Initial Experience with the Advanced Breast Biopsy Instrumentation Device

Murray Rebner[1]
Richard Chesbrough[2]
Nancy Gregory[2]

OBJECTIVE. The Advanced Breast Biopsy Instrumentation (ABBI) device (United States Surgical; Norwalk, CT) is designed to percutaneously excise nonpalpable breast lesions. Because this is a new technique, we report our initial experience with regard to technical success, complications, and histologic margins for malignancies.

SUBJECTS AND METHODS. From May 14, 1997, until March 4, 1998, 89 consecutive patients elected to undergo the ABBI procedure. Preprocedure imaging included screening mammography and additional mammographic and sonographic studies when deemed necessary. Lesions were targeted by the surgeons. Specimen radiography was performed for all lesions, and the images were interpreted by radiologists. Pathologic analysis was provided or reviewed by a dedicated breast pathologist. Parameters analyzed included technical success, complications, lesion size, histologic diagnosis, and margin status for malignant lesions.

RESULTS. There were 29 patients with 30 noncalcified masses, 53 patients with clustered calcifications, three patients with masses and calcifications, three patients with asymmetric densities, and one patient with architectural distortion. Eighteen ABBI procedures were aborted, converted to core biopsy, or failed to remove the targeted lesion. Fifteen patients experienced a total of 19 complications; 10 of the complications required treatment and follow-up after the biopsy. Of 11 malignant tumors revealed by ABBI, four had negative margins. Seven of these 11 malignant tumors had positive margins.

CONCLUSION. The ABBI procedure had a high number of complications and technical failures and did not reliably provide cancer-free margins for malignant tumors. Women with nonpalpable breast lesions that need a tissue diagnosis are better treated by stereotactic or sonographically guided needle biopsy.

Over the past decade, there has been an evolution in biopsy techniques for nonpalpable breast lesions. Freehand needle localization gave way to radiographically guided hookwire localization [1]. Radiographically guided fine-needle aspiration biopsy was supplanted by stereotactic fine-needle aspiration biopsy. In the early 1990s, 18-gauge and then 14-gauge stereotactic core needle biopsy procedures were developed [2, 3]. Subsequently, we witnessed the advent of a directed vacuum-assisted biopsy device that used either 14-gauge or 11-gauge needles [4, 5]. Most recently, a new device, Advanced Breast Biopsy Instrumentation (ABBI) (United States Surgical; Norwalk, CT), was introduced to percutaneously excise nonpalpable breast lesions [6, 7]. This device is designed to remove a cylinder of tissue 5–20 mm in diameter. The procedure also requires the use of a dedicated stereotactic prone table.

The success rates for stereotactic core needle biopsy vary among different authors. Ranges of 71–100% for sensitivity have been reported [8]. Factors that may have influenced these results include the size of the needle, the number of samples, the size and type of lesion biopsied, and the experience level of the physician who performed the biopsy. If a device could percutaneously excise a lesion in toto with no tissue fragmentation, provide a tumor-free surgical margin around the lesion, and not introduce significant morbidity, perhaps there would be a role for this device. This role would be especially important in patients with noninvasive or minimally invasive breast cancer. We evaluated the ABBI device for our breast practice. We were interested in the technical success of the

Received November 9, 1998; accepted after revision January 7, 1999.

[1]William Beaumont Hospital, 3601 W. Thirteen Mile Rd., Royal Oak, MI 48073. Address correspondence to M. Rebner.

[2]Henry Ford Hospital, 2799 W. Grand Blvd., Detroit, MI 48202.

AJR 1999;173:221–226

0361–803X/99/1731–221

procedure, the types of complications, and the histologic analysis of the lesions.

Subjects and Methods

At our institution, all patients who underwent screening or diagnostic mammography received a final assessment code based on the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) lexicon. All patients with final assessment codes 4 (suspicious abnormality) and 5 (highly suggestive of malignancy) were referred to general surgeons for consultation. Some referring primary care physicians also elected to refer to surgeons patients with final assessment code 3 (probably benign) lesions. As far as we were aware, all patients discussed the risks and benefits of needle localization and excisional biopsy, stereotactic and sonographically guided core needle biopsy, and the ABBI procedure with the consulting surgeon. The final decision regarding which procedure to undergo was made between the patient and the surgeon. The radiologist was not present during these discussions.

From May 14, 1997, until March 4, 1998, 89 consecutive patients elected to undergo the ABBI procedure, and these patients constitute the basis of this report. Follow-up for all patients ranged from 9 to 18 months. Five patients had imaging examinations performed at outside institutions, and they did not receive final assessment codes. Preprocedure workup included screening mammography and additional mammographic and sonographic studies when deemed necessary. Eight board-certified general surgeons with experience in breast surgery attempted 90 ABBI procedures (one patient had two lesions). The lesions were targeted by the surgeons, who only rarely requested assistance from the mammographers. Specimen radiography was performed for all lesions, and these images were interpreted by radiologists experienced in breast imaging. A copy of the specimen radiograph and the tissue were sent to pathology. All the specimens were inked and sectioned. Final histologic analysis was performed by a dedicated breast pathologist.

Relative contraindications to the procedure include the following: body weight of more than 136.3 kg, presence of a bleeding diathesis, inability to lie prone for a minimum of 1 hr, or compressed breast thickness less than 30 mm. Also suggested for exclusion were patients with a lesion larger than 10 mm, a lesion palpated by the surgeon, or a lesion less than 20 mm away from the chest wall or skin surface.

Technical success was defined as actual removal of the targeted lesion from the breast. This was confirmed by a postprocedure digital radiograph and a specimen radiograph. Parameters analyzed included technical success, lesion size, histologic diagnosis, margin status for malignant lesions, and type and number of complications.

All patients were told to abstain from food and drink after midnight the day of the procedure. Patients were also instructed to discontinue any aspirin-containing products 1 week before the procedure and to not take these products for 5 days after the procedure. Most patients were given 10 mg of diazepam orally 2 hr before the onset of the procedure. Positioning involved placing the patient prone on the dedicated stereotactic biopsy table with the involved breast hanging through the aperture. The approach to the lesion was based on the shortest distance, provided that a minimum of 20 mm existed between the skin surface and the lesion or between the lesion and the chest wall. The breast was then compressed and the lesion was identified on a scout digital image, with occasional assistance from radiologists. The lesion was then centered in the plate, and paired scout stereotactic images were obtained. Three-dimensional coordinates (x, y, and z) were generated to target the lesion within 1 mm.

The skin was sterilely prepped and draped, and the appropriate-sized ABBI gun was selected. To provide a margin of normal tissue around the lesion, we chose a cannula size that was approximately two times the maximum diameter of the lesion. In our series, only 15-mm and 20-mm cannulas were used. The coordinates were then downloaded from the computer to the motor, which moved the gun holder to the proper x (horizontal) and y (vertical) coordinates. Local anesthesia was administered, and a small incision was made in the skin. The needle of the ABBI was advanced to the predetermined depth (z coordinate). Paired digital stereotactic images verified the correct placement of the needle. A T-bar was then introduced through the needle and advanced 10 mm beyond the lesion to fix the path of the cutting trocar. A second pair of stereotactic images confirmed the position of the T-bar at the proper site.

Additional lidocaine was injected, and the incision was enlarged to approximately 3 cm to accommodate the cannula. The motorized oscillating blade was slowly advanced along the course of the wire at 0.1-mm increments to an end point 10 mm past the lesion on the z axis. After reconfirming the position of the T-bar with stereotactic images, a snare (garroting wire) was used to cut the tissue. Forty-five watts of electrocautery was applied intermittently to the snare as it traversed the breast tissue. The entire instrument was removed and the wound packed with gauze. After bleeding ceased, the gauze was removed, the wound sutured closed, and a surgical dressing applied. Specimen radiography was then performed.

Results

Eighty-nine consecutive patients with 90 lesions (one patient had a mass in each breast) were selected for the ABBI procedure. Forty-one lesions were in the right breast, 49 in the left breast. Twenty-nine patients had 30 noncalcified masses (one patient had a mass in each breast) that were proven to not represent simple cysts at sonography. Fifty-three patients presented with clustered calcifications, three patients presented with masses containing calcifications, three patients had asymmetric densities, and one patient had architectural distortion. Twenty-four lesions were coded as probably benign (BI-RADS category 3), 57 as suspicious for malignancy (category 4), and three were interpreted as highly suggestive of malignancy (category 5) (Table 1). Six lesions were worked up at outside institutions and did not receive final BI-RADS assessment codes.

Technical Success (Defined as the Lesion Removed at ABBI)

Of the 90 ABBI procedures attempted, 18 were either aborted, converted to core biopsy, or failed to remove the targeted lesion (Table 2). Seven lesions (five masses and two asymmetric densities) disappeared or were unable to be reproduced during the targeting and needle-place-

TABLE 1 Histologic Results in 90 Lesions According to BI-RADS Category

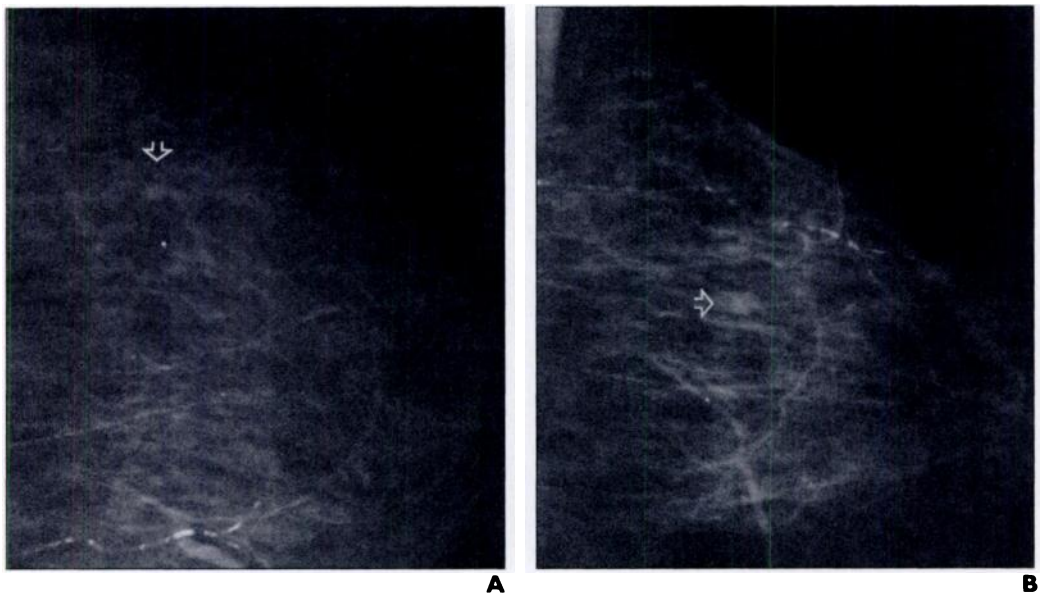
BI-RADS Category	Benign	Malignant	Failure	Total
3 (probably benign)	15	3	6	24
4 (suspicious abnormality)	40	6	11	57
5 (highly suggestive of malignancy)	1	2	0	3
Not categorized	5	0	1	6

Note.—BI-RADS = American College of Radiology Breast Imaging Reporting and Data System.

TABLE 2 Technical Results of ABBI Procedures According to Lesion Type

Lesion Type	Technical Success	Technical Failure	Total
Masses	21	9	30
Calcifications	46	7	53
Masses and calcifications	3	0	3
Asymmetric density	1	2	3
Architectural distortion	1	0	1
Total	72	18	90

Note.—ABBI = Advanced Breast Biopsy Instrumentation (United States Surgical, Norwalk, CT). Technical success is defined as lesion removed at ABBI.



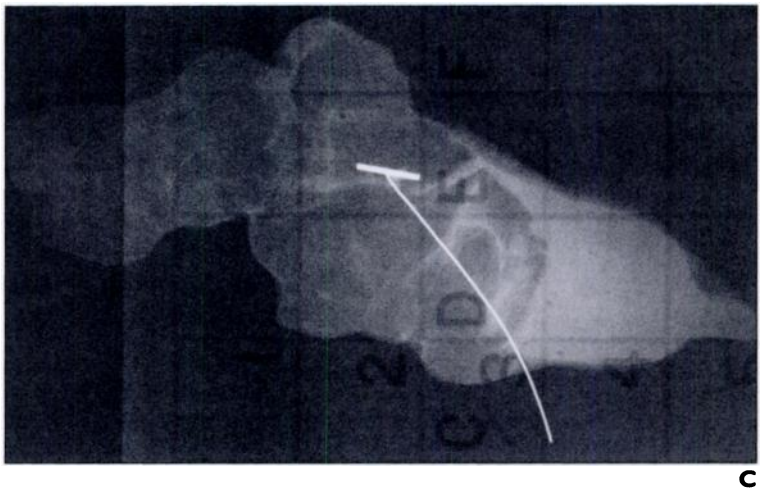


Fig. 1.—65-year-old woman with 7-mm mass in left breast.
A and **B**, Craniocaudal (**A**) and mediolateral oblique (**B**) views of left breast show mass to be located at 3-o'clock position (*arrows*). Minification factor, 1:2.
C, Advanced breast biopsy instrumentation specimen radiograph reveals no mass in specimen. Follow-up mammogram obtained 3 months later (not shown) showed resolution of mass. Magnification factor, 2:1.

ment phase of the procedure. These procedures were aborted before tissue removal. It was believed that these lesions represented asymmetric fibroglandular tissue or complex cysts that ruptured during the ABBI procedure rather than a mass. All of these patients were treated with 6-month mammographic follow-up.

In five patients, the targeted lesions were not visible in the specimen radiograph (Fig. 1). One of these patients underwent immediate blind reexcision by the surgeon, two underwent subsequent wire localization and excisional biopsy, and two were placed into short-term follow-up.

Four lesions were too faint to adequately visualize and target. No incision was made. Two of these patients underwent needle localization excisional biopsy, and the other two (who both had lesions with final assessment code 3) were treated with short-term follow-up.

Two patients had lesions that were inaccessible to ABBI biopsy: One was too superficial, and one was too close to the chest wall. No incision was made, and both patients were converted to immediate core biopsy, which was successfully performed by the supervising radiologist. The overall technical success rate was 72 (80%) of 90 lesions. As of January 1999, none of the remaining 18 lesions represented in situ or invasive carcinoma.

Complications

Complications were defined as any untoward event that occurred at the time of the procedure or that required additional postoperative visits. Follow-up data were extracted from the electronic medical records. Of the 72 patients who underwent the procedure, 15 patients (20.8%) experienced 19 complications (four patients each suffered two complications). These included hematomas, significant hemorrhage (estimated 100 ml blood loss or greater), pneumothorax from injection of the deep anesthetic, superficial venous thrombosis, scarring and wound problems (delayed healing, protruding sutures) (Table 3). Ten of these 15 patients required additional postoperative visits. Six patients had two visits, and four patients had three or more. One patient with a large hematoma and postprocedure scar required five postoperative visits to evacuate and monitor the hematoma.

Most complications were divided among all of the eight surgeons, with the highest number of complications occurring among the sur-

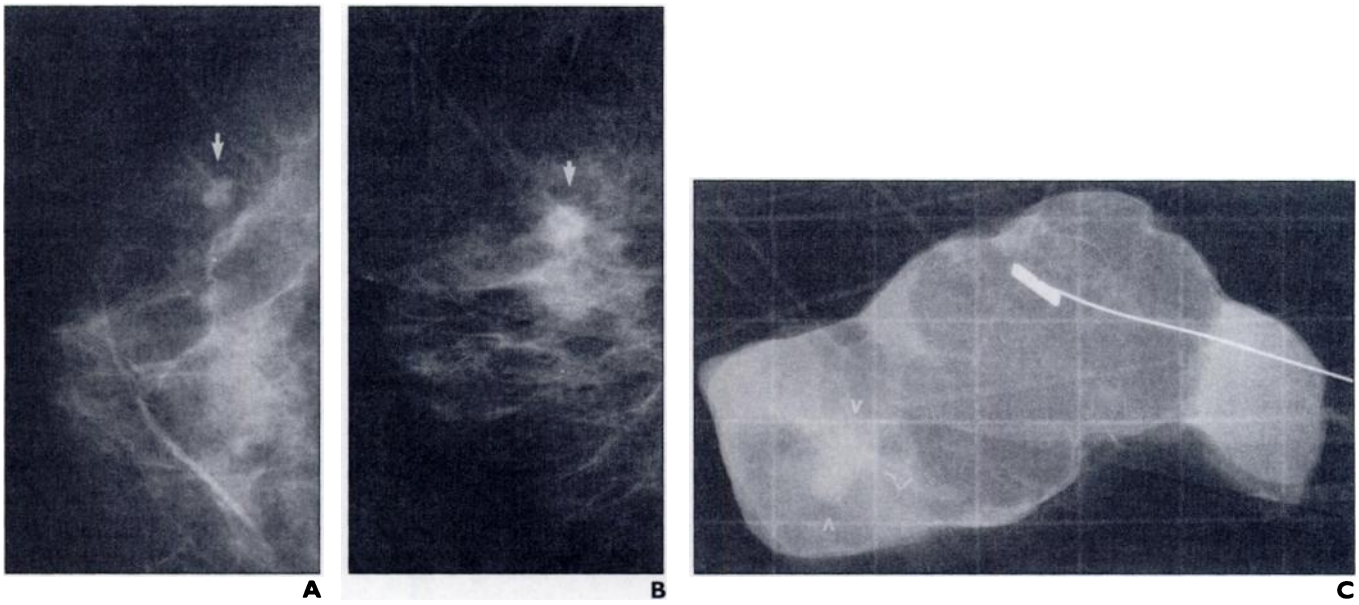


Fig. 2.—70-year-old woman with mass at 9-o'clock position of right breast.
A and **B**, Craniocaudal (**A**) and mediolateral oblique (**B**) views show mass (*arrows*). Minification factor, 1:2.
C, Advanced breast biopsy instrumentation specimen radiograph with mass in specimen. Mass (*arrowheads*) is near surgical margin. Histologic diagnosis revealed mucinous carcinoma with multiple positive margins. Note suture artifact in specimen. Magnification factor, 2:1.

geons who performed the most procedures. Complications occurred throughout the time frame of the study: six in the first 3-month period, nine in the second, and four in the third.

TABLE 3 Complications in 15 Patients Who Underwent ABBI Biopsy

Complication	No. of Complications
Hematoma	9[a]
Hemorrhage (>100 ml)	3
Pneumothorax	1
Venous thrombosis	1
Scar	3[b]
Wound problems	2[c]
Total	19

Note.—ABBI = Advanced Breast Biopsy Instrumentation (United States Surgical, Norwalk, CT).
[a] Four large, five small.
[b] The largest was a 3-cm depression.
[c] Delayed closure, protruding suture.

Pathology Results

For the 72 successful ABBI biopsies, the lesion was contained within the specimen (Fig. 2). Twenty-one lesions were isolated masses with no internal calcifications that ranged in size from 4 to 9 mm, with an average maximum diameter of 7.6 mm. Three additional masses with internal calcifications ranged in size from 4 to 10 mm, with an average size of 8 mm (three of the total 24 masses were in patients from outside institutions, and full imaging workups were not available). Forty-six lesions were clustered calcifications with an overall average diameter of less than 10 mm and a size range of 3 to 15 mm. One 8-mm asymmetric density and one 15-mm area of architectural distortion were seen.

Of the 21 isolated masses, 19 were benign and two were malignant. Of the three masses with internal calcifications, two were benign and one was malignant. Of the 46 cases of clustered calcifications, 39 were benign and seven were malignant. The one asymmetric density proved to be benign, and the one case of architectural distortion was malignant (Table 4).

Margin Analysis

Each of the 72 excised lesions was removed in toto, and only one specimen radiograph was obtained for each ABBI lesion. Patients in our series had 11 malignancies. Three represented invasive ductal carcinoma not otherwise specified, one was a mucinous carcinoma, and seven represented ductal carcinoma in situ (Table 5). Of these 11 carcinomas, four had negative margins on histologic analysis. Three of these represented ductal carcinoma in situ and were estimated to be 3 to 5 mm. These patients were placed into observation, without further surgical resection. The fourth lesion was a 10-mm invasive ductal carcinoma with negative margins to 0.5 mm. However, the pathologist noted findings at the tumor margin that suggested angiolymphatic invasion. This patient then underwent axillary lymph node dissection and radiation therapy.

The remaining seven lesions had positive margins; of these, four were ductal carcinoma in situ, two were invasive carcinoma and ductal carcinoma in situ, and one represented invasive ductal carcinoma. All of these seven patients were treated with either lumpectomy or mastectomy. Three of the four patients with ductal carcinoma in situ received radiation therapy. The other patient with ductal carcinoma in situ underwent a mastectomy because the tumor had multiple positive margins. All patients with invasive carcinoma underwent further surgery with axillary lymph node dissection, chemotherapy and radiation therapy, or both.

TABLE 4 Analysis of Lesions

Lesion Type	Not Removed	Removed		Total
		Benign	Malignant	
Masses	9	19	2	30
Calcifications	7	39	7	53
Masses and calcifications	0	2	1	3
Asymmetric density	2	1	0	3
Architectural distortion	0	0	1	1
Total	18	61	11	90

TABLE 5 Carcinomas Found Using Advanced Breast Biopsy Instrumentation[a]

Case No.	Type of Lesion	Size of Lesion (mm)	Histologic Grade	Status of Margins	Treatment
1	Calcifications	7	High-grade DCIS	Positive	Lumpectomy and radiation therapy
2	Calcifications	3	Low-grade DCIS	Negative to 1 mm	Observation
3	Calcifications	3	Low-grade DCIS	Negative to 1 mm	Observation
4	Calcifications	3	Low-grade DCIS	Positive	Lumpectomy and radiation therapy
5	Calcifications	15	Intermediate-grade DCIS	Positive	Lumpectomy and radiation therapy
6	Calcifications	12	Intermediate-grade DCIS	Positive (multifocal)	Mastectomy
7	Mass	9	Invasive mucinous carcinoma	Positive	Lumpectomy , axillary lymph node dissection, and radiation therapy
8	Mass	10	Invasive ductal carcinoma	Negative to 0.5 mm	Axillary lymph node dissection and radiation therapy
9	Calcifications	5	Intermediate-grade DCIS	Negative to 2 mm	Observation
10	Architectural distortion	10	Invasive ductal carcinoma and DCIS	Positive (DCIS)	Lumpectomy , axillary lymph node dissection, and radiation therapy
11	Mass and calcifications	10	Invasive ductal carcinoma and DCIS	Positive	Mastectomy, axillary lymph node dissection, and chemotherapy

Note.—DCIS = ductal carcinoma in situ.

[a] United States Surgical, Norwalk, CT.

Discussion

When one advocates a new breast biopsy technique, it must be compared to an acceptable "gold standard." For nonpalpable breast lesions, that standard is needle localization and excisional biopsy. This procedure, when done by experienced physicians, should have a success rate of 98% or more [9]. It also allows the pathologist to make a definitive diagnosis and to assess the margin status of the specimen in cases of malignancy. Drawbacks to this procedure include time, morbidity, and cost.

Stereotactic fine-needle aspiration began in the United States in 1986 [10]. The hope was that this technique would reduce the number of excisional biopsies. The procedure requires a skilled radiologist to properly aspirate the cellular material under imaging guidance and a dedicated cytopathologist to interpret the slides. The major drawbacks to this technique include a high insufficient or inadequate sample rate, a high false-negative rate, and the inability to diagnose invasion for carcinoma [11].

In our study population, we believe too many patients with probably benign lesions underwent the ABBI procedure. Twenty-four (26.7%) of the 90 lesions were classified as probably benign. We do not know what percentage of the total number of category 3 lesions this number represents because all patients referred were evaluated only by the surgeon, not by the radiologist. Furthermore, the patient's decision as to which procedure to undergo likely was influenced by what data the surgeon presented to the patient and what the individual surgeon's beliefs were. For nonpalpable lesions that require a tissue diagnosis, we believe that the skilled breast imager should be part of the treatment team that discusses risks, benefits, and options with the patient.

Another concern is the high number of technical failures. Of the seven lesions that disappeared during the procedure, five represented masses that were seen on sonography. These lesions could have been aspirated with sonographic guidance with lower cost and morbidity. It is also noteworthy that the two patients with inaccessible ABBI lesions were able to be converted to successful stereotactic core needle biopsies. Furthermore, despite proper targeting, five lesions were missed and remained visible on postprocedure images.

The number of complications exceeds that of other reported series [6, 7]. Three patients experienced significant hemorrhage (>100 ml blood loss). The surgeon had to immediately turn the patient supine and attempt to localize the vessel and stop the bleeding. In one case a second senior staff surgeon was needed to achieve hemostasis. Although the ABBI device cauterizes as the oscillating probe is advanced into the breast, the inability to properly visualize surrounding blood vessels, either mammographically or with the naked eye, is problematic. Experience with the technique does not seem to prevent complications because the surgeons who performed the most procedures experienced the most complications. Significant scar and wound problems, pneumothorax, superficial venous thrombosis, and additional follow-up visits suggest that the patients might be better served by another type of procedure. In one other published series of 23 cases, the complication rate was 0% [7]. In the series of 34 consecutive patients described by Ferzli et al. [6], seven technical failures and complications occurred (20.6%). In four patients the snare did not work, in two patients the lesion was not able to be properly targeted, and one patient fainted postoperatively and required overnight monitoring.

The positive predictive value for malignancy in our series was 11 (15.3%) of 72, which is at the lower end of the scale for either wire localization excisional biopsy or core biopsy [11]. The low positive predictive value is likely due to the high number of category 3 lesions included in our series.

Although all 72 biopsied lesions were excised in toto and were able to be inked, the margin status for malignancy was disappointing. Seven of 11 malignant lesions had positive margins. It is not surprising that five of these seven lesions contained ductal carcinoma in situ at the positive margin because mammography often underestimates the extent of microscopically visible ductal carcinoma in situ [12]. However, the procedure also failed to achieve negative margin status for two pure invasive carcinomas. These failures may be the result of inexact targeting, procedure error, or patient movement during the procedure. Other series noted positive margins in three of six and five of five malignancies [6, 7]. Not all patients with carcinoma underwent reexcision. Because we were not at the follow-up meeting

between patient and surgeon, we are unaware of the reasons why reexcision was not performed in three patients with ductal carcinoma in situ. The ABBI device is not approved for therapeutic purposes.

The ABBI device was designed to percutaneously excise nonpalpable breast lesions with a diameter of 1 cm or smaller. Given the fact that stereotactic and sonographically guided core needle biopsy already have a high level of success for establishing a diagnosis, the question that must be answered is, what purpose does this device serve? If this instrument could excise a small invasive carcinoma and provide tumor-free margins, then perhaps it might be useful in a limited number of patients. However, in our series, only one of the four invasive carcinomas had negative margins. A diagnosis of ductal carcinoma in situ at core needle biopsy can be treated by wide lumpectomy, if the patient is a candidate for conservative therapy [3]. Four of seven patients with pure ductal carcinoma in situ and two of two patients with mixed invasive and in situ carcinoma had positive margins. These patients required a second operative procedure for breast conservation. Moreover, considerably more tissue is removed for benign lesions than is necessary to make a diagnosis. The subsequent cosmetic defect and mammographic scarring are detrimental results of this technique.

Our study documents the initial results of an ABBI biopsy practice carried out by experienced breast surgeons. Given the high number of complications and technical failures, the inability to provide tumor-free margins for seven of 11 malignancies, and the high number of postprocedure visits, we believe that this technique should not be performed. Since we began our study, several of the participating breast surgeons have declined to perform any more ABBI procedures. Equally important, we believe that the breast imager should be an integral part of the decision-making process for the diagnosis and treatment of women with breast abnormalities.

Acknowledgment

We thank Judi Kreiselmeier for her excellent work in preparation of this manuscript.

References

1. Feig SA. Localization of clinically occult breast lesions. *Radiol Clin North Am* **1983**;21:155–172
2. Parker SH, Lovin JD, Jobe WE, et al. Stereotactic breast biopsy with a gun. *Radiology* **1990**; 176:741–747
3. Parker SH, Lovin JD, Jobe WE, Burke BJ, Hopper KD, Yakes WF. Nonpalpable breast lesions: stereotactic automated large-core biopsies. *Radiology* **1991**;180:403–407
4. Burbank F. Mammographic findings after 14-gauge automated needle and 14-gauge directional, vacuum-assisted stereotactic breast biopsies. *Radiology* **1997**;204:153–156
5. Liberman L, Dershaw DD, Morris EA, Abramson AF, Thornton CM, Rosen PP. Clip placement after stereotactic vacuum-assisted breast biopsy. *Radiology* **1997**;205:417–422
6. Ferzli GS, Hurwitz JB, Puza T, VanVorst-Bilotti S. Advanced breast biopsy instrumentation: a critique. *J Am Coll Surg* **1997**;185:145–151
7. D'Angelo PC, Galliano DE, Rosemurgy AS. Stereotactic excisional breast biopsies utilizing the advanced breast biopsy instrumentation system. *Am J Surg* **1997**;174:297–302
8. Morrow M. When can stereotactic core biopsy replace excisional biopsy? A clinical perspective. *Breast Cancer Res Treat* **1995**;36:1–9
9. Kopans DB, Meyer JE, Lindfors KK, McCarthy KA. Spring-hook wire breast lesion localizer: use with rigid compression mammographic systems. *Radiology* **1985**;157:537–538
10. Dowlatshahi K, Gent HJ. Nonpalpable breast tumor diagnosis with stereotactic localization and fine needle aspirations. *Radiology* **1989**;170:424–433
11. Kopans DB. *Breast imaging*, 2nd ed. Philadelphia: Lippincott-Raven, 637–720
12. Rebner M, Raju U. Noninvasive breast cancer. *Radiology* **1994**;190:623–631