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Presentation

Surgical benefits conveyed by biopsy site marking system using ultrasound localization

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Abstract

Background: With vacuum-assisted biopsy technology all, or most, of a breast lesion may be removed during the initial biopsy; in such cases a metallic marker is often inserted at the site of the biopsy for future localization. The aim of this study was to evaluate the efficacy and impact of the Gel Mark Ultra biopsy site marking system (SenoRx, Aliso Viejo, CA) on the practice of needle localization breast biopsy.
Methods: We retrospectively analyzed the experience of 45 general surgeons across the United States in a variety of practice settings using the Gel Mark Ultra clip. Imaging-guided biopsy technique, localization quality, surgeon confidence, and margin status were assessed and compared against the broad data reported in the literature.
Results: A total of 432 records of patients who underwent imaging-guided breast biopsy with placement of Gel Mark Ultra clip were reviewed. Of these, 63 (15%) patients required definitive surgical intervention, for which 41 cases were localized with ultrasound and assessed for margin clearance. Clear margins were achieved in 37 (90%) of the 41 cases. These results are statistically superior ($P < .01$) to positive margins rates reported in the literature.
Conclusions: The Gel Mark Ultra biopsy site marking system is a new localization device that provides a safe and effective alternative to traditional localization methods with a significant reduction in the percentage of positive margins, as well as advantages in terms of surgical approach, time, and patient comfort.

Keywords: Ultrasound; Breast; Biopsy; Image-guided; Clip; Marking device

Imaging-guided core breast biopsy has become the preferred approach for the diagnostic evaluation of suspicious radiographic and palpable breast lesions. With vacuum-assisted biopsy technology all, or most, of the lesion may be removed during the initial biopsy, eliminating the radiographic findings necessary for identifying the site of the lesion. In such cases a metallic marker is often inserted at the site of the biopsy for future radiographic localization. Certain potential advantages are realized if the site of the biopsy can be accurately localized in the operating room rather than the radiology suite. The discomfort of the localization procedure is eliminated since it proceeds under anesthesia and enhanced efficiency is likewise achieved from a logistics point of view by omitting the prerequisite trip to the radiology suite. In addition, the surgeon faced with the challenge of obtaining histologic negative margins has the opportunity to place the wire along the path he/she judges most optimal to achieve the goal.

The advent of a breast biopsy site marker that is visible by sonography allows for the desired intraoperative localization. The Gel Mark Ultra biopsy site marking system, manufactured by SenoRx Inc. (Alisa Viejo, CA), consists of a combination of markers that can be identified by ultrasound, mammography, and magnetic resonance imaging (Fig. 1). Early reports from surgeons with extensive experience and expertise with breast ultrasound confirm that this technology reliably localizes the biopsy site intraoperatively [1,2]. The goal of this study was to determine the reliability of breast ultrasound performed by a group of surgeons of varied experience to localize the breast biopsy site.

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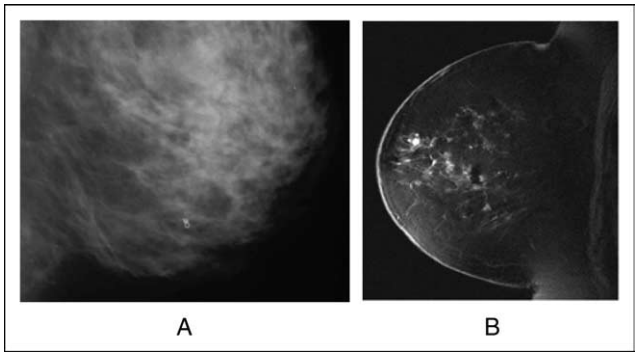

Fig. 1. (**A**) Mammographic visualization of GelMark Ultra clip marking the previous biopsy site. (**B**) Magentic resonance imaging–compatible clip for identification of the biopsy site.

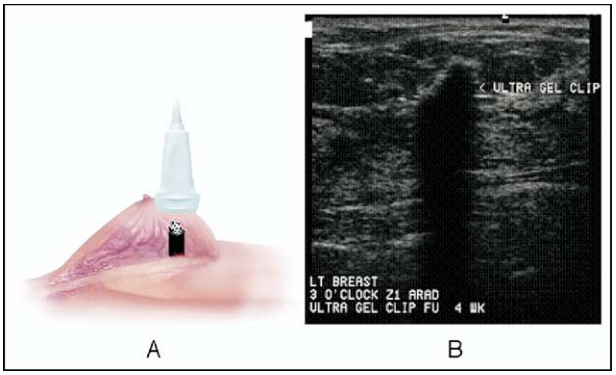

Fig. 3. (**A**) Picture demonstrating proper placement of ultrasound probe and intraoperative localization of the biopsy site. (**B**) Ultrasound image demonstrating the posterior shadowing produced by the reabsorbable pellets.

Materials and Methods

The *B*iopsy *E*valuation by *S*onography *T*est (BEST) registry is a retrospective database of consecutive cases derived from the clinical practice of 45 of broad-based general surgeons from across the United States. Each was allowed to enroll no more than 10 patients so that the cumulative database would better reflect the average practice setting, rather than the practice of a few highly specialized individuals. Eligible records for chart abstraction had 2 requirements: (1) they must originate from consecutive patients having undergone the placement of the Gel Mark Ultra Biopsy marking device at the time of biopsy; and (2) all such patients must have been evaluated by a follow-up clinical and ultrasound examination within 6 weeks of the procedure.

Among the information included for analysis was data regarding ultrasound visualization characteristics of the biopsy site, and the surgeons' confidence in visualizing the site. For those cases where the patient underwent surgical excision with a partial mastectomy, a second form was submitted with relevant information related to the case and whether the margins of the excision were free of malignant cells.

The Gel Mark Ultra System consists of a disposable applicator containing 11 reabsorbable pellets; the sixth pellet is embedded with a stainless steel–formed marker, which is visible by radiographs as a white wire form (Fig. 2). This is designed to mark the biopsy cavity for the long term. The syringe-like applicator fits within the 11-gauge vacuum-assisted cannula to access the biopsy cavity. After placement, the absorbable poly-lactic and poly-glycolic acid pellets are visible via ultrasound as hyperechoic pellets with posterior shadowing that are typically absorbed by about 6 weeks (Fig. 3).

Results

A total of 429 patient records were abstracted for the study; 81% (349) underwent stereotactic-guided breast biopsy with Gel Mark Ultra clip placement and 19% (80) underwent marker placement by ultrasound-guided biopsy. The pathologic summary from the image-guided biopsy was reported as benign in 77% (325), cancer in 9% (37), atypical ductal hyperplasia in 4% (20), ductal carcinoma in situ in 4% (20), and as a collection of other benign pathologies in 2% (9); in 4% (18) of the cases, the

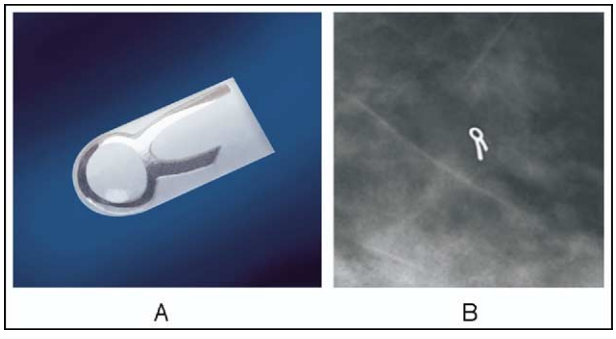

Fig. 2. (**A**) Picture of the pellet containing the metallic clip. (**B**) Mammographic image with visualization of the clip after placement within the breast tissue.

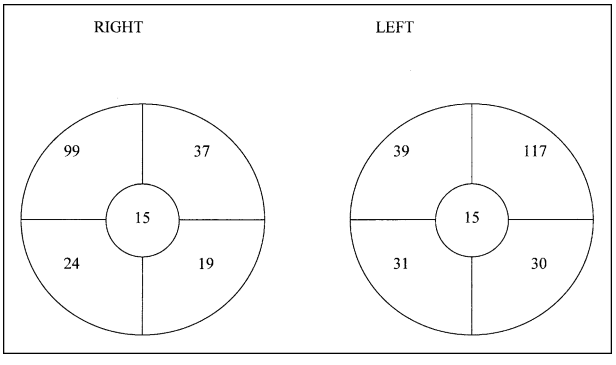

Fig. 4. Distribution by quadrants of the number of biopsies performed based on lesion localization within the breast tissue.