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

Priya H. Jadeja MD1 | Victoria Mango MD2 | Sejal Patel MD3 | Lauren Friedlander MD3 | Elise Desperito MD3 | Everick Ayala-Bustamante MD3 | Ralph Wynn MD3 | Margaret Chen-Seetoo MD1 | Bret Taback MD1 | Sheldon Feldman MD4 | Richard Ha MD3

1Columbia University Medical Center, New-York Presbyterian Hospital, New York, NY, USA
2Department of Radiology, Memorial Sloan Kettering Cancer Center, New York, NY, USA
3Department of Radiology, Columbia University Medical Center, New York, NY, USA
4Montefiore Hospital and Medical Center, Bronx, NY, USA

Correspondence
Richard Ha, Department of Radiology, Columbia University Medical Center, New York, NY, USA.
Email: rh2616@cumc.columbia.edu

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.\textsuperscript{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.\textsuperscript{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\textsuperscript{2}; 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.\textsuperscript{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.

\section{METHODS

\subsection{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.

\subsection{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.

\subsection{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.

\section{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-risk, and
The above reflects the outcomes of 42 patients who underwent excision of 68 lesions.

**TABLE 1** Outcomes of multiple SAVI SCOUT localizers

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rate, %, n (n = 42)</th>
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<tbody>
<tr>
<td>Localization success (bracketing</td>
<td>100% (42)</td>
</tr>
<tr>
<td>and multiple lesions)</td>
<td></td>
</tr>
<tr>
<td>Two reflectors placed</td>
<td>85.7% (36)</td>
</tr>
<tr>
<td>Three reflectors placed</td>
<td>14.3% (6)</td>
</tr>
<tr>
<td>Bracketing technique</td>
<td>45.2% (19)</td>
</tr>
<tr>
<td>Positive margins</td>
<td>10.3% (4)</td>
</tr>
<tr>
<td>Close margins (&lt;1 mm)</td>
<td>10.3% (4)</td>
</tr>
</tbody>
</table>

Note: 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.
detection.\textsuperscript{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 is 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.

ORCID

Priya H. Jadeja  \textsuperscript{10} http://orcid.org/0000-0001-7643-4997

REFERENCES