

Multicenter Evaluation of a New Ultrasound-Guided Biopsy Device: Improved Ergonomics, Sampling and Rebiopsy Rates

Nathalie Duchesne, MD,* Steve H. Parker, MD,[†] Mary C. Lechner, MD,[‡] Mark A. Gittleman, MD,[§] Catherine A. Kusnick, MD,[¶] Eugene E. Elvecrog, MD,[‡] Terese I. Kaske, MD,[†] and Terri-Ann Gizienski, MD[†]

*Ottawa Regional Women's Breast Health Center, Ottawa, Ontario, Canada; [†]Sally Jobe Breast Center, Englewood, Colorado; [‡]Park Nicollet Clinic, Minneapolis, Minnesota; [§]Breast Care Specialists, Allentown, Pennsylvania; and [¶]SenoRx, Aliso Viejo, California

Abstract: The purpose of this study was to evaluate performance, ergonomics, and immediate rebiopsy rate of a new vacuum-assisted biopsy (VAB) device for ultrasound-guided breast biopsies. Between December 2002 and April 2003, 113 patients meeting study criteria were biopsied at four centers using the new 9 gauge VAB device. The device has a radio-frequency-tipped probe, 360° vacuum, a circumferential cutter, and a coaxial cannula for multiple sampling. Patient and procedural data included breast composition, lesion characteristics, number of samples, procedure time, and complications. Quality of samples, lesion access, and ergonomic features were assessed qualitatively and compared with prior experience with other biopsy devices. Immediate rebiopsy rate included high-risk lesions requiring surgical excision (obligate rebiopsy) and lesions requiring rebiopsy due to discordance or insufficient samples yielding nondiagnostic material. Data were analyzed using the Wilcoxon signed-rank test. One hundred thirteen patients aged 20–83 years (mean 52) were successfully biopsied with dense/fibrous breast tissue in 60% and dense/fibrous lesions in 49%. Lesions measured 6–63 mm (mean 17); 97% were masses. Five circumferential specimens (range 2–19) were obtained in 6 minutes (range 2–20). Operators rated safety and comfort comparable with existing devices and rated sample quality, breast/lesion penetration, and positioning ease/accuracy superior ($p < 0.01$). Diagnoses included 37 cancers, 70 benign, and six high-risk lesions with one upgrade from atypical ductal hyperplasia to ductal carcinoma in situ at surgery. Excluding obligate excision in high-risk diagnoses, the immediate rebiopsy rate was 2%. No complications required intervention. The new VAB device provides diagnostic samples and reduces sampling error defined by immediate rebiopsy rate. Compared with other devices, it is more ergonomic to target and position for sampling, particularly in dense breast tissue or lesions. ■

Key Words: breast biopsy, intervention, radiofrequency, ultrasound

Several minimally invasive breast biopsy instruments enable physicians to percutaneously retrieve various sized specimens from breast lesions using ultrasound guidance for histologic diagnosis. Although generally accurate, false-negative rates of 0.5–1% (i.e., benign lesions upgrading to malignancy) and repeat

biopsy rates of 6.3–17% have been reported in ultrasound-guided series (1–6). Imaging-pathologic discordance is one of the major reasons necessitating repeat biopsy. The second biopsy procedure is generally excisional surgery with studies reporting a diagnostic upgrade rate of 0–50% (1–6), i.e., atypical disease upgrading to malignancy and in situ disease upgrading to invasive cancer. Underdiagnosis in the initial biopsy usually results from sampling error, either due to inaccurate lesion targeting or due to sample volume insufficient to accurately represent the pathology. In small masses (<1.5 cm), a multicenter study reported a false-negative rate of 1.4%, attributed to inaccurate targeting of lesions with ultrasound-guided 14 gauge biopsy (7,8). In spite of ultrasound guidance, the

This study was presented at the ARRS Annual Meeting 2004.
N. Duchesne, S. Parker, M. Gittleman, M. Lechner, T. Kaske, and C. Kusnick are shareholders for SenoRx.

Address correspondence and reprint requests to: Nathalie Duchesne, MD, Radiologist, Head, Breast Imaging and Intervention, Ville Marie Radiology Center, 1538 rue Sherbrooke Ouest, Montreal, Quebec H3G 1L5, Canada, or e-mail: nathalie@thebreastcourse.com.

© 2007, Copyright the Authors
Journal compilation © 2007 Blackwell Publishing, Inc., 1075-122X/07
The Breast Journal, Volume 13 Number 1, 2007 36–43

biopsy probe may be deflected away from the target lesion by dense breast tissue or by a dense lesion itself. In larger masses, diagnostic discrepancies may result when a relatively small sample does not accurately represent the heterogeneity of the pathologic process (9,10).

Improved targeting and positioning in dense breast tissue and dense breast lesions with a radiofrequency (RF)-tipped introducer have been demonstrated in a randomized, controlled clinical trial compared with 11 gauge vacuum-assisted biopsy (VAB) using a trocar-tipped device alone (9,11). Due to differences in breast tissue composition, the force required to advance these devices into the breast and accurately position them at the lesion may vary even within the same breast. This advanced technology has been integrated into a new biopsy device, designed to overcome mechanical disadvantages and sampling errors of ultrasound-guided breast biopsies by facilitating the penetration of the breast and retrieval of tissue samples from the target lesion, regardless of breast tissue composition or lesion density.

The purpose of this study was to evaluate performance, ergonomics, and immediate rebiopsy rate of the new RF-tipped VAB device for ultrasound-guided breast biopsies.

MATERIALS AND METHODS

Materials

The 9 gauge SenoCor 360 Biopsy System (SenoRx, Aliso Viejo, CA) is comprised of a biopsy device (sterile probe and handheld driver), a control module, vacuum system, and electro-surgical generator. The tip of the probe contains a “thin wire” monopolar electro-surgical stainless steel cutting tip. When activated, RF energy is delivered to the tip. Although similar to the Bovie knife and other electro-surgical instruments used in breast surgery since the late 1920s (12–16), this device employs “pure cutting” techniques rather than coagulation.

After local disinfection and anesthesia, the SenoCor 360 is inserted through the breast tissue to the target lesion, using RF energy in the pure cut mode. Once the lesion has been reached, the 360° vacuum holes capture the tissue in a sleeve fashion and stabilize it during cutting by the rotating circumferential stainless steel cutter (Fig. 1). Following specimen acquisition, the operator removes the probe and specimen from

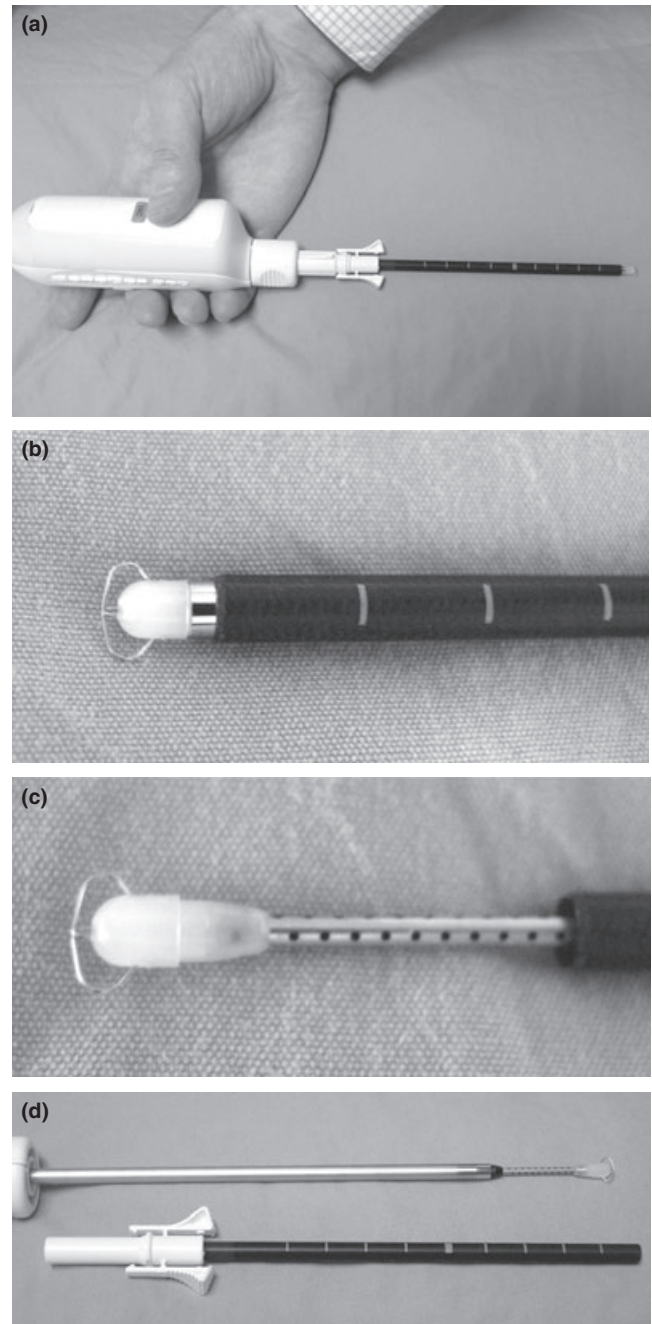


Figure 1. (a) SenoCor 360 handpiece showing its small size and ease of handling. (b) SenoCor 360 obturator and cannula. The obturator tip (wire) is stainless steel which cuts by activating radio-frequency. The stainless steel cutter that provides 360° cutting. (c) The obturator of the SenoCor 360 bears 360° vacuum holes to capture the lesion specimens. (d) The coaxial outer cannula of the SenoCor 360 remains in the breast (black), while the obturator (stainless steel) is removed with the specimen stabilized by vacuum for retrieval.

the coaxial cannula, which maintains position at the biopsy site allowing multiple sampling with a single insertion into the breast. This cannula is also used to

introduce a marker at the biopsy site once sampling is complete. The design bivalves the specimen, effectively doubling the surface area available for cut sections and histologic evaluation.

Methods

To ensure adequate training with the device, investigators at each site targeted and sampled lesions in phantoms. Biopsies were guided with the breast ultrasound units routinely used for patient care at each site. Biopsies were performed in accordance with each physician's standard practice regarding preparation of the biopsy site, anesthetic use, number of tissue samples obtained, biopsy marker placement, and postbiopsy patient management. For lesions completely removed at the time of biopsy, a marker was left in place and an immediate postbiopsy mammogram was obtained.

The biopsy physician recorded data on a standardized form including patient age, breast composition, and lesion characteristics; biopsy procedural information; postprocedure assessment in accordance with their standard practice; and histopathology information on the specimens obtained. Patient confidentiality was protected by assigning a unique identifier (site number and sequential case number).

Diagnosis and sufficiency of the specimen were assessed per each site's pathologist's standard practice and extracted from the clinical pathology report by the biopsy physician. Additional representative slides were cut from the tissue blocks, collected centrally, uniquely identified, masked to patient identity, history, and initial diagnosis, and reviewed in random order by a single independent pathologist.

Study Design and Patient Recruitment

This prospective multicenter clinical trial was conducted at four sites. The appropriate local Institutional Review Board approved the study as a descriptive quality assurance trial with a device cleared by the Food and Drug Administration used in accordance with approved labeling. There was no significant additional risk compared with equivalent devices marketed for similar indications. Patients were informed of this and signed a consent form.

Between December 2002 and April 2003, subjects scheduled for ultrasound-guided vacuum-assisted breast biopsy, who met study criteria, were capable of comprehending the study, and were able to give consent, were invited to participate. One hundred thirteen patients agreed to participate were enrolled in the

study and biopsied with the SenoCor 360. Patients were excluded from the study if they had a simple cyst as the target lesion. Also excluded were patients presenting with contraindications to biopsy such as disorders or medications that affect bleeding and/or coagulation, to electrosurgical procedures (cardiac pacemaker), had an implant or concurrent infection in the ipsilateral breast.

Data Analysis

Device Performance—Tissue Acquisition and Diagnosis Patient characteristics included age and breast composition graded according to the American College of Radiology nomenclature. Lesion characteristics included size in millimeters measured on ultrasound and type of lesion (mass with well-defined margins, mass with irregular margins, others). Lesion density was subjectively assessed by ultrasound appearance, palpable characteristics (if applicable), and resistance to a local anesthetic needle. BI-RADS assessment was based on ultrasound and/or mammographic criteria. The biopsy operator rated overall sample quality and compared this with prior experience with other biopsy devices.

Procedural success was defined as acquisition of sufficient biopsy samples from the target lesions to enable a histologic diagnosis. Pathologists at each site reviewed the slides for clinical care; reporting the diagnosis or determining the specimens was insufficient for diagnosis. The biopsy physician extracted information from the pathology report and recorded it on standardized data forms. For malignant lesions, tumor grading and receptor status were also assessed in accordance with the standard of care at each site.

All samples were also centrally reviewed and graded in random order by an experienced breast pathologist, masked to patient identity, history, and initial diagnosis.

Device Performance—Ergonomics The study investigators specialize in breast diagnosis and are experienced in ultrasound-guided breast biopsy techniques. The operators assessed ease of tissue and lesion penetration, positioning and holding the device, acquiring satisfactory specimens, and positioning accuracy. They also assessed safety, particularly in small breasts or lesions close to the pectoralis muscle, in or near the nipple-areolar complex. Based on their personal experience, ratings on the device itself were done by the operators on a four-point scale from excellent to suboptimal. The operators also compared the SenoCor

with existing spring and vacuum devices using a three-point scale from superior to suboptimal. Ease of use and performance assessment were compared with the operator's experience with other devices in similar presentations. Patient comfort level was assessed at the time of biopsy and by a visit or telephone call 24 hours after the biopsy.

Immediate Rebiopsy Rate Immediate rebiopsy rate was separated into two components: high-risk lesions requiring surgical excision (obligate rebiopsy) and lesions requiring rebiopsy due to discordance or insufficient samples yielding nondiagnostic material. Obligate rebiopsy was reported as upgrades or false negatives and not included in the rebiopsy rate.

For patient with benign results, participation was considered complete after a 6 month follow-up mammogram and ultrasound confirming the benign nature of the biopsied lesion. For patients requiring surgical treatment for malignancy, the surgical diagnosis was considered definitive and compared with the ultrasound-guided biopsy diagnosis. For the two patients with repeat percutaneous biopsies, the rebiopsy was performed with surgical excision.

The diagnosis from second biopsy was compared with the initial diagnosis. Data were analyzed using the Wilcoxon signed-rank test.

RESULTS

One hundred thirteen patients aged 20–83 years (mean 52) were enrolled and successfully biopsied. Breast composition was rated dense in 60% of cases and the targeted lesions were rated dense in 49% (Tables 1 and 2).

Device Performance Tissue Acquisition and Diagnosis

A histologic diagnosis of the target lesion was obtained in 100% of the patients with sample quantity deemed sufficient for all patients but one by the central and sites pathologists. An average of five samples was obtained, ranging from 2 to 19 with a stand-

Table 2. Lesion Characteristics

	Patients (n = 113)
Type of lesion	
Mass alone	110 (97%)
Others (distortion, hypoechoic area, etc.)	3 (3%)
Pathologic diagnosis	
Benign	70 (62%)
Malignant	37 (33%)
High risk	6 (5%)
Mean lesion size (longest linear diameter in mm)	16.7 (6–63)

ard deviation of 2.9. In 16% of the cases, all imaging evidence of the lesion was excised, although this was not the aim of this study. No significant complication occurred.

For the 37 cancers, tumor grading and receptor status could be obtained. The pathologists did not report RF-related artifacts that were significant but for one patient. This patient had a repeat biopsy with the same histologic result, benign fibroadenoma.

Overall quality of the retrieved specimens was rated good to excellent in 94% (106/113). When compared with specimens usually acquired with other biopsy devices, those of the study were judged superior to spring-loaded device in 79% (89/113) and equivalent to other vacuum-assisted device in 74% (83/113) (p < 0.01). They were rated superior to other vacuum-assisted device in 23% (26/113) (p < 0.01) (Figs. 2 and 3). Examples of biopsies are shown in Figures 4 and 5.

Device Performance—Ergonomics

The ease of penetration of the breast parenchyma and the lesion was judged equivalent to a 14 gauge biopsy device but superior to other vacuum-assisted device (p < 0.01). The same finding was true for the

Table 1. Breast Composition

Breast composition	Patients (n = 113)
Almost entirely fat or scattered fibroglandular densities	41 (36%)
Heterogeneously dense	54 (48%)
Extremely dense	13 (12%)
Not reported	5 (4%)

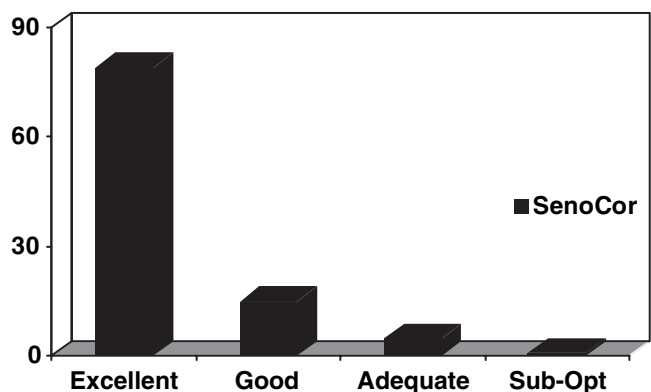


Figure 2. Specimen quality rated by biopsy operator.

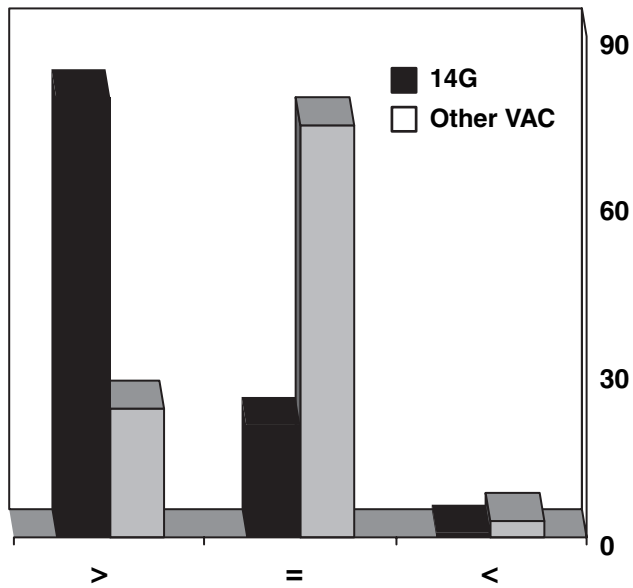


Figure 3. Comparison of the specimen quality of the new radio-frequency (RF) device with other existing biopsy tools. >, RF device superior to existing device; <, RF device inferior to existing device; =, RF device equivalent to existing device.

ease of positioning of the device at the desired location within the breast (Fig. 6). Patients' comfort was judged equivalent to other types of biopsies (Fig. 7).

Immediate Rebiopsy Rate

There were 37 cancers, six high-risk diagnoses, and 70 benign lesions. One case of atypical ductal hyper-

plasia was upgraded to ductal carcinoma in situ at surgery. Obligate excisions for atypical or high-risk diagnoses were performed and the results are summarized in Table 3. The immediate rebiopsy rate, as defined by the need for rebiopsy because of radiopathologic discordance was required for two patients (1.8%), with no change in the rebiopsy pathologic result. The rebiopsy was performed with surgical excision (Table 4).

DISCUSSION

Factors contributing to successful ultrasound-guided breast biopsy include accurate lesion targeting regardless of lesion location or density of the intervening tissue and acquisition of a sufficient volume of tissue which is representative of the most aggressive area of the lesion. For ultrasound-guided biopsies, targeting is accomplished by using freehand technique to advance the biopsy device through an uncompressed breast to the lesion. The radiologist may encounter resistance due to fibrous tissue or the lesion/tissue interfaces. This may deflect the probe, potentially resulting in inaccurate probe placement and missed lesions (3). Some lesions may resist penetration, while intracystic and well-margined masses may deflect away from the biopsy device. Operator experience, skill, and the choice of biopsy device may have a greater influence on clinical outcome in ultrasound-guided biopsies than in stereotactic-guided procedures.

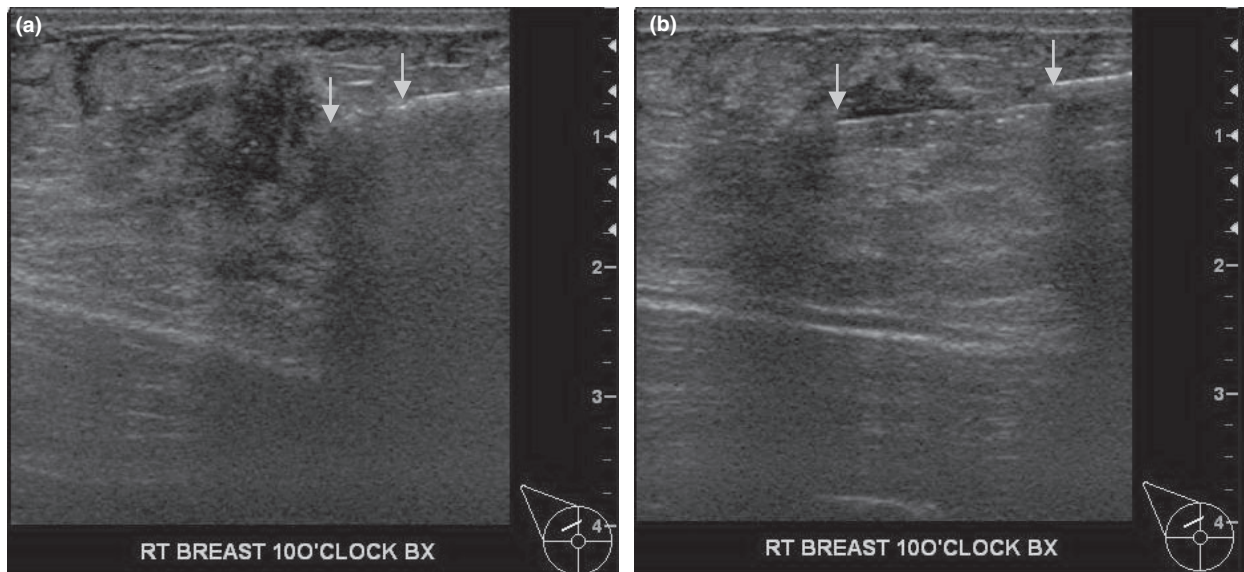


Figure 4. (a) Solid BI-RADS 5 mass located in the right breast at 10 o'clock 2B. The tip of the biopsy device is demonstrated (arrows) before entering the lesion. (b) SenoCor 360 device positioned within the lesion. The aperture is located between the two arrows. The vacuum holes are well demonstrated by the hyperechoic dots. The histologic diagnosis was an invasive ductal carcinoma.

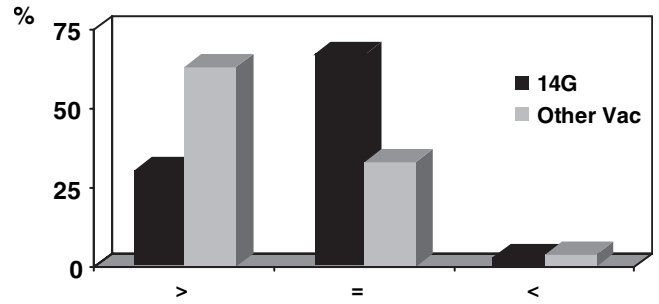
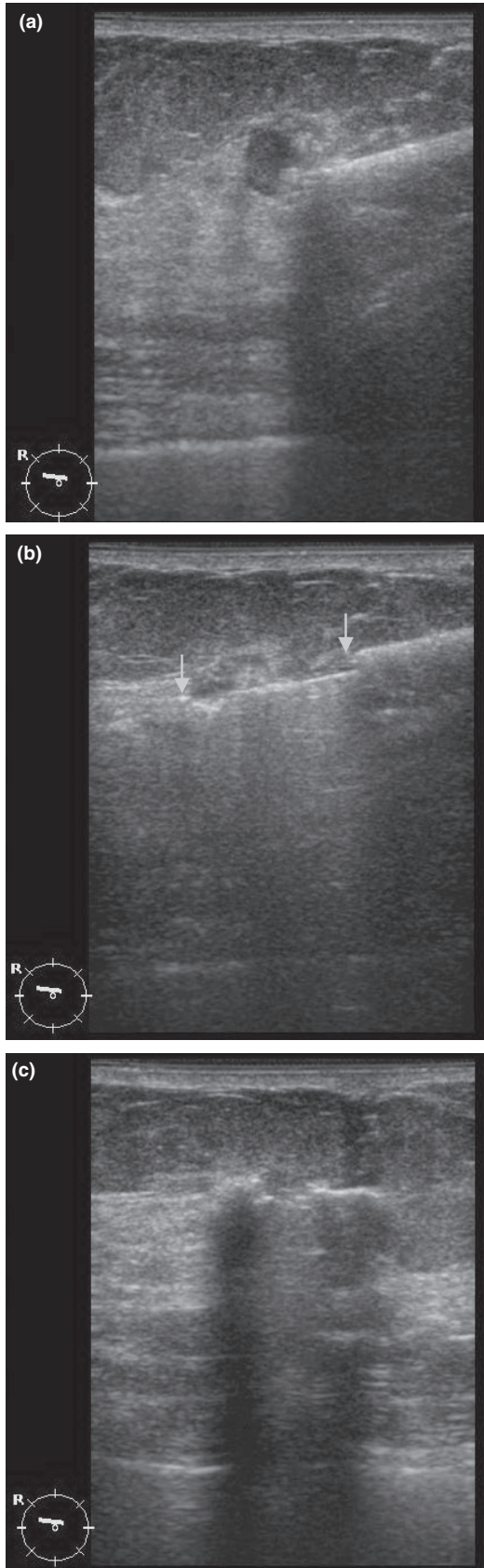


Figure 6. Ease of penetration and ease of positioning of the radio-frequency (RF) device in comparison with other existing biopsy tools. >, RF device superior to existing device; <, RF device inferior to existing device; =, RF device equivalent to existing device.

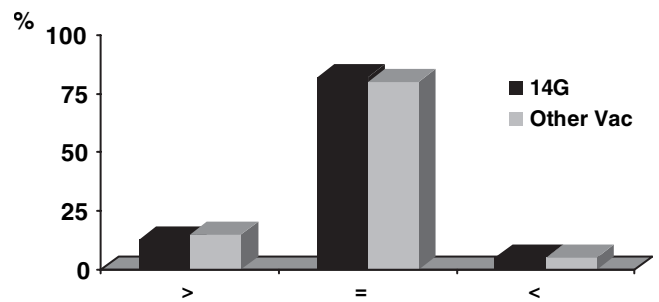


Figure 7. Patient comfort during the biopsy procedure rated by the biopsy physician.

Table 3. Obligate Re-excision Patients

Patient	RF device	Rebiopsy
1	ADH	DCIS
2	ADH	ADH
3	Phyllodes	Phyllodes
4	Papilloma	Papilloma
5	Papilloma	Papilloma
6	Papilloma	Papilloma

RF, radiofrequency; ADH, atypical ductal hyperplasia; DCIS, ductal carcinoma in situ.

Table 4. Immediate Rebiopsy Patients

Patient	RF device	Rebiopsy
1	PASH	PASH
2	Papilloma	Papilloma

RF, radiofrequency; PASH, pseudo-angiomatous stromal hyperplasia.

Figure 5. (a) Hypoechoic BI-RADS 4c solid mass located at 12 o'clock 1B. The tip of the SenoCor 360 device is demonstrated just before entering the lesion. (b) SenoCor 360 device positioned at the lower part of the lesion. The device aperture is located between the two arrows. (c) Complete excision of the lesion performed by the SenoCor 360 device. An ultrasound visible gel marker is left in place. The histologic diagnosis was an infiltrative carcinoma.

Table 5. Published Rebiopsy Rate of Ultrasound-Guided Breast Biopsies

Author	Philpotts et al. (1)	Philpotts et al. (1)	Mainiero et al. (2)	Lieberman et al. (3)	Berg et al. (6)	Simon et al. (4)	Duchesne et al. (11,17)	Duchesne et al. (11,17)
Biopsy device	11 gauge	14 gauge	14 gauge	14 gauge	14 gauge	11 gauge	14 and 11 gauge	SenoCor
No. of cases	100	181	480	151	1,107	71	13,582	113
Rebiopsy rate (%)	10	8.30	3	4.60	1.40	1.40	0.02–3.21	1.80

The SenoCor 360 is designed to be an ergonomic, easy-to-hold biopsy device instrument for use during an ultrasound-guided breast biopsy procedure. It is also designed to have a coaxial guide which allows multiple sampling at the biopsy site as well as facilitating marker placement.

The results from this study demonstrate that the device met its design performance objectives. Investigators from four different clinical sites easily grasped the key operational steps and were able to achieve success in penetrating breast tissue and reaching the target lesion regardless of tissue composition, density, or location of the lesion. This ease of penetration was demonstrated to be equivalent to the ease of advancing smaller gauge devices providing smaller samples.

Despite the size of the needle, the ease of penetration and targeting compared with other existing vacuum-assisted devices can be explained by the advantages of using RF to penetrate the breast and accurately target the lesion, as previously reported (9,11). Although many radiologists may not be familiar with the use of RF, with proper biopsy and anesthetic techniques, both the procedure and the recovery may be less painful for the patient than biopsy with a spring-loaded device or DVAB (11). The new breast biopsy device is ergonomic and easy to use, which also improves the procedure for the operator (17). Procedure time is shortened by the use of RF, as the breast tissue offers no resistance during positioning of the device.

For ultrasound-guided breast biopsies, immediate rebiopsy rate ranges from 1.4% to 10% as reported in previous studies (Table 5) (1–9,11). Using a different biopsy device for the second procedure and/or proceeding to a diagnostic surgical excision are usually performed in these cases to provide diagnostic concordance. Considering the direct financial costs of re-excision, as well as indirect patient costs such as dissatisfaction and anxiety, physicians should aim to eliminate the need for rebiopsy in ultrasound-guided cases. Our study has demonstrated a very low immediate rebiopsy rate (1.8%) with no change in the histo-

logic diagnosis after the second procedure. This suggests that the use of the new device could help improve the immediate rebiopsy rate.

In conclusion, the improved ergonomics, ease of needle positioning, and ease of targeting as well as the very low immediate rebiopsy rate suggest that the SenoCor 360 device should be considered for use as a first-line biopsy device for ultrasound-guided breast procedures.

Acknowledgments

This study was funded by SenoRx, Aliso Viejo, CA. The authors would like to thank Elsja Lundquist for data management.

REFERENCES

- Philpotts LE, Hooley RJ, Lee CH. Comparison of automated versus vacuum-assisted biopsy methods for sonographically guided core biopsy of the breast. *AJR Am J Roentgenol* 2003;180:347–51.
- Mainiero MB, Koelliker SL, Lazarus E, et al. Ultrasound-guided large-core needle biopsy of the breast. *J Women's Imaging* 2002;4:52–57.
- Lieberman L, Feng TL, Dershaw DD, et al. US-guided core breast biopsy: use and cost-effectiveness. *Radiology* 1998;208:717–23.
- Simon JR, Kalbhen CL, Cooper RA, et al. Accuracy and complication rates of US-guided vacuum-assisted core breast biopsy: initial results. *Radiology* 2000;215:694–97.
- Chesbrough RM, Hunt KA, Swinford A, et al. Ultrasound-guided 14-gauge large-needle core biopsy of the breast: accuracy in 700 patients with three-year mammographic and clinical follow-up. *AJR Am J Roentgenol* 2003;180(Suppl. 3):9.
- Berg WA, Berg AP, Ioffe OB. Initial success and frequency of rebiopsy after ultrasound guided 14-gauge core breast biopsy. *AJR Am J Roentgenol* 2003;180(Suppl. 3):10.
- Parker SH, Burbank F, Jackman RJ, et al. Percutaneous large-core breast biopsy: a multi-institutional study. *Radiology* 1994;193:359–64.
- Parker SH, Klaus AJ, Mc Wey PJ. Sonographically-guided directional vacuum-assisted breast biopsy using a handheld device. *AJR Am J Roentgenol* 2001;177:405–8.
- Duchesne N, et al. Initial experience from a multicenter, prospective, randomized, controlled study using a new radiofrequency device to facilitate ultrasound-guided hand-held mammatome breast biopsy. *Radiology* 2001;221(Suppl.):430.
- Morris EA, Liberman L, Trevisan SG, et al. Histologic heterogeneity of masses at percutaneous breast biopsy. *Breast J* 2002;8:187–91.

11. Duchesne N, Parker S, Klaus A, *et al.* Multicenter, prospective, randomized, controlled study using a radiofrequency device (Easy Guide™) to facilitate ultrasound-guided hand-held mammo-tome breast biopsy: initial experience. *Radiology* 2004;232:205–10.

12. Glover JL, Bendick PJ, Link WJ. The use of thermal knives in surgery: electrosurgery, lasers, plasma scalpel. *Curr Probl Surg* 1978;15:1–78.

13. Anderson J. Surgical diathermy in breast cancer: the application of the arc electrode or cutting current to the radical operation. *Br J Surg* 1928;15:500–13.

14. O'Connor JL, Bloom DA, William T. Bovie and electrosurgery. *Surgery* 1996;119:390–96.

15. Miller E, Paull DE, Morrissey K, Cortese A, Nowak E. Scalpel versus electrocautery in modified radical mastectomy. *Am Surg* 1988;54:284–86.

16. Sheen-Chen SM, Chou FF. A comparison between scalpel and electrocautery in modified radical mastectomy. *Eur J Surg* 1993;159:457.

17. Duchesne N, *et al.* *San Antonio Breast Cancer Conference Meeting*, San Antonio; December 2002.