 2008[33]	Prospective study. Patients underwent core-needle biopsy followed by open surgery 6-8 days later. The needle track was excised and examined by a pathologist.	21 with DCIS and 10 with invasive ductal carcinoma	Vacuum-assisted 11G Mammotome device	No cases of dissemination of cancerous cells were observed. In two cases benign epithelial displacement was observed. The duration of the core-needle procedure was significantly longer in these two cases than for cases with no displacement observed.
Uematsu and Kasami 2007[96]	The exterior of the core needles was washed immediately following withdrawl and the washings were examined for cells.	207	US-guided 18G automated Bard Magnum gun	65% of the washings were positive for cells. Lesions diagnosed as invasive lobular carcinoma were significantly less likely to have had cells in the washings than lesions diagnosed as DCIS or invasive ductal carcinoma. Biopsies that had been performed using multiple passes were slightly but not significantly more likely to yield cells in the washings than biopsies performed with a single pass.
Fitzal et al. 2006[110]	Retrospective case-control study of patients treated with breast-conserving surgery and radiotherapy, with or without chemotherapy/hormonal therapy.	189 with preoperative core-needle biopsy, 530 without preoperative core-needle biopsy	14G or 11G; stereotactic or US guidance; vacuum-assisted or not.	In patients with preoperative core-needle biopsy, the local recurrence rate was 1.1% with a median followup of 78 months (range 46 to 108 months); the mortality rate was 0%. In patients without preoperative core-needle biopsy, the local recurrence rate was 2.1% with a median followup of 71 months (range 8 to 128 months); the mortality rate was 4.7%.
Newman et al. 2006[130]	Retrospective chart review of women who underwent sentinel lymph node biopsy	279 with core-needle biopsy, 41 with fine-needle biopsy, and 217 with open excisional biopsy	Not described	The method of biopsy did not correlate with metastasis to the sentinel lymph node; however, patients who underwent excisional biopsy were more likely to have micrometastases to the sentinel lymph node than patients who underwent needle biopsies.
Uriburu et al. 2006[139]	Case report	3	14G under stereotactic guidance	Three women treated with skin-sparing mastectomy are reported on. All three developed recurrences of their breast tumors at the core-needle biopsy scar. Two of the three had invasive ductal carcinomas and one had a mucinous carcinoma.
Hansen et al. 2004[188]	Retrospective chart review of women who underwent sentinel lymph node biopsy	126 with fine-needle biopsy, 227 with core-needle biopsy and 323 with open excisional biopsy	11 or 14G, under stereotactic or US guidance	The incidence of metastases to the sentinel lymph node was significantly higher in women who underwent needle biopsies compared to women who had excisional biopsy.

Table E13. Studies of the dissemination of cancerous cells during biopsy procedures (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Hoorntje et al. 2004[190]	Prospective study. Patients underwent core-needle biopsy followed by open surgery a mean of 21 days later. The needle track was excised and examined by a pathologist.	13	14G automated device Bard under stereotactic guidance	Needle tracks were visible in 11 cases, and of these, 7 had displaced cells in the needle track.
Peters-Engl et al. 2004[195]	Retrospective review of women who underwent sentinel lymph node biopsy	1,048 with fine-needle or core-needle biopsy, 842 with open excisional biopsy	Not described	Patients who had undergone a needle biopsy had a 1.37 times increased risk of metastases to the lymph nodes, but after adjusting for known risk factors of axillary node metastases this result was overturned, 1.09 times increased risk (95% CI: 0.85% to 1.40%).
Chen et al. 2002[244]	Retrospective review of women treated with breast-conserving surgery and radiation therapy	86 with core-needle biopsy, 465 with open excisional biopsy	14G Bard device or 11G vacuum-assisted device Mammotome, all under stereotactic guidance	At a mean followup of 4.9 years (range 2.0 to 8.9 years), tumor recurrence rate was 2.3% in the core-needle group and 7.7% in the open biopsy group.
Knight et al. 2002[256]	Retrospective review of women treated with breast-conserving surgery; 78.6% had radiation therapy as well	297 with core-needle biopsy, 101 with open excisional biopsy	14G Bard device under stereotactic or ultrasound guidance	At a mean followup of 29.7 months (range: 2 to 90 months), 3.7% of the patients with core-needle biopsy had a tumor recurrence compared to 3.96% of patients with open biopsy who had a tumor recurrence.
Chao et al. 2001[282]	Case report	3	14G under stereotactic guidance	Two of the patients developed tumor recurrences at the site of the core-needle biopsy; the third patient had the needle track excised 1 month after biopsy and cancer cells were detected in the needle track. None of the patients received radiation therapy for the primary tumor.
King et al. 2001[295]	Retrospective review of women diagnosed with breast cancer by either core-needle biopsy or wire-localized open excisional biopsy and then treated with breast-conserving surgery; 91% had radiation therapy as well	132 with core-needle biopsy, 79 with open excisional biopsy	14G under US or stereotactic guidance	At a median followup of 44.4 months, 3.0% of patients with core-needle biopsy had tumor recurrences; at a median followup of 50.1 months, 2.5% of patients with open biopsy had tumor recurrences.

Table E13. Studies of the dissemination of cancerous cells during biopsy procedures (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Stoller et al. 2000[342]	Prospective study. Patients underwent core-needle biopsy followed by open surgery a mean of 10.5 days later. The needle track was excised and examined by a pathologist.	89	14 or 11G, stereotactic or US guidance, multiple puncture or vacuum-assisted	2 patients had tumor cells in the needle tract. One of these patients had a local tumor recurrence 34 months after surgery at the biopsy site. Both of these patients had multiple puncture core-needle biopsies and no radiation treatment.

US = Ultrasound

Table E14. Surgical procedures avoided

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Friese et al. 2009[592]	Analysis of data from the SEER data of women diagnosed with DCIS or stage I/II breast cancer between 1991 and 1999	45,542	Needle or surgical	Needle biopsy use was associated with a reduced likelihood of multiple breast surgeries (odds ratio 0.35, 95% CI: 0.34 to 0.37)
Altomare et al. 2005[145]	Retrospective chart review of patients with nonpalpable breast lesions who underwent core-needle biopsy between January 2001-January 2004.	591	US- or stereotactic-guided vacuum-assisted biopsy (Mammotome) 11-gauge needle or ABBI	Core-needle biopsy spared a surgical procedure for 128 cancer patients and 134 non-cancer patients, but did not spare a procedure in 17 women
Bolivar et al. 2005[497]	Prospective case series of patients with non-palpable suspicious breast lesions who underwent core-needle biopsy from August 1997-August 2001.	198	US-guided (7.5 MHz linear array transducer) using a freehand technique with patient in supine or supine oblique position.	Core-needle biopsy spared 155/198 (or 78%) women a surgical procedure.
Chapellier et al. 2005[494]	Prospective case series of the first 318 aspiration-guided macrobiopsy procedures performed at one institution. The majority of patients had microcalcifications; approximately 50% were BIRADS 4 while 35% were BIRADS 3 but had risk factors.	301	Fischer stereotactic imaging table, vacuum-assisted biopsy (AND).	128 BIRADS 4 patients and six BIRADS 5 patients were spared an additional operation by use of core-needle biopsy.
Carmon et al. 2004[176]	Retrospective chart review of patients with nonpalpable breast lesions who were ultimately operated on for primary breast carcinoma between 1997-mid-2001.	167	Percutaneous image-guided core biopsy	From 1997 to 2001, the percent of patients requiring a second operation decreased from 56.2% to 11.1%, with increased availability of a preoperative diagnosis. 79.2% of subjects with a preoperative diagnosis of invasive duct carcinoma had axillary lymph node dissection vs. 37.7% of those without a preoperative CNB diagnosis.

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Apesteguia et al. 2002[518]	Prospective consecutive case series of patients with nonpalpable breast lesions non-visible or non-accessible by US.	126	Vacuum-assisted core biopsy on a digital stereotaxic table with an 11-gauge needle.	Second surgical procedures due to involved margins were required in 17.4% of cases and 5 additional lymphadenectomy procedures were needed based on core-needle biopsy's inability to predict invasion.
Liberman et al. 2002[522]	Retrospective study. Rate of spared surgical procedures was compared for those whose lesion was completely excised compared to those whose lesion was only sampled.	800 (565 calcifications, 194 mass, 41 both)	Vacuum-assisted core biopsy (Mammotome) with 11-gauge needle	466 lesions were totally removed by the core-needle procedure. Surgery was spared in 80.6% of lesions. There was not a significant difference between the excised versus sampled lesion groups in spared surgery rates (81.5% vs. 82%, p = 0.95).
Becker et al. 2001[527]	Retrospective chart review of lesions with indeterminate microcalcifications	218	DMR regular mammography machine plus either a Stereotix 2 conventional add-on unit or a SenoVision digital add-on unit. Core-needle biopsy was performed with a 14-gauge needle in all but 5 cases (in which a 16-gauge needle was used)	Open biopsy was avoided in 78 (69.6%) of patients in the conventional treatment group and in 78 (73.6%) of the digital treatment group.
Liberman et al. 2001[298]	Retrospective review of women with calcifications highly suggestive of malignancy who underwent a diagnostic biopsy procedure from 1993-2000.	139	Stereotactic vacuum-assisted biopsy with 11 or 14-gauge needle	The mean number of surgical procedures was 1.2 and 1.6 for core-needle biopsy vs. surgical biopsy. 62% of surgical biopsy patients overall and 83.8% of diagnostic surgical biopsy with cancer needed two procedures. The likelihood of requiring a single operation was greater for women who had core-needle biopsy. A surgical procedure was spared in 58.4% of this group.

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Perez-Fuentes et al. 2001[534]	Prospective case series of patients seen between August 1998-December 2000 with palpable or nonpalpable breast masses	83	US-guided vacuum-assisted biopsy (Mammotome) with 11-gauge needle	Of the 83 patients studied, 79 were spared a surgical procedure (95.2%).
Verkooijen et al. 2001[593]	Prospective comparison of patients with nonpalpable breast lesions	164	Patient prone, 14-gauge needle	In 75% of core-needle cases, only a single surgical procedure was needed, while this was true in only 16% of open biopsy cases ($p < 0.001$). Mean number of surgical procedures was 1.31 vs. 1.91 ($p < 0.001$) in the core-needle and open biopsy groups, respectively.
Liberman et al. 2000[542]	Retrospective chart review of patients with breast masses that were palpable on physical examination from 1992 to 1998.	107	Stereotactic- or US-guided core biopsy with a 14-gauge needle.	Core-needle biopsy spared 74% of subjects in this study an additional diagnostic tissue sampling
Morrow et al. 2000[305]	Prospective nonrandomized comparative study of patients with nonpalpable mammographically-detected abnormalities	1,550	Core-needle or open biopsy	Among those with cancer, a single procedure was performed in 33% of the excisional biopsy subjects versus 84% of the core-needle group ($p < 0.001$). The core-needle group consistently had a larger proportion of subjects treated with a single procedure, regardless of lesion type: for architectural distortions 71% vs. 46% and for highly suspicious lesions 83% vs. 45%.

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Al-Sobhi et al. 1999[346]	Retrospective review of patients found to have cancer	67	Vacuum-assisted with an 11 or 14-gauge needle	The number of surgical procedures performed in an operating room differed significantly for the two groups overall (CNB mean 1.1 ±0.3 and wire localization mean 1.8 ±0.4). For the subset who underwent breast-conserving treatment a significant difference between groups was also evident, mean surgical procedures were 1.2 ±0.4 and 2.1 ±0.2, respectively.
Williams et al. 1999[384]	Prospective case series of patients with impalpable breast lesions diagnosed by stereotactic CNB on a prone table vs. a historical cohort of patients with similar lesions diagnosed prior to the use of prone stereotactic CNB.	222	Stereotactic prone core-needle with Mammotest and 14-gauge needle.	More patients in the prone group required only a single operation ($p < 0.03$). The average number of operations was 1.33 (SE 0.053) vs.1.47 (SE 0.054) in the prone and control groups, respectively.
Johnson et al. 1998[395]	Retrospective review of patients with malignant-appearing microcalcifications without an associated parenchymal abnormality on mammography.	167	Stereotactic biopsy was performed using Lorad Stereotactic prone biopsy table with 14-gauge needle. Digital mammography was used to localize the lesions. US biopsies were performed using a 7.5 MHz probe with real-time imaging using the same CNB device.	The mean number of procedures required until definitive treatment was 2.4 and 1.7 for the initial IGBB and initial NLOB, respectively ($p = 0.0002$)

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Kaufman et al. 1998[396]	Retrospective review of consecutive mammographically-detected nonpalpable breast lesions ultimately diagnosed as in situ or invasive carcinoma.	113	Core-needle or open biopsy	Negative margins were achieved twice as often in the core-needle group as in the open biopsy group after the first surgical procedure (77% vs. 38%, p <0.001). A one-stage surgical procedure was possible in many more of the core-needle patients than in the open biopsy group (79% vs. 21%, p <0.001). On average, 2.2 procedures (surgery and biopsy) were needed in the core-needle group vs. 1.8 among the open biopsy patients. However, the average number of surgeries was 50% higher in the open biopsy group (1.8 vs. 1.2).
Liberman et al. 1998[556]	Retrospective review of patients with nonpalpable breast masses.	151	US-guided biopsy was performed in the supine or supine oblique position using high resolution (7.5 MHz linear array transducer) equipment with a 14-gauge cutting needle.	85% of patients in this study were spared a surgical procedure by use of core-needle biopsy.
Lind et al. 1998[402]	Retrospective review of patients with mammographically-detected breast cancer that underwent breast-conserving surgery	117	Biopsies were performed on a dedicated prone table with 14-gauge needle	Only 6% of patients in the core-needle group had positive margins vs. 55% of the open biopsy patients (p <0.01). One patient with positive margins in the core-needle group was re-excised vs. 34/38 of those with positive margins in the open group (p <0.01).

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Fenoglio et al. 1997[419]	Retrospective chart review of patients with mammographically-detected breast cancer	40	14-gauge long throw Biopty gun plus Mammotest Stereotactic System	All 20 patients diagnosed with core-needle biopsy required one surgical procedure only whereas among the 20 initially diagnosed with open biopsy a total of 41 procedures were required to diagnose and treat their cancers
Liberman et al. 1997[428]	Retrospective chart review of nonpalpable breast cancers	197	Stereotactic CNB were done with patient in prone position using StereoGuide; sonographically-guided CNB were done with patients in supine or supine oblique using a 7.5 MHz linear array transducer and high resolution sonographic equipment; all CNB used a 14-gauge needle or an ultra-core biopsy needle.	84% of patients in the CNB group underwent a single surgical procedure vs. 29% of those diagnosed by surgical biopsy ($p < 0.00001$). 16% of the CNB patients required two surgical procedures while 66% of the open-biopsy patients needed two surgeries and 5% underwent three surgical procedures.
Smith et al. 1997[433]	Retrospective review.	677	US-guided Mammotest (67) or wire localized excisional biopsy (610)	On average, 1.25 surgical procedures were required by the core-needle group versus 2.01 in the surgical biopsy group ($p < 0.001$).
Sutton et al. 1997[568]	Retrospective review of patients with nonpalpable mammographic abnormalities detected at routine screening in a community-based clinic.	200	Biopsies were performed on a dedicated prone stereotactic table (Mammotest) with an autoguide attachment and 14-gauge 22 mm-throw Bard Biopty-cut needles held in a Bard Biopty gun.	The authors estimated that open biopsy was avoided in 82% of cases by using core-needle biopsy for diagnosis.
Whitten et al. 1997[435]	Retrospective review	171	Stereotactic- or US-guided biopsy with a 14-gauge needle	Among the 86 subjects diagnosed by image-guided core-needle biopsy, 98 surgical procedures were completed (1.1 surgeries per patient) compared with 1.9 operations on average for the 85 patients undergoing a diagnostic needle localized biopsy (157 surgeries total in 85 subjects).

Table E14. Surgical procedures avoided (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Yim et al. 1996[454]	Retrospective review	52	Stereotactic biopsy with a 14-gauge needle was performed on a dedicated prone table	At the time of excision, surgical margins were more frequently positive in the open biopsy group (55%) vs. the CNB group (0%); the distance of the tumor from the surgical margin was greater for the CNB vs. open biopsy patients among the negative margins; and, among those having breast conservation surgery, the rate of re-excision was higher for the open biopsy group (74%) vs. no patients in the CNB treatment group.
Liberman et al. 1995[458]	Retrospective chart review of patients with impalpable speculated masses.	43	Biopsies were performed with patients prone on a dedicated table using either a 14-gauge Bard Biopty needle or a 14-gauge Manan needle and either a Bard Biopty gun with 23 mm throw or Manan ProMag 2.2 gun with a 22 mm throw.	The use of core-needle biopsy in the diagnosis of breast cancer reduced the number of procedures required in 33 (77%) patients.
Strong et al. 1995[463]	Prospective study of patients with mammographically-detected, asymptomatic, nonpalpable breast lesions	97	Mammotest stereotactic device using 14-gauge Manan needle.	In eight benign cases, open biopsy was performed, adding an extra procedure to the diagnostic protocol for these patients. However, 74 women (76%) were spared an open biopsy by core-needle biopsy. As the 15 women with carcinoma went directly to mastectomy without an open biopsy, core-needle biopsy did not add a diagnostic procedure in these cases.
Elliott et al. 1992[479]	Retrospective review of 12-month period of patients with nonpalpable breast lesions.	115	Mammotest II with 18-gauge Bard biopsy needle using Bard Biopty gun	Core-needle biopsy spared 97 patients an open surgical biopsy.

Table E15. Patient procedure preference

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Duschesne et al. 2007[61]	Prospective trial of new device	113	US-guided radiofrequency tipped vacuum-assisted with 9-gauge needle (SenoCor 360 Biopsy System).	They rated patient comfort as equivalent with other types of biopsies.
Krainick-Strobel et al. 2007[73]	Prospective case series of patients with benign lesions undergoing biopsy for the purpose of complete extirpation.	45	Hand-held US-guided vacuum-assisted biopsy (Mammotome) using either an 8- or 11-gauge needle.	Ninety-five percent of respondents said they would prefer core-needle to open excisional biopsy if they needed a future procedure. A minimum of 7 days post-procedure, patients were given a questionnaire about their experience. The mean level of satisifaction with the procedure, on a scale of 0-10, was 9.2 (range 3-10).
Killebrew et al. 2006[120]	Retrospective comparison study of patients with BIRADS 4 or 5 and mammographic lesions presenting as microcalcifications.	1600	Vacuum-assisted procedure (Mammotome) with 11-gauge needle vs. vacuum-assisted intact specimen biopsy with 10 or 15 mm probe.	Self-reports by patients showed that those undergoing both treatments tolerated their respective procedures equally. Patients were asked to rate the biopsy procedure for comfort and to rate comfort of lying on stereotactic table, as a comparison. In the vacuum-assisted arm, ratings of 5.8 and 2.0 (with 10 = extreme pain) were given for lying on table and actual biopsy procedure, respectively. In the other group, the ratings were 4.1 and 1.9, respectively.

Table E15. Patient procedure preference (continued)

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Chapellier et al. 2005[494]	Prospective case series of the first 318 aspiration-guided macrobiopsy procedures performed at one institution. The majority of patients had microcalcifications; approximately 50% were BIRADS 4 while 35% were BIRADS 3 but had risk factors.	301	Fischer stereotactic imaging table, vacuum-assisted	Patient tolerance of procedure was excellent, as measured by a self-administered patient questionnaire. The authors also found that the post-procedure psychological state was associated with the procedure outcome, the information given to patients and the attitudes of medical staff members.
Weber et al. 2005[502]	Retrospective comparison study of patients with nonpalpable breast lesions	387	Stereotactically-guided vacuum-assisted (Mammotome) technique with 11-gauge needle or ABBI	Three patients in this series underwent both procedures but they did not indicate a preference for one over the other.
Wong et al. 2005[171]	Prospective trial of Asian patients with nonpalpable mammographic abnormalities	114	Vacuum-assisted (Mammotome) on a prone biopsy table with 8- to 11-gauge needle	Bruising (one week post-procedure) occurred in 79 patients (46 minimal, 25 mild, 5 moderate and 3 severe). All patients were able to be discharged after 2-3 hours following the procedure and all reported the procedure was acceptable without undo discomfort.
Alonso-Bartolome et al. 2004[504]	Prospective study of women with probably benign breast lesions who refused radiologic followup and, instead, insisted on removal. Complete lesion removal was the intended goal for all lesions.	97	US-guided vacuum-assisted biopsy (Mammotome) with 11-gauge needle	Patients estimated that the time lost to core-needle biopsy is less than 20% of the time required for a surgical biopsy.

Table E15. Patient procedure preference (continued)

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Geller et al. 2004[183]	Survey of women with nonpalpable breast lesions	315	US-guided core-needle biopsy or open excisional biopsy	Survey results 1-3 months post procedure measured convenience of the procedure (distance travelled, procedure time, and number of days of work missed post procedure). No difference was found between two groups in terms of miles travelled for procedure, but the excisional biopsy group missed more work.
March et al. 2003[514]	Prospective study of women with breast masses who underwent biopsy in which complete removal of the lesion was attempted.	34	US-guided vacuum-assisted biopsy with an 11-gauge biopsy device	Radiologists examined the biopsy site 2-5 days post-procedure and found 24 subjects (71%) had ecchymosis, nine (26%) had no visible abnormality aside from the skin incision and one (3%) had slight skin convexity without ecchymosis at the biopsy site. Twenty-one subjects who did not undergo an open procedure were examined at 6 months post core-needle biopsy. All 21 said they would recommend the procedure to others.
Mariotti et al. 2003[228]	Retrospective study of patients with suspicious non palpable mammographic lesions not confirmed by ultrasonography.	360	Vacuum-assisted (Mammotome) with an 11-gauge needle or ABBI	Patient acceptance of the biopsy procedure was high.

Table E15. Patient procedure preference (continued)

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Fine et al. 2003[217]	Women with low risk palpable masses were assessed prospectively.	216	Vacuum-assisted (Mammotome) with US guidance with either an 8- or 11-gauge probe	A majority of patients stated that they would recommend the procedure to others in a survey conducted 10 days post-procedure (82% and 92%, respectively).By the 6-month follow-up visit, 100% stated they would recommend the procedure to others, while 97% stated they themselves would have the procedure again, if needed.
Chun et al. 2002[245]	Retrospective review and survey of patients who had undergone a Mammotome, ABBI or wire localized biopsy more than 2 years ago for benign disease.	59	Stereotactic vacuum-assisted 11-gauge (Mammotome) or stereotactic excisional biopsy with ABBI (15 or 20 mm cannula) or wire localized open biopsy	The biopsy experience was rated as satisfactory by 90%, 75% and 80% of patients in the open, ABBI, and Mammotome groups, respectively. Complaints about the procedures included uncomfortable (2 Mammotome, 4 ABBI), pain (2 each open and Mammotome), painful breast compression (3 ABBI), delay in getting results (1 each Mammotome and ABBI), rude doctors (2 Mammotome) and length of procedure (1 open).
Hui et al. 2002[252]	Prospective case series of patients with nonpalpable breast lesions requiring a biopsy procedure.	79	Stereotactic-guided breast biopsy (StereoGuide with Digital Spot Mammography): Trucut with a 14-gauge needle, vacuum-assisted (Mammotome) with 11-gauge probe	31.6% of patients were very satisfied with the procedure; 73.7% felt the level of pain associated with the biopsy was less severe than erect mammography; 34.2% felt the pain experienced was less severe than needle pricking; and 14.5% felt it was less severe than previous free-hand or ultrasound-guided breast biopsy.

Table E15. Patient procedure preference (continued)

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Beck et al. 2000[539]	Retrospective review of first experience using vacuum-assisted core-needle biopsy.	560	Digital stereotaxic biopsy table, vacuum-assisted (Mammotome) with 11-gauge needle.	A majority of patients tolerated the procedure well.
Gukas et al. 2000[326]	Prospective study of 112 consecutive patients with palpable breast lesions	108	Tru-Cut and excisional biopsies.	A majority of patients, 90.7%, accepted the procedure. The authors note that patients experienced more apprehension about the procedure than actual discomfort.
Welle et al. 2000[545]	Retrospective review of patients who underwent a stereotactic CNB in a decubitus or recumbent position from September 1995-March 1999.	225	Stereotactic-guided core-needle biopsy in a decubitus or recumbent position.	Two patients out of the 225 had experienced a traditional prone position CNB and both stated they preferred the decubitus position, preferring to lie on their sides. Overall, 29% of patients reported mild discomfort or numbness in the dependent arm with the decubitis or recumbent position.
Doyle et al. 1999[552]	Retrospective study of patients with mammographically-detected lesions	151	Senographe 600T was used for 136 biopsies; 15 using Mammomat 3000; all in decubitus position unless the patient couldn't tolerate that positioning and with a 14-gauge needle.	90% of subjects were able to tolerate the decubitus position although some developed discomfort in the dependent arm and required supporting the arm away from the body on a chair or small trolley.
Helbich et al. 1998[393]	Prospective randomized study of consecutive patients with indeterminate or suggestive lesions on mammography	64	Mammotest stereotactic system with 13-gauge coaxial needle.	Author reports that all patients tolerated the procedure well.

Table E15. Patient procedure preference (continued)

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Handy et al. 1996[445]	Prospective survey of patients. Patients completed a pre-procedure survey, one immediately after the procedure, one 24 hours post-procedure and 5 days later.	58	StereoGuide SM Breast Biopsy System with 14-gauge needle. The majority of patients were in a prone position.	67% of patients reported that they understood the procedure they were about to undergo. Immediately after the procedure, 78% said they understood the procedure but the remainder still felt they did not understand it. Five of those who initially thought they understood decided they really had not after experiencing it. 38% said the clinic nurse/technologist was the best source of information about the procedure, 26% said it was the physician, 15% said there was no good source of information available to them and 21 said other (books, friends, popular media). Pre-procedure, 79% were most concerned about the results of the biopsy while 10% were most concerned about the procedure itself. 31% reported none or slight anxiety about the impending procedure, 60% said they were mild to moderately anxious and 9% were extremely anxious. Five days post procedure, 97% said they would have the procedure again in the future, if needed.
Elliott et al. 1992[479]	Retrospective review of 12 month period	115	Mammotest II with 18-gauge Bard biopsy needle using Bard Biopty gun	The authors explain that patients are very accepting of the CNB procedure and found the test easy to perform in the office.

US = Ultrasound

Table E16. Cosmetic outcome

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Krainick-Strobel et al. 2007[73]	Prospective case series of patients with benign lesions undergoing vacuum-assisted biopsy for the purpose of complete lesion removal	45	Hand-held ultrasound-guided vacuum-assisted CNB biopsy (Mammotome) using either an 8- or 11-gauge needle.	Ninety-five percent of respondents said they would prefer CNB to open excisional biopsy if they needed a future procedure. A minimum of seven days post-procedure, patients were given a questionnaire about their experience. All patients said that the scar from the needle was cosmetically unimportant to them and, on a scale of 0-10, their mean level of satisfaction with CNB was 9.2 (range 3-10).
Weber et al. 2005[502]	Retrospective comparison study of patients with impalpable breast lesions undergoing either Mammotome or ABBI	387	Stereotactically-guided vacuum-assisted CNB biopsy (Mammotome) technique with 11-gauge needle or ABBI	Incomplete satisfaction with the cosmetic result occurred at a higher rate in the ABBI group (6.7% vs. 1.3%, p = 0.03).
Wong et al. 2005[171]	Prospective trial of Asian patients with nonpalpable mammographic abnormalities underwent either ABBI (N = 7) or Mammotome (N = 107).	114	CNB was performed on a prone biopsy table with vacuum-assisted CNB (Mammotome) with 8- to 11-gauge needle or ABBI.	Bruising (one week post-procedure) occurred in 79 patients (46 minimal, 25 mild, 5 moderate and 3 severe) and at one-month followup a scar was visible in 79 patients (40 minimal, 32 mild, 7 moderate, 0 severe).
Mariotti et al. 2003[228]	Retrospective study of patients undergoing either ABBI or Mammotome from June 1999-December 2001 for suspicious non palpable mammographic lesions not confirmed by ultrasonography	360	Vacuum-assisted CNB (Mammotome) with 11-gauge needle or ABBI	Both surgeons and patients were pleased with the cosmetic outcome.

Table E16. Cosmetic outcome (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
March et al. 2003[514]	Prospective study of women with breast masses who underwent CNB in which complete removal of the lesion was attempted.	34	Ultrasound-guided vacuum-assisted CNB with an 11-gauge biopsy device	The twenty-one subjects who did not undergo an open procedure following CNB were examined at 6 months post-CNB. Nineteen (90%) were very satisfied with appearance of biopsy area, 2 were satisfied and none were dissatisfied. Sixteen were very satisfied with how the biopsy area felt, 5 satisfied, none dissatisfied. At 6-month follow-up examination, four (19%) had no visible scar, 17 (81%) minimal scarring = 2-9 mm, none had skin retraction concavity, convexity, or other changes in breast contour.
Fine et al. 2003[217]	Women who underwent CNB for low risk palpable masses were assessed prospectively.	216	Ultrasound-guided vacuum-assisted handheld biopsy device (Mammotome) with either an 8- or 11-gauge needle	A majority of patients were both satisfied with the appearance of their incisions and stated that they would recommend the procedure to others in a survey conducted 10 days post-procedure (82% and 92%, respectively).By the 6-month follow-up visit, 100% were happy with the incision's appearance and would recommend the procedure to others, while 97% stated they themselves would have the procedure again, if needed.
Kettritz et al. 2003[594]	Retrospective analysis of patients who underwent a CNB between January 1996-June 2000 for indeterminate lesions and microcalcifications.	2874	Vacuum-assisted CNB on a digital prone table (Mammotest) with an 11-gauge needle.	Scarring at the latest postbiopsy visit was graded as not relevant (86%), slight (14%) or relevant (0.3%).

Table E16. Cosmetic outcome (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Chun et al. 2002[245]	Retrospective review and survey of patients who had undergone a Mammotome, ABBI or wire localized biopsy more than 2 years ago for benign disease, 20 patients per group.	59	Stereotactic vacuum-assisted CNB biopsy (Mammotome) with 11-gauge needle or stereotactic excisional biopsy with ABBI (15 or 20 mm cannula) or wire localized open biopsy	Patients were asked to rate the appearance of their scar, if they were satisfied with the biopsy procedure, and which mattered most to them, complete lesion removal or scar appearance. Ninety-five percent of the core-needle biopsy group and only 25% of the open biopsy group were very satisfied with the appearance of their breast. None of the core-needle biopsy group said the cosmetic results were unacceptable compared to 20% of the open biopsy group who found the results unacceptable. Overall, eighty percent of subjects were more concerned with complete lesion removal than scar appearance.
Perez-Fuentes et al. 2001[534]	Prospective case series of patients seen between August 1998-December 2000 with palpable or nonpalpable breast masses diagnosed with CNB.	83	Ultrasound-guided vacuum-assisted CNB (Mammotome) with 11-gauge needle	No scarring was evident at followup.
Beck et al. 2000[539]	Retrospective review of first experience using vacuum-assisted CNB	560	Digital stereotaxic biopsy table and vacuum-assisted CNB (Mammotome) 11-gauge needle.	In 90% no scar was visible at final followup.

CNB = Core-needle Biopsy

Table E17. Physician experience

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Duschesne et al. 2007[61]	Prospective trial of new device used on patients already scheduled for CNB between December 2002-April 2003.	113	US-guided radiofrequency tipped vacuum-assisted CNB with 9-gauge needle (SenoCor 360 Biopsy System).	Operators of the new device rated it in terms of ease of penetration, positioning and holding the device, acquiring a satisfactory specimen, positioning accuracy, safety, and patient comfort and compared it to existing spring and vacuum devices based on their past experiences with these. All operators of the study device were experienced in US breast biopsy techniques. Operators found the new device to be equivalent to 14-gauge biopsy devices but superior to other vacuum-assisted devices in terms of penetration of the lesion and positioning of the device at the desired location. They rated patient comfort as equivalent with other types of biopsies.
Holloway et al. 2007[67]	Retrospective review of patients with breast abnormality seen between April 2002-December 31, 2002 who were diagnosed by CNB or fine-needle aspiration and/or surgery as the initial procedure in Ontario Canada.	17,068	Fine-needle aspiration or CNB or mastectomy	Differences in the availability of the CNB (specialized expertise) may account for some of the geographic variation in how often women received a needle-biopsy procedure rather than proceeding immediately to open surgery.
Liberman et al. 2007[80]	Retrospective chart review of patients who had lesions detected with MRI and then had an MRI-guided CNB	237 lesions	MRI-guided vacuum-assisted CNB with a 9-gauge needle	The median number of previous MRI-guided CNB performed by the radiologists was 21 (Range: 1-55).

Table E17. Physician experience (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Hoffman 2005[115]	To compare the quality of service at a clinic only partially staffed with breast specialists in 1998 to the same clinic in 2003 after it had become fully specialized. Technologically, the only change in diagnostic equipment in that time period was more sophisticated US scanners, which were used in a majority of 2003 procedures but only a small percent of 1998 procedures.	5,451	CNB vs. excisional biopsy	Over time, excisional biopsy was used less, more women had breast-conserving surgery and complication rates decreased. It is the author's conclusion that a dedicated, specialized breast care center improved the quality of care.
Lehman et al. 2004[160]	Retrospective review of consecutive patients with nonpalpable lesions not clearly visible on mammography or targeted sonography, many of whom had recently been diagnosed with breast cancer.	28	MRI-guided vacuum-assisted CNB with the ETEC Breast Biopsy and Excision System.	The experience level of those performing the procedures was low, with half having no prior experience and the other half having one month of experience performing the procedure only (although they had one year of experience with MRI-guided CNB).
Popiela et al. 2002[263]	Retrospective review of asymptomatic women without pathological resistance on physical examination but with breast pathologies below 0.5 cm confirmed by complementary examination.	122	Vacuum-assisted CNB (Mammotome) biopsy with either ultrasonography or digital mammography guidance	The authors contend that a lack of experience, rather than a problem with the equipment, explains problems encountered early on in precise targeting and complete removal of the lesion.
Schneider et al. 2001[312]	Prospective case series of patients undergoing a new unilateral MR-guided breast lesion localization and core biopsy system.	14	MR image guidance CNB using a mechanical needle guide and trajectory planning software with 14-gauge needle.	The authors report that the new device is intuitive and easy to use as well.
Wunderbaldinger et al. 2001[537]	Prospective nonconsecutive first-experience case series of patients with nonpalpable breast lesions diagnosed by CNB followed by surgical excision.	45	New dedicated US system for computer-guided CNB (Sonopsy) with a 14-gauge needle.	The authors also comment that this new device may hold promise for non-skilled physicians.

Table E17. Physician experience (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
McMahon et al. 1992[588]	Prospective randomized trial of consecutive patients with palpable breast lumps. Patients were randomized to percutaneous biopsy using Tru-Cut 14-gauge needle, Biopty-cut 14-gauge needle or a Biopty-cut 18-gauge needle.	151	Biopty-cut needles were used with the Biopty gun. A standard technique was used for the Tru Cut.	Tru Cut's poor performance (sensitivity 68%) may be related to the fact that eight different surgeons performed the 49 Tru Cut biopsies included in this study whereas the Biopty gun, with an absolute diagnostic sensitivity of 92%, may be less dependent on operator experience.
Parker et al. 1990[591]	Prospective case series of consecutive patients referred for biopsy of nonpalpable mammographically-suggestive lesions. Subjects underwent CNB followed by wire localization and excisional surgery.	103	14-, 16-, or 18-gauge Biopty-cut needles were used in conjunction with a Biopty gun. The first 30 patients were treated with Senographe Mammographic System 600T coupled with Stereotix computerized stereotactic needle localization device. Logistical problems caused investigators to switch to the Mammotest Stereotactic System for remaining patients.	Increased operator experience brought about a reduction in procedure time.

CNB = Core-needle Biopsy

Table E18. Procedure duration time

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Duschesne et al. 2007[61]	Prospective trial of new device used on patients already scheduled for CNB between December 2002-April 2003.	113	US-guided radiofrequency tipped vacuum-assisted (SenoCor 360 Biopsy System) with 9-gauge needle	Procedure time is decreased for this device as the breast tissue offers no resistance to penetration, but the authors do not report a time estimate.
Liberman et al. 2007[80]	Retrospective chart review of patients who had lesions detected with MRI and then had a MRI-guided CNB	237 lesions	MRI-guided vacuum-assisted (Mammotome) with 9-gauge needle	Median procedure time was 31 minutes, with procedures ranging from 17-57 minutes in total
Michalopoulos et al. 2007[33]	Prospective review of nonpalpable mammographic lesions diagnosed by CNB as either DCIS or IDC then surgically excised.	31	Vacuum-assisted CNB (Mammotome) with 11-gauge needle	Two cases of benign epithelial cell displacement occurred. The duration of the procedure was significantly longer in the two cases with displacement (52.5 ±3.5 minutes) vs. in cases without any displacement (42.0 ±4.4 min., p = 0.018).
Uematsu et al. 2007[97]	Retrospective study of all patients who had had an 18-gauge CNB performed from July 2003-June 2004 followed by a surgical excision.	235 lesions	US-guided 18-gauge CNB	Average procedure time was 10 minutes.
Viehweg et al. 2006[142]	Retrospective review of consecutive patients with a family history, but no personal history, of breast cancer.	63	Either MR-guided preoperative wire localization or vacuum-assisted CNB.	Examination time was approximately 40 minutes per wire localization and 20-30 minutes for the vacuum-assisted CNB procedure, including pre- and post-interventional imaging.
Bolivar et al. 2005[497]	Prospective case series of patients with non-palpable suspicious breast lesions who underwent 14-gauge US-guided CNB from August 1997-August 2001.	198	US-guided (7.5 MHz linear array transducer) CNB using a freehand technique with patient in supine or supine oblique position.	Examination time did not exceed 20 minutes in any cases.
Chapellier et al. 2005[494]	Prospective case series of the first 318 aspiration-guided macrobiopsies procedures performed at one institution.	301	Fischer stereotactic imaging table system, AND vacuum-assisted CNB	The procedure, including manual pressure application, took less than one hour in 79% of cases, 90 minutes in 16% of cases, and two hours in about 5% of cases.
Diebold et al. 2005[152]	Prospective consecutive case series of patients with mammographic BI-RADS IV microcalcifications who underwent stereostatic vacuum-assisted CNB.	58	Vacuum-assisted CNB (Mammotome) with 8-gauge needle with the ST driver (Holster) on a Mammotest plus S biopsy table.	Mean biopsy time was 28.2 minutes (Range: 10-120 minutes). Removing 5 highly complicated cases from this analysis reduced the average procedure time to 16.1 minutes.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Orel et al. 2005[131]	Retrospective review of patients with suspicious lesions identified at MR imaging who either underwent surgery or had six month follow-up imaging.	75	MR-guided vacuum-assisted CNB with a 9-gauge needle	Total MRI-guided procedure time (including pre-biopsy imaging examination, biopsy and postbiopsy care) ranged from 30-60 minutes.
Perlet et al. 2005[132]	Prospective study of MR-guided vacuum-assisted CNB visible by CE-MRI alone or localized in 3 dimensions by MRI alone	538	Impact, Expert or Vision MR scanner guidance, vacuum-assisted CNB (Mammotome) with an 11-gauge needle	On average, MR-guided CNB lasted 70 minutes if the patient was having one lesion biopsied and 90 minutes for patients with two lesions.
Weber et al. 2005[502]	Retrospective comparison study of patients with impalpable breast lesions undergoing either Mammotome or ABBI.	387	Stereotactically-guided vacuum-assisted CNB (Mammotome) with 11-gauge needle or ABBI	Median duration of the Mammotome procedure was shorter than the ABBI procedure ($p < 0.0001$).
Wong et al. 2005[171]	Prospective trial of Asian patients with nonpalpable mammographic abnormalities underwent either ABBI (N = 7) or vacuum-assisted CNB (N = 107).	114	Vacuum-assisted CNB (Mammotome) with an 8- to 11-gauge needle prone or ABBI.	Procedures lasted from 30-128 minutes (Median: 68.5).
Alonso-Bartolome et al. 2004[504]	Prospective study of women with probably benign breast lesions who refused radiologic followup and, instead, insisted on removal. Complete lesion removal was the intended goal for all lesions.	97	US-guided vacuum-assisted CNB (Mammotome) with 11-gauge needle	Mean procedure time was one hour (Range: 40-75 minutes). Based on a cost to patient estimate in terms of hours lost, investigators report that the time lost to CNB is less than 20% of the time required for a surgical biopsy.
Geller et al. 2004[183]	Survey of women with nonpalpable breast lesions who had an US-guided CNB or excisional biopsy between 1997-1999.	315	US-guided CNB vs. excisional biopsy.	Survey results 1-3 months post procedure measured convenience of the procedure (distance travelled, procedure time, and number of days of work missed post procedure). No difference was found between two groups in terms of miles travelled for procedure, but the excisional biopsy group missed more work.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Lehman et al. 2004[160]	Retrospective review of consecutive patients with nonpalpable lesions not clearly visible on mammography or targeted sonography, many of whom had recently been diagnosed with breast cancer.	28	MRI-guided vacuum-assisted CNB with the ETEC Breast Biopsy and Excision System.	Time to perform procedure was defined as the start of the first MRI sequence (localizing) to the last scan sequence (clip deployment). The average time for single biopsy procedures was 38 minutes (range: 23-57 minutes). Average time for multiple biopsy procedures in a single breast was 59 minutes (51-68 minutes) and for bilateral procedures 64 (46-80 minutes).
Rotenberg et al. 2004[200]	Prospective case series of patients with palpable tumors and patients with tumors which were visible on ultrasound imaging or radiology.	30	Spirotome System with 8- to 10-gauge needle. No stereotactic tables were used in the study.	Biopsies took a maximum of 20 minutes to complete, with 80% of the biopsies being completed in only 10 minutes.
Chen et al. 2003[210]	Retrospective study of patients with nonpalpable breast lesions from January 1998-2001 undergoing either a CNB or open biopsy.	232	Comparison of vacuum-assisted CNB (Mammotome) with 11-gauge needle vs. ultrasound-guided excisional biopsy	Procedure times were measured from initial skin incision to wound closure or needle withdrawal. Procedure times were as follows: for benign tumor cases 44.3 and 21.5 minutes ($p < 0.001$); for malignant cases 44.0 and 27.0 ($P = 0.036$); for tumors <1 cm in diameter, 43.5 and 20.6 ($p < 0.001$) and for tumors 1-2 cm, 44.2 and 23.6 minutes ($p < 0.001$) for open and CNB, respectively. Procedure time for the older model Mammotome device (used in first year of study) vs. newer handheld variant , which was used in the second year, was 24 and 18 minutes on average, respectively ($p < 0.001$).
Liberman et al. 2003[227]	Prospective case series of women with one of the following: a nonpalpable mammographically-occult lesion at high risk for breast cancer or for extent of disease assessment.	20	MRI-guided 9-gauge vacuum-assisted breast biopsy.	Imaging time was 20 minutes, on average, including three contrast enhanced acquisitions. Median MRI-guided CNB time, from localizing image to imaging after clip deployment was 35 minutes (Mean: 35, Range: 24-48 for a single lesion and 65 minutes (Mean: 69, Range: 62-86) for patients with two lesions. Median tissue acquisition time was 38 seconds (Mean: 41, Range: 29-87).
Mariotti et al. 2003[228]	Retrospective study of patients undergoing either ABBI or CNB from June 1999-December 2001 for suspicious non palpable mammographic lesions not confirmed by ultrasonography.	360	Vacuum-assisted CNB (Mammotome) with 11-gauge needle vs. ABBI	ABBI and Mammotome procedure times were 20 and 10 minutes, on average, respectively, for the operative portion of the procedure only.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Pleiderer et al. 2003[515]	Prospective nonconsecutive case series of patients with suspicious breast lesions who had a diagnostic CNB with a new device.	14	Remote controlled MRI compatible prototype manipulator system (ROBITOM) using 14-gauge large core breast biopsy.	Total procedure time was between 50-70 minutes.
Apesteguia et al. 2002[518]	Prospective consecutive case series of patients with nonpalpable breast lesions non-visible or non-accessible by US.	126	Vacuum-assisted CNB on a digital stereotaxic table with an 11-gauge needle.	Mean procedure time was 29.6 ±14 minutes (Range: 15-90 minutes).
Hui et al. 2002[252]	Prospective case series of patients with nonpapable breast lesions requiring a biopsy procedure.	79	Stereotactic-guided breast biopsy (StereoGuide with Digital Spot Mammography): Trucut with a 14-gauge needle, Mammotome with 11-gauge probe, or FNA with a 22-gauge needle, depending on the characteristics of the lesion.	Mean duration of the biopsy procedure was 49 minutes (range: 30-90).
Mainiero et al. 2002[259]	Prospective nonrandomized comparison study of patients with suspicious breast lesions undergoing a CNB between 1997-1999.	193	Either freehand high resolution sonographically-guided large core biopsy with 14-gauge needle vs. stereotactic vacuum-assisted CNB (Mammotest with 11-gauge needle).	The authors examined how much room time and physician time was expended for each type of procedure. They found stereotactic VABB took more room and physician time when all biopsies were examined together. When only room and physician time for patients with masses was examined, only room time significantly differed in the same direction by procedure type. The authors conclude that sonographically-guided breast biopsies reduce procedure time compared with stereotactic biopsy.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Becker et al. 2001[527]	Retrospective chart review of 232 lesions with indeterminate microcalcifications in 218 women.	218	DMR regular mammography machine plus either a Stereotix 2 conventional add-on unit or a SenoVision digital add-on unit. CNB was performed with a 14-gauge needle in all but 5 cases (in which a 16-gauge needle was used)	Changing from a conventional to a digital add-on unit cut the procedure time by half (from 50 to 20 minutes). Most of this time savings is related to the speed of displaying digital images, 15 seconds per image, versus 3 minutes to develop radiographs.
Perez-Fuentes et al. 2001[534]	Prospective case series of patients seen between August 1998-December 2000 with palpable or nonpalpable breast masses diagnosed with CNB.	83	Sonographically-guided vacuum-assisted CNB (Mammotome) with 11-gauge needle	Median procedure time (acquisition of prebiopsy sonogram to positioning of sterile bandage on skin) was 17 minutes (Range: 10-40)
Schneider et al. 2001[312]	Prospective case series of patients undergoing a new unilateral MR-guided breast lesion localization and core biopsy system.	14	MR image guidance AND CNB using a mechanical needle guide and trajectory planning software with 14-gauge needle.	Mean procedure time was 15 ±5 minutes (Range: 5-24), including 3D acquisition scan, completion of the verification scan, placement of single and multiple stylettes for multiple localization wire placements, and multiple tissue sampling by CNB.
Wunderbaldinger et al. 2001[537]	Prospective nonconsecutive first-experience case series of patients with nonpalpable breast lesions diagnosed by CNB followed by surgical excision.	45	New dedicated US system for computer-guided CNB (Sonopsy) with a 14-gauge needle.	Average procedure time (including patient positioning, biopsy, localization but not post procedural handling) was 30 ±2.7 minutes.
Beck et al. 2000[539]	Retrospective review of first experience using vacuum-assisted CNB	560	Digital stereotaxic biopsy table and vacuum-assisted CNB (Mammotom) with 11-gauge needle.	The authors report that patient positioning took approximately 15 minutes; 30 minutes for the actual procedure; 15 minutes for compression; 10 minutes for a final mammogram; and another 30-45 for observation.
Welle et al. 2000[545]	Retrospective review of patients who underwent a stereotactic CNB in a decubitus or recumbent position from September 1995-March 1999.	225	Stereotactic CNB in a decubitus or recumbent position.	Procedure time was recorded as minutes in compression (mean 25, range: 20-50). Procedures done with digital mammographic equipment and the Mammotome were approximately 10 minutes shorter
Bloomston et al. 1999[348]	Prospective consecutive case series of women with nonpalpable breast abnormalities who had an ABBI.	100	Stereotactic ABBI.	Average procedure time was 20 ±8 minutes.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Doyle et al. 1999[552]	Retrospective study of patients with mammographically-detected lesions on CNB from 1994-1998.	151	Senographe 600T was used for 136 biopsies; 15 using Mammomat 3000; all in decubitus position unless the patient couldn't tolerate that positioning and with a 14-gauge needle.	Mean procedure time was 20 minutes
Bolivar et al. 1998[558]	Patients seen between October 1993-October 1996 having a CNB for nonpalpable breast lesions.	180	Stereotactic CNB (Stereotix localization stereotaxic device attached to Senix 500T screen film mammographic unit) with the Menghini nonautomatic 15-gauge needle with multiple pass technique (Surecut).	THE CNB procedure averaged between 45-55 minutes.
Whitman et al. 1998[559]	Retrospective chart review of 12 CNB in 11 women.	11	Mammographically-guided coaxial CNB procedure performed with a fenestrated alphanumeric compression device with a 15-gauge Tru Guide outer cannula and a 16-gauge Monopty biopsy instrument	The CNB procedure ranged in time from 30-80 minutes.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Burbank 1997[413]	Retrospective study comparing the accuracy of directional, vacuum-assisted stereotactic CNB with stereotactic automated gun CNB	101	Prone position under stereotactic guidance on the Mammotest with 14-gauge needles	Directional, vacuum-assisted biopsy tissue harvest time was 18.6 ±15.8 minutes per lesion, on average, meaning 26.5 specimens can be obtained in that amount of time, at a tissue harvest rate of 1.4 specimens per minute. No information is given for automated procedure.
Florentine et al. 1997[421]	Retrospective review of patients with palpable breast lesions who underwent a combined FNA/CNB procedure.	12	CNB using an 18-gauge Temno needle	The CNB procedure took approximately 20 minutes, on average.
Helbich et al. 1997[563]	Prospective randomized trial of patients with mammographically-suspicious solid lesions. Patients were randomized to stereotactic CNB in a sitting position; stereotactic CNB in the prone position; or CNB with US guidance. CNB was followed by surgical excision.	210	CNB with either stereotactic or US guidance using a 14-gauge needle.	Acquisition of the CNB specimen took an average of 19±3 minutes with stereotactic guidance vs. 13±4 minutes with US guidance.
Howisey et al. 1997[424]	Retrospective review of Medicare patients with mammographic abnormalities who went on to have ultrasound-guided CNB, stereotactic-guided CNB or wire localization with surgical excision between July 1994-December 1995.	139	Ultrasound or stereotactic-guided CNB	US-guided CNB had a shorter procedure time (<20 minutes per case) than stereotactic-guided CNB. No time given for stereotactic procedure.
Yim et al. 1996[454]	Retrospective chart review of subjects with invasive breast cancer diagnosed by either CNB or needle localization surgical biopsy.	52	Stereotactic CNB with a 14-gauge needle was performed on a dedicated prone table (Lorad, Danbury, CT) vs. needle localized open biopsy	Average total procedure time for the CNB was 40-50 minutes, but the biopsy time itself was shorter than for open biopsy.
Janes et al. 1994[469]	Prospective case series of initial 300 CNBs performed by a group of five surgeons.	288	CNB using Fischer Imaging Mammotest with Auto-Guide and the Mammoscan System, 14-gauge needle Biopty-Cut Biopsy Needle.	By the 100th procedure, total procedure time, from initial image taking to completion of the acquisition, rarely exceeded 30 minutes. Acquisition times for lesions centered on the initial image were 15-20 minutes.

Table E18. Procedure duration time (continued)

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Elvecrog et al. 1993[586]	Prospective study of women with a single nonpalpable breast lesion imaged by mammography who underwent CNB followed by hook-wire localization and open surgical biopsy.	100	Mammotest stereotaxic system and 14-gauge needle.	Average per case procedure time, including obtaining preliminary views, was 50-60 minutes. The CNB alone took between 30-40 minutes, on average. No data on average time for the open biopsy procedure was presented.
Parker et al. 1990[591]	Prospective case series of consecutive patients referred for biopsy of nonpalpable mammographically-suggestive lesions. Subjects underwent CNB followed by wire localization and excisional surgery.	103	14-, 16-, or 18-gauge Biopty-cut needles were used in conjunction with a Biopty gun. The first 30 patients were treated with Senographe Mammographic System 600T coupled with Stereotix computerized stereotactic needle localization device. Logistical problems caused investigators to switch to the Mammotest Stereotactic System for remaining patients.	Average procedure time by end of the study was 20-30 minutes without localization wire placement. No data on procedure time for early cases was provided.

CNB = Core-needle Biopsy

Table E19. Wait time for test results

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Verkooijen et al. 2001[593]	Prospective comparison of patients with nonpalpable breast lesions	164	Stereotactic guidance on a prone table with a 14-gauge needle.	Median wait time was 9 days for core-needle biopsies and 19 days for wire-localized open biopsies.
Gukas et al. 2000[326]	Prospective study of patients with palpable lesions	108	Tru-Cut	Reduced wait time to get back a test result was, on average, 7.3 days less for Tru-Cut than excisional biopsy.

Table E20. Availability of a qualified pathologist

Reference	Design of study	Number of patients	Biopsy methods	Conclusion
Collins et al. 2004[179]	Retrospective chart review of patients with nonpalpable lesions	2,004	CNB using either stereotactic mammography or ultrasound. In some cases a 14-gauge needle was used, in others a vacuum-assisted procedure was done with either a 14- or 11-gauge needle.	Local pathology diagnoses were compared to those made by a central pathologist. In 96% of CNB cases the two pathologists were in agreement. Agreement rates were as follows for the subcategories of benign lesions, invasive cancers, DCIS cases, ADH, and lobular neoplasia: 99%, 97%, 83%, 63%, and 53%, respectively. Agreement rates remained stable regardless of biopsy guidance system and biopsy device used.
Gukas et al. 2000[326]	Prospective study of 112 consecutive patients with palpable breast lesions.	108	Tru-Cut and excisional biopsies.	The pathologist in this study was not highly experienced with Tru-Cut, which the authors believe explains its poor diagnosis rate in this study.

Table E21. Availability of equipment

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Deurloo et al. 2001[285]	Retrospective review of patients with nonpalpable breast lesions.	84	StereoGuide with 14-gauge needle	Vacuum-assisted biopsy is increasingly being used in the United States. But, in Europe, acceptance of vacuum-assisted biopsy is considerably less whereas core biopsy devices are used much more.
Verkooijen et al. 2001[593]	Prospective comparison of patients with nonpalpable breast lesions	164	Stereotactic guidance, on a prone table with a 14-gauge needle.	Median wait times for access to core-needle biopsy equipment were only 4 days while access to open surgical biopsy had a median wait time of 13 days.
Williams et al. 1999[384]	Prospective case series of patients with impalpable breast lesions diagnosed by stereotactic core-needle biopsy on a prone table vs. a historical cohort of patients with similar lesions diagnosed prior to the availability of a prone table.	222	Stereotactic prone CNB with Mammotest and 14-gauge needle.	There was no significant difference in lag time between screening and definitive diagnosis for the two groups. However, there was a delay in having the prone procedure due to the longer waiting list.

Table E22. Resource usage

Reference	Design of Study	Number of Patients	Biopsy Methods	Conclusion
Mainiero et al. 2002[259]	Prospective nonrandomized comparison study of patients with suspicious breast lesions	193	Either freehand high resolution US-guided large core biopsy with 14-gauge needle or a stereotactic-guided vacuum-assisted biopsy (Mammotest) with 11-gauge needle	The authors examined how much room time and physician time was expended for each type of procedure. They found vacuum-assisted procedures took more room and physician time when all biopsies were examined together. When only room and physician time for patients with masses was examined, only room time significantly differed in the same direction by procedure type.
Wunderbaldinger et al. 2002[277]	Prospective randomized study	200	Stereotactic-guided biopsies in either sitting or prone position with a 14-gauge needle.	In the conclusion the authors report that prone systems require four times the amount of space as a regular unit and are often underused as their only function is breast biopsy. In addition, there is a weight limit to prone machines.

Appendix F. Data Analysis

Table F23. Accuracy data freehand biopsies

Study	Type Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimates	N DCIS	N DCIS Underestimates
Wong and Hisham 2003[517]	Freehand automated gun 14G	42	1	3	50	NR	NR	NR	NR
Wong and Hisham 2003[517]	Freehand automated gun 16G	23	0	1	30	NR	NR	NR	NR
Scopa et al. 1996[578]	Freehand TruCut	83	1	10	14	6	5	NR	NR
McMahon et al. 1992[588]	Freehand Bioptycut 14G	21	0	3	27	NR	NR	NR	NR
McMahon et al. 1992[588]	Freehand Bioptycut 18G	23	0	1	27	NR	NR	NR	NR
McMahon et al. 1992[588]	Freehand Trucut 14G	17	0	8	24	NR	NR	NR	NR
Barreto et al. 1991[589]	Freehand automated gun 18G	62	0	34	11	NR	NR	NR	NR
Cusick et al. 1990[590]	Freehand	78	0	10	6	NR	NR	NR	NR

Table F24. Accuracy data for US-guided automated gun biopsies

Study	Type of core biopsy	TP	FP	FN	TN	N atypia	N atypia underestimated	N DCIS	N DCIS underestimated
Schueller et al. 2008[487]	US guidance automated gun 14G	698	59	11	584	86	27	52	19
Youk et al. 2008[24]	US guidance automated gun 14G	1,281	68	31	1,040	93	25	126	36
de Lucena et al. 2007[491]	US guidance automated gun 14G	95	0	6	49	0	0	0	0
Bolivar et al. 2005[497]	US guidance automated gun 14G	118	2	4	79	2	0	NR	NR
Crystal et al. 2005[498]	US guidance automated gun 14G	313	3	10	389	5	2	6	4
Sauer et al. 2005[501]	US guidance automated gun 14G	604	0	11	44	2	2	18	11
Delle and Terinde 2004[505]	US guidance automated gun 14G	124	0	4	39	NR	NR	NR	NR
Fishman et al. 2003[511]	US guidance automated gun 14G	14	0	0	38	NR	NR	2	0
Philpotts et al. 2003[516]	US guidance automated gun 14G	35	4	1	81	4	0	2	0
Smith et al. 2001[535]	US guidance automated gun 14G	118	2	0	275	4	2	5	1
Wunderbaldinger et al. 2001[537]	US guidance automated gun 14G	21	3	0	20	3	0	2	0
Yeow et al. 2001[538]	US guidance automated gun 14 or 16G	66	2	0	30	2	0	2	0
Liberman et al. 1998[556]	US guidance automated gun 14G	51	1	3	64	1	0	4	2
Schulz-Wendtland et al. 1998[557]	US guidance automated gun 14G	155	0	3	147	1	1	8	2
Khattar et al. 1997[564]	US guidance automated gun	41	0	3	13	NR	NR	NR	NR
Parker et al. 1993[587]	US guidance automated gun 14G	34	4	0	143	4	0	NR	NR

Table F25. Accuracy data stereotactic guidance automated gun core-needle biopsies

Study	Type of Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Peters et al. 2008[486]	Stereotactic guidance automated gun 14G	483	16	0	312	22	6	196	55
Koskela et al. 2005[500]	Stereotactic guidance automated gun 14G	82	2	1	117	4	3	33	7
Han et al. 2003[512]	Stereotactic guidance automated gun 14G	44	8	11	33	8	0	39	4
Verkooijen et al. COBRA 2002[526]	Stereotactic guidance automated gun 14G	480	20	15	307	26	6	190	32
Becker et al. 2001[527]	Stereotactic guidance automated gun 14G	43	6	2	101	14	8	36	NR
Brenner et al. 2001[528]	Stereotactic guidance automated gun 14G	230	0	24	234	NR	NR	NR	NR
Dahlstrom and Jain 2001[530]	Stereotactic guidance automated gun 14G	56	4	11	219	15	11	NR	NR
Levin et al. 2001[532]	Stereotactic guidance automated gun 14G	22	0	2	46	NR	NR	NR	NR
Kirwan et al. 2000[540]	Stereotactic guidance automated gun 14G	23	6	0	34	11	5	3	0
Ward et al. 2000[544]	Stereotactic guidance automated gun 14G	26	3	1	73	6	3	NR	NR
Jackman et al. 1999[547]	Stereotactic guidance automated gun 14G	159	13	2	305	29	16	56	8
Soo et al. 1999[550]	Stereotactic guidance automated gun 14G	12	0	0	48	1	1	0	0
Doyle et al. 1998[552]	Stereotactic guidance automated gun 14G	51	4	0	77	4	4	21	NR
Vega-Bolivar et al. 1998[558]	Stereotactic guidance Surecut 15G	74	5	0	44	11	6	18	6
Whitman et al. 1998[559]	Stereotactic guidance automated gun 16G	6	2	0	3	2	0	4	3
Zannis and AliaNo 1998[560]	Stereotactic guidance automated gun 14G	31	6	0	77	7	1	3	2
Bauer et al. 1997[561]	Stereotactic guidance automated gun 14G	85	12	1	697	20	8	32	8
Liberman et al. 1997[565]	Stereotactic guidance automated gun 14G	144	34	7	162	55	21	NR	NR
Pitre et al. 1997[566]	Stereotactic guidance automated gun	10	2	1	100	3	1	NR	NR
Sutton, et al. 1997[568]	Stereotactic guidance automated gun 14G	58	1	1	80	8	7	NR	NR

Table F25. Accuracy data stereotactic guidance automated gun core-needle biopsies (continued)

Study	Type of Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Walker et al. 1997[569]	Stereotactic guidance automated gun 14G	95	9	14	60	14	5	43	6
Frazee et al. 1996[570]	Stereotactic guidance automated gun	6	0	0	45	0	0	2	0
Fuhrman et al. 1996[571]	Stereotactic guidance automated gun 14G	48	12	1	268	21	9	NR	NR
Head and Haynes 1996[572]	Stereotactic guidance automated gun 18G	12	6	0	84	12	6	NR	NR
Mainiero et al. 1996[573]	Stereotactic guidance automated gun 14G	23	10	3	79	14	4	13	6
Meyer et al. 1996[574]	Stereotactic guidance automated gun 14G	60	1	0	210	2	1	2	2
Pettine et al. 1996[576]	Stereotactic guidance automated gun 14G	6	0	1	17	NR	NR	1	0
Rosenblatt et al. 1996[577]	Stereotactic guidance automated gun 14G	15	0	0	6	NR	NR	2	2
Cross et al. 1995[579]	Stereotactic guidance automated gun 14G	44	0	0	172	NR	NR	NR	NR
Gisvold et al. 1994[583]	Stereotactic guidance automated gun 14G	60	1	6	93	4	3	NR	NR
Smyth and Cederbom 1994[585]	Stereotactic guidance automated gun 14G	14	0	0	44	NR	NR	NR	NR
Elvecrog et al. 1993[586]	Stereotactic guidance automated gun 14G	31	8	0	64	8	0	NR	NR
Parker et al. 1990[591]	Stereotactic guidance automated gun	15	0	1	80	NR	NR	NR	NR

Table F26. Accuracy data ultrasound-guided vacuum-assisted core-needle biopsies

Study	Type of Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Vag et al. 2007[493]	US guidance vacuum-assisted 10G	28	0	1	41	NR	NR	NR	NR
Wu et al. 2005[503]	US guidance vacuum-assisted 11G	0	0	1	112	0	0	0	0
Alonso-Bartolome et al. 2004[504]	US guidance vacuum-assisted 11G	1	1	0	100	1	0	NR	NR
March et al. 2003[514]	US guidance vacuum-assisted 11G	8	2	0	21	2	0	1	0
Philpotts et al. 2003[516]	US guidance vacuum-assisted 11G	19	2	1	37	2	0	1	1
Johnson et al. 2002[521]	US guidance vacuum-assisted 11 or 8G	3	2	0	70	2	0	0	0
Perez-Fuentes et al. 2001[534]	US guidance vacuum-assisted 11G	14	1	0	42	1	0	NR	NR

Table F27. Accuracy data stereotactic guidance vacuum-assisted core-needle biopsy

Study	Type of Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Jackman et al. 2009[485]	Stereotactic guidance vacuum-assisted 11G or 14G	503	97	5	604	NR	NR	NR	NR
Sim and Kei 2008[488]	Stereotactic guidance vacuum-assisted 11G	16	7	0	69	7	0	15	0
Tonegutti and Girardi 2008[489]	Stereotactic guidance vacuum-assisted 11G	56	22	0	140	27	5	35	3
Uematsu et al. 2007[492]	Stereotactic guidance vacuum-assisted 11G	34	7	0	59	8	1	31	4
Chapellier et al. 2006[494]	Stereotactic guidance vacuum-assisted 11G	85	17	0	209	19	2	51	11
Dhillon et al. 2006[496]	Stereotactic guidance vacuum-assisted 11G	46	16	0	88	18	2	34	4
Weber et al. 2005[502]	Stereotactic guidance vacuum-assisted 11G	62	8	2	118	9	1	40	6
Kettritz et al. 2004[507]	Stereotactic guidance vacuum-assisted 11G	669	103	1	1461	135	32	434	49
Lomoschitz et al. 2004[508]	Stereotactic guidance vacuum-assisted 11G	45	2	2	22	4	2	12	2
Ambrogetti et al. 2003[510]	Stereotactic guidance vacuum-assisted 11G	144	12	15	66	17	5	115	20
Apesteguia et al. 2002[518]	Stereotactic guidance vacuum-assisted 11G	47	13	0	70	14	1	32	5
Georgian-Smith et al. 2002[519]	Stereotactic guidance vacuum-assisted 11G	29	7	1	106	9	2	17	2
Liberman et al. 2002[522]	Stereotactic guidance vacuum-assisted 11G	213	38	3	321	49	11	120	17
Meloni et al. 2002[523]	Stereotactic guidance vacuum-assisted	40	1	0	64	2	1	22	1
Morris et al. 2002[524]	Stereotactic guidance vacuum-assisted 14G	4	1	0	12	1	0	0	0
Pfarl et al. 2002[525]	Stereotactic guidance vacuum-assisted 11G	207	11	7	93	17	6	91	11
Cangiarella et al. 2001[529]	Stereotactic guidance vacuum-assisted 11G	15	8	0	92	10	2	12	1
Lai et al. 2001[531]	Stereotactic guidance vacuum-assisted 11G	148	8	2	321	10	2	48	6
Beck et al. 2000[539]	Stereotactic guidance vacuum-assisted 11G	105	13	0	477	13	0	74	0
Soo et al. 1999[550]	Stereotactic guidance vacuum-assisted 14G	10	1	0	22	1	0	2	0
Heywang-Kobrunner et al.	Stereotactic guidance vacuum-	45	6	0	129	6	0	30	0

Table F27. Accuracy data stereotactic guidance vacuum-assisted core-needle biopsy (continued)

Study	Type of Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Jackman et al. 2009[485]	Stereotactic guidance vacuum-assisted 11G or 14G	503	97	5	604	NR	NR	NR	NR
Sim and Kei 2008[488]	Stereotactic guidance vacuum-assisted 11G	16	7	0	69	7	0	15	0
1998[554]	assisted 11 or 14G								
Zannis and AliaNo 1998[560]	Stereotactic guidance vacuum-assisted 11G	17	4	0	33	4	0	9	0

Table F28. Accuracy data miscellaneous methods of biopsy

Study	Type Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimates	N DCIS	N DCIS Underestimates
Pfleiderer et al. 2003[515]	MRI guidance automated gun 14G	5	0	1	8	1	1	NR	NR
Puglisi et al. 1999[549]	Perforated compression grid automated gun 14G	32	2	3	63	4	1	7	2

Table F29. Accuracy data mixed methods of biopsy not reported separately

Study	Type Core Biopsy	TP	FP	FN	TN	N Atypia	N Atypia Underestimated	N DCIS	N DCIS Underestimated
Ciatto et al. 2007[490]	Multiple methods	1,158	207	71	1,532	NR	NR	NR	NR
Cipolla et al. 2006[495]	Multiple methods	182	11	1	232	16	6	8	3
Dillon et al. 2005[499]	Multiple methods	1,299	120	85	461	181	71	NR	NR
Fajardo et al. 2004[506]	Multiple methods	358	31	17	1,025	54	23	NR	NR
Abdsaleh et al. 2003[509]	Multiple methods	104	1	16	18	NR	NR	7	2
Kirshenbaum et al. 2003[513]	Multiple methods	117	20	2	253	24	6	NR	NR
Jackman and Lamm 2002[520]	Multiple methods	11	3	0	17	3	0	5	0
Margolin et al. 2001[533]	Multiple methods	158	14	0	1,120	26	12	NR	NR
White et al. 2001[536]	Multiple methods	231	31	7	464	39	10	65	18
Latosinsky et al. 2000[541]	Multiple methods	85	13	6	246	21	8	30	8
Liberman et al. 2000[542]	Multiple methods	62	4	1	36	4	2	4	2
Makoske et al. 2000[543]	Multiple methods	139	28	0	377	38	10	39	19
Welle et al. 2000[545]	Multiple methods	36	15	0	122	13	4	7	3
Meyer et al. 1999[548]	Multiple methods	493	63	0	855	88	25	133	20
Caruso et al. 1998[551]	Multiple methods	67	0	0	7	NR	NR	2	2
Fuhrman et al. 1998[553]	Multiple methods	295	31	3	852	67	36	84	30
Loffe et al. 1998[555]	Multiple methods	50	7	0	125	10	3	NR	NR
Britton et al. 1997[562]	Multiple methods	94	2	7	95	NR	NR	NR	NR
Helbich et al. 1997[563]	Multiple methods	100	2	3	105	4	2	12	0
Stolier et al. 1997[567]	Multiple methods	30	6	2	170	12	3	10	0
Nguyen et al. 1996[575]	Multiple methods	183	9	4	217	NR	NR	NR	NR
Doyle et al. 1995[580]	Multiple methods	23	2	0	119	6	4	NR	NR
Burbank et al. 1994[582]	Multiple methods	14	3	0	88	3	1	6	0
Parker et al. 1994[584]	Multiple methods	967	129	15	2,654	186	57	148	18

Table F30. Miscellaneous accuracy data

Study	Accuracy by Breast Lesion Factors	Accuracy by Patient Characteristics	Accuracy by Biopsy Methods	Accuracy by Clinician and Facility Factors
Ciatto et al. 2007[490]	Palpable lesions: 400 true positives, 63 false positives, 27 false negatives, 493 true negatives Non-palpable lesions: 758 true positives, 144 false positives, 44 false negatives, 1038 true negative Masses on mammography: 540 true positives, 103 false positives, 36 false negatives, 839 true negatives Distortions on mammography: 17 true positives, 27 false positives, 1 false negative, 29 true negatives Microcalcifications: 601 true positives, 77 false positives, 34 false negatives, 663 true negatives	NR	NR	Overall sensitivity improved over the course of the study, 88% first year, 96% final year.
de Lucena et al. 2007[491]	NR	NR	The rate of false negatives decreased from 9.9% with only one core to 5.9% with two cores. Adding additional cores beyond 2 didn't improve the accuracy of the biopsy.	NR
Cipolla et al. 2006[495]	Correspondence between the core-biopsy and surgical specimen was 100% in palpable lesions but only 88.6% in non-palpable lesions	NR	NR	NR
Koskela et al. 2005[500]	Masses on mammography: 40 true positives, 1 false-negative, 55 true negatives Microcalcifications: 43 true positives, 0 false-negatives, 66 true negatives	NR	More than three samples are needed for a diagnosis of a mass lesion	NR
Fajardo et al. 2004[506]	Nonpalpable lesions: Sensitivity 90.7% Masses on mammography: Sensitivity 97.4% Microcalcifications: 90.7%	NR	NR	NR
Lomoschitz et al. 2004[508]	Masses on mammography: 25 true positives, 1 false-negative, 23 true negatives Microcalcifications: 18 true positives, 1 false-negative, 28 true negatives	NR	12 specimens were necessary to yield correct diagnoses in 96% of patients with masses and 92% of patients with microcalcifications, and addition of further cores did not improve accuracy.	NR

Table F30. Miscellaneous accuracy data (continued)

Study	Accuracy by Breast Lesion Factors	Accuracy by Patient Characteristics	Accuracy by Biopsy Methods	Accuracy by Clinician and Facility Factors
Abdsaleh et al. 2003[509]	NR	34 of the 35 technical failures occurred in dense breasts	For one core there were 12 false-negatives out of 107 biopsies; for two cores there were 3 false-negatives out of 34 biopsies.	NR
Fishman et al. 2003[511]	NR	NR	Cells indicating the final diagnosis were present in the first core in 51 cases, in the second core in 67 cases, in the third core in 70 cases, and in the fourth core in all 73 cases.	
Pfarl et al. 2002[525]	Masses on mammography: 96 true positives, 3 false negatives, 52 true negatives Microcalcifications: 111 true positives, 4 false negatives, 42 true negatives	NR	NR	In six of the seven false-negative cases the biopsy was performed by an operator who had previously performed 15 or fewer stereotactic vacuum-assisted biopsies.
Doyle et al. 1998[552]	NR	NR	Of 14 biopsies performed in the seated position, there were no technical failures and no false negatives Of 137 biopsies performed in the decubuitus position, there were 2 technical failures and no false negatives	NR
Helbich et al. 1997[563]	NR	NR	Patients were randomly assigned to supine, prone, sitting; authors comment they did not find patient position to impact the biopsy procedure.	NR
Walker et al. 1997[569]	Masses on mammography: Sensitivity 93% Distortions on mammography: Sensitivity 89% Microcalcifications: Sensitivity 85%	NR	NR	NR

Table F30. Miscellaneous accuracy data (continued)

Study	Accuracy by Breast Lesion Factors	Accuracy by Patient Characteristics	Accuracy by Biopsy Methods	Accuracy by Clinician and Facility Factors
Barreto et al. 1991[589]	Tumor size did not affect accuracy; however, patients with the lesion located in the right breast had a higher rate of false-negatives (right side, 45% were false negative, left side, 27% were false negative).	Age of patients did not affect accuracy	NR	Accuracy improved over time- first 25% of biopsies performed there were 50% true positives; second and third 25% of biopsies performed there were 63% true positives; last 25% of biopsies performed there were 83% true positives.
Cusick et al. 1990[590]	24% of lesions smaller than 2 cm had false-negative findings compared to only 7% of larger lesions having false-negative findings	NR	NR	NR

Table F31. Harms data

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Peters et al. 2008[486]	948	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sim and Kei 2008[488]	105	Stereotactic guidance vacuum-assisted 11G	9 had small hematomas that did not require treatment	NR	2	NR	NR	NR	NR	NR	NR
Tonegutti and Girardi 2008[489]	268	Stereotactic guidance vacuum-assisted 11G	3 had large hematomas that did not require treatment	2, but did not require treatment	1	NR	3 had acute localized inflammation, and one large abscess that required surgery	NR	NR	NR	NR
Youk et al. 2008[24]	4,359	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Ciatto et al. 2007[490]	4,035	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
de Lucena et al. 2007[491]	150	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Uematsu et al. 2007[492]	100	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Vag et al. 2007[493]	70	US guidance vacuum-assisted 10G	NR	No severe bleeding occurred	1	No severe infections occurred	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Chapellier et al. 2006[494]	318	Stereotactic guidance vacuum-assisted 11G	123 subclinical	NR	NR	NR	No abscesses occurred	NR	NR	269 found procedure had good tolerability and 49 reported it was acceptable or poor. Of these 49, 17 complained of intense pain, 23 of pain that didn't respond to the local anesthetic, and 12 reported the procedure was stressful	NR
Cipolla et al. 2006[495]	426	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dhillon et al. 2006[496]	150	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Bolivar et al. 2005[497]	214	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Crystal et al. 2005[498]	715	US guidance automated gun 14G	NR	NR	NR	NR	No major complications occurred	NR	NR	NR	NR
Dillon et al. 2005[499]	2,427	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Koskela et al. 2005[500]	213	Stereotactic guidance automated gun 14G	No hematomas that required treatment occurred	NR	2	No infections that required treatment occurred	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Sauer et al. 2005[501]	962	US guidance automated gun 14G	NR	Some cases of minor bleeding that did not require treatment	NR	1 that required surgery and antibiotics	NR	NR	NR	NR	NR
Weber et al. 2005[502]	225	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	2	1 biopsy was terminated after complaints of severe pain by the patient, 5 patients had severe bruising and 2 complained of persistent pain	NR	NR	2 patients were not satisified with the cosmetic result	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Wu et al. 2005[503]	113	US guidance vacuum-assisted 11G	NR	NR	NR	NR	2 cases pneumothorax that resolved without treatment, 13 cases of severe ecchymosis that also resolved without treatment; All complica-tions occurred during the first year of the study, no complications occurred during the second and third years	NR	NR	NR	NR
Alonso-Bartolome et al. 2004[504]	102	US guidance vacuum-assisted 11G	37 that did not require treatment	3, only one required treatment	NR	NR	1 patient complained of pain.	NR	NR	NR	NR
Delle and Terinde 2004[505]	169	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fajardo et al. 2004[506]	2,403	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Kettritz et al. 2004[507]	2,893	Stereotactic guidance vacuum-assisted 11G	25 hematomas of which 3 were hospitalized overnight and 1 required surgery	4 patients were hospitalized for persistent bleeding, of which 3 needed surgery	5	5 that required antibiotics	1 seizure	NR	NR	NR	In 196 patients a slight mammo-graphic density was observed. In 4 patients a scar that might cause diagnostic difficulty was observed.
Lomoschitz et al. 2004[508]	100	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Abdsaleh et al. 2003[509]	180	Multiple methods	NR	Mild bleeding occurred in all cases	NR	NR	No significant complications occurred	NR	NR	NR	NR
Ambrogetti et al. 2003[510]	364	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fishman et al. 2003[511]	73	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Han et al. 2003[512]	271	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Kirshenbaum et al. 2003[513]	506	Multiple methods	NR	Three cases of minor bleeding and one case of major bleeding that required surgery	5 vasovagal reactions; the most experienced radiologist had 3 reactions in 409 procedures while the two more inexperienced radiologists had 1 reaction out of 47 procedures and 1 reaction out of 53 procedures	NR	NR	NR	NR	NR	NR
March et al. 2003[514]	34	US guidance vacuum-assisted 11G	9 hematomas that did not require treatment	NR	NR	NR	19 reported no pain, 13 reported mild pain, 2 reported moderate pain. 24 patients had ecchymosis 2-4 days after the procedure	16 reported the procedure had not interferred with usual activity at all, 14 a little, 4 somewhat	20 took acetamino-phen	NR	NR
Pfleiderer et al. 2003[515]	14	MRI guidance automated gun 14G	NR	NR	NR	NR	No severe side effects were observed	NR	None used	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Philpotts et al. 2003[516]	281	Multiple methods	3 hematomas in 11G no surgery required	3 cases of bleeding with 14G	NR	NR	NR	NR	NR	NR	NR
Wong and Hisham 2003[517]	150	Freehand automated gun 14G/16G	NR	1 patient in 14G group experienced troublesome bleeding	NR	3 patients from 14G group developed infections	There was no difference in the amount of pain experienced between 14G and 16G as meausured on a VAS, p >0.05	NR	NR	NR	NR
Apesteguia et al. 2002[518]	132	Stereotactic guidance vacuum-assisted 11G	Some hematomas that did not require treatment	8 cases of bleeding which caused premature termination of the procedure in 3 of the 8 cases	NR	NR	2 cases of severe pain	NR	NR	NR	NR
Georgian-Smith et al. 2002[519]	185	Stereotactic guidance vacuum-assisted 11G	3, one case of which it became infected and required antibiotics to treat	5, 2 of which were severe enough to require termination of the biopsy	10, 2 of which were severe enough to require termination of the biopsy procedure	NR	1 patient vomited	NR	NR	NR	NR
Jackman and Lamm 2002[520]	31	Multiple methods	NR	2 serious bleeding	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Johnson et al. 2002[521]	101	US guidance vacuum-assisted 11 or 8G	1 large hematoma requiring narcotics	1 significant bleeding requiring surgery; less than 5% of cases had bleeding requiring treatment	NR	2 infections requiring antibiotics and surgical drainage	NR	NR	1 case required narcotics	NR	NR
Liberman et al. 2002[522]	800	Stereotactic guidance vacuum-assisted 11G	2 that required treatment	12	2	NR	1 patient was in such severe pain that the procedure was terminated	NR	NR	NR	NR
Meloni et al. 2002[523]	129	Stereotactic guidance vacuum-assisted	2 that did not require treatment	1	5	NR	NR	NR	NR	NR	NR
Morris et al. 2002[524]	21	Stereotactic guidance vacuum-assisted 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pfarl et al. 2002[525]	332	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Verkooijen et al. COBRA 2002[526]	984	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Becker et al. 2001[527]	232	Stereotactic guidance automated gun 14G	NR	3 minor	2	NR	NR	NR	NR	NR	NR
Brenner et al. 2001[528]	1,003	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Cangiarella et al. 2001[529]	160	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Dahlstrom and Jain 2001[530]	310	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lai et al. 2001[531]	673	Stereotactic guidance vacuum-assisted 11G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Levin et al. 2001[532]	70	Stereotactic guidance automated gun 14G	NR	NR	3	NR	NR	NR	NR	NR	NR
Margolin et al. 2001[533]	1,333	Multiple methods	NR	NR	NR	2 that required antibiotics	NR	NR	NR	NR	NR
Perez-Fuentes et al. 2001[534]	88	US guidance vacuum-assisted 11G	NR	1 patient with implants experienced severe bleeding that required surgical treatment	NR	NR	NR	NR	NR	NR	NR
Smith et al. 2001[535]	500	US guidance automated gun 14G	0	NR	NR	0	26 had large areas of ecchymosis; one patient had a small pneumothorax that resolved without treatment	NR	NR	NR	NR
White et al. 2001[536]	1,042	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Wunderbaldinger et al. 2001[537]	45	US guidance automated gun 14G	NR	NR	4	NR	NR	NR	NR	NR	NR
Yeow et al. 2001[538]	98	US guidance automated gun 14 or 16G	0	NR	NR	0	1 patient had a puncture site ecchymosis	NR	NR	NR	NR
Beck et al. 2000[539]	594	Stereotactic guidance vacuum-assisted 11G	1 that required surgical treatment	NR	NR	NR	1 patient had a seizure	NR	NR	NR	In 90% of patients no scarring was seen on subsequent mammo-graphy; in 10% a faint density could be seen at the biopsy site; 1 patient had a diagnostically confusing scar that was evidentally benign on MRI
Kirwan et al. 2000[540]	72	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Latosinsky et al. 2000[541]	692	Multiple methods	NR	NR	NR	NR	There were no significant complications of bleeding or infection	NR	NR	NR	NR
Liberman et al. 2000[542]	155	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Makoske et al. 2000[543]	887	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Ward et al. 2000[544]	121	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Welle et al. 2000[545]	225	Multiple methods	1 did not require treatment	1 did not require treatment	4 (in seated patients)	NR	NR	NR	NR	NR	NR
Helbich et al. 1999[546]	44	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Jackman et al. 1999[547]	483	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Meyer et al. 1999[548]	1,836	Perforated compression grid automated gun 14G	0 that required treatment	NR	NR	1 that required antibiotics	Complications were minor and infrequent. 1 pneumothorax requiring no treatment occurred	NR	NR	NR	NR
Puglisi et al. 1999[549]	106	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	No complications resulted from this technique	NR	NR	NR	NR
Soo et al. 1999[550]	116	Stereotactic guidance vacuum-assisted 14G	NR	NR	NR	NR	One patient was in such severe pain that the procedure was terminated	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Caruso et al. 1998[551]	92	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Doyle et al. 1998[552]	151	Stereotactic guidance automated gun 14G	NR	NR	4 (in seated patients)	1 minor	No serious complications occurred	NR	NR	Most of our patients found that decubitus position was reasonably comfortable and that discomfort was mostly related to prolonged breast compression	NR
Fuhrman et al. 1998[553]	1,440	Multiple methods	NR	NR	NR	NR	Hospitalization was not required for any subjects. The only complication encountered was minor breast ecchymosis, which resolved uneventfully in all cases	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Heywang-Kobrunner et al. 1998[554]	261	Stereotactic guidance vacuum-assisted 11 or 14G	NR	1	NR	NR	No side effects occurred. No patients complained about pain.	NR	NR	NR	117 of 129 patients had no scarring visible at 6-month mammo-graphy. Very slight scarring occurred in ten patients, and mammo-graphically visible scarring in 2 patients, one of whom was sent for MRI to verify it was a scar and not a tumor.
Ioffe et al. 1998[555]	224	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Liberman et al. 1998[556]	151	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Schulz-Wendtland et al. 1998[557]	2,307	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Vega-Bolivar et al. 1998[558]	182	Stereotactic guidance Surecut 15G	NR	NR	12	NR	NR	NR	NR	NR	NR
Whitman et al. 1998[559]	12	Stereotactic guidance automated gun 16G	NR	NR	1	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Zannis and AliaNo 1998[560]	424	Multiple methods	NR	Bleeding requiring operative intervention was not required in any group	NR	NR	Open biopsy: 12 cases cellulitis and 4 abscesses out of 190 procedures; zero cases of cellulitis and abscesses out of 234 core-needle biopsy procedures	NR	Open biopsy: all 190 were sent home with oral narcotic analgesia; zero patients out of 157 SCNB and 77 VAB procedures required oral narcotic analgesia	NR	NR
Bauer et al. 1997[561]	799	Stereotactic guidance automated gun 14G	10 that did not require treatment	NR	NR	0	NR	NR	NR	NR	NR
Britton et al. 1997[562]	202	Multiple methods	0	NR	7		No complications that required treatment occurred	NR	NR	NR	NR
Helbich et al. 1997[563]	210	Multiple methods	NR	NR	4 (in seated patients)	NR	No serious complications, patients tolerated it well	NR	NR	NR	NR
Khattar et al. 1997[564]	106	US guidance automated gun	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Liberman et al. 1997[565]	442	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pitre et al. 1997[566]	128	Stereotactic guidance automated gun	NR	NR	NR	NR	NR	NR	NR	NR	NR
Stolier et al. 1997[567]	244	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sutton, et al. 1997[568]	206	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	There were no cases of long-term morbidity and only 3 patients (1.5%) had a biopsy-related problem 3 days after their core-needle biopsy	NR	NR	Pain: 36% none, 27.6% un-comfortable, 12.3% slight, 7% quite, 0% very Discomfort: 50% none, 40% un-comfortable, 6% slight, 4% quite, 0% very	NR
Walker et al. 1997[569]	200	Stereotactic guidance automated gun 14G	NR	0	1	0	A few patients complained of pain; bruising was not infrequent	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Frazee et al. 1996[570]	103	Stereotactic guidance automated gun	NR	NR	NR	NR	Patients rating of post-operative pain was evaluated using a Pain Analog Scale. The mean score for open biopsy was 2.5 and for stereotactic biopsy was 2.8 (P = NS)	The interval of returning to normal activies was measured. This averaged 3.8 days for open biopsy and 1.5 days for stererotactic biopsy (P = NS)	NR	Overall patient satisfaction was evaluated. No significant differences were seen in overall patient satisfaction between the two biopsy techniques	NR
Fuhrman et al. 1996[571]	451	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Head and Haynes 1996[572]	115	Stereotactic guidance automated gun 18G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mainiero et al. 1996[573]	138	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Meyer et al. 1996[574]	388	Stereotactic guidance automated gun 14G	3	NR	NR	NR	Ecchymosis at the biopsy site occured in 48% of patients	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Nguyen et al. 1996[575]	431	Multiple methods	A few small superficial ones that required no treatment	NR	NR	NR	There were no serious complications. Several patients complained of pain related to lying on the biopsy table for a prolonged period of time	NR	NR	NR	NR
Pettine et al. 1996[576]	25	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Rosenblatt et al. 1996[577]	58	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Scopa et al. 1996[578]	120	Freehand TruCut	NR	NR	NR	NR	NR	NR	NR	NR	NR
Cross et al. 1995[579]	250	Stereotactic guidance automated gun 14G	NR	NR	NR	0	Pain was reported to be minimal	NR	NR	NR	NR
Doyle et al. 1995[580]	365	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Burbank et al. 1994[582]	105	Multiple methods	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gisvold et al. 1994[583]	160	Stereotactic guidance automated gun 14G	Hemotoma formation was infrequent	NR	0	1 serious systemic infection	Two patients had significant pain	NR	NR	NR	NR
Parker et al. 1994[584]	6,152	Multiple methods	3 that required surgery	NR	NR	3 that required antibiotics	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
Smyth and Cederbom 1994[585]	58	Stereotactic guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Elvecrog et al. 1993[586]	100	Stereotactic guidance automated gun 14G	1 that required surgical treatment	NR	NR	NR	NR	NR	NR	Some patients complained of pain from biopsy, but usually with only 1 or 2 needle passes. In a few cases, deep anesthesia was administered with the biopsy needle still in the lesion. There were frequent complaints of neck, shoulder, and arm discomfort from patients lying in the same position for an extended period of time	NR
Parker et al. 1993[587]	181	US guidance automated gun 14G	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table F31. Harms data (continued)

Study	Number of Lesions Enrolled	Type of Biopsy	Hematomas	Bleeding	Vasovagal Reactions	Infections	Other	Time to Recovery or Time to Return to Work	Use of Pain Medications	Patient Satisfaction, Quality of Life Data	Impact of Biopsy Procedure on Accuracy of Subsequent Mammography Procedures
McMahon et al. 1992[588]	151	Freehand 14/1618G	NR	Troublesome bleeding occurred in 3 patients in Bioptycut 14G, 2 patients in Bioptycut 18G, and 1 in Trucut	NR	NR	There were no major complications. Minor bruising was common. No patients developed pneumothorax	NR	NR	Pain scores on a 0 to 3 scale were recorded after the procedure: Trucut 40% had a 0, 40% a 1, 15% a 2, 5% a 3. Biopty 14G 70% had a 0, 12% a 1, 15% a 2, 3% a 3. Biopty 18G 60% had a 0, 30% a 1, 10% a 2, 0% a 3. B18 was reported to have significantly p = 0.01 less pain thanTrucut	NR
Barreto et al. 1991[589]	107	Freehand automated gun 18G	NR	NR	NR	NR	NR	NR	NR	NR	NR
Cusick et al. 1990[590]	96	Freehand	NR	NR	NR	NR	NR	NR	NR	NR	NR
Parker et al. 1990[591]	103	Stereotactic guidance automated gun	NR	No significant bleeding occured, even with use of the 14-gauge needle	2 (in seated patients)	Three that required treatment with antibiotics	None of the patients suffered immediate significant complications.	NR	NR	NR	NR

NR = Not Reported

Table F32. Data for women diagnosed with cancer by biopsy

	Number who were able to be treated with only one surgical procedure	
Reference	**Core-needle diagnosis**	**Open biopsy diagnosis**
Friese et al. 2009[592]	Odds ratio 2.9 (2.7 to 2.9)	
Verkooijen et al. 2001[593]	63 out of 84	13 out of 80
Morrow et al. 2000[305]	222 out of 264	47 out of 142
Kaufman et al. 1998[396]	52 out of 66	10 out of 47
Lind et al. 1998[402]	47 out of 48	35 out of 69
Fenoglio et al. 1997[419]	20 out of 20	1 out of 20
Liberman et al. 1997[428]	76 out of 90	31 out of 107

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

All biopsies

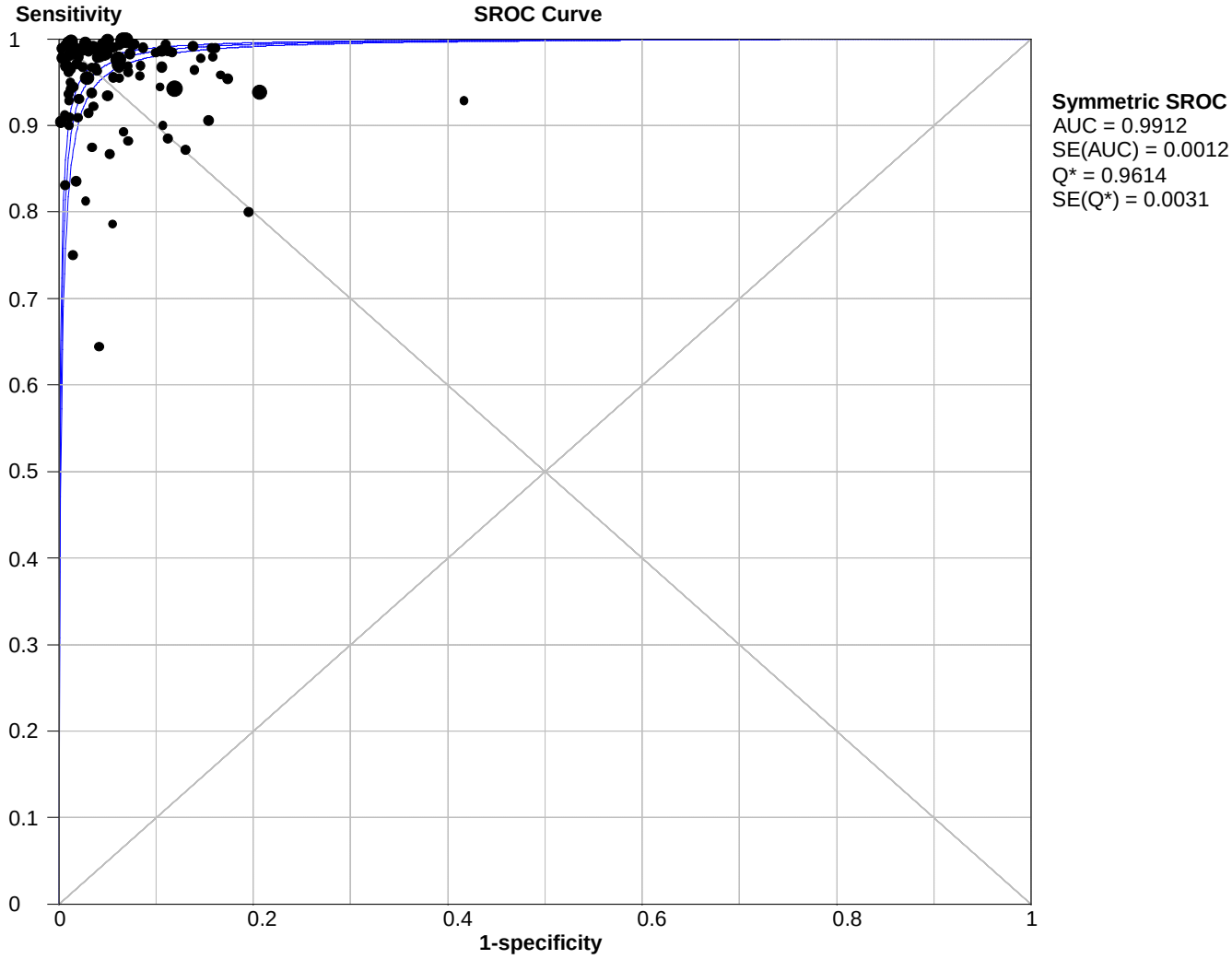
Could not fit a bivariate binomial model

Random-effects model:

Summary sensitivity: 96.4% (96.1% to 96.7%), I^2 = 83.2%

Summary negative likelihood ratio: 0.038 (0.030 to 0.050), I^2 = 86.6%

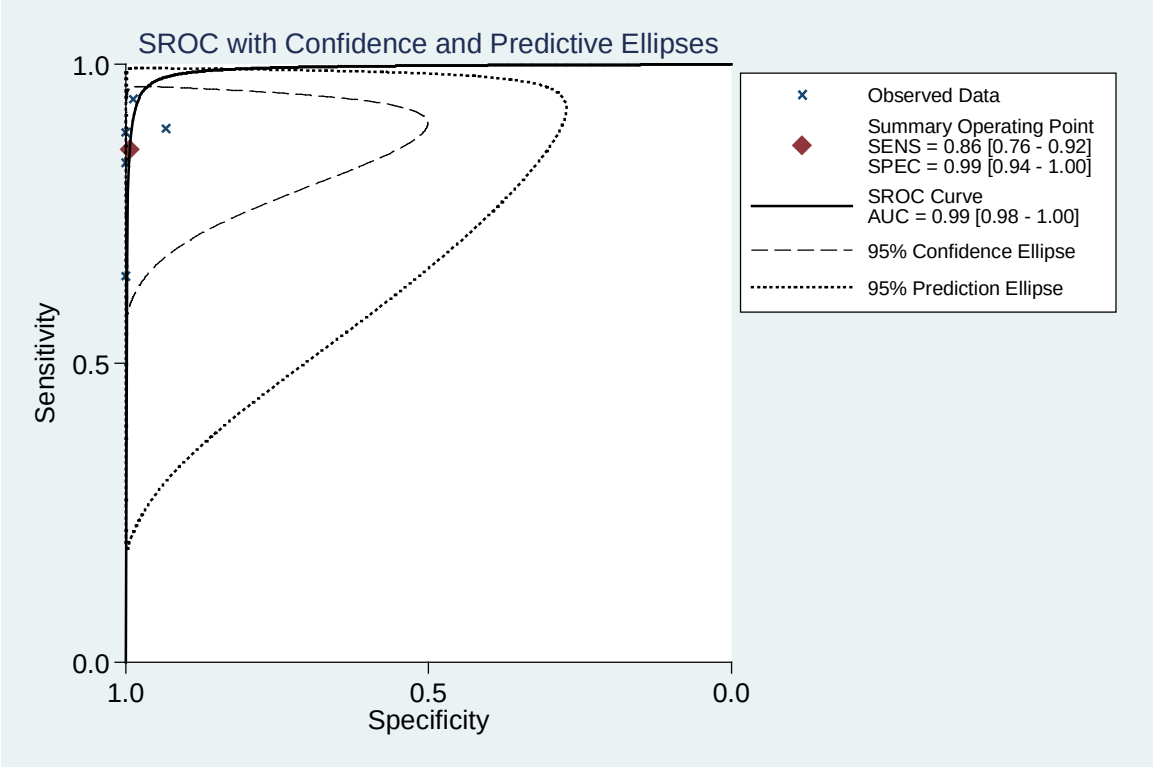
Figure F1. Summary ROC of all core-needle biopsy studies



META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES
Freehand biopsies
SUMMARY DATA AND PERFORMANCE ESTIMATES
Bivariate Binomial Mixed Model
Number of studies = 5
Reference-positive Subjects = 419
Reference-negative Subjects = 191
Pretest Prob of Disease = 0.687
Between-study variance (varlogitSEN) = 0.438, 95% CI = [0.096-1.994]
Between-study variance (varlogitSPE) = 0.562, 95% CI = [0.001-309.743]
Correlation (Mixed Model) = -1.000
ROC Area, AUROC = 0.99 [0.98 - 1.00]
Heterogeneity (Chi-square): LRT_Q = 2.149, df = 2.00, LRT_p = 0.171
Inconsistency (I-square): LRT_I^2 = 6.95, 95% CI = [0.00-100.00]

Parameter	Estimate	95% CI
Sensitivity	0.858	[0.758, 0.921]
Specificity	0.993	[0.939, 0.999]
Positive Likelihood Ratio	121.004	[13.764, 1063.749]
Negative Likelihood Ratio	0.143	[0.082, 0.250]
Diagnostic Score	6.738	[4.613, 8.863]
Diagnostic Odds Ratio	844.025	[100.826, 7065.427]

Figure F2. Summary ROC of freehand core-needle biopsies

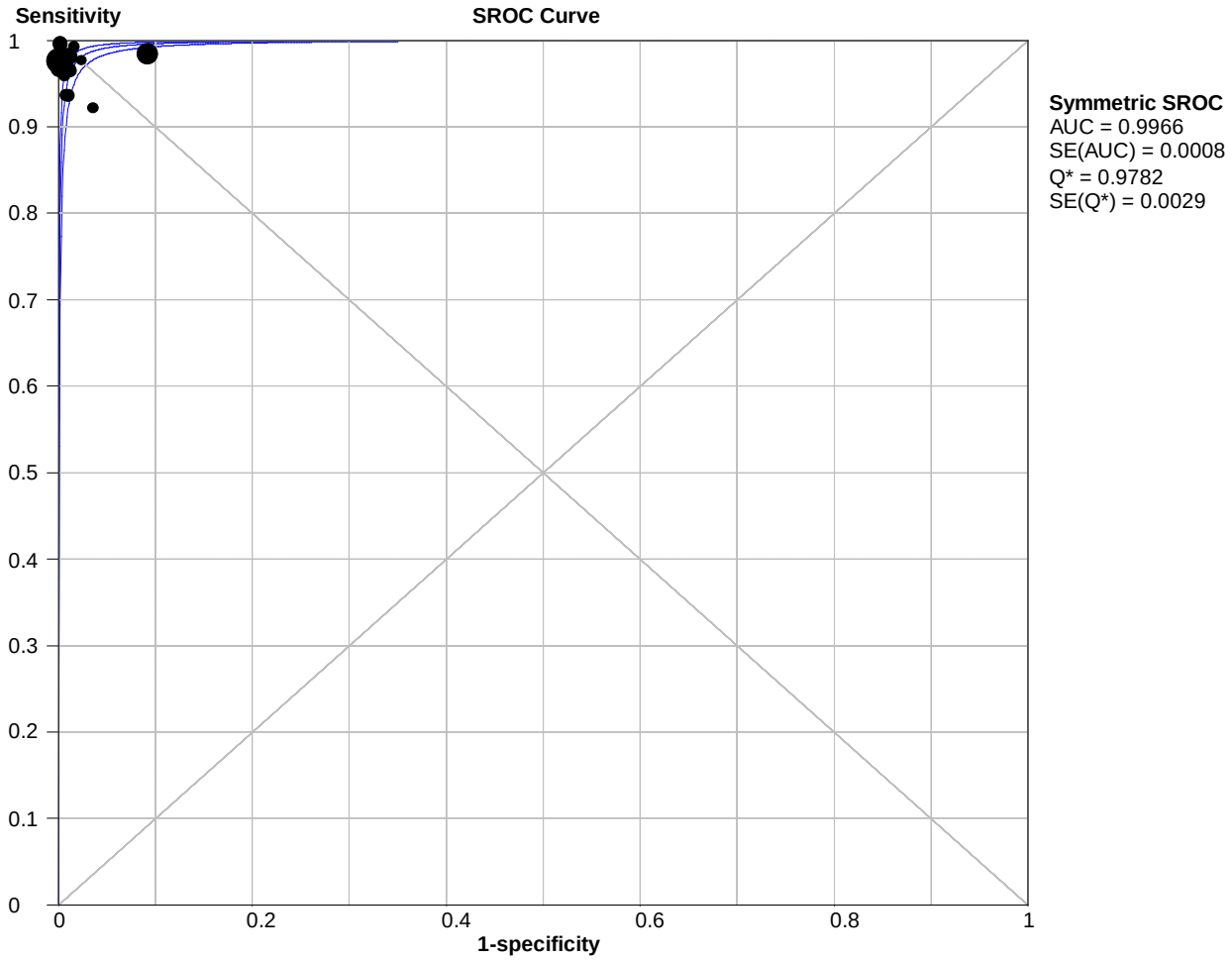


META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES
Ultrasound-guided automated gun biopsies
Could not fit a bivariate binomial model
Random-effects model:

Summary sensitivity:	97.7% (97.2 to 98.2%)	I^2 =	39.9%
Summary negative likelihood ratio:	0.030 (0.022 to 0.040)	I^2 =	32.7%
Summary atypia underestimation rate:	0.292 (0.234 to 0.359)	I^2 =	0.0%
Summary DCIS underestimation rate:	0.355 (0.271 to 0.450)	I^2 =	17.9%

Meta-regression results:
Country study conducted in p = 0.25
Open surgery to verify all results vs. surgery + patient followup p = 0.7919
Open surgery + at least 2 years followup to verify results vs. open surgery + some patients had less than 2 years followup p = 0.341

Figure F3. Summary ROC of ultrasound-guided automated gun core-needle biopsies



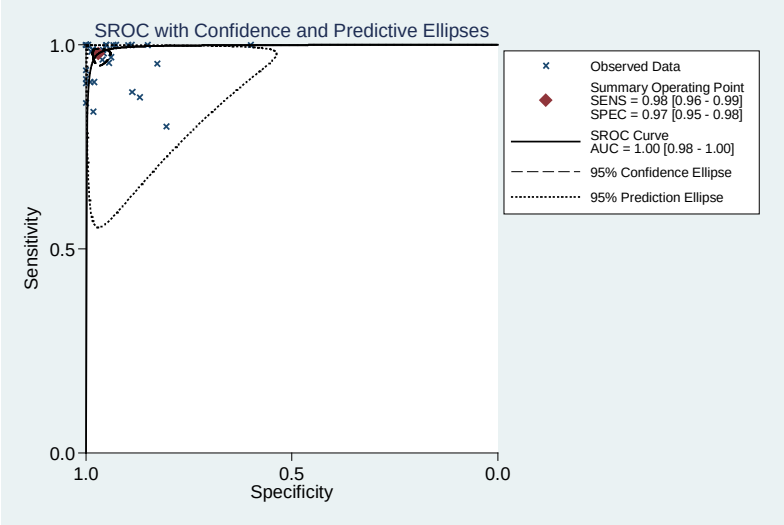
META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES
Stereotactic-guided automated gun biopsies
SUMMARY DATA AND PERFORMANCE ESTIMATES
Bivariate Binomial Mixed Model
Number of studies = 33
Reference-positive Subjects = 2,653
Reference-negative Subjects = 4,482
Pretest Prob of Disease = 0.372
Between-study variance (varlogitSEN) = 1.836, 95% CI = [0.777-4.339]
Between-study variance (varlogitSPE) = 1.592, 95% CI = [0.724-3.501]
Correlation (Mixed Model) = 0.062
ROC Area, AUROC = 1.00 [0.98 - 1.00]
Heterogeneity (Chi-square): LRT_Q = 76.751, df = 2.00, LRT_p = 0.000
Inconsistency (I-square): LRT_I^2 = 97.39, 95% CI = [95.65-99.14]

Parameter	Estimate	95% CI
Sensitivity	0.978	[0.958, 0.989]
Specificity	0.970	[0.950, 0.982]
Positive Likelihood Ratio	32.208	[19.313, 53.711]
Negative Likelihood Ratio	0.022	[0.012, 0.043]
Diagnostic Score	7.269	[6.398, 8.140]
Diagnostic Odds Ratio	1435.328	[600.670, 3429.782]

Atypia underestimation rate =0.435 (0.357 to 0.517) I^2 = 35.7%
DCIS underestimation rate = 0.244 (0.18 to 0.321) I^2 = 57.0%
Meta-regression results:

Gauge of needle p = 0.423
Number of centers p = 0.235
Type of facility p = 0.685
Country conducted in p = 0.543
Open surgery to verify all results vs. surgery + patient followup p = 0.459
Open surgery + at least 2 years followup to verify results vs. open surgery + some patients had less than 2 years followup p = 0.681

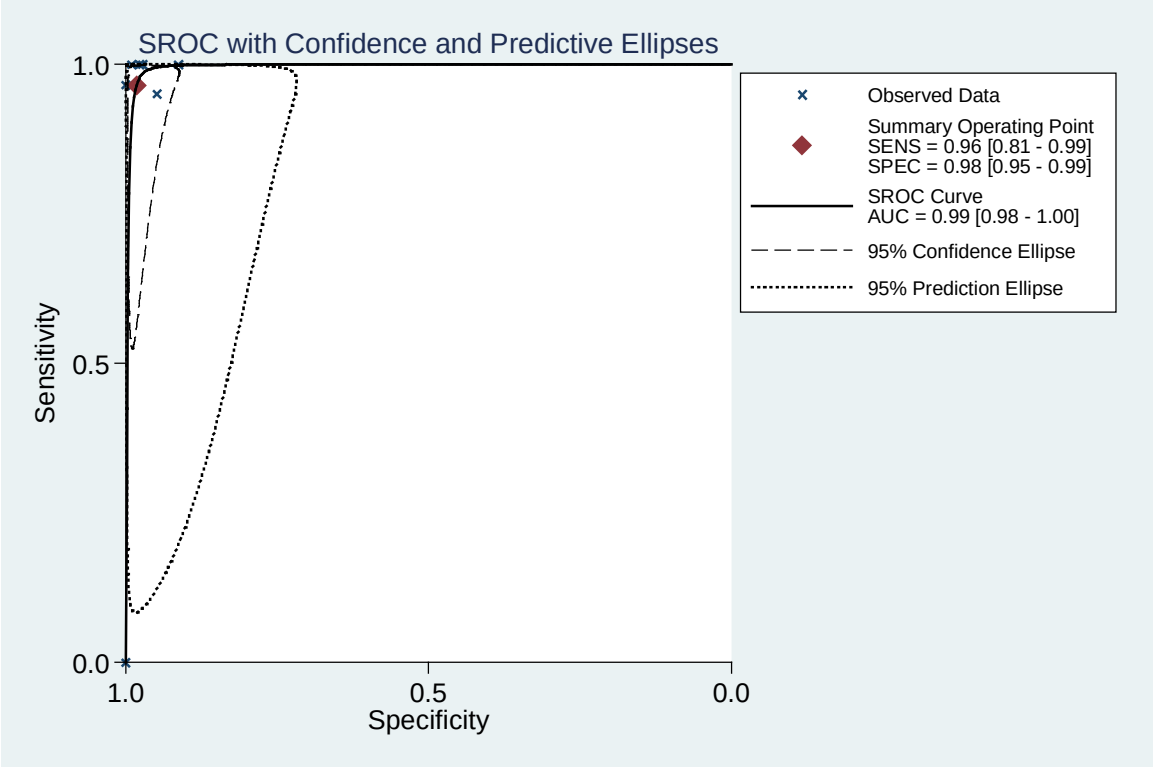
Figure F4. Summary ROC of stereotactic-guided automated gun core-needle biopsies



META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES
Ultrasound-guided vacuum-assisted biopsies
SUMMARY DATA AND PERFORMANCE ESTIMATES
Bivariate Binomial Mixed Model
Number of studies = 7
Reference-positive Subjects = 76
Reference-negative Subjects = 431
Pretest Prob of Disease = 0.150
Between-study variance (varlogitSEN) = 1.928, 95% CI = [0.014-270.021]
Between-study variance (varlogitSPE) = 0.574, 95% CI = [0.031-10.757]
Correlation (Mixed Model) = -1.000
ROC Area, AUROC = 0.99 [0.98 - 1.00]
Heterogeneity (Chi-square): LRT_Q = 1.085, df = 2.00, LRT_p = 0.291
Inconsistency (I-square): LRT_I^2 = 0.00, 95% CI = [0.00-100.00]

Parameter	Estimate	95% CI
Sensitivity	0.965	[0.812, 0.994]
Specificity	0.982	[0.954, 0.993]
Positive Likelihood Ratio	53.843	[21.308, 136.059]
Negative Likelihood Ratio	0.036	[0.006, 0.212]
Diagnostic Score	7.319	[5.502, 9.136]
Diagnostic Odds Ratio	1509.018	[245.261, 9284.523]

Figure F5. Summary ROC of ultrasound-guided vacuum-assisted core-needle biopsies



META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES
Stereotactic-guided vacuum-assisted biopsies
SUMMARY DATA AND PERFORMANCE ESTIMATES
Bivariate Binomial Mixed Model
Number of studies = 22
Reference-positive Subjects = 2,578
Reference-negative Subjects = 5,049
Pretest Prob of Disease = 0.326
Between-study variance (varlogitSEN) = 1.458, 95% CI = [0.416-5.116]
Between-study variance (varlogitSPE) = 0.271, 95% CI = [0.112-0.657]
Correlation (Mixed Model) = 0.429
ROC Area, AUROC = 0.99 [0.97 - 0.99]
Heterogeneity (Chi-square): LRT_Q = 13.534, df = 2.00, LRT_p = 0.001
Inconsistency (I-square): LRT_I^2 = 85.22, 95% CI = [69.26-100.00]

Parameter	Estimate 95% CI
Sensitivity	0.992 [0.981, 0.996]
Specificity	0.921 [0.899, 0.939]
Positive Likelihood Ratio	13.057 [10.069, 16.930]
Negative Likelihood Ratio	0.009 [0.004, 0.021]
Diagnostic Score	7.317 [6.262, 8.372]
Diagnostic Odds Ratio	1505.306 [524.041, 4323.988]
Atypia underestimation rate	0.217 (0.177 to 0.264) I^2 = 0.0%
DCIS underestimation rate	0.129 (0.111 to 0.151) I^2 = 0.0%

Meta-regression results:
Type of facility study conducted in p = 0.787
Country study was conducted in p = 0.1034
Open surgery + at least 2 years followup to verify results vs. open surgery + some patients had less than 2 years followup p = 0.456

Figure F6. Summary ROC of stereotactic vacuum-assisted core-needle biopsies

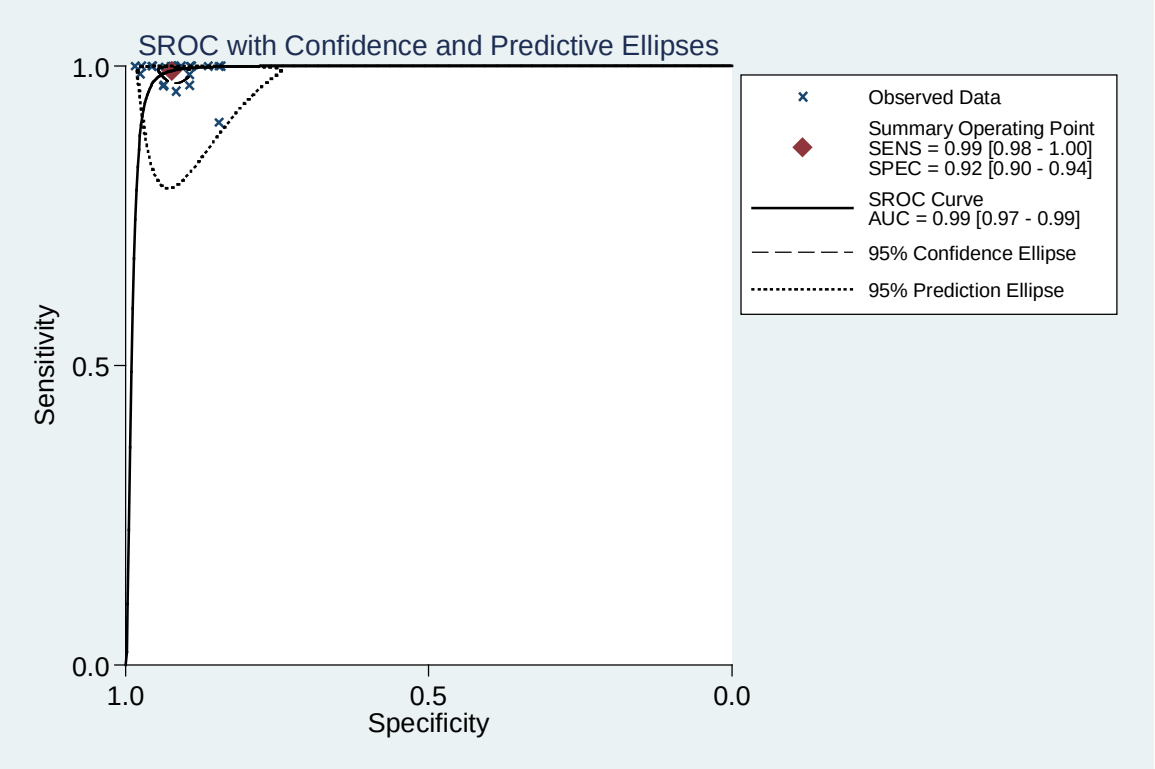


Figure F7. Meta-analysis of surgeries avoided

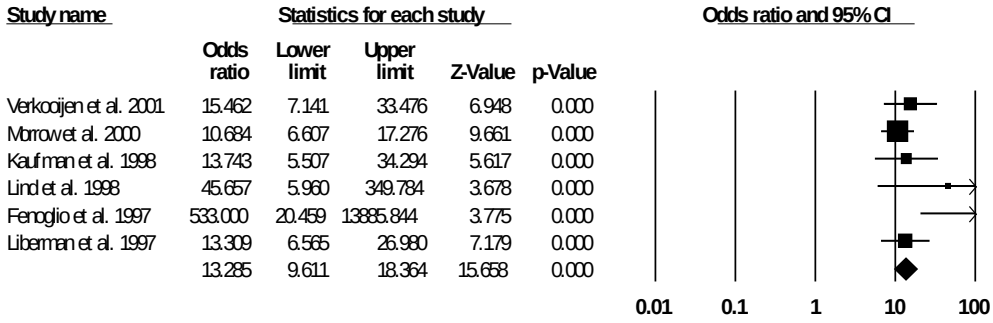


Figure shows the odds of women to require only one surgical procedure for treatment of their cancer, after being diagnosed with cancer by either a core-needle biopsy procedure or an open biopsy procedure. $I^2 = 31.3\%$.

Appendix G. Grading the Strength of Evidence

Ideally, the body of evidence to support a conclusion would be strong. Often, however, the evidence suffers from various limitations concerning the possible risk of bias in available studies, small numbers of studies and patients, and/or inconsistent effects. These limitations often mean that the strength of the evidence is only moderate, weak, or even insufficient to permit any conclusion. In order to gauge the impact of these possible limitations, we applied a formal rating system that conforms with the CER Methods Guide Manual recommendations on grading the strength of evidence.

The strength of evidence supporting each major conclusion was graded as High, Moderate, Low, or Insufficient. The grade was developed by considering four important domains: the quality (risk of potential bias) of the evidence base, the size of the evidence base, the consistency (agreement across studies) of the findings, and the robustness of the findings (as determined by sensitivity analysis). The grading system moves stepwise to consider each important domain. These steps are described below.

Step 1: What is the quality of individual studies?

We used an internal validity rating scale for diagnostic studies to grade the internal validity of the evidence base. This scale is based on a modification of the QUADAS instrument.[595] Each question in the instrument addresses an aspect of study design or conduct that can help to protect against bias. Each question can be answered "yes", "no", or "not reported," and each is phrased such that an answer of "yes" indicates that the study reported a protection against bias on that aspect. A summary score was computed with each "yes" given a +1, each "no" a -1, and each "not reported" a zero. As all of the factors captured by the questions on the quality instrument were thought to be of equal importance for this topic, no weighting was utilized in computing the summary score. This summary score was then normalized to a scale from 0 to 10, with the lower the score the greater the risk that the study was affected by biases.

Step 2: What is the overall quality of evidence?

To evaluate the overall quality of the evidence base for each conclusion, we computed the median quality score of the studies contributing to that conclusion. We used the median because it is the appropriate measure of central tendency to represent the "typical" quality score, and is less sensitive to outliers than the mean. An evidence base with a median score higher than 8.4 was considered to be of high quality; an evidence base with a median score 8.4 or less but greater than 6.7 was considered to be of moderate quality; an evidence base with a median score 6.7 or less but greater than 5.0 was considered to be of low quality; and an evidence base with a median score less than 5.0 was considered to be of insufficient quality. The quality rating was considered to be the "baseline" grade of strength of evidence.

Step 3: Is the evidence base large enough to be informative?

For this Step, we first count the number of included studies. If there are fewer than three studies, the evidence grade is automatically set to Insufficient. Next, we determined whether the precision of the evidence base was sufficient to permit a conclusion. Precision is to a large degree dependent on the size of the evidence base- in general, as the evidence base increases in size the confidence interval around the summary effect becomes tighter due to the increase in statistical power. If the effect is statistically or clinically significant we conclude the data are

informative. For diagnostic test evaluations, we consider the precision of the primary measures of diagnostic test accuracy, sensitivity and specificity. If the confidence interval bounds are within 20% of the point estimate for these measures we conclude the data are informative. Other measures of diagnostic test accuracy, such as likelihood ratios and predictive values, are calculated from the same analysis and data used to calculate sensitivity and specificity and therefore are not rated separately. If the data are not sufficiently precise, we down-grade the evidence rating by one level, for example, a rating of High from Step 2 would be down-graded to Moderate.

Step 4: Are data consistent?

Consistency refers to the extent to which the study findings are similar. Quantitative consistency can be tested with the Higgins and Thompson's I^2 statistic. For this report, we considered an evidence base to be quantitatively consistent when I^2 <50%. The evidence base is considered to be qualitatively consistent when the studies all report the same qualitative conclusion. If the data are not sufficiently consistent, we down-grade the evidence rating by one level, for example, a rating of High from Steps 2 and 4 would be down-graded to Moderate.

Step 5: Are data robust?

In this step we determine whether the data are robust to minor alterations of the data. What types of robustness tests should be performed may vary. For example, if some data were imputed, the analysis should be re-done using reasonable variations in the value(s) of the imputed data. Other robustness tests may include removing one study at a time from the analysis, or performing cumulative meta-analyses. We considered findings to not be robust only if a robustness analysis significantly altered the conclusion (e.g., a statistically significant finding becomes non-significant as studies are added to the evidence base, or the point estimate changed by more 20% after removal of any single study from the analysis). If the data are not sufficiently robust, we down-grade the evidence rating by one level, for example, a rating of High from Steps 2, 4, and 5 would be down-graded to Moderate.

In addition to the conclusions about diagnostic accuracy, we also rated the strength of evidence for one conclusion about a patient-oriented outcome, surgeries avoided. The method of rating patient-oriented outcomes is similar to, but not identical to, the method of rating the conclusions about diagnostic accuracy. In addition to the four important domains used for rating conclusions about diagnostic accuracy we also considered the domain Strength of Association (magnitude of the size of the effect). If the size of the effect was determined to be very small, we down-graded the rating of the strength of evidence by one level; and if the size of effect was determined to be very large we up-graded the strength of evidence by one level.

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