

# Beyond Wires and Seeds: Reflector-guided Breast Lesion Localization and Excision<sup>1</sup>

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## Purpose:

To evaluate outcomes of Savi Scout (Cianna Medical, Aliso Viejo, Calif) reflector-guided localization and excision of breast lesions by analyzing reflector placement, localization, and removal, along with target excision and rates of repeat excision (referred to as re-excision).

## Materials and Methods:

A single-institution retrospective review of 100 women who underwent breast lesion localization and excision by using the Savi Scout surgical guidance system from June 2015 to May 2016 was performed. By using image guidance 0–8 days before surgery, 123 nonradioactive, infrared-activated, electromagnetic wave reflectors were percutaneously inserted adjacent to or within 111 breast targets. Twenty patients had two or three reflectors placed for bracketing or for localizing multiple lesions, and when ipsilateral, they were placed as close as 2.6 cm apart. Target and reflector were localized intraoperatively by one of two breast surgeons who used a handpiece that emitted infrared light and electromagnetic waves. Radiographs of the specimen and pathologic analysis helped verify target and reflector removal. Target to reflector distance was measured on the mammogram and radiograph of the specimen, and reflector depth was measured on the mammogram. Pathologic analysis was reviewed. Re-excision rates and complications were recorded. By using statistics software, descriptive statistics were generated with 95% confidence intervals (CIs) calculated.

## Results:

By using sonographic (40 of 123; 32.5%; 95% CI: 24.9%, 41.2%) or mammographic (83 of 123; 67.5%; 95% CI: 58.8%–75.1%) guidance, 123 (100%; 95% CI: 96.4%, 100%) reflectors were placed. Mean mammographic target to reflector distance was 0.3 cm. All 123 (100%; 95% CI: 96.4%, 100%) targets and reflectors were excised. Pathologic analysis yielded 54 of 110 malignancies (49.1%; 95% CI: 39.9%, 58.3%; average, 1.0 cm; range, 0.1–5 cm), 32 high-risk lesions (29.1%; 95% CI: 21.4%, 38.2%), and 24 benign lesions (21.8%; 95% CI: 115.1%, 30.4%). Four of 54 malignant cases (7.4%; 95% CI: 2.4%, 18.1%) demonstrated margins positive for cancer that required re-excision. Five of 110 radiographs of the specimen (4.5%; 95% CI: 1.7%, 10.4%) demonstrated increased distance between the target and reflector distance of greater than 1.0 cm (range, 1.1–2.6 cm) compared with postprocedure mammogram the day of placement, three of five were associated with hematomas, two of five migrated without identifiable cause. No related postoperative complications were identified.

## Conclusion:

Savi Scout is an accurate, reliable method to localize and excise breast lesions with acceptable margin positivity and re-excision rates. Bracketing is possible with reflectors as close as 2.6 cm. Savi Scout overcomes many limitations of other localization methods, which warrants further study.

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**N**onpalpable breast lesion localization and excision is customarily directed by preoperative image-guided wire placement through or adjacent to the targeted lesion or clip. Since the 1970s, wire localization has been used successfully with some notable disadvantages that include patient discomfort, potential for wire displacement because of its external component, and the possibility of wire transection or breakage leaving fragments in the breast (1–7). The wire entry point through the skin may be suboptimal for the desired surgical approach. In addition, wire localization must be performed the day of surgery; at our institution, it is usually performed early in the morning to accommodate surgery schedules. This coupling of the radiology and surgery schedules limits operating room (OR) scheduling and leads to OR delays.

#### Advances in Knowledge

- The Savi Scout (Cianna Medical, Aliso Viejo, Calif) surgical guidance system is an accurate method to localize and excise nonpalpable breast lesions with acceptable margin positivity and repeat excision (referred to as re-excision) rates; four of 54 malignant cases (7.4%; 95% confidence interval [CI]: 3.4%, 18.1%) demonstrated margins positive for cancer (ie, ink on tumor) that required re-excision.
- Placement and excision of more than one reflector in the same breast is possible; in our series it was performed in 18 patients with reflectors as close as 2.6 cm.
- Increased distance between the reflector and target greater than 1.0 cm was observed in five of 110 targets (4.5%; 95% CI: 1.7%, 10.4%) when the postprocedure mammogram was compared with the radiograph of the specimen; three of five cases were associated with a postbiopsy hematoma, which suggested that caution should be exercised when hematoma is present.

Recently, 125 iodine (<sup>125</sup>I) radioactive seed localization gained popularity by overcoming many of the disadvantages of wire localization; however, necessary radiation safety precautions limit implementation of radioactive seed localization at some institutions and outpatient centers (8–14).

The Savi Scout surgical guidance system (Cianna Medical, Aliso Viejo, Calif) is an alternative method to localize and excise nonpalpable breast lesions (15,16). Savi Scout helps the radiologist to implant an infrared-activated, electromagnetic wave reflector device (referred to as a reflector) into the breast with image guidance, which can then be percutaneously detected by using a handpiece-and-console system. The reflector is not radioactive, has no external component, and is U.S. Food and Drug Administration–approved for placement up to 30 days before the surgical procedure. It is 12-mm long and consists of an infrared light receptor, resistor, and two antennae (Fig 1). The reflector is placed into or near the target tissue and is enveloped by the surrounding tissue. The reflector antennae, by their offset configuration, serve

#### Implications for Patient Care

- The Savi Scout reflector provides a nonradioactive method to localize breast lesions preoperatively and appeared to overcome many of the limitations associated with wire localization and radioactive seed localization; this warrants further study.
- Breast reflectors overcome wire localization disadvantages, including potential for wire displacement because of its external component, and the possibility of wire transection or breakage, which leaves fragments in the breast.
- The ability to place the reflector within the breast before the day of surgery uncouples the radiology and surgery schedules, which eliminates wire localization–related delays in the operating room.

the additional function of securing the reflector in tissue. The reflector antennae are constructed of nitinol, a robust shape-memory material used in numerous medical device implants, such as coronary stents and heart valves, where strength and flexibility are important and therefore not prone to breakage.

An initial feasibility study of 15 lesions demonstrated that Savi Scout is a feasible tool to localize and excise nonpalpable breast lesions (15). In a larger multi-institution pilot study of 50 patients, Cox et al (16) demonstrated successful reflector and lesion excision with no adverse events. Although these initial studies were promising because they involved small numbers of patients without bracketing and did not assess for reflector migration, additional investigation is necessary to evaluate this technique before its widespread adoption.

Our goal was to evaluate outcomes of Savi Scout reflector-guided localization and excision of breast lesions by analyzing reflector placement, localization, and removal, along with target excision and rates of repeat excision (referred to as re-excision).

#### Materials and Methods

We performed an institutional review board–approved, Health Insurance Portability and Accountability

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#### Abbreviations:

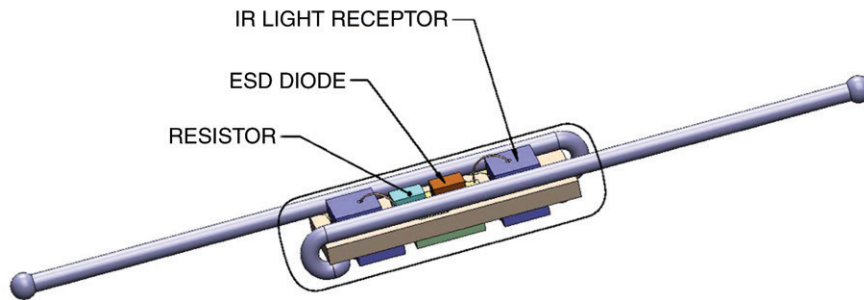
CI = confidence interval  
OR = operating room

#### Author contributions:

Guarantors of integrity of entire study, V.L.M., S.F.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; agrees to ensure any questions related to the work are appropriately resolved, all authors; literature research, V.L.M., S.F., S.N.P., A.G., R.H.; clinical studies, V.L.M., S.F., L.F., E.D., S.N.P., R.H.; experimental studies, V.L.M., R.H.; statistical analysis, V.L.M., A.G., R.H.; and manuscript editing, all authors

Conflicts of interest are listed at the end of this article.

Figure 1



**Figure 1:** A Savi Scout reflector. Savi Scout reflector measures 1.2 cm and is inserted into the breast under mammographic or sonographic guidance. Transcutaneous reflector detection is performed by using an infrared (IR) light and electromagnetic-wave-emitting handpiece. The infrared light receptor creates an electrical connection between the two antennas (facilitated by the resistor), which results in electromagnetic waves reflecting back to the handpiece. The electrostatic discharge (ESD) component prevents shortage of the reflector should it contact the electrocautery during surgery.

Act-compliant, single-institution retrospective review of 100 patients who underwent localization by using the Savi Scout surgical guidance system at our institution from June 2015 to May 2016. No financial support or materials were provided by Cianna Medical for this study. Patient informed consent was waived. One-hundred women (mean age, 56.4 years; age range, 24–82 years) had 123 Savi Scout reflectors placed to enable localization of 111 breast lesions. We included 13 of 100 patients in an initial feasibility study (15). Ten patients required bracketed localization with placement of more than one reflector requested by the surgeon if the targeted area for excision was greater than 2 cm, which is also the criteria used for bracketed wire localization. Patients were selected by one of two breast surgeons after image review with a radiologist on the basis of the following criteria: women, 18 years or older, had a nonpalpable breast lesion for which surgical excision with preoperative image-guided localization with mammography or ultrasonographic (US) imaging was planned, and lesion depth was less than 4.5 cm. Lesions had to be amenable to US- or mammography-guided localization because the delivery system is not compatible with magnetic resonance (MR) imaging. Patients who did not meet the inclusion criteria or those

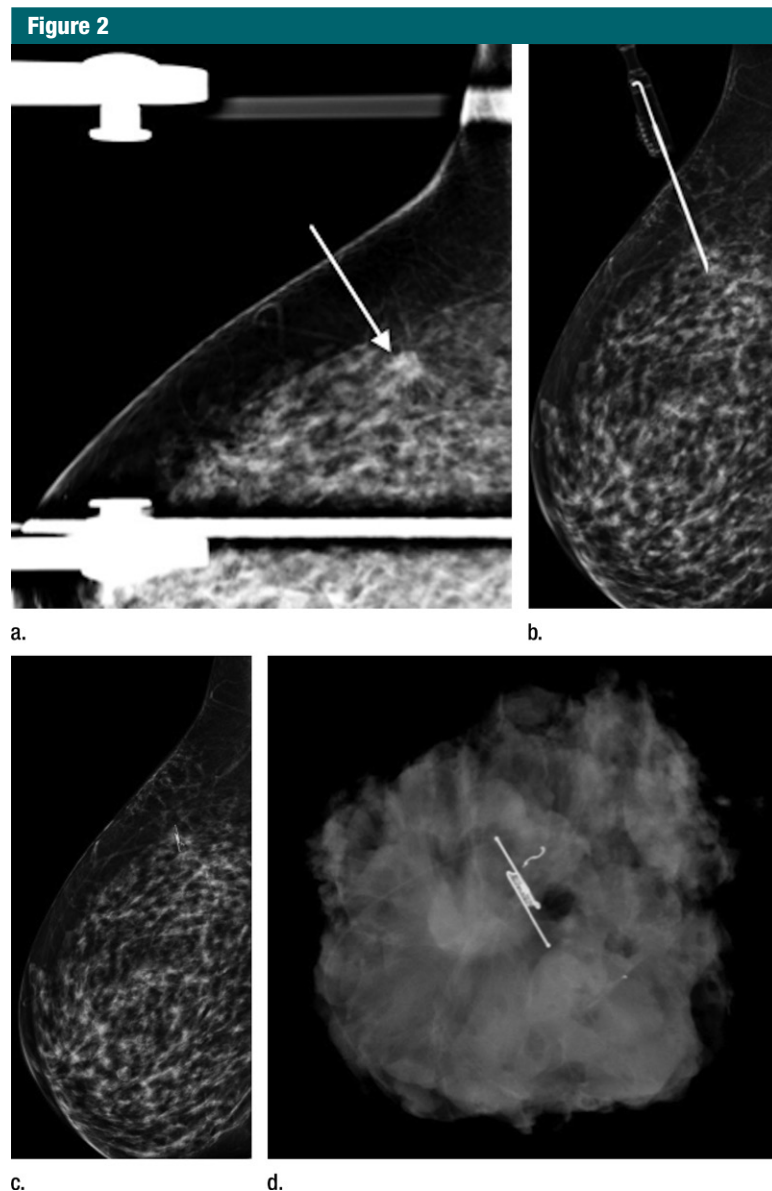
with nickel allergy were excluded because of the composition of the device. The reflector does not contain toxic heavy metals. During this same period, 161 wire localization cases were performed by these two surgeons. Most wire localization cases were performed during the initial learning period while surgeons, radiologists, and staff got comfortable with this new technique and technology.

Reflector placement was percutaneously performed by one of five breast radiologists (V.L.M., R.T.W., L.F., E.D., and R.H., with 4–27 years of experience performing image-guided breast localizations) after administration of local anesthesia. Reflectors were placed 0–8 days before surgery (average, 2.2 days; median, 1 day), and we recorded any OR delays that were because of reflector placement. In 93 patients, the reflector was placed before the day of surgery. The reflector was preloaded in a sterile 16-gauge needle (available in 5-cm, 7.5-cm, or 10-cm lengths). An alphanumeric grid was used for mammogram target localization in a fashion similar to wire localization; the reflector was deployed when the needle tip was accurately positioned on an orthogonal image (Fig 2). US-guided reflector placement was viewed in real time, which was similar to US-guided wire localization (Fig 3). Transcutaneous detection of the

reflector device was determined in the radiology department the day of placement by using a handpiece-and-console system to confirm successful reflector placement and functionality.

On the day of placement, the patient underwent mammography that consisted of craniocaudal and mediolateral views after reflector deployment. These images were reviewed by the radiologist to confirm reflector placement. The distance between the reflector and the target and the distance from the reflector to the skin were measured. The shortest distance from the skin to the reflector was recorded. For cases with more than one reflector in the same breast, we measured the distance between the reflectors on both images and recorded the greatest distance. All distances were measured by using electronic calipers on our Picture Archiving and Communication System (Centricity 6.0; GE Healthcare, Barrington, Ill). All images were available to the surgeon to intraoperatively assist with localization.

After reflector placement, transcutaneous signal detection that was confirmed in the radiology department by using the handpiece-and-console system was performed in the radiology department. For three of 122 reflectors (2.5%; 95% confidence interval [CI]: 0.5%, 7.3%), a signal was difficult to obtain. In two patients (one patient with a hematoma and one patient with a large [2 cm] densely calcified fibroadenoma located between the reflector and the skin), a weak signal was obtained after placing the patient in a supine position to flatten the breast and pressing more firmly with the handpiece. In one patient, no signal could be obtained, likely because of a hematoma that formed after biopsy. In our experience, we mitigate this limitation by placing the reflector immediately adjacent to the hematoma (rather than within it) and marking the skin for the surgeon if the transcutaneous signal is weak (ie, the audible feedback is intermittently obtained). On the day of the surgical procedure, the surgeon had difficulty obtaining a signal transcutaneously before incision in the same three



**Figure 2:** Images in a 60-year-old woman with left invasive ductal carcinoma at 1-o'clock position who underwent mammography-guided reflector placement. **(a)** Left mediolateral oblique spot compression view of a 0.9 cm spiculated mass, biopsy revealed invasive ductal carcinoma (arrow). **(b)** Mammography-guided localization of the mass and S-shaped clip. **(c)** Reflector deployed within the mass, immediately adjacent to the clip. **(d)** Radiograph of the specimen shows the spiculated mass, clip, and reflector.

patients (2.5%; 95% CI: 0.5%, 7.3%). Following skin incision, an audible signal was detected in all cases.

We localized 111 breast lesions; 10 patients required bracketed lesion localization with placement of more than one reflector. Eighty patients had one reflector placed, 17 patients had two

reflectors placed (15 patients had reflectors placed in the ipsilateral breast: eight patients had reflectors placed for bracketing one lesion and seven patients had reflectors placed for additional ipsilateral lesions; two patients had reflectors placed in the contralateral breast), and three patients had

three reflectors placed (two patients in the ipsilateral breast to bracket a larger area for excision and one patient with two reflectors placed in one breast and one reflector placed in the contralateral breast).

The Savi Scout reflector was placed 1.8 cm medial to the target in one patient; because of the patient's distress during mammographic compression, the radiologist needed to deploy the device where the needle tip was at the time. Reflector displacement in this case was not from migration of the reflector. Because of reflector displacement, wire localization was also performed the morning of surgery. The target and reflector were successfully excised; however, this case was excluded from further result analysis because of the presence of the wire that aided localization.

Two breast surgeons at our institution (with 35 and 20 years of experience) adopted Savi Scout localization in most patients who underwent preoperative image-guided localization of a breast lesion and they performed all the surgical procedures in this study. Reflectors and targeted lesions were localized in the OR by one of two breast surgeons who used a console-and-handpiece system that emitted infrared light and electromagnetic waves. Infrared light from the handpiece is detected by the reflector and creates an electrical connection between the antennae, which causes pulsatile reflection of the handpiece-emitted electromagnetic waves back to the handpiece (15). The console detects only these pulsing waves and thus does not mistake biopsy-marker clips or surgical instruments for the reflector. Audible feedback from the console guided dissection and reflector excision during surgery.

Removal of the reflector and targeted breast lesion and/or clip was verified by radiography of the specimen and interrogation of the specimen with the handpiece. Distance between the target and reflector on the radiograph of the specimen was measured and compared with the target-reflector distance on the mammogram obtained after the procedure performed on the day of



**Figure 3:** US image in a 59-year-old woman with a 2.2-cm fibroadenoma for which the patient elected surgical excision. US-guided reflector placement was performed. Reflector is linear and echogenic (arrow) within the oval circumscribed mass (a fibroadenoma).

localization. Pathologic results were reviewed for presence of the target and/or postbiopsy change and margins. We evaluated re-excision rates and complications. By using statistical software (SPSS Statistics for Windows, version 24.0; IBM, Armonk, NY), descriptive statistics (ie, proportions, frequencies, and means) were generated with 95% CIs calculated.

### Results

By using image guidance, 123 reflectors (100%; 95% CI: 96.4%, 100%) were placed in the breasts of 100 female patients (mean distance between the target and reflector on postlocalization mammogram, 0.3 cm; range, 0–1.8 cm). Forty of 123 reflectors (32.5%; 95% CI: 24.9%, 41.2%) were placed by using US guidance for localization and 83 of 123 reflectors (67.5%; 95% CI: 58.8%, 75.1%) were placed by using mammogram guidance. No OR delays related to reflector placement were identified.

We excised 122 reflectors (100%; 95% CI: 96.3%, 100%) by using the Savi Scout surgical guidance system. We found 110 (100%; 95% CI: 96.0%, 100%) targeted lesions and/or postbiopsy changes present in the surgical specimens. In 106 targeted lesions, a biopsy marker clip was the target or was associated with the targeted lesion; however, in six of 106 targeted lesions (5.7%; 95% CI: 2.4%, 12.1%), the clip was not present on the radiograph of the specimen. In these six cases, five cases demonstrated definitive postbiopsy change

at pathologic analysis. One case demonstrated equivocal postbiopsy change at pathologic analysis but had a visible hematoma cavity at surgical excision. Of six patients, one underwent postoperative mammography that showed clip excision, and one patient underwent re-excision for margins positive for cancer with the clip visible in the re-excision specimen.

Final surgical pathologic analysis yielded 54 of 110 malignancies (49% [95% CI: 39.9%, 58.3%]; average size, 1.0 cm; range, 0.1–5 cm), 32 of 110 high-risk lesions (29%; 95% CI: 21.4%, 38.2%), and 24 of 110 benign lesions including one benign axillary lymph node (22%; 95% CI: 15.1%, 30.4%). Malignant lesions included 35 invasive ductal carcinomas, one invasive lobular carcinoma, 17 ductal carcinomas in situ, and one papillary carcinoma. Of 54 malignant cases, four (7.4%; 95% CI: 2.4%, 18.1%) had margins that were positive for cancer (ie, ink on tumor) that required re-excision. An additional 10 of 54 cases (18.5%; 95% CI: 10.2%, 31.1%) demonstrated a close margin of less than 1 mm. All bracketed cases demonstrated margins negative for cancer.

Postlocalization mammograms showed an average reflector depth of 2.6 cm (range, 0.3–6.6 cm). For the 40 patients who underwent US localization, average reflector depth at US was 1.2 cm (range, 0.5–2.8 cm). These same 40 reflectors had an average depth of 2.4 cm (range, 0.6–5.1 cm) on postlocalization mammograms, which reflected the overestimation of depth

measurements at mammography because of differences in positioning.

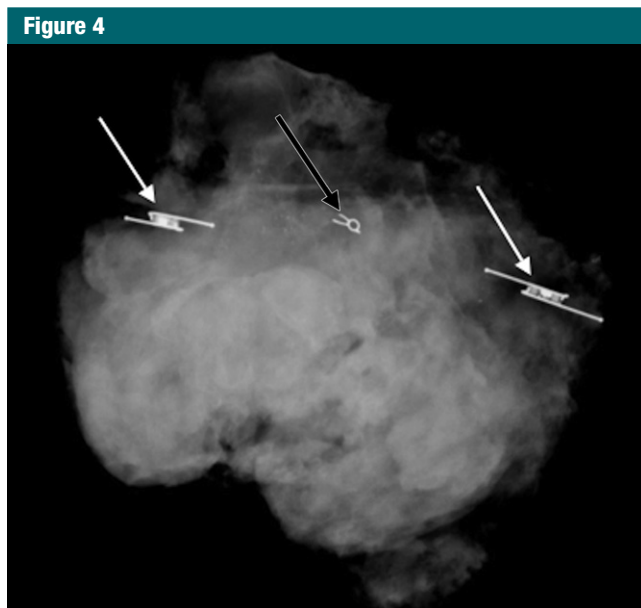
Five of 110 radiographs of the specimen (4.5%; 95% CI: 1.7%, 10.4%) showed an increased distance between the reflector and the target of more than 1.0 cm (range, 1.1–2.6 cm) compared with postprocedure mammograms obtained the day of reflector placement. In three of these five patients, a postbiopsy hematoma was evident on the prelocalization mammogram, and in two of five patients the reflector migrated without identifiable cause. In total, 19 of 100 (19.0%; 95% CI: 12.4%, 28.9%) patients had postbiopsy hematomas that were evident on the mammogram the day of localization. There was no reflector damage or transection evident on any postlocalization mammogram or radiograph of the specimen.

In patients with more than one reflector in a breast, postlocalization mammograms demonstrated an average distance between reflectors of 4.0 cm (range, 2.6–7.7 cm), and the radiologist and surgeon were able to detect each reflector as a separate signal. Radiographs of the specimen confirmed removal of reflectors and targets (Fig 4).

We did not identify any complications of reflector placement and we did not observe any related postoperative complications.

### Discussion

One-hundred twenty-three Savi Scout-guided localizations were placed in 100 women (100%; 95% CI: 96.4%, 100%), and reflectors were placed on average within 0.3 cm of the target (range, 0–1.8 cm), which was comparable to radioactive seed localization study results (10). After reflector placement, challenges were encountered in transcutaneous detection in 2.5% of Savi Scout-guided localizations (three of 122; 95% CI: 0.5%, 7.3%) both at radiology the day of placement and in the OR prior to skin incision. These were attributed to the presence of hematomas and, in one patient, because of a large densely calcified fibroadenoma that interfered with handpiece detection. After skin incision, all reflectors



**Figure 4:** Image in a 50-year-old woman after biopsy of calcifications yielded ductal carcinoma in situ. Two Savi Scout reflectors (white arrows) were placed by using mammographic guidance 3 cm apart to bracket the clip (black arrow) that was placed at the time of biopsy and residual calcifications. Radiograph of the specimen demonstrates successful excision of both reflectors, the clip, and residual calcifications.

had a clear audible signal and were able to be localized.

We found 110 targeted lesions and/or postbiopsy changes (100%; 95% CI: 96.0%, 100%) present in the surgical specimens. In six of 106 cases (5.7%; 95% CI: 2.4%, 12.1%), targeted clips were not present on the radiographs of the specimen, although these cases demonstrated evidence that the biopsy site had been localized. This is higher than previously reported (17) for wire localization, with clips absent in 3.8% of specimens, but within the 95% CI range of our cases and likely not statistically different. This is most commonly attributed to removal with suction (17). In general, our surgeons do not obtain a postoperative mammogram or re-excision if a clip is absent from the specimen as long as lesion excision and/or postbiopsy change is demonstrated at pathologic analysis. The lack of postoperative mammograms in our study limits assessment of clip removal.

In our study, four of 54 malignancies (7.4%; 95% CI: 2.4%, 18.1%) demonstrated margins positive for

cancer (ie, ink on tumor) that required re-excision and 10 of 54 malignancies (18.5%; 95% CI: 10.2%, 31.1%) demonstrated a close margin of less than 1 mm. This is similar to Cox et al (16) who reported a 7% positive margin rate and 22% close margins by using Savi Scout. This is comparable to radioactive seed localization and better than reported for wire localization with positive margins in 12%–60% of cases (11). Notably all bracketed cases had clear margins. Because patients who undergo excision of a larger amount of tissue usually undergo oncoplastic mastopexy at the time of surgery, negative margins are essential because re-excision is usually not possible because larger tissue rearrangements and mastectomy may be required.

In one of our patients, it was necessary for a wire to be placed in addition to the Savi Scout reflector after it was deployed 1.8 cm medial to the target. It may be prudent to include in the procedure consent process the possibility of needing wire placement the morning of surgery, should the reflector

be displaced or hematoma interfere with reflector detection.

Placement of the Savi Scout reflector deeper than 4.5 cm may interfere with detection according to the manufacturer; the initial pilot study reported difficulty with detection of two reflectors at 4.5- and 6-cm deep (16). This is a potential limitation of the system. It is challenging to estimate the true lesion depth (observed when the patient is supine) from the mammographic images because breast compression and distance from the skin on the image does not necessarily reflect the shortest distance to the lesion. Because patients are supine during surgical excision, the sonographic measurement may be more relevant.

Five of 110 radiographs of the specimen (4.5%; 95% CI: 1.7%, 10.4%) demonstrated an increased distance between the reflector and the target of greater than 1.0 cm compared with postprocedure mammogram obtained the day of reflector placement, in three of five cases in the setting of a postbiopsy hematoma. Surgeons were able to excise the targeted lesion by using postprocedure mammograms for guidance and because the periphery of the hematoma was excised when hematoma was present. Caution should be exercised when using Savi Scout in the setting of hematomas because of the possibility of increased target reflector distance and challenges obtaining a transcutaneous signal. Similar challenges in the setting of hematomas are reported for radioactive seed localization (18).

Our study demonstrated that up to three reflectors may be placed in the same breast with successful reflector and lesion excision in the setting of bracketing or more than one lesion. We placed reflectors as close as 2.6 cm apart with demonstration of separate distinguishable signals transcutaneously.

Preliminary, subjectively observed benefits of the device that warrant further study include independent procedure optimization for the radiologist and surgeon and lack of an external component. The initial Savi Scout pilot study (16) reported that radiologists

found the Savi Scout more difficult to use than wires; however, this pilot study used a 13-cm pilot needle that was cumbersome for mammography-guided localization. Additionally, similar to radioactive seed localization, the reflector provides a point source around which the surgeon can reorient during surgery. Logistically, there were no OR delays related to device placement, and radiology and surgery schedules were uncoupled. We did not assess vasovagal rates; however, because patients were not fasting at the time of Savi Scout reflector placement, vasovagal reactions may be decreased, and this is an area that warrants further study. No radiation safety precautions were necessary.

Limitations of the device include both the inability to reposition the reflector after it is deployed because this could damage the reflector and possible reflector migration particularly in the setting of a hematoma. Cost is a potential limitation of the Savi Scout device compared with wire localization and radioactive seed localization; however, reducing OR-related wire localization delays may provide substantial financial savings. The Savi Scout localization system requires an initial capital purchase and disposable purchase per procedure. Although it is substantially more expensive than wire localization on a simple cost level, the total cost to the institution is a multifactorial economic analysis considering purchase price, reimbursement, radiology efficiencies, OR efficiencies, patient satisfaction, and other relevant quality metrics. This article focuses on clinical utility. We are conducting a full cost analysis at our institution to investigate this issue further.

Our study is limited because it is a single-institution retrospective review without direct comparison to our wire localization cases. Patients were individually selected for Savi Scout by the surgeon after consultation with the radiologist, which introduces selection bias. A prospective randomized trial would be necessary to fully

compare wire localization and radioactive seed localization to Savi Scout-guided localization.

In conclusion, the Savi Scout surgical guidance system is an accurate and reliable method to localize and excise breast lesions with acceptable margin positivity and re-excision rates, and it may overcome many of the limitations of other localization methods, which warrants further study. Bracketing is possible with reflectors as close as 2.6 cm. It was used in women without nickel allergy who had breast lesions less than 4.5-cm deep who underwent US or mammography-guided preoperative localization (not MR imaging-guided localization). Caution should be exercised in the setting of hematomas, which may increase reflector or target distance and impede reflector detection.

**Disclosures of Conflicts of Interest:** V.L.M. disclosed no relevant relationships. R.T.W. disclosed no relevant relationships. S.F. disclosed no relevant relationships. L.F. disclosed no relevant relationships. E.D. disclosed no relevant relationships. S.N.P. disclosed no relevant relationships. A.G. disclosed no relevant relationships. R.H. disclosed no relevant relationships.

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