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Gamma Finder™ III

Wireless Gamma Detector

GammaFinder™ III Wireless Gamma Detection Device
Indications for use: The Gamma Finder™ III is intended for the detection of gamma radiation in the energy range from 20 keV to 512 keV. The Gamma Finder™ III is indicated for the extra- and intra-operative detection of radioactively labelled substances mainly in the fields breast cancer and malignant melanoma. Contraindications: Dosimetric applications, detection of radiation other than gamma, and detection of radiopharmaceuticals with radiation energies outside the above listed energy range are contraindicated. Safety notes: 1. Only trained technicians and qualified personnel may use the device. 2. U.S. law stipulates that this device be used only by a physician or under supervision of a physician.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and directions for use.

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COMMENTARY

A single-institution analysis of reflector-guided localization using SAVI SCOUT® in nonpalpable breast carcinoma compared to traditional wire localization

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Breast-conservation therapy (BCT), now considered standard of care, was introduced as an alternative to total mastectomy in patients with early-stage breast cancer. Preoperative image-guided wire localization (WL) has traditionally been used to help surgeons localize these nonpalpable tumors.[1] WL is typically performed on the day of surgery, which may lead to scheduling conflicts with the surgical and radiology teams. In addition, the external wire component may be displaced and often causes patient discomfort. To circumvent this issue, alternative localization modalities such as radioactive iodine seed, magnetic seed, radiofrequency identification device (RFID) seed, or infrared-emitting SAVI SCOUT® (SS) reflector devices have been recently developed.[2–4]

We describe our experience with the SS (Merit Medicals) reflector device as a new alternative to the traditional WL technique in the setting of BCT. We began using SS for localization in early 2017. Prior to that date, all our localizations were done by the WL technique.

We did a preliminary retrospective analysis, under an IRB approval, comparing the novel SS and traditional WL methods. The excision volume, maximum tumor dimension, and margin positivity rate were compared between the SS and WL groups. Analysis of variance and Student's *t* test were used for statistical analysis of continuous data, and the chi-square distribution test was used for categorical data. The Kolmogorov-Smirnov test was performed to confirm normal distribution of the data. *p* values were calculated with a *p* value of <0.05 defined as significant. Margin positivity was defined as having tumor on ink for either invasive or in situ carcinoma. Specimen volume was then calculated in cm^3 by multiplying the three dimensions of the specimen. In cases when additional margin excisions were performed following removal of the main specimen during the same surgery, the volume of the additional margins was added to the volume of the main excision specimen.

The traditional WL was performed in the radiology department on the day of planned lumpectomy. Ultrasound or mammographic guidance was used for placement of the 20 G Hawkins needle (Argon Medical Devices). The needles were placed percutaneously in the region of interest in the breast. Standard 2 view mammograms (CC and ML) were obtained postprocedure and the site of tumor circled, to help surgical planning.

The procedure for SS reflector (Merit Medical System) placement was also performed by the radiologists with initial needle placement technique like WL. However, in the SS procedure, the radiologist instead deployed a 12-mm reflector at the target site. The reflector position was confirmed on a subsequent mammogram as described above. In addition, a cadence test was performed immediately postprocedure to confirm the SS reflector was in the breast with a detectable signal.

Out of a total of 518 needle localization cases between the period of July 2018 and March 2020, 325 patients met inclusion criteria (exclusions included benign indications, prior neoadjuvant chemotherapy, and palpable masses). The distribution of breast carcinoma was 227 invasive ductal carcinoma (IDC), 62 ductal carcinoma in situ (DCIS), and 36 invasive lobular carcinoma (ILC). Of the 325 patients, 202 had SS excisions and 123 had WL. The excised specimen volume, tumor volume, margin positivity, histology subtype of the breast cancer were recorded as outlined in Table 1.

TABLE 1 Comparison of various SAVI SCOUT localization and wire localization specimen and tumor parameters with corresponding *p* values

	SAVI SCOUT© (n=202)	Wire Localization (n=123)	*p* value
Specimen volume (mean, cm^3)	114.14 ± 100.18	157.43 ± 145.47	0.002
Overall tumor size (mean, mm)	151.7 ± 11.2	152.7 ± 12.3	0.517
DCIS size (mean, mm)	211.9 ± 15.9	350.3 ± 14.1	0.004
Invasive tumor size (mean, mm)	135.4 ± 8.94	134.8 ± 9.53	0.957
Margin positivity, total	8.4% (17/202)	13.8% (17/123)	0.123
Positive margin, by histologic subtype			
DCIS	23.5% (4/17)	35.3% (6/17)	0.452
IDC	53.0% (9/17)	23.5% (4/17)	0.078
ILC	23.5% (4/17)	41.2% (7/17)	0.271

Some of the shortcomings of the WL technique were the inconveniences related to the timing of wire placement, longer wait times for patients presurgically, and its potential for displacement and patient discomfort. In 2014, the SS surgical guidance system was cleared by the FDA after pilot studies showed its reliability in localizing nonpalpable breast lesions. For surgeons, SS is preferred for multiple reasons such as patient flow and time in the hospital on operative day, reduction in discomfort associated with wire protrusion, reduced risk of localization migration or dislodgement, operative case flexibility if cases require day of adjustment, incision site decision, lesion localization, confirmation of target removal in the operating room, with ability to obtain preliminary assessment of distance to target as surrogate of margin assessment.[2–4]

To our knowledge, to date, only one study has been conducted comparing SS localization to traditional WL. In that study of 84 subjects, Patel et al. showed no significant difference in the volume of tissue excised between the two techniques.[5] Furthermore, the study showed that patients who underwent SS localization had higher rate of positive margins compared to those who had WL (9% vs. 7.1%). In contrast, our study demonstrates that patients who underwent localization excisions using SS had lower positive surgical margin rates (8.4%) compared to those with similar-sized breast carcinomas who underwent WL excisions (13.8%), independent of tumor size and histologic subtype. Furthermore, this reduction in positive margin rates was associated with a statistically significant reduction (27.5%) in the volume excised, even after the addition of volume of scouting margins that are taken in select cases. Based on our data, SS localization procedure can provide breast cancer patients with lower excision volumes ($p < 0.002$), which may be associated with improved cosmetic outcomes, without compromising margin status, when compared with the traditional WL technique.

As with any new technology, SS is not without limitations. The reflector, like biopsy clips, cannot be repositioned once deployed and can migrate slightly from the original deployment position. The reflector can also be disabled by electrocautery equipment during surgery. Cost is another potential limitation because the SS localization system requires an initial capital purchase of the console and delivery system; and following the capital purchase, there is the additional cost of the disposable purchase per procedure.

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