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SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting☆

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ABSTRACT

Objective: The purpose of our study was to determine the frequency of successful SAVI SCOUT® localizations, to identify the factors contributing to unsuccessful procedures, and to provide a problem-solving algorithm to address those factors.

Subjects and methods: This retrospective study was performed following IRB approval. We included all consecutive patients with SCOUT® reflector placement performed at a single tertiary-care cancer center. Each case was reviewed and the following data were recorded: patient age, breast density, localization target, imaging modality used for guidance, post procedure mammogram reflector to skin and reflector to target distances, presence of the reflector in the specimen radiograph, excisional biopsy pathology and any procedure complications.

Results: In 129 women, 152 SAVI SCOUT® reflectors were placed. Most patients had only 1 reflector placed, but 19 (15%) women had multiple reflectors placed for the purposes of bracketing, multiple excisions in 1 breast, bilateral excisions, or any combination thereof. The most common target was a mass (65%) and the most common modality for guidance was ultrasound (73%). SAVI SCOUT® localization was successful in 97%of reflectors, including 89% of reflectors targeting axillary lymph nodes. The most common failure encountered was the inability to obtain a signal in the radiology suite, due to (1) excessive target depth for the radiology suite handpiece and console, (2) obscuration by a hematoma, or (3) faulty reflector. No post-operative complications occurred.

Conclusion: The SAVI SCOUT® surgical guidance system is an accurate and reliable method for localization of non-palpable breast lesions, bracketing, and axillary lymph nodes.

1. Introduction

Since the implementation of screening mammography in the 1980's, detection of non-palpable, early stage breast cancers has increased, and as such, so has breast conservation surgery [1]. Image guided wire localizations (WL) of nonpalpable breast lesions have been the mainstay of surgical excision since wire development in the 1970s [2]. However, several disadvantages of wire localizations include wire breakage/transection, wire migration, patient discomfort, discrepancy between wire entry site and preferred surgical approach, and, scheduling constraints due to wire placement coordination with the surgery time [3–6]. In recent years, new devices have been developed to help overcome the disadvantages with WL, such as ^{125}I-radioactive seed localizations (RSL), MagSeed®, and wireless radiofrequency identification (RFID) system [5–8]. The most widely adopted alternative is RSL; however, seeds introduce radiation safety concerns, resulting in limited adoption of the technique [5, 6].

The SAVI SCOUT® surgical guidance system was approved by the U.S. Food and Drug administration in 2014. The methodology has been previously described in detail [3–6]. Briefly, a nonradioactive infrared (IR)-activated electromagnetic wave reflector is implanted into the breast under imaging guidance. Because reflector deployment is similar to biopsy clip placement, very little training is required for the radiologist. The reflector is typically placed under ultrasound or mammographic guidance, and an audible signal from the implanted reflector is then detected percutaneously using the manufacturer's handpiece-and-

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console system [6].

At our institution, we implemented the SAVI SCOUT® infrared-activated electromagnetic wave reflector device placements as an alternative to wire placements. The purpose of our study was to measure the frequency of successful localization on nonpalpable breast lesions using SAVI SCOUT® as well as to identify factors contributing to unsuccessful procedures.

2. Methods & materials

This single-institution, retrospective study was Health Insurance Portability and Accountability Act compliant and Institutional Review Board approved. Patient informed consent requirement was waived. No financial support was provided from Cianna Medical (Cianna Medical, Aliso Viejo, CA). From our institutional database, we retrospectively identified all consecutive patients with SAVI SCOUT® reflector image guided placements and subsequent excision performed between November 2016 and August 2017.

Image guided percutaneous reflector placement was performed by 1 of 7 sub-specialized breast radiologists (1 to 12 years of experience), and excision was performed by 1 of 6 sub-specialized breast surgeons. At the time of radiology-pathology correlation, the radiologist stated if the findings were eligible for SCOUT® reflector localization based on the manufacturer's guidelines. At the time of our study, the SAVI SCOUT® reflector was approved for up to 30 days of implantation.

Ultrasound guided reflector placements were performed in real time under local anesthesia. Mammographic guided reflector placements were performed under local anesthesia and utilized an alphanumeric grid and orthogonal views, similar to that previously described for wire localizations [9]. Due to the presence of ferromagnetic elements, the SCOUT® reflector is MR conditional while the delivery system is not recommended for use in the MR environment [10]. One MRI guided bracketed reflector placement was performed utilizing the grid method with a Sentinelle dedicated breast biopsy table (Invivo Corporation, Gainesville, FL) and Aegis software (Hologic, Inc., Marlborough, MA).

After reflector placement and prior to leaving the procedure room, each reflector's audible signal was verified with the manufacturer's handheld probe and console system by the breast radiologist. The probe emits transcutaneous electromagnetic waves and infrared light and in return receives an electromagnetic wave signal from the reflector, which is confirmed by an audible beep [4]. During the study time period, the SCOUT® console in the radiology suite was approved to obtain signal from a reflector placed ≤5 cm in depth. After confirming reflector function, post procedure mammography was performed to verify reflector position. On the day of surgical excision, the surgical specimen radiograph was reviewed by one of the breast radiologists while the patient remained in the operating room.

For each reflector placement within our data set, one of four board-certified breast radiologists (S.F., R.J.W., B.M., and B.L.N.) reviewed each patient's images and electronic medical record. On post-procedure mammography, the reflector to target distance and the skin to reflector depth were measured using electronic calipers on a SecurView Breast Imaging Workstation (Hologic, Inc., Marlborough, MA). Target depth was measured on the ultrasound guided SCOUT® localization images by using electronic calipers on our Picture Archiving and Communication System. Reflector presence within the surgical specimen was recorded. Details and complications related to the procedures were investigated using our electronic medical record. SCOUT® procedures were categorized as successful if they met the following four criteria documented in the medical record: 1) successful deployment at the targeted abnormality, 2) audible reflector signal using the console in the radiology suite, 3) audible reflector signal using the console in the operating room, and 4) specimen radiograph containing an intact reflector as well as the localized target. Descriptive statistics were calculated using Microsoft Excel Software 2010 (version 14.0, Redmond, WA), and exact binomial confidence intervals were computed for patient-level and reflector level analyses.

Table 1
Imaging modality and targets.

	Number of reflectors (%) N = 152
Imaging modality	
Mammography	39 (26%)
Ultrasound	111 (73%)
MRI	2 (1%)
Imaging finding targeted for localization	
Mass	99 (65%)
Calcifications	13 (9%)
Clip	26 (17%)
Axillary lymph node	9 (6%)
Architectural distortion	3 (2%)
Other[a]	2 (1%)

[a] Includes hematoma and post-surgical bed with positive margins.

3. Results

Of 524 image-guided localizations performed at our institution during the study time period, 152 (152/524 = 29%) reflectors were placed in 129 women (average age, 62 years; age range 33–90 years). The most common breast density was scattered fibroglandular (50%), followed by heterogeneously dense (38%), almost entirely fatty (11%) and extremely dense (1%). The majority (73%) of reflectors were placed with sonographic guidance due to radiologist preference, and a mass was the most frequent imaging finding targeted for SAVI localization (Table 1). In addition, 6% of the reflectors were placed outside of the breast in an axillary lymph node. The average reflector-to-target distance was 0.6 mm (range: 0 to 14 mm). The average depth from skin to target on ultrasound was 1 cm (range: 0.4 to 2.5 cm). On post procedure mammogram, the average closest distance from skin to reflector was 3.2 cm (range: 0.4 to 8.5 cm). Reflectors were placed 0–27 days prior to surgery (average 6.9 days, median 7 days).

SCOUT® localization was successful in 125 [125/129 = 97%; 95% confidence interval (CI) 92–99%] patients and 148 [148/152 = 97%; 95%CI 93–99%] reflectors. Of the 4 unsuccessful cases, 3 were due to inability to obtain an audible signal.

In the first of the 3 cases with SCOUT® audible signal failures, the reflector signal was neither detected at the time of placement in the radiology suite with the radiology console nor at the time of surgery in the operating room with the surgery console. This patient underwent SCOUT® reflector bracket of calcifications in heterogeneously dense breasts with oncoplastic reduction. The specimen radiographs demonstrated the targeted clip, calcifications, and one reflector but not the inaudible reflector. The surgeon anecdotally visualized the inaudible reflector during surgery. The audible failure was ultimately attributed to a faulty reflector (Fig. 1).

In the second patient, the radiologist could not obtain audible signal immediately after reflector placement using the radiology console. The reflector was placed into a biopsy proven metastatic level I axillary lymph node that was 1.6 cm deep from the skin on ultrasound. On the post procedure mammogram, the reflector was 8 cm from the skin margin but seen on the axillary tail view only. On the day of surgery 7 days later, because of the lack of audible signal, the patient was brought back to the radiology suite with plan for wire localization. Given the close distance of the lymph node to skin on ultrasound, the audible signal was rechecked with the radiology console, but again not acquired. Finally, because the operating room console has enhanced technical capabilities as compared to the radiology console, it was brought to the radiology suite, and audible signal was obtained without difficulty. Therefore, no wire was placed (Fig. 2).

The third case of audible signal failure was due to reflector placement associated with a hematoma. The patient underwent ultrasound