Medicare Coverage Policy ~ NCDs

Breast Biopsy (#CAG-00040N)

Appendix A: Articles Reviewed

Author/ Journal/ Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCF Con
Acheson M, Patton RG, Howlsey RL, et al. *Archives of Surgery* 1997 "Histologic correlation of image-guided core biopsy with excisional biopsy on nonpalpable breast lesions"	Nonrandomized prospective study	Histologic diagnoses of image-guided large core needle biopsies (LCNB) and excision specimens	552 patients with nonpalpable mammographic detected abnormalities	Benign findings in 389 LCNB specimens Abnormal in 163 specimens Of benign findings, one malignant diagnosis missed. 173 patients underwent excision following LCNB, 10 benign, 163 abnormal. 102 LCNB lesions confirmed on excision. Of 54 showing DCIS, 10 showed DCIS plus invasion on excision.	Fairl stud larg LCN follo exci show sens spec imag core
Bernstein JR. *Seminars in Surgical Oncology* 1996 "Role of stereotactic breast biopsy"	Review article Commentary	NA	NA	"Most patients who are referred for surgical excisional biopsy for a nonpalpable breast could have SNCB of their lesions." Radial scar is a contraindication.	Artic com som docu stud his p note supp choi BIRA lesic

				contraindication.	lesio
Bloodstone M, Dangle P, et al *Annals of Surgical Oncology* 1999 "One hundred consecutive advanced breast biopsy instrumentation procedures: complications, costs, and outcome"	Prospective Registry Patients with benign findings by ABBI were followed radiographically; patients with malignant findings by ABBI were advised to undergo therapeutic surgery.	Mammographic findings, procedure time, anesthesia type, pathologic findings, follow-up monitoring and overall costs of procedure Follow-up mammography within 6 months	100 women avg. age 62 years range 34-87 years breasts compressed to > 30 mm all lesions nonpalpable	99 patients underwent ABBI technique (1 women converted to OSB due to technical problems) 60% lesions solid nodular, 27% microcalcification incision length 2.7 cm procedure time 20 min 5 patients had complications 55 pts had followup mammography – one missed lesion avg charge $3406	Seve of M with lesio Ther seve failu devi Only mor the follo man Auth ABB pote ther tech alth labe diag
Burbank F, Parker SH, Fogarty TJ *The American Surgeon* 1996 "Stereotactic breast biopsy: improved tissue harvesting with	Clinical trial For mammographic detected lesions requiring biopsy breast composition type was scored by the 4 point BIRAD system (score 1 breast tissue almost entirely fat, score	Comparison of weight and quality of biopsy specimens obtained by Mammotome and Biopty. quality of biopsy specimen, 5 scores: 1- very good, full size, little blood, obtained quickly	284 women who underwent 345 Mammotome procedures mean age 52.7 years, age range 30-84 years Avg lesion 9.2mm	Authors found that Mammotome biopsies had higher scores than Biopty for all four BIRAD categories of breast composition. Percent of Mammotome	The spec are 3 no sele who Biot inad sam inclu subj of th cate

the Mammotome"	4 breast tissues extremely dense) Quality of Mammotome biopsy specimen was compared to quality of Biopty biopsy specimens by breast composition type. Weight comparisons relied on 3 patients who underwent Biopty then Mammotome. "These 3 patients were selected for breast composition to obtain tissue from a mammo-graphically fatty breast, an average breast, and a dense breast" pg. 740.	obtained quickly 2-good, 3/4 to full size, little blood, obtained quickly 3-average (approximately the same as usually obtained by automated true cut device) 4-poor, small amount, lots of blood, obtained very slowly 5-inadequate, no histological diagnosis possible		biopsies which received quality scores of: 1 (very good)- 84.9% 2 (good)- 13% 3 (average)- 2.1% For 3 patients Biopty was performed and then Mammotome- Mammotome specimens weighed two times more than Biopty (34.3 mg vs. 17.2 mg, p=0.0002) 3 Mammotome related complications- 1 site infection, 1 painful hematoma, 1 marked pain during procedure	com The syst subj size com Rely scor of a of B spec be f Que clini Do s incr harv caus com rate Do i spec and impr of d Auth fina com mar Mam devi
Burbank F *The American Surgeon* 1997 "Stereotactic breast biopsy: comparison of 14-	Not clear if all measures were prospective or if some were retrospective. 186 lesions biopsied with 14 gauge Mammotome	Compare specimens obtained by 11 gauge and 14 gauge Mammotome devices for average aggregate tissue weight, average number of specimens, weight per specimen, time to harvest	Women who underwent 14 gauge Mammotome: mean age 55 years. Women who underwent 11	Comparison of 11 gauge vs. 14 gauge for: weight of breast tissue obtained - 1730 mg vs 1067 mg ($p \leq 0.0001$,)	The that beca skill oper Mam devi of th at th Sinc swit

Mammotome probe performance and complication rates"	62 lesions biopsies with 11 gauge Mammotome	specimen, number of specimens obtained per minute, and milligrams of tissue obtained per minute.	Mammotome: mean age 54 years. Statistically significant difference between groups only for BIRADS scoring for breast composition. Almost all of the lesions were nonpalpable and were detected by imaging study.	specimens - 18 vs 27 ($p \leq 0.0001$), weight per specimen- 96mg vs 40mg ($p \leq 0.0001$), average tissue harvesting time- 15.6 min vs 15.4 min (not significant $p \geq 0.8$), weight of tissue harvested per minute - 111 mg/min vs 69 mg/min ($p \leq 0.0001$). Complications: 14 gauge - 1 painful hematoma, 1 pain at incision site, 1 marked pain during procedure; 11 gauge- 1 nonpainful hematoma (no statistically significant difference in complication rate)	gaug gaug this proc the devi perf clini acqu expe the than whe man with devi It is expe larg devi a lar but valu be p valu spec not with impr diag accu The fina the whic man Mam devi artic com type Mam anot
Burbank F	Retrospective study	Concordance of diagnosis between	Results are from 101 patients mean	The authors found a	Auth stati

Radiology 1997 "Stereotactic breast biopsy of atypical ductal hyperplasia and ductal carcinoma in situ lesions: improved accuracy with directional, vacuum-assisted biopsy"	Compared diagnoses for lesions diagnosed as ADH or DCIS by percutaneous biopsy which also had followup surgical biopsy. The type of percutaneous biopsy performed (Biopty or Mammotome) was based solely on when the procedure was performed; before or after the treatment center switched from Biopty to Mammotome.	breast biopsy and open surgical biopsy for 113 lesions which had been diagnosed as ADH or DCIS at percutaneous biopsy	age range 37-85 years who had 113 lesions diagnosed as ADH or DCIS by percutaneous biopsy and followed up with open surgical biopsy. These patients were drawn from 997 women w/ 1,135 lesions who were referred to the treatment center, 1,041 lesions underwent percutaneous biopsy (765 automated tru cut, 276 directional vacuum assisted), 288 lesions were followed up by open surgical biopsy, 113 of these 288 lesions had been initially diagnosed as ADH or DCIS.	based diagnosis of ADH or DCIS to be statistically significantly more accurate (as confirmed by open biopsy) than a Biopty diagnosis. ADH diagnoses by percutaneous biopsy: of 18 ADH diagnoses by Biopty 8 were DCIS and 10 ADH or lesion gone by surgery, of 8 ADH diagnoses by Mammotome 8 were ADH or lesion gone by surgery (significant difference in upgrades $p<0.03$). DCIS diagnoses by percutaneous biopsy: of 55 DCIS diagnoses by Biopty 9 were IDC and 46 were DCIS or lesion gone by surgery, Of 32 diagnoses of DCIS by Mammotome 32 were DCIS or lesion gone by	diffe betw Mam Biop for c ADH mea upgr surg How stud from gene shor retr stud excl lesio ADH diag perc biop wha did surg Surg of M Proc yield "lesi diag cann that lesio initi by s that wou mat The sele were that refe clini unde man

				(significant difference p=0.02).	not whe the palp Pote of b has stak com man Mam devi
Burbank F *Radiology* 1997 "Mammographic findings after 14-gauge automated needle and 14-gauge directional, vacuum-assisted stereotactic breast biopsie"	Clinical trial 861 stereotactic breast biopsies were performed 592 by 14-gauge automated needle, 269 by 14-gauge directional, vacuum-assisted probe. Based on benign results from these biopsies 557 lesions were recommended for first imaging follow-up after 6 months.	Study radiologists (blinded to type of biopsy woman underwent) scored first follow-up mammogram compared to pre-biopsy mammogram. Score 1 = larger or more calcifications Score 2 = no meaningful change Score 3 = small decrease in lesion size or number of microcalcification Score 4 = no residual lesion	Study population comprised of women who underwent stereotactic breast biopsy, and complied with the recommendation to have first imaging follow-up of the biopsied lesion. Number of lesions = 495 Number of women = ? Mean age of women 55 yrs	percent of lesions biopsied by automated needle / vacuum assisted device receiving various scores for first follow-up mammogram of lesions Score = 0 / 0 Score 2 = 40 / 30 Score 3 = 44/ 23 Score 4 = 15 / 48	The sugg imag biop less disfi than biop caus conf inte futu man This pote term imag biop oper biop How stud failu a se imag for s biop scor radi wea asse com

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Burbank F, Forcier N *Radiology* 1997 "Tissue marking clip for stereotactic breast biopsy: initial placement accuracy, long-term stability, and usefulness as a guide for wire localization"	Nonrandomized clinical trial Control group - 22 patients with benign lesions used to calibrate the accuracy of the measurement system 149 patients underwent biopsy by 11- or 14-gauge Mammotome device with placement of a MicroMark metallic marker	Accuracy of placement of marker clip - distance off target as measured on post-biopsy mammogram (measured for 43 markers deployed by straight-needle method and 106 deployed by through-probe method) stability of placement of marker clip at first follow-up mammogram (measured for 31 lesions) usefulness of marker clip to guide wire localization before therapeutic breast surgery	171 patients 22 patients in control group mean age 46.8 yrs age range 38-85 yrs 149 patients in study group mean age 53.5 yrs age range 32-86 yrs Of 36 lesions which underwent subsequent surgical therapy, the marker was used as the target for wire localization in 28 lesions	average distance off target: 12.6 mm for both marker deployment methods 7.7 mm for control at first imaging followup average distance off target was 8.7 mm (p>0.4 for comparison to control, suggesting little migration from site of placement over time)	Dist esti base mea man imag for i (the esti inhe vari com supe avai Limi info pati char and Not only were radi well were cont Stud som that pote erro into mar prov usef of le whic perc

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Cady B, Steele GD, Morrow M, et al. *Cancer Journal for Clinicians* 1998 "Evaluation of common breast problems: guidance for primary care providers"	Review article	NA	NA	In stereotactic breast biopsy section, authors note: "Its indiscriminate application in all breast lesions detected by mammography is unjustified, and its use in obvious cancers to confirm diagnosis before surgical excision is probably not cost-effective."	Revi sugg • ar clus micr and susp • Lo but repe repe a pa wan OSB Thes seen cons limit Uncl auth thes
Chilcote WA, Quinn CA. 1997 *Cleveland Clinic Journal of Medicine*	Review article	NA	NA	Particularly useful for microcalcification Contraindication: Pts who cannot lie prone; obese	A go this nonp lesic Sup BIRA cove

Medicine "Stereotactic breast biopsy: a less-invasive option"				breasts which compress to less than 2 cm	
Cross MJ, Evans WP, Peters GN, et al *Annals of Surgical Oncology* 1995 "Stereotactic breast biopsy as an alternative to open excisional biopsy"	Prospective	Concordance between histologic diagnosis and mammographic characterization	225 women underwent 250 stereotactic biopsies avg age 54 years range 2-89 years Nonpalpable mammographic lesions	78% of lesions characterized as low suspicion of malignancy 22% high suspicion 97% of low suspicion lesions benign 78% of high suspicion lesions were malignant Approx cost for stereotactic biopsy was $1200	"Ste brea relia alte oper biop in th of b dise "alte oper biop diag nonp man lesio Like artic emp tech diag ther focu nonp rath palp Spe indi ster biop nonp lesio Rec agai esio axill

Galliano DE, Rosemurgy AS *American Journal of Surgery* 1997 "Stereotactic excisional breast biopsies utilizing the advanced breast biopsy instrumentation system"	clinical trial 23 women underwent breast biopsy with the ABBI 23 women underwent needle localization and excisional breast biopsy	of the mammographic lesion as measured by radiography of the biopsy specimen. Patient acceptance of the biopsy technique.	nonpalpable mammographically detected breast lesions; either microcalcifications or noncystic nodular densities suspicious for cancer Mean age: 62 years for ABBI, 68 years for OSB	acceptance of the ABBI system was high" Radiography of the biopsy specimens showed complete removal of the mammographic abnormality for all biopsies. No complications were reported.	that may in pa lesio iden ster man lesio brea or in brea pati lie p proc The not info wou com diag accu ABB auth gold OSB
Fajardo LL, DeAngleis GA. *Surgical Oncology Clinics of North America* 1997 "The role of stereotactic biopsy in abnormal mammograms"	Review article	NA	NA	"For most asymmetric opacities or microcalcification stereotactic guidance is preferred. US guidance better for superficial lesions, breasts that compresses to less than 2 cm."	Poin perc brea shou used adds to th work Goo stati accu com surg 90%
Ferzli GS, Hurwitz JB *Surgical*	Retrospective	Accuracy of specimen targeting, success rate of lesion removed,	34 consecutive patients who presented with nonpalpable	Of 28 biopsies, 27 specimens removed successfully	Atte emp exci than

Endoscopy 1997 "Initial experience with breast biopsy utilizing the advanced breast biopsy instrumentation"		complication	on mammography 6 patients excluded. Mean age 49 years	Pathology malignant in 3 cases	How poor deta of tw No s anal Lists cont such 300 to li 30 r brea lesic ches Doe defi that com rem
Fuhrman G, Cederrborn G, Bolton J, et al. *Annals of Surgery* 1998 "Image-guided core-needle breast biopsy is an accurate technique to evaluate patients with nonpalpable imaging abnormalities"	Prospective study	Histologic diagnosis All patients with nonpalpable lesions evaluated by image-guided needle biopsy from 1993 to 1997 Positive cores evaluated by wire-localization excisional breast biopsy. Sensitivity and specificity compared.	1440 image-guided breast biopsies performed.	Of 1440 image guidance biopsies, 1106 were benign. Only one pt found to have a cancer on followup. For ADH, there was 100% sensitivity, 88% specificity. For CIS, 65% sensitivity, 97% specificity.	Well stud dem exce sens spec facil Of n com ADH requ exci to d exte path such circu imag an a proc
Fuhrman G,	Prospective	Histologic diagnosis	451 patients over	367 benign	Focu

Champagne J, et al. *Journal of Louisiana State Medical Society* "Stereotactic core needle breast biopsy is an accurate diagnostic technique to asses nonpalpable mammographic abnormalities"		All cases evaluated by surgery dept to confirm pathologic finding	18 months	cases 84 malignant cases one benign stereotactic biopsy proved to be malignant at subsequent surgical biopsy; one malignant core biopsy could not be confirmed at subsequent surgical biopsy	lesio calci Emp tech diag Inclu eval not surg Fair man follo Exce accu histo eval man abno
Gisvold JJ, Goellner JR, Grant CS, et al *AJR* 1994 "Breast biopsy: a comparative study of sterotaxically guided core and excisional techniques"	Retrospective	Pathologic features of core and excisional specimens compared	Of 471 patients referred to a breast imaging center for preop wire localization procedure, 104 patients underwent SNCB,	Of 104 lesions with at least 5 specimens 56 were benign and 48 malignant. Concordance between core and excisional biopsy was 96% for benign lesions, 83% for malignant lesions. Of 56 lesions with fewer than 5 specimens, 37 benign, 19 malignant. Concordance 81% for benign, 79% for malignant. 2 malignant	All le nonp Poss bias No r follo beni No c conc base of sp Stat biop unne expe lesio appe mali Sug ster

				lesions missed on core biopsy.	lesic
Israel PZ, Fine RE. *The American Surgeon* 1995 "Stereotactic needle biopsy for occult breast lesions: a minimally invasive alternative"	Retrospective	Histologic diagnoses Analysis of detected malignancies Compares histology of core biopsies with histology of open biopsies Lesions biopsied were indeterminate: microcalcification, nodular densities, stellate lesions, asymmetric densities with architectural distortions All patients are from one surgical practice	500 consecutive stereotactic core biopsies in 454 patients in a surgical practice	365 lesions – benign and no surgery recommended. 135 lesions went to OSB. Core biopsy followed by OSB when cores showed either malignancy or cytologic atypia. Of the 135 lesions, 88 cancers 8 ductal hyperplasia, 9 fibroadenomas 30 other 18 core showing atypia went to OSB. 6 showed atypia but no carcinoma 6 benign 6 showed in situ CA Only 2 cases in the 135 open biopsies (1.5%) failed to show a cancer that was present in OSB. 97.8%	Very accu diag How does the only Non a fai desi Also abou up c beni need idea nega prec Set OSB stat judg som to re OSB with susp man and hist guid littl here pati have gone Stat perc biop silic impl

				sensitivity 85.4% specificity	
Jackman RJ, Burbank F, Parker SH et al *Radiology* 1997 "Atypical ductal hyperplasia diagnosed at stereotactic breast biopsy: improved reliability with 14-gauge, directional, vacuum-assisted biopsy"	Retrospective	Compare accuracy of ADH diagnosis by 14 gauge automated large core biopsy or 14 gauge Mammotome biopsy with results of follow-up surgical excisional biopsy. Underestimation of carcinoma - lesions diagnosed as ADH at percutaneous biopsy which were later diagnosed as DCIS or invasive breast cancer at open surgical biopsy.	Patients who underwent large core biopsy: mean age 57 years age range 33-85 years 55 nonpalpable breast lesions. Women who underwent Mammotome procedure: mean age 58 years age range 38-92 years 88 nonpalpable breast lesions. No statistically significant differences between groups noted.	Of 54 lesions diagnosed as ADH by LCB and followed up with surgical biopsy - 18 DCIS, 8 IDC (26 carcinomas, 48% underestimation) Of 74 lesions diagnosed as ADH by Mammotome and followed up with surgical biopsy 10 DCIS, 3 IDC (13 carcinomas, 18% underestimation) for difference of underestimation rate $p<0.0004$. The authors conclude that carcinoma is sufficiently underestimated by both LCB and Mammotome to necessitate surgical biopsy follow-up for diagnoses of ADH by either percutaneous procedure. 3 complications out of total 2,093	The emp retro desi lesio as A Mam 98% lesio by L docu have surg Resu pati a di ADH perc biop wha did surg unde surg a sit infor unav rese Stud othe perc biop have com rate Part repo diffe accu arise Mam proc

				Mammotome procedures (not just those diagnosed as ADH) 2 hematomas 1 infection. 6 complications out of 3,765 LCB procedures, 3 hematomas, 3 infections. Complication rate 0.14% vs 0.16%, p>0.99. Carcinoma underestimation mammotomies vs LCBs taking 10 or fewer specimens 44% vs 50%; for >10 specimens 10% vs 43%	sign spec LCB (15. p<0 The a fin in th whic Mam devi
Liberman L, LaTrenta L, Dershaw D, et al. *AJR* 1997 "Impact of core biopsy on the surgical management of impalpable breast cancer"	Retrospective review	Compared impalpable breast carcinomas revealed by core biopsy with those revealed by surgical biopsy, with respect to frequency of performing a single surgical procedure and finding tumors at the margins of the lumpectomy specimen.	197 solitary impalpable breast carcinomas 90 core biopsy 107 OSB median age core: 59 yrs (33-85) median age OSB: 57 yrs (35-87) other characteristics similar between	Single surgical procedure performed in 84% of the patients who underwent core biopsy vs 29% of patients who underwent surgical biopsy. P<0.00001 Tumor margins present in 8% of core biopsy vs 5 % by OSB (p=0.7)	A sin proc perf ofte with und biop diffe obta free This g da pote redu num surg proc requ pati impa

			statistical analysis not provided		canc Wea inclu retr revi crite pati und type *prio*
Kelley,WE, Bailey, R, BertelsenC, et al *The Breast Journal* 1998 "Stereotactic automated surgical biopsy using the ABBI biopsy device: a multicenter study"	Retrospective study	Characteristics of mammogram findings, size of ABBI biopsy, xray confirmation, surgical pathology, correlation of pathologic and radiologic findings. Need for second diagnostic procedures, incidence of postop complications, adequacy of cosmetic results, and postop analgesia	654 nonpalpable breast lesions were biopsied at 8 institutions No data on actual number of patients and age range	In all but one case, pathology correlated with mammographic findings (0.15%) 1.8% complication rate 99.8% cosmetic satisfaction 2.4% pain med use	This key abou desi num pati Man outc mea subj cosm and valu stati sign the repo If da accu good and com surg
Kessler H, Smith RL. *American Journal of Managed Care* 1998 "Managed Care	Commentary Includes brief description of 2 cases	NA	Case A: woman underwent stereotactic core biopsy Case B: woman underwent ultrasound directed core biopsy	Authors gives opinion that vacuum-assisted biopsy is safe and efficacious, with concordance equivalent to that of excisional biopsy for mass	Nice adva disa brea tech Stat need proc resu

Case for Large-Core biopsy procedures in the diagnosis of breast cancer"			biopsy	lesions. Authors suggest that ability to perform stereotactic biopsy may be limited by breast size and lesion proximity to the chest wall. Author summarizes frequent criticism or suggested benefits of image-guided biopsies as alternative to OSB.	sens spec equi of o biop – re abn type This opin Of n abou over cove are
Liberman L, Fahs MC, Dershaw D, et al. *Radiology* 1995 "Impact of stereotaxic core breast biopsy on cost of diagnosis"	Retrospective analysis	Frequency with which stereotaxic core biopsy obviated diagnostic surgical biopsy; estimated savings in cost of diagnosis	182 nonpalpable lesions, suspicious on mammography in 182 patients stereotaxic biopsy offered as an alternative to OSB	Stereotaxic core biopsy replaced a surgical procedure in 140 of 182 patients. Mean adjusted direct savings was *893. Decreased cost of diagnosis was 55%.	No s anal repo Lists and crite ster offe alte pati impt Focu rath char disti pref appr Ever impe anal appe expe tech mea

					addi hype still OSB
Liberman L, Feng TL, Dershaw, et al. *Radiology* 1998 "US-guided core breast biopsy: use and cost-effectiveness"	Retrospective	Frequency with which ultrasonographically guided core biopsy obviated diagnostic surgical biopsy of nonpalpable breast masses Cost estimates	151 consecutive solitary, nonpalpable breast masses in 151 women age range 23-80 yrs (out of 179 nonpalpable breast masses)	US-guided core biopsy obviated a surgical procedure in 85% of cases 128/151 Mean-adjusted cost savings $744/case. If stereotactic guidance instead of US used, cost savings $519.case	Stat anal prov
Liberman L, LaTrenta L, Van Zee KJ, et al *Radiology* 1997 "Stereotactic core biopsy of calcifications highly suggestive of malignancy"	Retrospective review	Frequency with which stereotactic core biopsy obviated a surgical procedure Cost estimates	31 women age 34-86 years All BIRADS 5 [highly suggestive of malignancy] Women underwent 14-gauge stereotactic core biopsy with an automated gun.	Of 31 patients: Stereotactic core— 19 carcinoma 8 ADH 4 benign surgical biopsies recommended for 12 patients. Of the 19 pts, 2 chose surgical biopsy 13 of 31 patients were spared a surgical	Inte as it BIRA Ever high seve still ster biop amo surg proc avoi No s anal and anal in d info as it use ster biop

				procedure. Cost savings estimated $100/patient.	BIRA Doe vacu devi
Liberman L, Smolkin JH, Dershaw DD, et al. *Radiology* 1998 "Calcification retrieval at stereotactic, 11-gauge, directional, vacuum-assisted breast biopsy"	Retrospective study	Frequency of calcification retrieval by 11-gauge Mammotome - defined as identification of calcification on radiographic imaging of biopsy specimen Histologic underestimation - defined as sterotactic diagnoses of ADH upgraded to carcinoma or DCIS upgraded to infiltrating carcinoma at open surgical biopsy	80 women median age 55 years age range 31-85 years 112 lesions detected on mammography as calcifications without a mass. All lesions underwent biopsy by 11-gauge Mammotome device.	Removal of all calcifications - 51 lesions (46%) removal of some calcifications - 55 lesions (49%) removal of no calcifications 6 lesions (5%) [4 of these 6 procedures were aborted- 1 secondary to mechanical failure, 1 to patient bleeding, 1 to patient vasovagal reaction, and 1 to patient nausea] surgical biopsy diagnosed DCIS in 1 of 10 (10%) lesions labeled ADH at percutaneous biopsy Surgical biopsy diagnosed infiltrating carcinoma in 1 of 21 lesions (5%) labeled DCIS at percutaneous biopsy. Authors noted	Sug biop Mam devi succ sam calc that diag disp surg Rep hist und excl perc biop whic wha reas follo surg Of n stat loca can whe 11-g the Mam prob Auth opin gaug man supe eval calc 14-g

				that failure to retrieve calcifications was more likely in small lesions, amorphous lesions, or lesions necessitating that the probe be fired outside of the breast (superficial lesion or thin breast) The authors noted that retrieval of all rather than some calcifications did not yield a statistically significantly lower rate of histologic underestimations (0 vs. 2 occurrences, no p value given)	auto core
Lind DS, Minter R, Steinbach B, et al. *Journal of Surgical Research* 1998 "Stereotactic core biopsy reduces the reexcision rate and the cost of mammographic detected cancer"	Retrospective	Method of diagnosis, time interval from detection to diagnosis and breast-conserving surgery, volume of breast tissue excised, margin status and reexcision rate, number of surgical procedures, and total charges/costs per patient.	117 patients with mammographically detected breast cancer who underwent breast-conserving surgery at the Univ of Florida. Patients who underwent mastectomy were excluded.	Malignancy 69 patients NLB 48 patients SCB Time to diagnosis: 6.8 days NLB 1.7 days SCB p<0.01 time to surgery:	Com outc mea with sign Of p impo fact stud dem redu reex Pron may

				16.9 days NLB 8.1 days SCB p<0.01 Vol excised: 75.2 cm2 NLB 117.9 cm 2 SCB p< 0.01 Pos margin rate: 55% NLB 6% SCB p<0.01 Reexcision rate: 50% NLB 2% p< 0.01 Total costs/pt: $4853 NLB $3537 SCB NLB=needle-localized surgical biopsy SCB=stereotactic core biopsy	anxi No stan crite whic met whic lesic unli sign sele Focu non lesic Econ uses poss unre
Meyer JE, Smith	Not specified if	Presence of	Scant information	Radiography of	Not

DN, DiPiro PJ, et al *Radiology* 1997 "Stereotactic breast biopsy of clustered microcalcification with a directional, vacuum-assisted device"	prospective, likely retrospective For five years clinic performed biopsies by 14 gauge Biopty procedure then for following 8 months by 14 gauge Mammotome procedure	biopsy specimen by radiography of specimen removed by 14 gauge Biopty or 14 gauge mammotome	patient selection. Patients had calcification clusters detected by imaging study. 130 clusters were biopsied by Biopty, 106 clusters were biopsied by Mammotome	showed calcifications in 106 of 106 Mammotome obtained biopsy specimens (100%) and 118 of 130 LCB obtained biopsy specimens (90.8%), statistically significant difference between Mammotome and LCB, p=0.0006	prov rega char Pati eith perc biop on h the they proc anal whe char both grou simi
Meyer JE, Smith DN, Lester SC et al. *JAMA*, 1999 "Large-core needle biopsy of nonpalpable breast lesions"	Case series 1333 lesions biopsied with 14-gauge Large Core Needle Biopsy (LCNB) by automated gun 372 with 14-gauge LCNB and Directional Vacuum Assisted (DVA) device (Mammotome) 131 with 11-gauge LCNB and DVA device (Mammotome) surgical excision to follow up malignancies detected by biopsy	Safety and accuracy of LCNB Confirmation of LCNB diagnosis by surgical excision only in certain cases: 43 lesions which were strongly suspicious by imaging study but had benign histology on LCNB, 13 other lesions for variety of other reasons	Mean age 50 yrs age range 20-85 1643 female subjects with 1836 nonpalpable lesions detected by mammogram or ultrasound mean mass size 1.3 cm., range 2mm - 4cm mean size calcification clusters 9mm range 2mm - 5.2cm	Complications of LCNB: 1 episode of pneumothorax, 1 of cellulitis Of 1424 lesions initially diagnosed as nonmalignant by LCNB, 202 were recommended for repeat biopsy (LCNB) based on correlation with abnormal mammogram or ultrasound, and technical quality of initial LCNB, detecting 32 cancers. For the 56 benign LCNB results which prompted confirmation by surgical excision	(Not refe Mam subs Ther be a high imag abn whic norm resu furth inve Auth spec qual susp is th the diag surg Auth is cl larg of ti rem

				diagnosis confirmed Upgrade of diagnosis from LCNB to surgical excision: 14 gauge DVA - of 24 diagnoses of ADH from calcium clusters - 7 upgrades to DCIS, 2 upgrades to IDC 11 gauge DVA - of 9 diagnoses of ADH, 1 upgrade to DCIS 14 gauge automated gun - of 18 lesions diagnosed as ADH 7 upgraded to DCIS and 3 to IDC	an u ADH diag LCN Give desi not biop are by c exci diffi cert form did canc latte wou dete How bett mos on t Doe conc over
Park ST, Galbo C, Ghosh BC *World Journal of Surgery* 1997 "Stereotactic breast biopsy as an alternative to excisional biopsy"	Clinical trial Pilot study- 26 patients with suspicious nonpalpable mammo-detected lesions underwent stereotactic LCNB followed by needle localization and surgical excisional biopsy. Main study – 169 14-gauge stereotactic biopsies were performed	Usefulness of stereotactic core biopsy to decrease the number of mammographically suspicious lesions which necessitate surgical biopsy.	165 patients Age range 33-79 years 169 lesions 101 calcifications 56 masses 1 mass and calcifications, 6 asymmetric densities, and 5 architectural distortions	For 26 patients in pilot study- no case of breast cancer was missed. For main study- 41 surgical biopsies were recommended, 36 were performed Of 6 atypia diagnoses at stereotactic biopsy, 5 went on to surgical biopsy, 3 were	Ther valu the conc seri ster biop whic follo surg pres decr num surg perf beni only does mali

	surgical biopsy was recommended to follow-up any abnormal pathology or inadequate sampling.		distortions	DCIS, 1 LCIS, 1 atypia. No false positives diagnoses of cancer at percutaneous biopsy. The authors suggest that using stereotactic biopsy to preselect which patients need surgical biopsy makes it possible to perform surgical biopsies in a way which yields malignant diagnosis 55% of the time (compared to a rate of 13.3% which the authors estimate would occur without preselection).	impo know false diag occu perc biop all w conf surg The an a ster diag is ur shou follo surg
Parker SH, Lovin JD, Jobe WE, et al. *Radiology* 1991 "Nonpalpable breast lesions: stereotactic automated large-core biopsies"	Clinical trial 102 stereotactic large-gauge needle core breast biopsies were performed (14 gauge) and were all followed up with needle localization and open surgical biopsy, and histologic diagnosis was made by the same pathologist	Concordance of diagnosis by percutaneous and surgical biopsies	102 nonpalpable mammographic detected breast lesions	Agreement of biopsy and surgical diagnosis in 98 of 102 cases (96%), 22 of 23 carcinomas (96%) 1 case of IDC was found at surgery but missed by Biopty (lesion was close to chest wall and authors hypothesize the	Stud allow infor rega accu core biop to su as a were by b Wea pati infor prov be u

				was not properly localized) 2 cases of fibroadenoma was diagnosed by Biopty and diagnosed as normal by surgery 1 radial scar was called FCC by Biopty	BIRA class Ove were Of n publ and has sinc
Seoudi H, Mortier J, Basile R, Curletti E *Arch Surg* 1998 "Stereotactic core needle biopsy of nonpalpable breast lesions: initial experience with a promising technique"	Retrospective review Most biopsies were performed by Mammotome, 12 biopsies were performed with 14-gauge needle and biopsy gun	Concordance between stereotactic core needle biopsy (SCNB) pathology result and the prebiopsy mammogram and pathology results of subsequent surgical excisions, when performed	97 female subjects with 100 nonpalpable breast lesions detected by mammogram mean age 58 yrs age range 30-85 Mammographic lesions graded by American College of Radiology Breast Imaging Reporting and Data System 5 grade V 91 grade IV 4 grade III	No significant complications of SCNB Discordance between SCNB and open surgical excision in 2 cases: one grade V lesion lipoma by SCNB later diagnosed as IDC by surgical excision, one grade IV lesion premalignant by SCNB, fibrocystic change by surgical biopsy	For IV le by S surg perf trus man follo not that fail t mali whic biop have Hav stud low rate
Tomaselli, MB *Surgical Physicians Assistant* 1998	Review article Describes 3 main categories of breast biopsy methods: surgical, core needle, and mammotome	NA	NA	p31 compared to surgical biopsy "strong evidence exists that the less invasive percutaneous biopsy, in general, and	Inte disc histo deve vari biop and desc

breast biopsy methods: surgical, core needle, and mammotome"	mammotome.			vacuum assisted biopsy in particular, are more accurate, comfortable, cost effective, and timesaving."	the proc How infor besi auth to su use inva alter surg
Velanovich V, Lewis FR, Nathanson D et al. *Annals of Surgery* 1999 "Comparison of mammographically guided breast biopsy techniques"	Review of all patients who underwent mammographically guided biopsies at one treatment center over a 15 month period. 245 biopsies by 14-gauge SCNB 107 biopsies by 11-gauge Mammotome 104 biopsies by ABBI 520 open surgical biopsies	Technical success, pathology, discordance between pathologic diagnosis and mammographic image, need for open surgical biopsy	Not much information about patient characteristics except that they underwent biopsies during the time period of the study	Authors conclude that ABBI provides the most efficient method of breast biopsy. Technical success: 94.3% for SCNB, 96.4% for Mammotome, 92.5% for ABBI, 98.7% for OSB Higher cancer yield for OSB than for other procedures ($p<0.01$) The discordance/ re-biopsy rate was lower for ABBI than for Mammotome or SNCB ($p=0.009$) For cancerous lesions the 63.6% positive margin rate for ABBI was slightly higher than the 50.9% rate for OSB (p=NS)	Pati rand assi biop and sugg pati mor lesi have pref stee OSB does suffi infor rega char whic and unde type proc All t seen spec few resu It is to d dete sens proc Iden

				ABBI sensitivity was higher than Mammotome or SCNB (no p value given)	not not follo
Zannis VJ, Aliano KM *Am J Surg* 1998 "The evolving practice pattern of the breast surgeon with disappearance of open biopsy for nonpalpable lesions"	Prospective clinical study One surgeon performed breast biopsies by 3 different techniques: stereotactic needle/wire localization with open biopsy (SNL/OBx), stereotactic needle core biopsy (SNCB), vacuum assisted biopsy (VAB) patients with abnormal histology by VAB or SCNB were advised to undergo SNL/OBx	study documented the number of biopsies performed by each technique SNCB employed a 14-gauge Tru-Cut needle and Biopty Gun VAB employed a Mammotome device with a 14 or 11-gauge probe	372 female subjects with 424 mammography detected breast lesions average age 57 yrs	Over the entire study period total number of lesions biopsied by each method/number of initial abnormal histology results SNL/OBx - 190/ 81 SNCB - 157/ 24 VAB- 77/ 21 follow-up lumpectomy for 43 of the 45 abnormal results of SNCB and VAB: histological upgrading for 4 SNCB and 0 VAB. Use of VAB increased over the study period while use of SNL/OBx and SNCB decreased. In the final 3 months of the study the surgeon used only VAB Complications	Artic char prac for over Wou inte com accu to S Limi info rega sens (onl fals resu dete repe man afte Low rate No s anal diffe com rate proc Like stud subr focu nonp lesic

				with SNL/OBx 12 occurrences of Cellulitis, 4 of abscess formation	

Breast Biopsy