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Preoperative localization of breast lesions: Current techniques

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ABSTRACT

Image-guided preoperative localization of breast lesions is a common procedure. This article describes several commercially available localization options—wire localization, radioactive seed localization, localization with a radiofrequency reflector, and magnetic seed localization—and outlines the advantages and disadvantages of each. This information may help radiologists initiate conversations at their facilities with surgeons, pathologists, and hospital administration as they seek to add value and provide patient-centered care.

1. Introduction

Breast cancer is the most common noncutaneous cancer affecting women in the United States; the latest data show an incidence of 12%, and it is estimated that 252,710 cases of invasive breast cancer and 63,410 cases of in situ disease were diagnosed in the U.S. in 2017 [1]. The National Comprehensive Cancer Network (NCCN) guidelines for treatment involve multidisciplinary use of surgery, chemotherapy, and radiation therapy, with surgery as the central component of treatment for early-stage breast cancer [2,3].

Surgical options for breast cancer include complete mastectomy and partial mastectomy, widely referred to as lumpectomy. Lumpectomy is usually followed by radiation therapy, and this combination is referred to as breast conservation therapy (BCT). In 1894, Halstead published a surgical technique known as the radical mastectomy, which represented a significant milestone in the treatment of breast cancer [4–6]. Surgical treatment of breast cancer was largely unchanged until the 1970s, when new imaging techniques allowed for improved visualization and characterization of breast cancer [7]. With increasing use of mammography and detection of smaller and smaller cancers, preoperative wire guided localization (WGL) of nonpalpable breast lesions became more popular and led to decreased utilization of mastectomy in favor of lumpectomy followed by radiation therapy (breast conservation therapy [BCT]) [8,9]. BCT not only has been demonstrated to be effective in several large randomized prospective trials but also has been shown to result in higher breast cancer–specific survival rates than mastectomy with lower morbidity [10–12]. One of these studies of 132,149 patients showed 5 year BCT survival rate of 97% while mastectomy alone survival rate was 94%. BCT has become the standard of care and is more commonly performed than mastectomy with recent studies showing that approximately 60% of patients choosing BCT over mastectomy [13].

Methods for preoperative localization of breast lesions in preparation for BCT have evolved over time. Wire localization has been the method of choice, but in the past two decades, new image-guided techniques have emerged that have several distinct advantages over wire localization. In both academic and community practice, four primary image-guided localization techniques are currently being used and/or investigated: wire localization, radioactive seed localization (RSL), localization with a radiofrequency reflector (RFR), and magnetic seed localization.

In this article, we review the history of wire localization and some of its drawbacks and compare and contrast wire localization with the newer localization techniques now available commercially. We also address specific clinical and operational issues (Tables 1 and 2) that should be considered by breast imaging centers deciding which type of localization to offer their patients. By summarizing the current literature of available techniques in a user-friendly and concise manner, we aim to educate practicing radiologists so they may make informed decisions about selecting new localization technique that could result in improve patient care.

2. Wire localization

Wire localization, introduced almost 50 years ago, was the first technique introduced to help localize nonpalpable, image-detected breast lesions [7,8]. Initially, mammography was the only imaging modality used to guide wire placement [14,15]. Today, wire localization can be performed under mammographic, tomosynthesis, sonographic, or magnetic resonance imaging guidance (Figs. 1 & 2).

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Table 1
Clinical comparison of different techniques for preoperative localization of breast lesions.

Characteristic	Technique			
	Wire	Radioactive seed	Radiofrequency reflector	Magnetic seed
Additional training of radiologists and surgeons needed	No	Yes	Yes	Yes
Limitations	No	Potential for canceled surgery Need for patient education on handling of radioactive materials	Reflector may be difficult to detect in the case of a very deep (> 6 cm from the skin) lesion	Seed may be difficult to detect in the case of a deep (> 3 cm from the skin) lesion
Data available for localization of axillary metastases	Yes	Yes	No	Yes
Patient comfort during and after procedure	Moderate	High	High	High
Decoupling of directional approach to placement of localization device and surgical incision	No (surgeon dependent)	Yes	Yes	Yes
Decoupling of surgical and radiology schedules	No	Yes	Yes	Yes
Cosmetic outcome after surgery influenced by localization device	Yes	No	No	No
Rate of positive surgical margins	Standard of care	Equivalent to surgical margins with wire localization	Equivalent to surgical margins with wire localization [48]	Equivalent to surgical with wire localization in our experience and early literature [49–50]
Fragmentation of localization device possible	Yes	Rare; would result in safety issue	No cases reported	No cases reported
Loss or migration of localization device possible	Yes	Yes	Migration possible but rare	Migration uncommon

A variety of wires are available for wire localization with different shapes, lengths, alloy materials, and numbers of thickened segments [7,8,14,15]. Following introduction, some of the wires are fixed, while others are adjustable for depth [7,8,14,15]. Ideally, the wire should be strong enough to avoid fragmentation and readily retractable by the radiologist to ensure targeted placement. Most breast surgeons and radiologists are familiar with localization wires as they are widely and readily available, relatively inexpensive with one study estimating the cost of the wire localization needle at $22.50 [16], emit no ionizing radiation, and can be stored safely within the imaging department [17,18]. In the case of more extensive disease, multiple wires are typically placed, a procedure known as "bracketing wire localization" to help guide excision [19].

Clinically, several complications of wire localization have been reported. A prospective study demonstrated vasovagal reactions in 7% of localizations [20]. Case reports of other infrequent complications have also been reported. Wire transection and fragmentation can also occur during transport or intraoperatively [21], leading to longer surgery times [22]. Retained post-operative wire fragments can be seen in mammograms [23]. Wire migration has been reported both within the breast and rarely outside the breast, including into the pleural space [24], pulmonary hilus [25], and pericardium [26].

While some surgeons make their incisions separate from the wire entry point, many surgeons make their incision directly over the wire to remove the lesion and the wire en-bloc. The wire entry point chosen by the radiologist may therefore dictate where the surgical incision and the associated scar will be located. Unfortunately, this approach does not always generate the best cosmetic result for the patient.

The success of wire localization depends on the surgeon's mental reconstruction of the images, the trajectory of the wire, and the perceived intraoperative position of the lesion [27,28]. Post wire localization images or films marked by the radiologist can assist the surgeon to grasp a three-dimensional location of the lesion. (These images may not be required by the surgeon in the setting of other localizing methods described below, in which site of signal is usually marked over the skin.) Approximately 2.5% of wire localizations are unsuccessful; factors associated with an increased risk of unsuccessful localization are multiple lesions, small lesions, lesion containing extensive microcalcifications, and small surgical specimen [29].

Operationally, needle localizations are often performed the same morning as surgery [27]. This marriage of the radiology and surgery schedules can lead to significant stress for both parties. In the case of a complicated localization, the radiologist may feel pressure to perform the localizations quickly to accommodate the surgery schedule. Just as increasing reading speed can lead to errors of interpretation [30,31], rushed localizations likely compromise patient safety. Surgical teams can experience down time as they wait for patients as a result of complicated localizations, patient transport issues, additional registration requirements, and perioperative protocols. Unnecessary delays cause lost efficiency and may cause lost revenue.

3. Radioactive seed localization

Preoperative RSL was one of the first alternatives proposed to avoid some of the limitations encountered with wire localization for nonpalpable breast lesions. The first randomized prospective trial comparing wire localization to RSL, published in 2001 by Gray et al., showed a lower rate of positive margins at lumpectomy and smaller volume of tissue removed at lumpectomy with RSL [32,33]. More recent studies, however, have demonstrated no significant differences between wire localization and RSL in the rate of close positive margins, re-excision rate, ratio of tumor volume to specimen volume, or clinical cosmetic outcome [34,35].

RSL involves the targeted image-guided placement of a 4.5 mm × 0.8 mm titanium seed containing 3.7 MBq to 10.7 MBq of iodine 125 [36]. ^{125}I has a half-life of 60 days and emits gamma rays

Table 2
Operational comparison of different techniques for preoperative localization of breast lesions.

Characteristic	Technique			
	Wire	Radioactive seed	Radiofrequency reflector	Magnetic seed
Cost of localization device	Low	Low	Moderate	Moderate
Ancillary surgery or pathology costs	None	Geiger counters in pathology; gamma probe at surgery	Handheld electromagnetic reader console at surgery	Handheld magnetic detection probe at surgery
Ancillary radiology costs	None	Ionizing radiation precautions	None	None
Time in radiology department	Low	Moderate; radioactivity education	Low	Low
Time in operating room	Standard of care	Equivalent to time for wire localization	Equivalent to time for wire localization	Equivalent to time for wire localization
Regulatory expenses/risk of shutdown	No	Yes	No	No
Application to community hospitals	High	Low	High	High

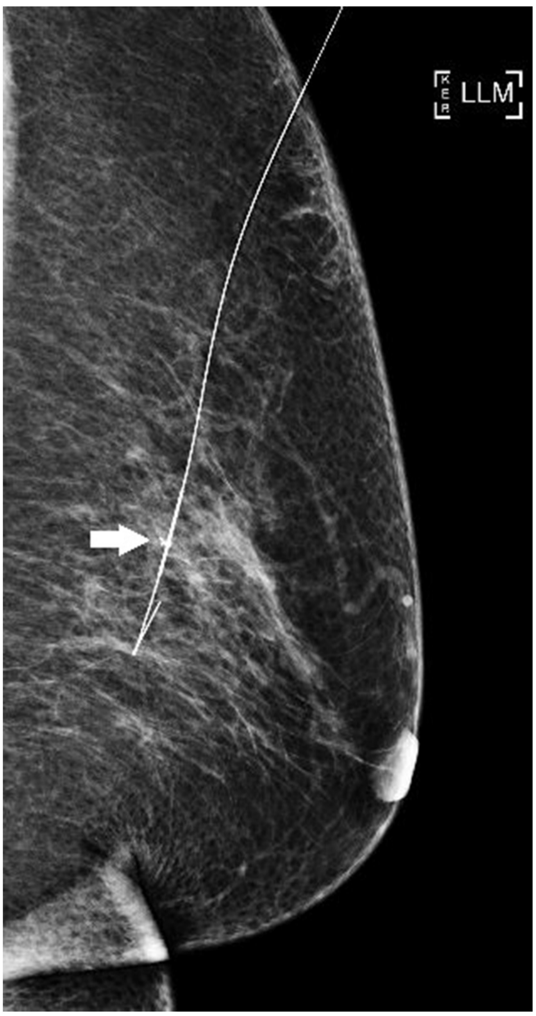

Fig. 1. Postprocedure LLM view after mammography-guided wire localization shows the thickened stiffener segment of the wire centered at the ribbon-shaped biopsy clip (arrow). Surgeon preference for depth of wire placement relative to the mass/clip varies, so good communication between the radiologist and surgeon is important.

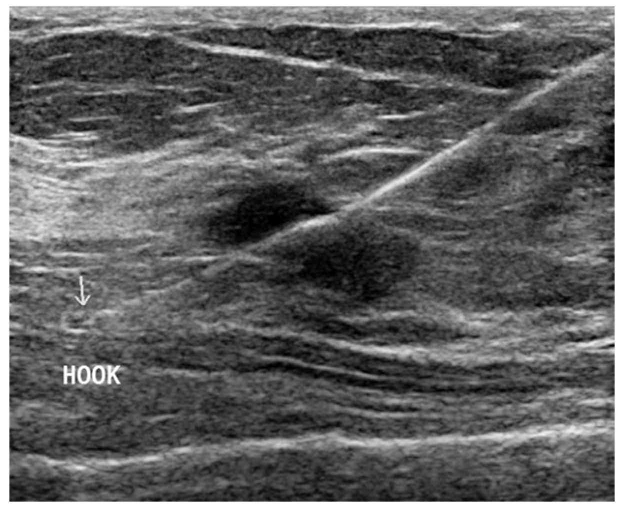

Fig. 2. Ultrasound image following ultrasound-guided wire localization shows the linear echogenic wire traversing an indistinct hypoechoic mass. Note the faintly visible hook (arrow) at the distal wire tip.

with a photon energy of 27 keV. The seed can be placed under mammographic or sonographic guidance (Figs. 3 and 4). The Nuclear Regulatory Commission established guidelines limiting the length of time that the seed can be placed in the breast to 5–7 days prior to surgery [37] The surgeon uses a handheld detection probe intraoperatively to guide excision of the targeted lesion and seed. The ^{125}I seed's activity signal differs from the 140-keV activity signal of technetium 99m, which is often injected for localization of sentinel lymph nodes for sentinel node excision. The same detection probe is used to perform both procedures by adjusting the activity detection setting of the probe. After surgery, the presence of ^{125}I activity in the tissue specimen and a concomitant lack of activity in the surgical bed confirm successful removal of the seed (Fig. 5).

The most commonly cited advantage of RSL over wire localization is the potential for decoupling of the radiology and surgery schedules. Radioactive seed placement and surgery can be scheduled independently, resulting in fewer delays on the day of surgery and overall improved patient satisfaction [38]. RSL has emerged as an established alternative to wire localization, and robust data published over the past two decades demonstrate the efficacy of RSL.

Another important advantage of RSL over wire localization is that the radiologist's approach to placement of the radioactive seed does not affect the surgeon's approach to excision. As there is no external component to the seed after placement, the radiologist can place the seed by any desired approach without impacting the surgeon's decisions at the time of surgery.

More recently, RSL has played an important role in the localization of biopsy-proven metastatic level I axillary lymph nodes in patients with breast cancer. Caudle et al. demonstrated efficacy of RSL in the selective removal of such metastatic lymph nodes [39]. Utilizing the same technique as the one used to localize breast lesions, radioactive seeds can be placed preoperatively under ultrasound guidance within lymph nodes previously marked with a biopsy clip. This procedure, termed targeted axillary dissection, permits delivery of both sentinel

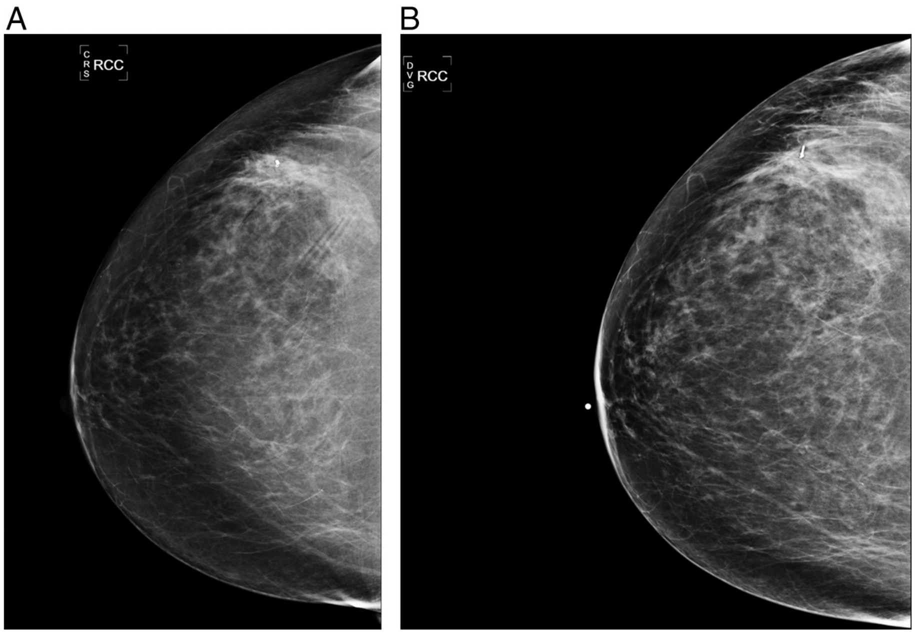

Fig. 3. (A) Post-biopsy, pre-localization RCC view of the right breast shows a coil-shaped clip in the lateral breast, posterior depth, which denoted the site of malignancy and the target for radioactive seed placement.
(B) Post-localization RCC view shows the coil-shaped clip with an adjacent radioactive seed, which appears as a small cylindrical density.

Fig. 4. Ultrasound-guided radioactive seed localization. Post-localization ultrasound image shows a brightly echogenic radioactive seed within a hypoechoic irregular cancer.

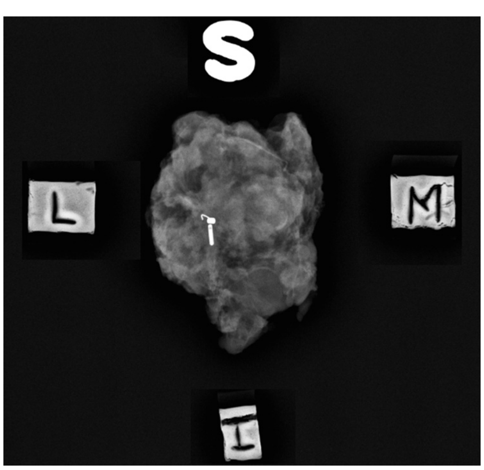

Fig. 5. Specimen radiograph from the patient shown in Figs. 3–4. Shows the marker clip, radioactive seed, and spiculated mass. Note the unchanged spatial relationship between the clip and seed. S, superior; M, medial; I, inferior; L, lateral.

nodes and radiographically biopsied nodes to the pathologist and results in improved concordance of true lymph node status for staging.

One of the most commonly cited disadvantages of RSL is the presence of radioactivity in the implanted seed. The seed emits low-energy radiation, and patients require education regarding restrictions with implanted radioactive materials. They are advised to avoid interactions with children and pregnant women to mitigate any potential risk. Pregnant women requiring breast surgery are not eligible for RSL. Additionally, MRI guided placement of radioactive seeds is contraindicated.

Implementation of RSL in nonacademic centers has been relatively slow because of the need for a well-defined multidisciplinary program and protocol to ensure safe handling of the seeds from their acceptance through in-house processing, deployment, surgical excision, and disposal [40]. The Nuclear Regulatory Commission mandates substantial regulatory procedures associated with ordering, transport, storage, and recovery of radioactive seeds as well as streamlining patient restrictions, radiologic placement, surgical retrieval, and pathological recovery. Any deviation from this multidisciplinary protocol converts a safe and straightforward procedure to one that jeopardizes patients and that may threaten closure of the RSL program [27]. Furthermore, institutions wishing to implement RSL must apply for, or amend, their radioactive materials licenses to cover receipt and handling of the radioactive seeds. As such, expensive infrastructure and operational adjustments may be required.

Additionally, placement of multiple seeds without unique identifiers to localize large lesions may pose a challenge in obtaining clear margins intraoperatively. A 1 cm minimum discerning distance between two radioactive seeds when bracketing can insist in reducing the signal interference. Postplacement mammographic imaging and preoperative review of the mammograms with the surgeon can help mitigate some of this risk (Fig. 6).

4. Radio frequency reflector localization

Non-ionizing devices for localizing nonpalpable breast lesions have recently emerged in the wake of progress made with RSL. One such device is a radio frequency reflector (RFR), which is implanted through a hollow needle at the site of the lesion before surgery (Fig. 7). The device is similar to a biopsy marker clip and can be placed under ultrasound or mammographic guidance. RFRs differ in size and shape

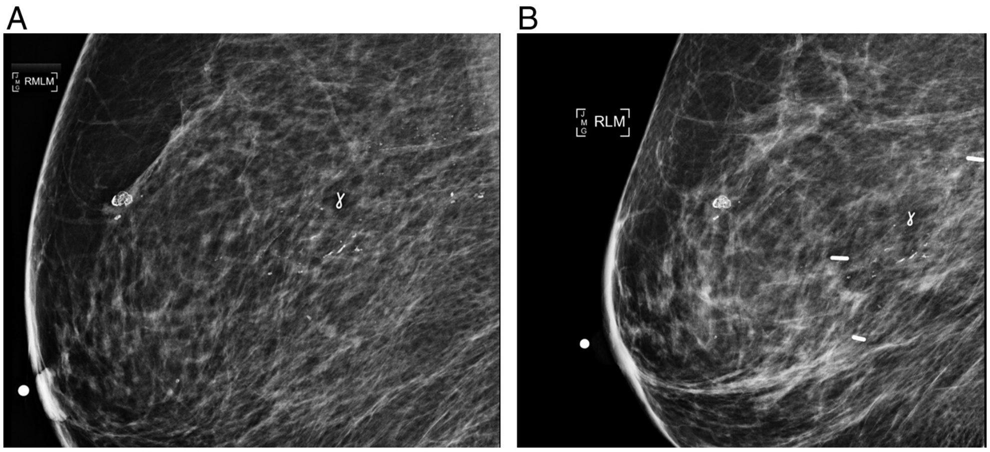

Fig. 6. Mammography-guided radioactive seed localization. (A) Pre-localization magnification LM view of the right breast shows segmental pleomorphic calcifications involving the middle and posterior thirds of the posterior breast. A marker clip in the central breast denotes the site of a recent biopsy showing ductal carcinoma in situ.
(B) Post-localization magnification LM view of the right breast shows three radioactive seeds bracketing the segmental pleomorphic calcifications and marker clip. As long as the distance between the radioactive seeds is at least 1 cm, multiple radioactive seeds can be placed and differentiated by the detection probe.

from vendor to vendor. One of the first available RFR is SAVI SCOUT (Cianna Medical, Aliso Viejo, CA) and another more recent device is the LOCalizer (Faxitron, Tucson, AZ). Both are U.S. Food and Drug Administration–approved and commercially available nonradioactive, electromagnetic wave tagging system. They are biocompatible and inert (only respond to signals from the reader), and each individual one has a

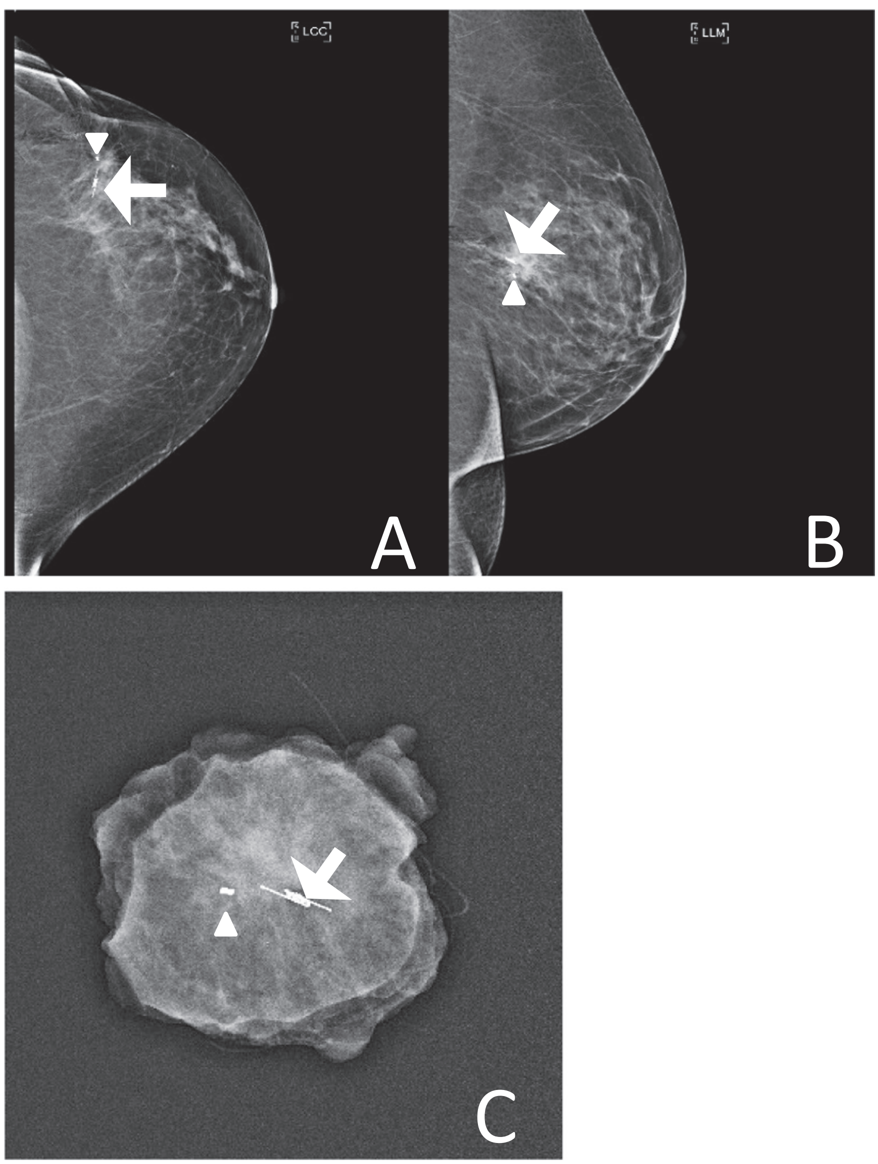

Fig. 7. Mammography-guided SAVI SCOUT reflector localization. (A, B) Post-procedure mammograms demonstrate satisfactory positioning of the reflector (arrow) adjacent to the targeted clip (arrowhead). (C) The specimen radiograph confirms retrieval of the clip (arrowhead) and reflector (arrow).

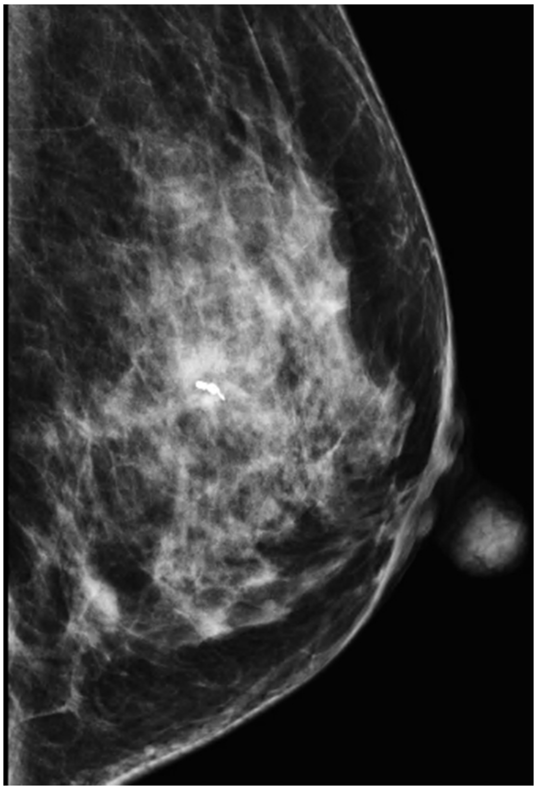

Fig. 8. LLM view demonstrating a cylindrical magnetic seed just posterior to a coil-shaped biopsy clip, both of which are within a biopsy-proven invasive ductal carcinoma.

unique identifier. Multiple tags can be inserted to localize larger lesions. In the operating room, the surgeon uses a handheld radiofrequency reader that provides both visual and audio feedback that is designed to detect the location and unique identifier of the tag(s). Once the tissue is removed, the reader console can be used to confirm that all tags have been removed from the tissue cavity.

The advantages of localization with a RFR over wire localization are similar to the advantages of other non-wire-guided localization techniques, primarily the decoupling of the radiology and surgery schedules and avoidance of the risk of complications associated with an external wire component. Similarly, the radiologist's approach at the time of reflector placement does not affect the surgeon's intraoperative approach. One of the primary advantages of the RFR over RSL is the absence of radiation, which may be more palatable to some patients. Unlike RSL, localization with a RFR does not require extensive multidisciplinary coordination or regulatory compliance.

The SAVI SCOUT has been commercially available for a longer period of time than the LOCalizer and therefore is in wider use. Deployment of the SAVI SCOUT has been reported to be easy given the procedural similarities between SAVI SCOUT placement and wire localization [41]. The SAVI SCOUT device has been assigned permanent implant status by the U.S. Food and Drug Administration, which removed limitations on the timing of device placement and potentially allows for placement at the time of biopsy, if desired. Placement of a SAVI SCOUT device at biopsy would require close coordination with the patient's surgeon, who in some practices may not be part of the multidisciplinary team until after diagnosis. A SAVI SCOUT device should not be placed until the patient and operating surgeon have discussed the management plan and agree that BCT is the best option.

Given the unique tag assigned to each deployed reflector, multiple reflectors can be placed at the time of localization. The SAVI SCOUT reflector has been rated as MR conditional and be considered safe to image in a static magnetic field of 3 Tesla or less and a maximum spatial gradient magnetic field of 3000 G or less [41]. RFRs are the only non-wire-guided localization device in use that can be used in magnetic resonance imaging without signal void artifact [42]. Whereas metallic interference from nearby surgical instruments can interfere with detection of magnetic seeds, metal does not interfere with detection of radiofrequency signals during surgery [42].

Disadvantages of localization with the SAVI SCOUT device include its relatively large size (12 mm) compared to the size of alternative localization devices, where MagSeed measures 5 mm and RSL 4.5 mm in maximal dimension. Because the SAVI SCOUT measures 1.2 cm, some may find it more challenging to place within subcentimeter lesions, and the role of its placement within biopsy-proven metastatic axillary lymph nodes is still under review [43]. The LOCalizer overcomes the size hurdle since it is smaller. Studies have also cited limitations in intraoperative detection of the reflector in women with large breasts and lesions located > 6 cm from the overlying skin surface [44]. Lesion depth has not been reported as a factor in alternative wire-free localization devices. Placement of the reflector, like other non-wire-guided localization techniques, is a one-step process, and malpositioning at the time of deployment may necessitate placement of additional devices and ultimately lead to additional tissue excision at the time of surgery.

From an operational standpoint, RFR systems require significant capital purchases and continual investment in single-use reflectors. The reader console can be purchased or leased depending on the program and vendor negotiation. Cost savings due to decoupling of the surgical and radiology scheduling may offset some of the up-front cost.

5. Magnetic seed localization

Magnetic seeds are very similar to radioactive seeds in terms of form and placement technique but quite different in terms of function. Magnetic seeds, first introduced by Sentimag (London, United Kingdom), measure approximately 5 mm × 1 mm and are paramagnetic steel seeds deployed through preloaded 18-G needles, which are available in different lengths to accommodate different breast sizes and lesion depths. Magnetic seeds emit a magnetic signal that can be detected with a special probe. Magnetic seeds may be placed via mammographic, stereotactic, or tomosynthesis or ultrasound guidance (Fig. 8). These seeds have a texturized surface to optimize their sonographic visibility to assist both placement and subsequent detection (Fig. 9). Seeds cannot be broken on deployment and may be placed up to 30 days before surgery. There is no signal decay between placement

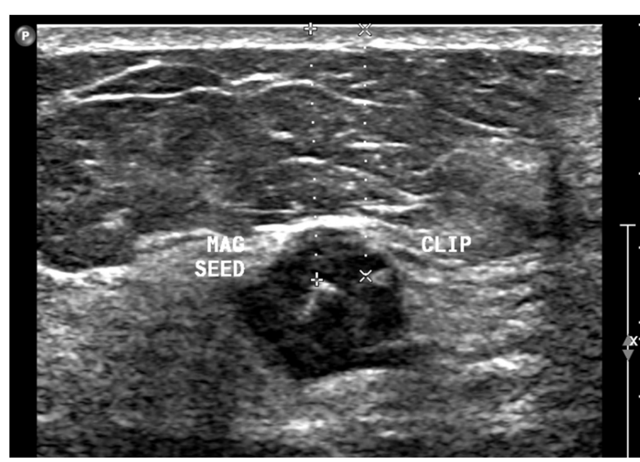

Fig. 9. Ultrasound image of invasive ductal carcinoma during ultrasound-guided magnetic seed localization. The marker clip on the right side of the image was placed at the time of biopsy. Note that the magnetic (“MAG”) seed placed during this procedure (left side of the image) is more echogenic than the marker clip.

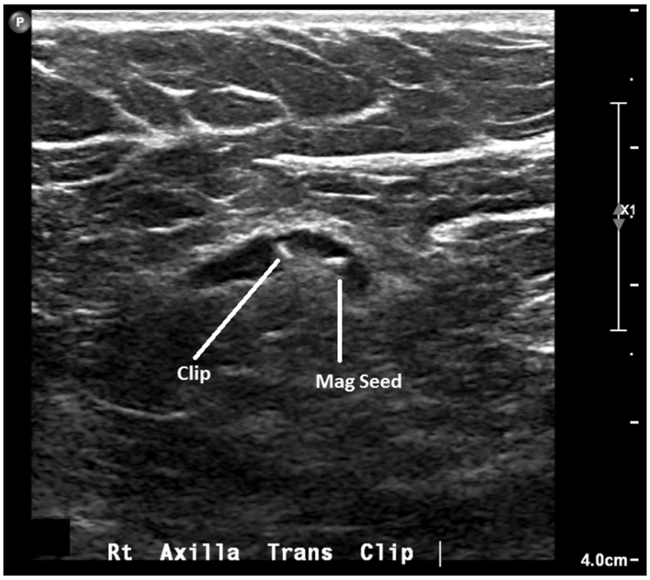

Fig. 10. Magnetic ("Mag") seed placed within a biopsy-proven metastatic lymph node as part of a targeted axillary dissection procedure.

and surgery, nor is signal strength attenuated by tissue type or breast density. Recently the FDA granted permanent implant status, so there is no time limit for retrieval. Magnetic seeds can be detected from any direction and have a detection depth of approximately 3 cm. Unlike the Geiger counter used to identify radioactive seeds, the magnetic detection probe used to find magnetic seeds provides the estimated distance from the probe to the lesion. Magnetic seeds may be placed within breast masses as well as lymph nodes (Fig. 10).

The greatest advantage of magnetic seeds over radioactive seeds is the lack of emitted ionizing radiation. This not only makes magnetic seeds a safer option but also avoids the substantial regulatory procedures required for use of radioactive seeds. Without these burdens, magnetic seeds may be used in a larger number of clinical settings. The greatest advantage of magnetic seed localization over localization with RFRs is the smaller size of the implanted device.

Disadvantages of magnetic seed localization include significant capital expenditure for the intraoperative detection equipment. Although other procedures are under investigation, currently there are few other applications for the proprietary magnetic detection probe that must be used for intraoperative detection. The detection range of 3 cm is also a limitation and requires careful patient and lesion selection. Another limitation of magnetic seed localization is the possibility of metallic interference from nearby surgical instruments, such as retractors, or even some biopsy clips. Dedicated non-magnetic instruments are available from the magnetic seed manufacturer to mitigate this issue. As expected, a small magnet within the field of view will yield significant signal distortion on magnetic resonance imaging images. Therefore, all diagnostic information should be obtained before a magnetic localization seed is placed. As with radioactive seeds and the RFRs, once a magnetic seed is deployed, it may not be repositioned. The magnetic seed is the newest of the localization devices discussed, and the limited literature available to date shows that magnetic seed localization is a safe, viable alternative to RSL [45,46]. It has shown no migration and has been detectable in all breast sizes up to the manufacture's depth limit [47]. Our experience with magnetic seeds supports these findings.

6. Conclusions

Image-guided preoperative localization of breast lesions is a common procedure that has evolved as surgical, imaging, and biomedical technology have progressed. There are multiple options for localization, and in choosing the optimal method for each facility, all stakeholders should be consulted, including surgeons, radiologists, pathologists, hospital administrators, and patients. The information in this article may serve as a foundation that allows radiologists to initiate conversations at their facilities as they seek to add value and provide patient-centered care [48].

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