The Evolution of Minimally Invasive Breast Biopsy: From FNA to Percutaneous Incisional and Excisional Biopsy

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Surgical biopsy of the breast has long been the most commonly accepted method of determining the nature of a clinical or mammographic abnormality. Because this method carries with it certain cost and morbidity drawbacks, physicians have investigated less invasive alternatives. Until recently, however, there has not been sufficient confidence in the minimally invasive techniques to supplant surgical breast biopsy. Fine needle aspiration (FNA) of the breast has been available for decades and, in some hands, performed reliably enough to avoid surgical biopsy in certain instances. For the most part, however, surgeons and other physicians have been reluctant to base definitive decision making upon the results of FNA. This is understandable in that FNA carries significant insufficient tissue and false negative rates.[1,2] As a result, FNA frequently represented an additional test and attendant cost without obviating the need for surgical biopsy.

With the advent of automated core biopsy of the breast, there began a gradual shift from surgical breast biopsy to minimally invasive, percutaneous biopsy. Because core biopsy of the breast resulted in a histologic (rather than a cytologic) diagnosis, a more definitive picture of the breast lesion could be painted. If the lesion turned out to be benign, such as a fibroadenoma, this diagnosis could be relied upon and surgery avoided entirely. If the diagnosis turned out to be malignant, then a distinction between in situ and invasive carcinoma could frequently be made, allowing for the definitive therapeutic

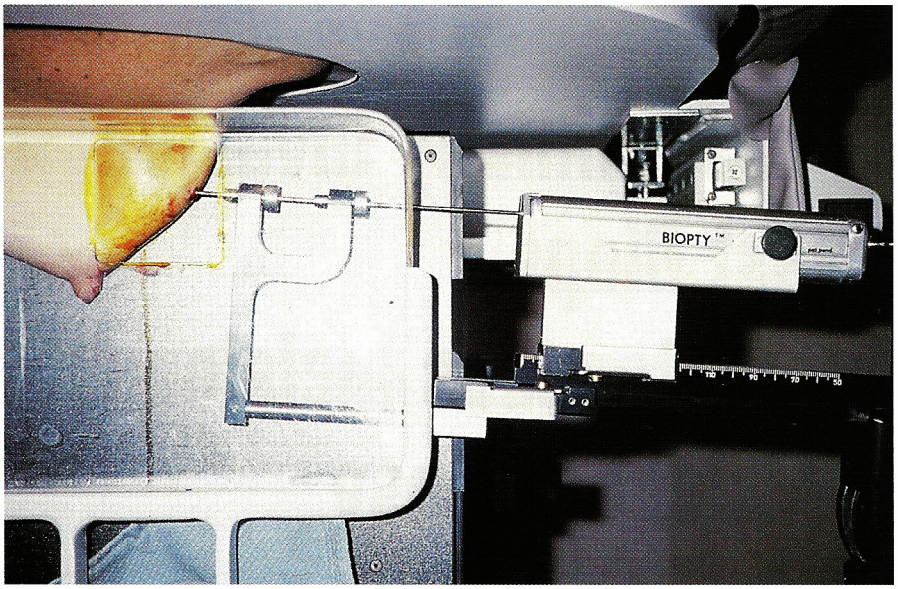


Figure 1. The lateral arm. With this approach, one can target a breast lesion in a plane orthogonal to the plane of compression (the standard plane of stereotactic biopsy). This is helpful when using an automated core biopsy device on a small breast.

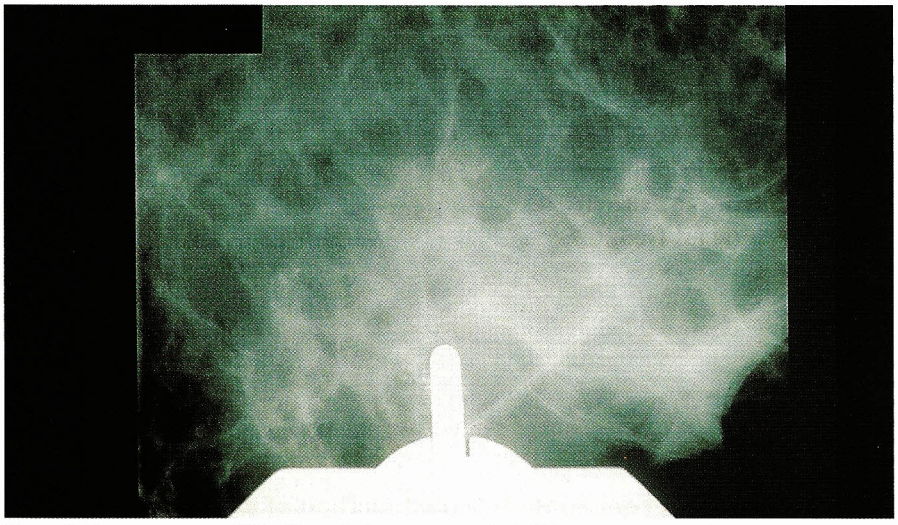


Figure 2. Target on scout. With this technique, one can look "down the barrel" of the biopsy needle or probe and immediately discern whether the targeting is off to the right or left. It can be an extremely helpful technique for targeting lesions far posterior in the breast or a lesion in the axillary tail where the patients shoulder is in the way of one of the conventional stereotactic views.

surgery to go forward with confidence. This process of core biopsy diagnosis prior to definitive surgery has been shown to dramatically decrease the number of surgeries performed in breast cancer patients.[3,4]

The question as to which specialties will emerge as the providers of minimally invasive breast biopsy is still unresolved. Radiologists have breast imaging and image guided needle technique expertise. Radiologists have also been the ones to develop and refine image guided, minimally invasive breast biopsy. However, surgeons have traditionally handled complex clinical breast conditions and were the ones performing breast biopsy in the past. Ob-Gyn physicians are also involved to some degree with breast care and some have voiced a desire to enter the percutaneous breast biopsy arena. Regardless of what has existed before, the surgeon who does very little breast work and has limited imaging skills is not likely to be the physician who will emerge as the accepted provider of minimally invasive breast biopsy. By the same token, the radiologist who spends the majority of time reading plain films and who has little training or experience in interventional radiology or ultrasound is also not likely to emerge as the preferred physician for breast biopsy. The reality is that image guided breast biopsy should not be performed by physicians who do not have a dedicated focus on breast disease and who do not have the requisite training and experience in the new diagnostic techniques. What follows is an encapsulation of those techniques and advances.

TECHNIQUE

Automated core biopsy of the breast was initially performed using stereotactic mammography as the image guidance modality.[5,6] In addition, ultrasound has also been extensively used to guide these biopsies.[7] The accuracy of the technique was found to be similar to surgical breast biopsy with either guidance modality.[8] Stereotactic mammography was found to be necessary for most cases of microcalcifications and mammographic assymetries that cannot be appreciated with ultrasound. Ultrasound guidance was found to be best for most nodules or masses, although stereotactic guidance could generally be used as well. The technique for core biopsy of the breast has been previously described in an earlier edition of Surgical Technology International.[9]

It has been eight years since the first automated large core breast biopsy was performed with stereotactic guidance.[5] Many improvements in equipment, technique, and protocol have occurred since that time. This has been due largely to vast improvements in the guidance technology, both stereotactic mammography and ultrasound.

IMAGE GUIDANCE

There has been revolutionary change in near-field ultrasound imaging over the past 5 years. Older equipment did not have adequate spatial or contrast resolution to differentiate between the normal tissues of the breast and breast lesions. The best one could do was to differentiate between cystic and solid lesions. This has all changed for the better with the introduction of dedicated electronically focused, high frequency (7.5-10.0 MHz) linear array transducers with a fixed elevation plane focus in the first 1.5-2.0 cm. A beam profile with a thin "slice thickness" allows for better needle visualization since the surrounding breast tissue is not "partial volume averaged" with the needle. In addition, subtle lesions are more easily identified. With the many improvements that have been made in ultrasound and transducer technology, breast ultrasound has assumed an essential role not only in image guided breast biopsy

but as a great problem solver in the general work up of breast problems.[10,11]

Stereotactic mammography has undergone dramatic improvement over the past eight years. Dedicated prone tables have proved themselves superior to upright "add-on" stereotactic units (adapted standard mammography machines). Automated alignment stages were developed to allow for fast, error proof targeting. Digital stereotactic imaging provides near instantaneous image reconstruction with better contrast resolution compared with film-screen. Software and hardware improvements have been made to allow for targeting orthogonal to the plane of compression (Fig. 1). Probably the most helpful software improvement has been the so called "target on scout" capability which allows one to target off the straight scout view in conjunction with one of the two 15 degree stereotactic images. This allows the physician to "look down the barrel" of the needle in the straight scout view so that one quickly understands whether they are to the right or left of a given lesion (Fig. 2). In addition, this technique allows for more accurate targeting of a lesion if the lesion is less well seen or not seen at all in one of the two stereo views.

TISSUE ACQUISITION

Although there have been great strides in the guidance technology, until recently, there has not been any improvement in the tissue acquisition process. Although the current automated core biopsy systems are reasonably functional, there is considerable room for improvement. Several drawbacks of the automated biopsy devices have become apparent when biopsying the breast. One of the most troublesome deficiencies is their tendency to function less well in the inhomogeneous fatty tissue of the breast compared with other anatomic areas of the body. Also, there must be pinpoint accuracy in targeting since the device depends upon "line-of-fire" sampling. In addition, only one sample is obtained with each insertion and firing, requiring multiple insertions and withdrawals in order to obtain the requisite number of cores (a minimum of 5 for masses and 10 for calcifications). Finally, because core biopsy does not obtain contiguous samples, there is some risk of sampling error. As a result, there are times when the core tissue does not fully describe that malignancy.[8] For instance, when the core biopsy reveals atypical duct hyperplasia or DCIS, these diagnoses were frequently found to underestimate the actual lesion present. This, in turn, can result in additional surgery with the net result being that the core biopsy represents an additional test, much like FNA (fine needle aspiration) described above.

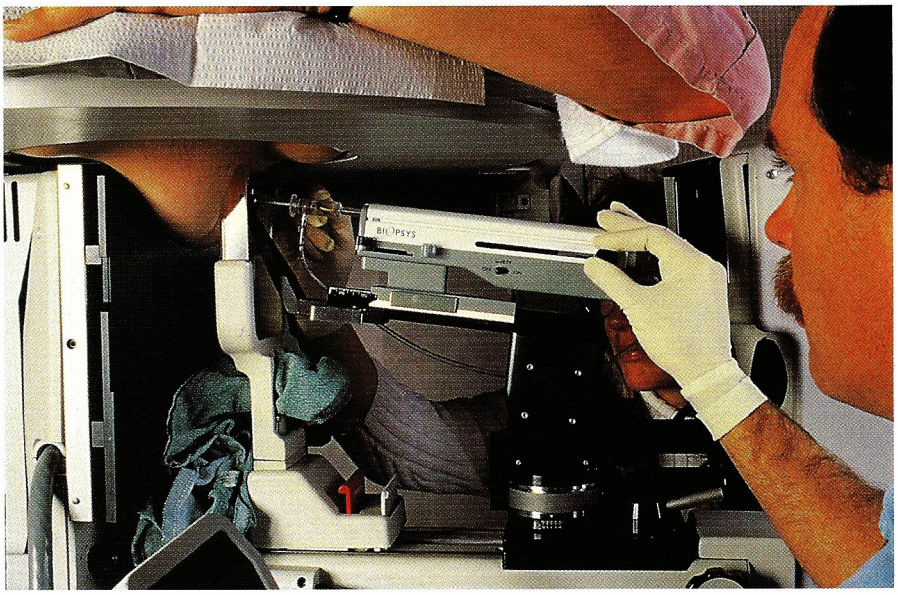


Figure 3. The Mammotome. The Mammotome cutter is advanced across the captured breast tissue by advancing and then rotating the side mounted knob. When the knob is then retracted back to its starting position, the tissue specimen is exposed in the specimen retrieval chamber.

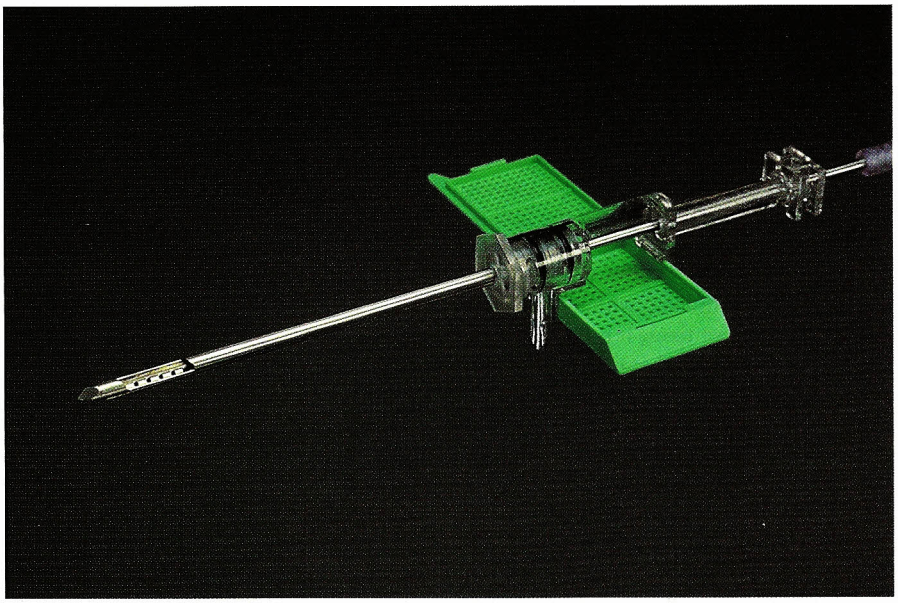


Figure 4. The Mammotome probe. The probe's specimen retrieval chamber can be mated to a standard pathology cassette which minimizes tissue handling both during the biopsy and in pathology.

In order to address the drawbacks of the core biopsy devices, a new breast biopsy device, the "Mammotome", was developed by Fred Burbank, M.D., a radiologist, in conjunction with Mark Ritchart, a medical device engineer. The Mammotome uses an entirely different principle of tissue acquisition than the conventional automated biopsy guns and requires only one insertion into the breast (Fig. 3).

The disposable Mammotome probe consists of an outer, hollow sleeve with a sharpened tip to penetrate breast tissue (Fig. 4). The probe can be manually advanced to and through a lesion or it can be fired through the lesion using a spring loaded mechanism within the probe housing or "driver". Because forward movement of the probe is not part of the tissue acquisition process, the method of probe advancement is at the discretion of the responsible physician.

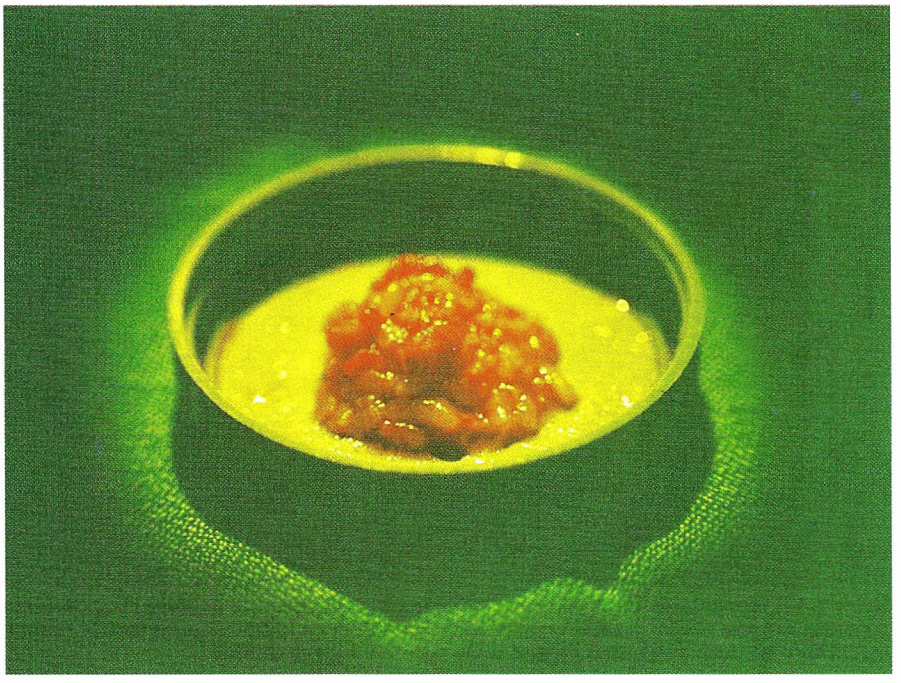


Figure 5. Tissue obtained with an 11 gauge Mammotome. Over 2 grams of tissue were obtained in less than 5 minutes.

Just proximal to the terminus of the outer hollow sleeve of the probe resides a 1.5 cm. long aperture. Multiple small vacuum holes are positioned on the opposite side of the aperture designed to actively pull adjacent breast tissue into the hollow outer sleeve of the probe when vacuum is activated. A hollow "cutter" with a sharpened end is positioned within the outer sleeve. After breast tissue is pulled through the aperture and into the probe, the cutter begins to rotate at high speed and is advanced through the tissue now residing within the probe. A large breast specimen which is equal to nearly the diameter of the entire probe and which is usually longer than the aperture is subsequently captured within the cutter.

By convention, the orientation of the probe aperture is described as an "o'clock" position. Commonly, the aperture of the probe is started at 12 o'clock. Following acquisition of the first sample, the aperture is rotated in preparation for the next sample acquisition. The cutter is then withdrawn rearward within the outer sleeve of the probe and the tissue specimen is carried back to a "knock-out" pin which pushes the captured specimen out into a "specimen retrieval chamber". The specimen is then grabbed with a small forceps and placed in sterile saline. Recently, the specimen retrieval chamber has been modified to accept a standard pathology tissue cassette.

Following the acquisition of the first sample, suction is reapplied and the cutter readvanced into the newly captured specimen from the next position. This process is continuously repeated as the probe is rotated entirely "around the clock" without ever having to withdraw or reinsert it. To sample contiguously, the sampling notch is moved at 1½ hour increments from 12 o'clock to 1:30 to 3 o'clock , etc. One 360 degree cycle results in 8 contiguously acquired samples and a 4 mm x 4 mm x 15 mm cavity. Subsequent revolutions increase the x and y dimensions of the cavity while the z dimension remains at 15 mm (the length of the aperture). If one desires to obtain more tissue along the Z axis, it's a simple matter of advancing or withdrawing the probe 1-1.5 cm. In this manner the final Z dimension of the cavity would be 2.5-3.0 cm.

The Mammotome probe's driver is a reusable device which attaches to the alignment arm of the stereotactic unit in a manner similar to the automated core devices. Inside the device is a motorized gear which mates with the Mammotome probe's cutter. A separate vacuum source is connected to the probe both forward and rearward to provide suction on the opposite side of the probe's sample aperture and through the cutter. These connections are outside the driver's housing. The forward movement of the coaxial cutter is controlled by hand. Micro-switches activate the vacuum and the cutter at the appropriate times during the manual forward advancement of the cutter.

The 14-gauge Mammotome obtains breast specimens which average 200% larger than those obtained with the conventional automated biopsy guns. The average time for performing a biopsy with the Mammotome has been shown to be half that of a biopsy performed using a conventional automated biopsy gun.[12] In addition, approximately one-third of mammographically detected (and therefore small) lesions are entirely removed (excisional biopsy) using the 14-gauge Mammotome. This is made possible by the contiguous sampling performed by the Mammotome. Contiguous sampling also decreases the odds of sampling error. Early clinical experience confirms this assumption with fewer underestimates of malignancy on percutaneous biopsy compared with conventional core biopsy. An 11 gauge version is now available which obtains 3 times the tissue per sample than the 14 gauge (Fig. 5). There is no noticeable difference in morbidity using the larger probe.

Because the Mammotome uses a vacuum principle, unlike the biopsy guns, it actually excels in the acquisition of fatty tissue. In addition, the Mammotome has an uncanny affinity for tissue containing calcifications, the most difficult lesions to acquire with conventional biopsy guns. In addition, fatty tissue prolapses into the lumen of the probe beyond the dimensions of the aperture so that one ends up with samples up to two times the length of the aperture.

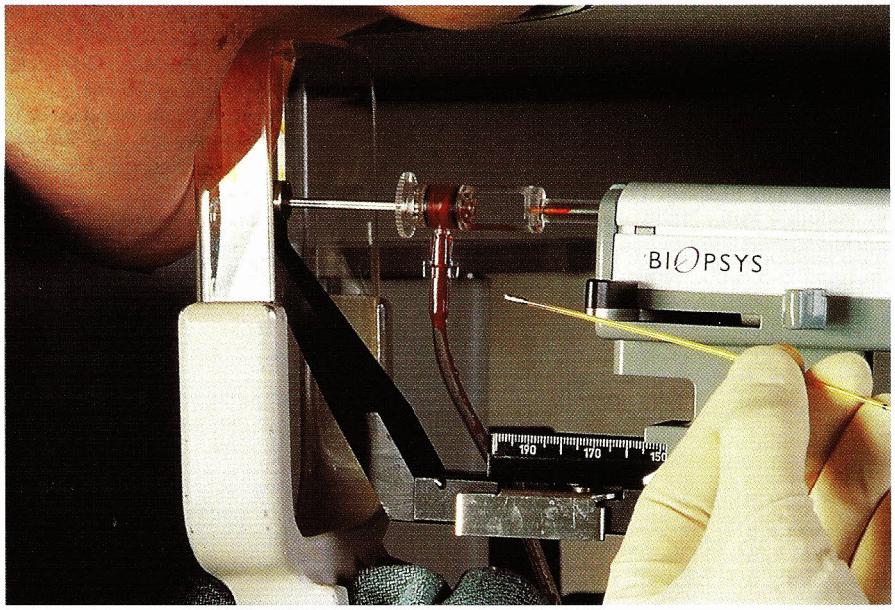
The need for pin-point accuracy with biopsy guns meant that a great deal of time might be expended re-targeting the lesion and re-positioning the needle attempting to realize the needed accuracy. Since the Mammotome is directional and can acquire tissue up to 5 mm distant, it does not need to be positioned in the breast with pin-point accuracy and, therefore, the initial targeting is almost always adequate. This saves a significant amount of time for the physician. In addition, because the Mammotome does not need to be fired for placement or tissue acquisition, one requires fewer stereotactic images. Only a single set of "positioning" stereotactic views need to be obtained rather than two sets of "pre-fire" and "post-fire" views. Also since pin-point accuracy is not necessary, fewer stereotactic "check" films are necessary. Thus, the patient is subjected to far fewer exposures. Finally, negative stroke margins, chest wall lesions, and lesions adjacent to implants are not a problem with

the Mammotome as they sometimes can be with biopsy guns. Therefore there is no danger of the probe accidentally striking the breast support plate on the opposite side of the compressed breast, the chest wall, or a breast implant.

Perhaps the most convenient aspect of the Mammotome from the physician's perspective is the elimination of the need for the multiple insertions which are required with biopsy guns. Once the probe is placed in the vicinity of a lesion, one can acquire an almost unlimited number of samples without removing the probe from the breast. In fact, one can leave the probe in one position (12 o'clock, for example) and repetitively acquire tissue from that position. In so doing, one continues to pull breast tissue from farther and farther away, enlarging the cavity asymmetrically in the 12 o'clock position. Occasionally, if the lesion represents more widespread calcifications, it may be necessary to remove and re-insert the probe in a different location in order to biopsy a more geographically diverse area.

Because contiguous sampling creates a small air-filled cavity, it is much easier to determine successful targeting. This also should eliminate the possibility of sampling error in the biopsied region. With the added confidence of complete and accurate removal of the targeted tissue, the procedure can be concluded much more quickly than was the case with core biopsy where lingering questions as to the adequacy of the targeting and tissue acquisition frequently led to the desire to continue the biopsy and acquire more cores. Thus, with the Mammotome, the physician saves time during both the targeting process and the tissue acquisition process reducing overall procedure time by one half.

Because the Mammotome frequently removes small lesions entirely, there is a need for marking the lesion site following a mammotomy. A percutaneous clip has been developed which fills this need (Fig. 6a). This clip is placed through the Mammotome and clips the cavity wall (Fig. 6b) If the lesion proves to be cancer, a conventional or stereotactic needle localization can easily be performed using the small previously placed clip as the target.



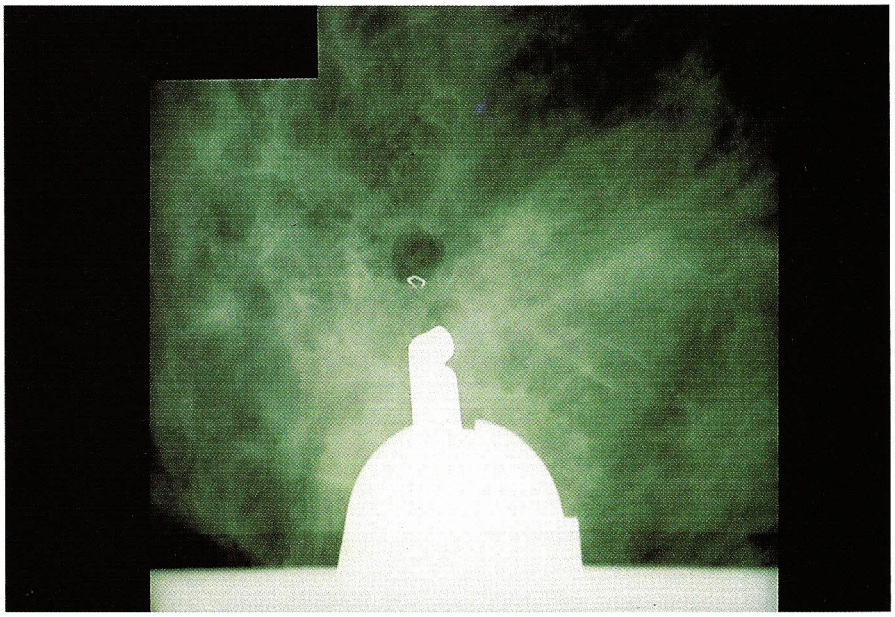


Figure 6. Percutaneous clip. (a) A small catheter bearing the tiny titanium clip is introduced through the Mammotome probe. When the clip is advanced to the biopsy site it is deployed into tissue drawn into the probe with vacuum or deployed directly through the probe's aperture. (b) The clip has been deployed into the anterior aspect of the biopsy cavity. Note the Mammotome probe in the foreground in this target on scout image.

CONCLUSION

Minimally invasive procedures are becoming more and more commonplace throughout medicine. The 21st century will see this trend continue. Breast biopsy is no exception.[13] Image guided percutaneous breast biopsy will eventually replace open surgical breast biopsy. Patients will be taken to the operating room for definitive treatment, not for diagnosis. From FNA through automated core biopsy to mammotomy, the non-surgical, minimally invasive breast biopsy has progressed to stand at the threshold of percutaneous lumpectomy. STI

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