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Utilization of multiple SAVI SCOUT surgical guidance system reflectors in the same breast: A single-institution feasibility study

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Abstract

SAVI SCOUT Surgical Guidance System has been shown to be a reliable and safe alternative to wire localization in breast surgery. This study evaluated the feasibility of using multiple reflectors in the same breast. We performed an IRB-approved, HIPAA-compliant, single-institution retrospective review of 183 patients who underwent breast lesion localization and excision using SAVI SCOUT Surgical Guidance System (Cianna Medical) between June 2015 and January 2017. We performed a subset analysis in 42 patients in whom more than one reflector was placed. Specimen radiography, pathology, distance between reflectors, target removal, margin positivity, and complications were evaluated. Among 183 patients, 42 patients had more than one reflector placed in the same breast to localize 68 lesions. Benign (n = 6, 8.8%), high-risk (n = 23, 33.8%), and malignant (n = 39, 57.4%) lesions were included. Thirty-six patients (85.7%) had a total of 2 reflectors placed and 6 patients had a total of 3 reflectors placed (14.3%). The indications for multiple reflector placement in the same breast included multiple separate lesions (n = 23) and bracketing of large lesions (n = 19). The mean distance between the reflectors was 42 mm (22-93 mm). All lesions were successfully targeted and retrieved. Of 39 malignant lesions, 10.3% (n = 4) had positive margins and 10.3% (n = 4) had close (<1 mm) margins at surgery. All patients with positive margins underwent re-excision. No complications occurred preoperatively, intra-operatively, or postoperatively. The use of multiple SAVI SCOUT reflectors for localizing multiple lesions in the same breast or bracketing large lesions is feasible and safe.

KEYWORDS
bracketing lumpectomy, breast cancer, SAVI SCOUT

1 | BACKGROUND

Wire localization has traditionally facilitated surgical excision of non-palpable breast lesions. The wire provides a visual and tactile guide for the surgeon when placed through or adjacent to the lesion targeted for excision. Although successfully used since the early 1970s, wire localization is not without inherent inconveniences. Primary concerns relate to patient satisfaction and system efficiency—all of

which are currently under significant scrutiny. First, wire displacement and fragmentation may result in inadequate excision or retained foreign body.[1-7] Secondly, wire localization is often scheduled the morning of surgery to avoid potential displacement; this leads to operating room (OR) delays and inefficiency.[8-14] A new technology introduced to attempt to overcome both issues is I-125 radioactive seed localization. Although this newer procedure addresses system efficiency by allowing non-same-day scheduling, radiation safety warrants new safety challenges and precautions.

Recently introduced, the SAVI SCOUT Surgical Guidance System (SAVI SCOUT®; Cianna Medical, Inc., Aliso Viejo, CA) may address workflow improvement without introducing radiation safety concerns. This new system involves implanting a 12 mm nonradioactive, infrared-activated, electromagnetic wave reflector device into the breast adjacent to the area to be excised. The reflector itself has no external component and consists of an infrared light receptor, resistor, and two nitinol antennae, which secure the reflector in the tissue. The surgeon uses a transcutaneous hand-piece, which produces an audible signal when immediately over the reflector. The reflector is FDA approved for placement up to 30 days preoperatively, allowing for optimal OR efficiency. The SAVI SCOUT localizer has been evaluated in an initial feasibility study with 15 patients as well as in a multi-institutional study with 154 patients.[15-17] Both studies confirmed successful reflector placement and excision with no complications.

Although these initial studies are promising, they have mainly focused on the use of a single reflector for localization of a single lesion per patient. The main objective of this study was to determine the feasibility, safety, and efficacy of placing multiple reflectors within a single breast for localization of multiple lesions or for bracketing large lesions.

2 | METHODS

2.1 | Patient population

Following institutional review board approval, we performed a retrospective review of the electronic health record to identify 183 patients who underwent breast lesion localization and excision using the SAVI SCOUT Guidance System between June 2015 and January 2017. We evaluated a subset of the 183 patients in whom more than one reflector was placed in one breast for the purpose of bracketing or localizing multiple lesions. Patients with malignant, high-risk, and benign lesions were included. Descriptive analysis was performed.

2.2 | SAVI SCOUT localization and surgical excision

The SAVI Scout localization device is a 12 mm long percutaneously inserted, nonradioactive, infrared-activated, electromagnetic wave reflector. It was placed by one of five breast radiologists with 4-27 years of experience using a single-use, sterile, preloaded 16-gauge needle (5, 7.5, or 10 cm long), using either mammographic or ultrasound guidance. Multiple reflectors were placed after multidisciplinary discussion between the radiologist and the surgeon to facilitate excision of multiple breast lesions or to bracket an area intended for segmental resection.

At the time of surgery, the surgeon used a sterile, single-use detector hand-piece connected to a console emitting IR light and an electromagnetic wave signal resulting in an audible signal. The probe was used to transcutaneously identify the point of maximal intensity. The SAVI SCOUT reflector was used throughout the procedure to guide resection and orient the specimen. The excised specimen was oriented with sutures and the handheld probe was again used to confirm the presence of the SAVI SCOUT reflector. Specimen radiography in the OR confirmed the presence of the SAVI SCOUT reflector and the targeted lesion. The images were electronically transmitted for radiologist confirmation (Figure 1). Specimens were then submitted for pathologic assessment. SAVI SCOUT reflectors did not require specific disposal, as they are nonradioactive.

2.3 | Margin assessment

Additional margin excision was performed at the discretion of the surgeon. Only malignant lesions were included when calculating re-excision rates. Positive margins were defined as tumor on ink. Close margins were defined as tumor less than 1 mm from the inked surface.

3 | RESULTS

Of 183 patients who underwent SAVI SCOUT localizer placement, 42 patients had more than one reflector placed in one breast (total of 90 reflectors) in a total of 68 lesions. Benign (n = 6, 8.8%), high-

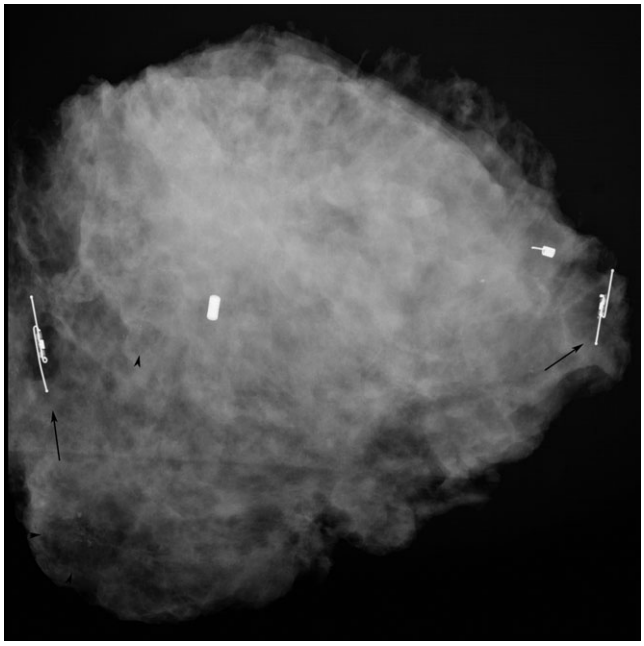

FIGURE 1 Two SAVI reflectors (arrows) bracketing two biopsy clips which yielded IDC/DCIS and residual calcifications (arrow head)

risk (n = 23, 33.8%), and malignant (n = 39, 57.4%) lesions were included. A total of 36 patients (85.7%) had a total of 2 reflectors placed; 6 patients had a total of 3 reflectors placed (14.3%). The indications for multiple reflector placement in the same breast included multiple separate lesions (n = 23) and bracketing of large lesions (n = 19) (Table 1).

We performed a subset analysis of patients with bracketing reflectors. The mean distance between the reflectors was 42 mm (SD 22 mm). The closest distance between the two reflectors was 22 mm and the farthest was 93 mm.

There were no failures in localization. Removal of the targeted lesion and retrieval of reflectors were successful in all cases. Specimen radiograph was obtained for all patients and demonstrated 90 reflectors in 42 patients, resulting in a 100% retrieval rate in the first specimen. Among the 39 malignant lesions excised, 10.3% (n = 4) demonstrated a positive margin, and 10.3% (n = 4) demonstrated close (<1 mm) margins. Of the subset of patients undergoing bracketed lumpectomy, 2 patients had a positive margin. All patients with positive margins underwent re-excision. No complications occurred with placement or removal of the reflectors. There were no postoperative complications.

4 | DISCUSSION

Bracketing technique was first described by Silverstein et al[23,24] in 1987. They suggested that large areas of disease may be better excised when the boundaries are delineated with multiple wires. Often, patients with extensive disease who undergo breast conservation risk positive margins. This may result in multiple re-excisions or ultimately mastectomy. Bracketing techniques for DCIS or invasive disease allow the boundaries of extensive disease to be demarcated. Feasibility of this technique has been proven using localization wires and radioactive I-125 seeds.[18-24] Our study focused on the feasibility and outcomes of surgical excision utilizing two or more SAVI SCOUT reflectors.

Our results demonstrate the feasibility and success of our technique of using more than one reflector in a single breast for either bracketing or for excision of multiple primary lesions. Our study shows that up to three reflectors may be placed in the same breast with successful reflector placement and lesion excision in the setting of bracketing or excision of more than one lesion. We placed reflectors at mean of 42 mm with reflectors placed as close as 22 mm apart. The manufacturer recommendation is to place reflectors at least 2.5 cm apart; this is to optimize distinguishable signals. In our experience, despite close proximity, two distinguishable signals were present from two SAVI reflectors as close as 2.2 cm apart with no specific changes to the handling of the probe. When approaching >1 reflector surgically, initial identification of at least 1 SAVI reflector can orient the surgeon to identify additional SAVI reflectors utilizing the provide post-SAVI reflector placement mammographic images. And in our experience, the cases with closer reflectors did not take longer than cases with reflectors that are further apart.

TABLE 1 Outcomes of multiple SAVI SCOUT localizers

Outcome	Rate, %, *n* (n = 42)
Localization success (bracketing and multiple lesions)	100% (42)
Two reflectors placed	85.7% (36)
Three reflectors placed	14.3% (6)
Bracketing technique	45.2% (19)
Positive margins	10.3% (4)
Close margins (<1 mm)	10.3% (4)

The above reflects the outcomes of 42 patients who underwent excision of 68 lesions.

Beginning in 1990, the National Institutes of Health released a statement endorsing breast-conserving therapy (BCT) as the surgical treatment of choice for women with early-stage breast cancer.[25] The goal of BCT is to obtain adequate oncologic control without compromising cosmesis. Positive margins, defined as tumor-on-ink for invasive disease, remain a challenge. The current re-excision rate documented in the literature varies between 15% and 40% with the positive margin rate in patients undergoing wire-bracketed lumpectomy varies from 21% to 60%.[18-21] Positive margins for I-125 bracketed lumpectomies were comparable at 34%.[22] In our study, 10.3% (n = 4) of malignant cases demonstrated positive margins (tumor on ink) requiring re-excision and 10.3% (n = 4) cases demonstrated a close margin of <1 mm. This is comparable to reported positive margin rates for both radioactive seed localization and wire localization with margin positivity in 21.1% and 26.3% of cases, respectively.[9] Among the bracketed cases, 10.3% (n = 2), while 10% (n = 2) of cases with two or more discrete excisions demonstrated positive margins.

Oncoplastic surgery (OPS) emerged in the mid-1980s and has gained significant popularity. Initially intended to improve cosmesis and decrease indications for mastectomy, OPS has provided better esthetic outcomes for patients electing breast conservation. The marriage of bracketed lumpectomies and OPS with contralateral reduction mastopexy allows an option for excellent cosmesis. However, due to the large tissue rearrangement, positive margins may require mastectomy. The placement of the incision can affect potential future procedures, including mastectomy. As the SAVI SCOUT reflector has no external component, incisions may be placed at the discretion of the breast and plastic surgeons to optimize cosmesis. This allows the surgeon to consider patient habitus and contralateral procedure of choice as he or she chooses from any number of oncoplastic incision techniques to best preserve the vascular supply to the remaining skin and pedicle. Similar to radioactive seed localization, the SAVI SCOUT reflector provides a point source allowing intraoperative reorientation, which is typically more critical during bracketed procedures with oncoplastic reconstruction than with traditional segmentectomies.

The limitations of SAVI SCOUT reflector placement include inability to reposition the reflector once placed as it could result in disruption of the antennae and inability to quantify the depth at which the reflector is encountered. Per the manufacturer, placement of the SAVI SCOUT reflector deeper than 4.5 cm may interfere with

detection.[16] As it is difficult to estimate the true depth of a lesion based on compression mammographic images, sonographic images in the supine position may be more concordant with surgical findings. This potential limitation may also play a role in women with larger breasts and deeper lesions. Although both the SAVI SCOUT localizer and radioactive seed techniques are more costly upfront than wire localization, the potential savings in OR efficiency and scheduling may prove worthwhile long-term. Our study is limited as it is a single-institution retrospective review of small number of patients without direct comparison to our wire localization cases.

5 | CONCLUSIONS

The use of the SAVI SCOUT localization system for localization of nonpalpable breast lesions in cases necessitating bracketing or excision of multiple lesions is technically feasible and safe. The placement of multiple SAVI SCOUT fiducial markers in a single breast does not result in interference even when placed at a minimum of 22 mm apart. This novel technology may be used as an alternative to wire localization for bracketed segmentectomies.

DISCLOSURE

None.

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