

ORIGINAL ARTICLE

Comparison of the Diagnostic Accuracy of a Vacuum-Assisted Percutaneous Intact Specimen Sampling Device to a Vacuum-Assisted Core Needle Sampling Device for Breast Biopsy: Initial Experience

Larry K. Killebrew, MD* and Ruth H. Oneson, MD[†]

*Oklahoma Breast Care Center, Oklahoma City, Oklahoma; and [†]Heartland Pathology Consultants, Edmond, Oklahoma

■ **Abstract:** The objective of this research was to determine whether biopsy of the breast using a percutaneous intact specimen sampling device influences the underestimation rate of ductal carcinoma in situ (DCIS) compared to a vacuum-assisted core needle biopsy (VACNB) device. This study was a retrospective comparison of two series of 800 consecutive patients that underwent stereotactic biopsy of the breast for mammographic lesions presenting as microcalcifications classified by our institution as Breast Imaging Reporting and Data System (BI-RADS) 4 or 5. In the first series of patients ($n = 800$), a VACNB device was used; in the second series ($n = 800$), a vacuum-assisted percutaneous intact specimen biopsy (VAPIB) device was used. Initial diagnoses were made from the histopathologic examination of the tissue retrieved at biopsy. Lesions presenting as DCIS or atypical ductal hyperplasia (ADH) after percutaneous biopsy were then compared to the histopathologic analysis of specimens retrieved at surgical biopsy. DCIS upgrades were defined as cases in which the diagnosis of the stereotactic biopsy was DCIS and the diagnosis of the subsequent surgical excision was infiltrating ductal carcinoma (IDC). ADH upgrades were defined as cases in which the diagnosis of the stereotactic biopsy specimen was ADH and the diagnosis of the surgical excision was DCIS, lobular carcinoma in situ (LCIS), or IDC. The lesions retrieved by both biopsy techniques yielded a similar pathology distribution. Underestimation of DCIS occurred less frequently ($p = 0.06$) in the biopsy samples taken using the intact biopsy device (1/31, 3.2%) as compared to biopsy samples taken using the core needle biopsy device (7/36, 19.4%). No significant adverse events were reported. Breast biopsy can be performed safely and accurately using a vacuum-assisted percutaneous intact specimen sampling device. In this study, such a device trended toward fewer underestimations of DCIS at biopsy compared to the vacuum-assisted core needle sampling biopsy method. ■

Key Words: atypia, atypical ductal hyperplasia, breast biopsy, ductal carcinoma in situ, invasive ductal carcinoma, RF biopsy, vacuum-assisted biopsy

Advances in breast biopsy methods have been dramatic since the early 1990s. Percutaneous image-guided core biopsy was pioneered by Parker et al. and confirmed by others in subsequent trials as contributing many advantages to the patient management algorithm for mammographically suspicious microcalcifications and masses (1–3). In 1996, Burbank et al. (3) published results on the vacuum-assisted core needle biopsy (VACNB) method. The effectiveness of the image-guided VACNB procedure has been established in numerous subsequent studies and is the accepted method of establishing an initial diagnosis

for most suspicious lesions presenting as calcifications (4). Recent advances aside, the literature still reports a 7–20% occurrence of underestimation of ductal carcinoma in situ (DCIS), depending on the percutaneous biopsy technique employed (4–9).

The standard by which the accuracy of percutaneous breast biopsy has been measured is open surgical biopsy (5). This has been a historically accepted method and was the initial means of breast biopsy. Mammographic-histopathologic correlation may be more accurate with an intact specimen of larger volume. Fragmentation or crushing of core biopsy specimens with processing may compromise the accuracy of pathology interpretation (10).

The literature supports the premise that a correlation exists between the amount of target tissue retrieved at biopsy and the frequency of underestimation of in situ disease. Both Liberman et al. (4) and Brem et al. (6) reported

Address correspondence and reprint requests to: Larry K. Killebrew, MD, Oklahoma Breast Care Center, 13509 N. Meridian, Suite 6, Oklahoma City, OK 73120, USA, or e-mail: lkillebrew@okbreastcare.com.

a correlative reduction in incidences of in situ upgrades with an increase in the percentage of the mammographic target area that is removed by the biopsy.

Vacuum-assisted core needle biopsy devices available today remove cylindrical specimens that are 2–3 mm in diameter and approximately 2 cm long. It is standard practice to remove multiple core specimens from each lesion. There is some debate in the literature regarding the optimal number of samples necessary to yield the correct diagnosis and avoid DCIS underestimation (6,11). Lomoscihtz et al. (12) recently reported that diagnostic yield increases with the number of specimens retrieved, but that the improvement in diagnostic yield is not increased when more than 12 specimens are retrieved.

A vacuum-assisted percutaneous intact specimen biopsy (VAPIB) device was introduced in 2003. This device differs from percutaneous core devices in that it removes one spheroid specimen rather than a set of smaller cylindrical cores. Our goal was to determine whether there was a difference in the diagnostic accuracy between the two methods. The purpose of this study was to measure the differences in diagnostic accuracy between the two methods, using DCIS upgrades as an indicator.

MATERIALS AND METHODS

This study was a retrospective comparison of two series of 800 consecutive patients that underwent stereotactic biopsy of the breast for mammographic lesions presenting as microcalcifications classified by our institution as Breast Imaging Reporting and Data System (BI-RADS) 4 or 5. The first series of consecutive patients ($n = 800$) underwent stereotactic VACNB with an 11-gauge probe (Mammotome Breast Biopsy System, Biopsy/Ethicon Endo-Surgery, Cincinnati, OH) from June 26, 2000, to February 28, 2002. The second series of consecutive patients ($n = 800$) underwent stereotactic VAPIB with either a 10 mm or 15 mm needle (en-bloc Biopsy System, Neothermia Corp., Natick, MA) from September 3, 2003, to November 11, 2004.

During the period in which the VACNB data were tabulated, the VACNB was the only biopsy method used for stereotactic biopsy in our practice except in instances where, in accordance with the manufacturer's instructions, the device was contraindicated. During the period when the VAPIB data were tabulated, VAPIB was the only biopsy method used for stereotactic biopsy except in the instances where, in accordance with the manufacturer's instructions, the device was contraindicated. Contraindications for VAPIB are identical to those for VACNB, with

the exception that patients with pacemakers are contraindicated for VAPIB. In both series, stereotactic biopsy was performed on a dedicated stereotactic table (Fischer Mammotest, Fischer Imaging Corporation, Denver, CO).

The consecutive nature of the retrospective study was designed to mitigate unintended selection bias. Both arms were collected over periods of more than 1 year (14 months for intact biopsy and 20 months for VACNB), and the devices studied in each arm were the only ones used during those periods (except in the cases of contraindications). There was no perceptible change in the demographic profile of patients attending our clinic during the earlier period versus the later. In addition, in both arms, all decisions to biopsy and all biopsy procedures were performed by a single physician. Although it may be argued that tabulating patient ages and lesion sizes may have provided additional insight regarding the nature of which lesions were upgraded, the study design provides a high level of confidence that the range of patient ages and lesion sizes were comparable in both groups.

Indication for Biopsy and Biopsy Technique

Percutaneous biopsy was indicated for all mammographically evident lesions presenting as microcalcifications and classified as BI-RADS 4 or 5 unless the patient exhibited a contraindication for percutaneous biopsy or the specific device. In both arms of the study, informed consent for the percutaneous biopsy was obtained from the patient.

Patient preparation is similar for both VACNB and VAPIB procedures; the patient's breast was cleaned and prepared according to our practice's standard protocol. Prepuncture application of local anesthetic was performed with lidocaine (3–5 cc) injected to achieve a skin weal. Deep injection of lidocaine (20–30 cc) was distributed posterior to the lesion as well as around the lesion to be sampled.

Vacuum-Assisted Core Needle Biopsy Technique

Vacuum-assisted core needle biopsy was performed with an 11 gauge VACNB needle. The VACNB method has been used in clinical practice since 1996 and its advantages and the procedure have been described in numerous articles (1–4,6–8). Our standard practice was to biopsy for representative tissue only rather than to remove all mammographic evidence of the lesion, harvesting 6 to 12 specimens per lesion. The specimens were immediately stored in a formalin solution and submitted to pathology for examination. The incision size for the 11 gauge VACNB needle is 5–6 mm. The incision size was measured

in a small series of patients ($n = 16$) on which VACNB was performed just prior to our adoption of the VAPIB procedure. Our standard technique was to make a stab incision with a no. 11 scalpel, and this incision size was consistent with the 5.5 mm width of the base of the scalpel. After the biopsy procedure, a specimen radiograph was obtained to confirm adequate sampling. After confirmation, a marker clip (Mammomark, Ethicon Endosurgery, Cincinnati, OH) was inserted and a postprocedure mammogram was performed.

Vacuum-Assisted Intact Specimen Biopsy Technique

Vacuum-assisted percutaneous intact specimen biopsy procedures were performed with 10 mm or 15 mm probes, depending upon the compression characteristics of the breast, location of the lesion, and availability of the 15 mm probe. After January 2003, a 15 mm probe became available and was used in approximately half of the remaining VAPIB cases. The 10 mm VAPIB probe used in this study produces a spheroid specimen size of 10 mm (diameter) by 16 mm, and the 15 mm VAPIB probe used in this study produces a spheroid specimen size of 15 mm (diameter) by 21 mm (see Fig. 1). The probe is mounted into a handle that contains a motor and drive mechanism which activates the mechanics of the capture basket. The handle is mounted on the stereotactic table by means of a bracket (see Fig. 2). Since the device employs a radio-frequency (RF) tissue cutting mechanism, a patient return electrode is applied to the upper thigh or lower lumbar back on the contralateral side of the breast to be biopsied.

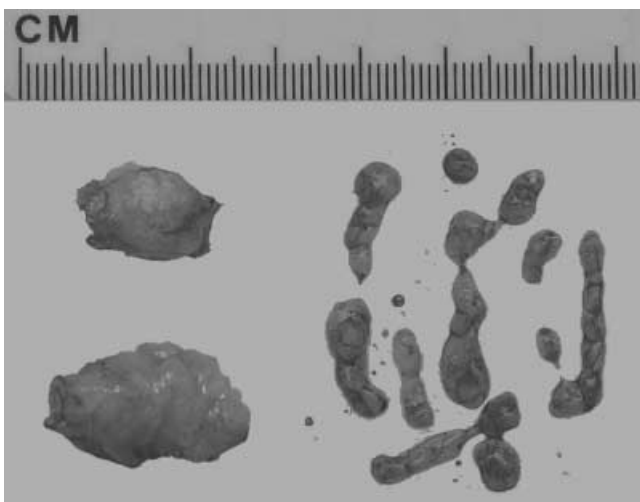


Figure 1. Typical vacuum-assisted intact biopsy specimens (10 mm and 15 mm en-bloc) and 11-gauge vacuum-assisted core needle biopsy specimens (Mammotome).



Figure 2. En-bloc biopsy handle mounted on a bracket on a Fischer MammoTest stereotactic table.

Vacuum-assisted percutaneous intact specimen biopsy is intended to retrieve a representative specimen only, and is not intended as an excisional method. Despite the size of the probes, the incision size required for either probe size ranges from 6 to 8 mm. The en-bloc VAPIB probe used in this study employs an RF capture snare to harvest the biopsy specimen. The snare is mounted on the distal end of a basket that expands to a maximum diameter then contracts to isolate the specimen tissue from the rest of the breast (see Fig. 3). Although the incision size is smaller than the diameter of the specimen removed, the skin of the breast is sufficiently compliant to expand and allow removal of the specimen without enlarging the incision.

The probe uses an RF cutting mechanism to navigate through the breast tissue and to harvest the specimen. In both the RF advancement and RF capture functions, the device incorporates a vacuum and vacuum ports to keep the cutting field clear of fluid and cellular debris. Keeping the field clear is essential to maintain the electro-surgical arc and is necessary for RF cutting.

The procedure is similar to the VACNB procedure. A set of targeting images was obtained and the target location confirmed. The target offsets for the 10 mm and



Figure 3. The en-bloc capture snare is mounted on the distal end of the basket. As the basket struts extend, the capture snare expands to a maximum diameter, then contracts to isolate the specimen tissue from the rest of the breast. Cutting is affected by RF electro-surgical power applied to the capture snare.

15 mm devices are 3 mm and 8 mm, respectively. Once the target location is confirmed, the stop is set at the appropriate location on the rail and the handle, with probe inserted, is mounted on the table.

The probe is advanced to the stop by activating the precursor electrode while simultaneously moving the device down the guide rail. RF is applied in short intervals, approximately 0.5 seconds each, which is usually sufficient to advance the probe 1–2 cm per interval until the target location is achieved.

Capture of the specimen is a two-step process. The capture activation foot pedal is depressed, followed by depression of the capture foot pedal. The capture snare is deployed by a motor in the handle and proceeds automatically. After the specimen capture sequence is complete, the probe and specimen are removed from the breast. A specimen radiograph is obtained and a marker clip placed if the specimen radiograph shows adequate sampling.

The biopsy channel remains intact and allows for application of the marker clip. Our facility uses clips from two manufacturers (Site Marker, Neothermia, Natick, MA; or Megamark, Artemis Medical, Hayward, CA). The specimen is placed in formalin solution and transported to pathology for diagnosis. Throughout the VACNB arm and early in our experience in the VAPIB arm, we dressed the incisions with steristrips. Later in our experience we included the use of tissue adhesive to augment tissue closure.

The purpose of the VAPIB and VACNB biopsies was to obtain diagnoses for suspicious lesions, not to perform therapeutic excision of the lesion in question. As such, margins were not a consideration and the specimens were not inked. The pathology department gross sectioned the specimens into 2–3 mm wafers, or approximately four sections for a 10 mm specimen and six sections for a 15 mm specimen. The gross sections were fixed, microtomed, and mounted on pathology slides according to standard technique. Slides were created from five levels within the wafers. This equates to approximately 20 levels for 10 mm specimens and 30 levels for 15 mm specimens.

Definitions

As the focus of this study is determining the effect of the two different vacuum-assisted breast biopsy techniques on the underestimation rate of DCIS, we defined the underestimation rate of DCIS as the ratio of the number of infiltrating ductal carcinoma (IDC) cases found at surgical follow-up after an initial biopsy diagnosis of DCIS to the total number of diagnoses of DCIS detected for each biopsy method. DCIS patients lost to follow-up

is defined as the number of patients in each arm whose surgical treatment was conducted at a facility that did not report their final diagnosis to us. Complete excision was defined as those patients whose initial biopsy produced a diagnosis of DCIS or atypical ductal hyperplasia (ADH) and whose surgical biopsy resulted in a benign diagnosis with no evidence of IDC, DCIS, or ADH.

Data Collection and Analysis

Procedural diagnostic data were collected retrospectively. Data for patients who were referred to subsequent surgery were collected from the managing surgeons. Probabilities were obtained from two-tailed Fisher's exact tests with $\alpha \leq 5\%$ indicating statistical significance. All statistical programs used SAS version 8.2 (SAS, Cary, NC) and were run on a PC.

RESULTS

The lesions in the VACNB and VAPIB arms of the study yielded a similar pathology distribution at biopsy (see Table 1), with a benign diagnosis accounting for 668 (83.5%) and 663 (82.9%) lesions, respectively. ADH was present in 16 (2.0%) VACNB procedures and 15 (1.9%) VAPIB procedures. DCIS at biopsy comprised 36 (4.5%) VACNB cases and 31 (3.9%) VAPIB cases. IDC was present at biopsy in 65 (8.1%) VACNB cases and 75 (9.4%) VAPIB cases. Other diagnoses included infiltrating lobular carcinoma (ILC) and lobular carcinoma in situ (LCIS) in 7 (0.9%) and 5 (0.6%) cases, respectively, and other cancers (intramedullary carcinoma [IMC], infiltrating papillary carcinoma [IPC], and mucinous carcinoma [MC]) were found in 10 (1.3%) cases in each arm. The positive predictive values for each arm were similar.

Ductal carcinoma in situ underestimation, the focus of this study, was 19.4% for the VACNB method and 3.2%

Table 1. Diagnoses for Stereotactic Vacuum-Assisted Breast Biopsy in 1600 Patients Using Two Different Methods

Biopsy method	VACNB	VAPIB
Biopsy device	Mammotome and Mammotome ST 11-gauge	en-bloc 10 or 15 mm
Diagnosis at biopsy		
Benign	668 (83.5%)	663 (82.9%)
ADH	16 (2.0%)	15 (1.9%)
DCIS	36 (4.5%)	31 (3.9%)
IDC	65 (8.1%)	75 (9.4%)
ILC or LCIS	5 (0.6%)	7 (0.9%)
Other cancer	10 (1.3%)	10 (1.3%)
Total	800	800

Table 2. Surgical Diagnoses of Lesions Presenting as DCIS at Vacuum-Assisted Breast Biopsy

Biopsy method	VACNB	VAPIB	p
Biopsy device	Mammotome or Mammotome ST 11-gauge	en-bloc 10 and 15 mm	
Diagnosis at surgery			
DCIS diagnosis confirmed	19/36 (53.0%)	16/31 (52%)	
DCIS underestimation	7/36 (19.4%)	1/31 (3.2%)	0.060
No residual DCIS at surgery	4/36 (11.1%)	12/31 (38.7%)	0.011
DCIS cases lost to follow-up	6/36 (16.7%)	2/31 (6.5%)	0.270
Total	36	31	

for the VAPIB method (see Table 2). Complete excision of the DCIS lesion was accomplished at biopsy in 11.1% of the VACNB cases and 38.7% of the VAPIB cases. DCIS cases for which there was no surgical follow-up were 16.7% for the VACNB arm and 6.5% for the VAPIB arm.

Although the p-value (0.06) did not reach the significance threshold of 0.05, there was a trend toward fewer DCIS upgrades to IDC in the VAPIB arm of the study (3.2% versus 19.4%)

Complications

Complications associated with the procedure were minimal for each arm of the study. There were no hematomas requiring surgical intervention, nor did any patients return with complaints of hematoma; however, based on our experience with the VACNB device, we suspect that some patients did experience minor hematomas, but did not return to our facility for intervention. Other complications included minor pain and minor bleeding, both anticipated as part of a vacuum-assisted breast biopsy procedure (13). These occurrences were anecdotal, as there were no instances severe enough to record. These complications are consistent with our experience with the VACNB procedure and have also been reported in the literature for the procedure (13). There were no instances of bleeding that required surgical intervention or extended compression.

Subjective ratings by patients indicate they tolerated the VAPIB procedure as well as they did the VACNB procedure. Toward the end of the VACNB arm ($n = 16$), we modified our protocol to include subjective assessment by the patient of the comfort of the biopsy procedure. A scale of 0 to 10 was used with 0 meaning no pain at all, and 10 equating to extreme pain. For comparative purposes, patients were also asked to rate the comfort of lying on the stereotactic table. The average comfort rating for the stereotactic table in the VACNB arm was 5.8, and the

average comfort rating for the VACNB device was 2.0. In the VAPIB procedures evaluated for comfort ($n = 500$), the average comfort rating for the stereotactic table was 4.1, while the average comfort rating for VAPIB device was 1.9.

Other complications associated with the VAPIB method included a small incidence of cases in which two probes were required to complete the biopsy. This phenomenon, similar to dry tapping with VACNB, is discussed in more detail in the following section.

Complications associated with the VACNB method included dry tapping and insufficient sampling. We experienced many of these complications during the period of the VACNB procedures in our study, but no instances were severe enough to warrant a notation.

DISCUSSION

Vacuum-assisted core needle biopsy procedures are the established alternative to open surgery as an initial diagnostic intervention. However, DCIS underestimation has persisted as a limitation to the procedure. Introduction of the 11-gauge device has been reported to reduce DCIS upgrade rates, with reports ranging from 20.0% to as low as 6.8% (4). In our study, there was a further trend toward fewer DCIS underestimations with the en-bloc VAPIB method (3.2% versus 19.4% in the VACNB arm). Although these data present a strong trend, with a p-value of 0.06, these data do not present a statistically significant p-value of 0.05. There were statistically significant differences in which surgery showed no residual DCIS after the initial diagnosis of DCIS (38.7% versus 11.1%, $p = 0.01$). These data suggest that the VAPIB procedure resulted in complete excision of the DCIS. We are not implying that these data indicate there is a possibility that VAPIB may be used as a therapeutic procedure for DCIS, but they do imply a reduction in sampling error between the two procedures. If the hypothesis holds true, the reduction in sampling error is a viable explanation for the reduction in upgrades. With such a large difference in upgrade rates, and a p-value approaching 0.05, the data in this article are suggestive of a trend. The VAPIB method warrants further study to determine whether these differences are indeed significant.

Procedural Differences

We encountered four differences between the VAPIB method and VACNB that merit mention. First, there was a small rim of RF artifact around the periphery of the lesion. Although not measured in all 800 specimens,

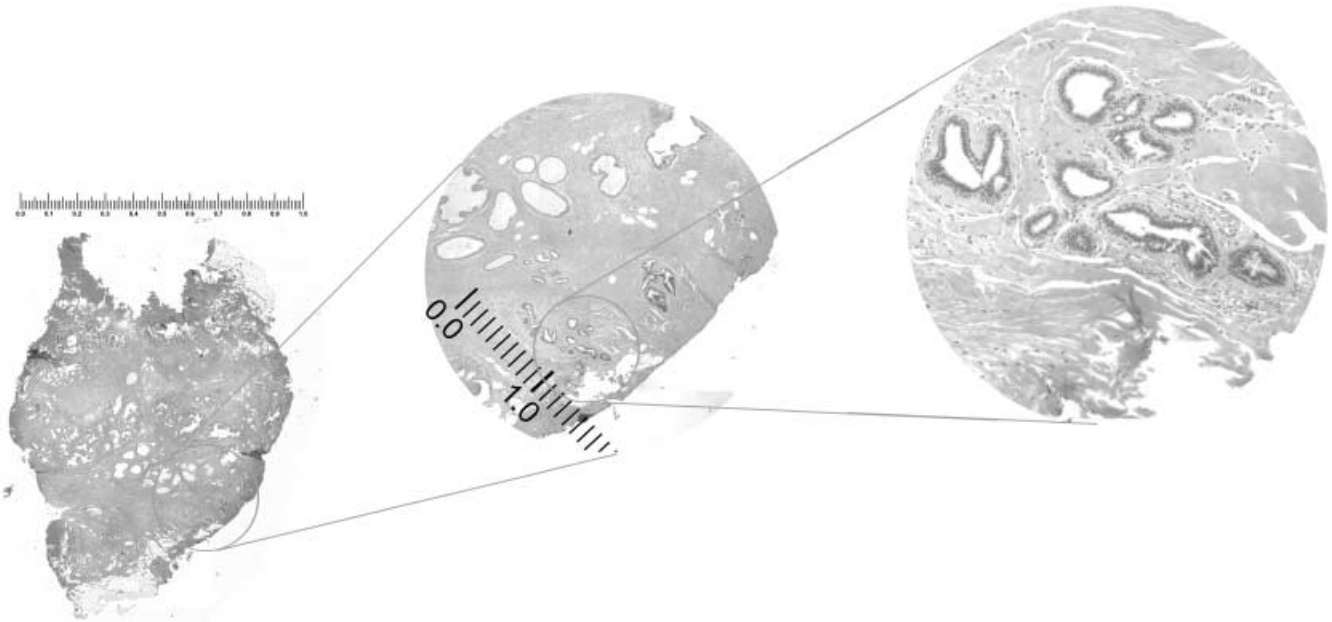


Figure 4. Thermal artifact in the vacuum-assisted intact specimen method averaged 0.2–0.5 mm around the periphery and approximately 1.0 mm in the region adjacent to the precursor electrode.

the pathology group that examined many of specimens indicated the zone averages 0.2–0.5 mm around the periphery, and about 1 mm at the edge, which is adjacent to the precursor electrode (see Fig. 4). This 0.2–0.5 mm zone was initially viewed as a complication by some of the pathologists, and was of no concern to others. There were no instances where a diagnosis was not made because of the artifact. After experiencing their own learning curve, these pathologists no longer have issues with the artifact.

Second, there were 29 empty baskets (3.6%) and 8 wire breaks (1.0%), which resulted in the need for use of a second probe. This phenomenon is similar to dry tapping with the VACNB method, and may be remedied by insertion of a new probe (approximately 1 minute). There is no financial penalty for use of a second probe with the device used in this study (a credit was issued). The cause of these incidents is thought to be associated with quenching of the cutting arc by unabsorbed lidocaine or ruptured cysts, or overheating of the wire when cutting in certain types of tissue (although there were no incidences in this study where a second probe in the same tissue structure did not successfully capture a specimen). Neither of these resulted in adverse events to the patient, and we do not consider these to be complications, but rather procedural differences that require a learning curve when adopting the VAPIB procedure.

Third, the anesthetic protocol for the VAPIB procedure must be followed rigorously. Although the average per-

ception of pain did not appear to differ from the small group of VACNB patients, the VAPIB procedure is a one-step procedure, allowing only one chance to provide the patient a painful or comfortable experience. Conversely, the VACNB procedure allows the physician to inject more lidocaine midprocedure, overcoming any intermittent pain that might be experienced. No such intervention is possible for the VAPIB procedure because there is only one tissue acquisition step. Performing the biopsy in a region that has not been anesthetized can result in intense pain. The protocol calls for liberal application of lidocaine in the region of the lesion, with particular attention paid to administering anesthetic behind the lesion (we recommend using a spinal needle). After administering the anesthetic, approximately 5 minutes is allowed for the lidocaine to disperse in the tissue.

Finally, there was a healing difference observed between the VACNB and VAPIB methods. Although comparative healing at postbiopsy review appeared similar (see Fig. 5), initial healing of the VAPIB site appeared to be delayed by approximately 1 week. As reported in a poster session at the American Society of Breast Disease, this delay is thought to be a function of the small degree of hemostasis associated with the RF cutting mechanism. In addition to inhibiting bleeding, vascular closure also inhibits the migration of fibrins and fibrinogens to the wound site. Similar differences between the healing rates of wounds cut with cold steel scalpels and electrocautery cutting



Figure 5. Longer-term healing outcomes for the vacuum-assisted intact specimen method are comparable to results from the vacuum-assisted core needle biopsy method.

devices have been reported in the surgical literature (14,15). Further study of this phenomenon is warranted.

In conclusion, the diagnostic results were similar between the VACNB arm with the Mammotome device and the VAPIB arm with the en-bloc device. The complication rates were also comparable. The VAPIB procedure appears to be a viable alternative to VACNB for breast biopsy. Further study is warranted to determine whether the improved diagnostic accuracy described in this article is repeatable and significant.

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