



Breast Imaging

SAVI SCOUT® localization of breast lesions as a practical alternative to wires: Outcomes and suggestions for trouble-shooting[☆]Shannon Falcon^{*}, R. Jared Weinfurtner, Blaise Mooney, Bethany L. Niell

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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/transsection, 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 ¹²⁵I-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

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.

reflector level analyses.

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

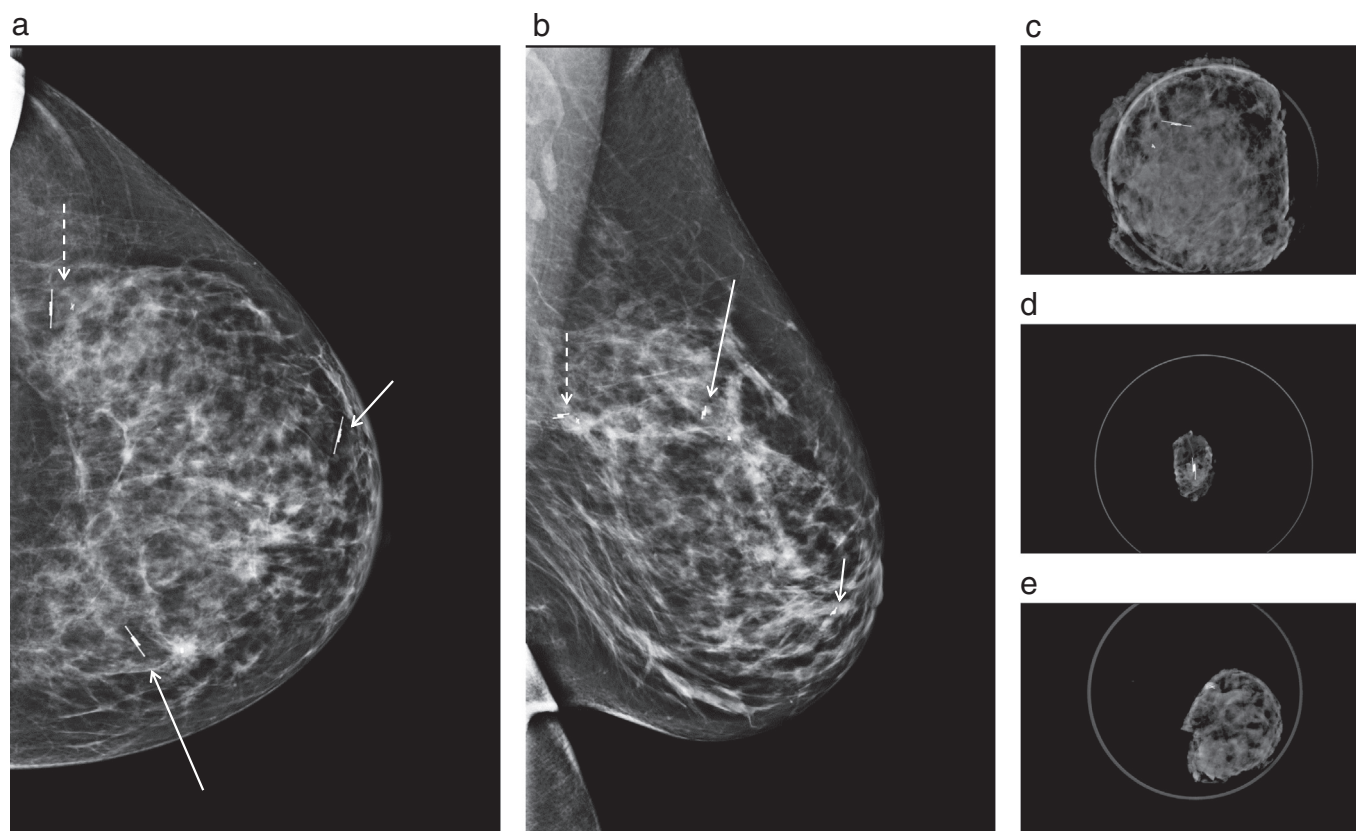


Fig. 1. A 57 year old female presented for oncoplastic reduction with mammographic guided SAVI SCOUT® localization of malignancy and atypia in the left breast. Left post-procedure digital mammograms in the CC projection (a) and the 90 degree lateromedial projection (b) demonstrate 3 SAVI reflectors: posterior bracket with calcifications and top hat clip at 11 o'clock (long arrow) denoting site of microinvasive ductal carcinoma, anterior bracket at subareolar calcifications associated with anterior extent of disease on pre-operative breast MRI (short arrow), and non-bracketed localization of atypia at the X shaped clip at 1 o'clock (dash arrow). The specimen radiographs from the bracket demonstrate a SAVI reflector and top hat clip from the posterior extent (c) and the SAVI reflector from the anterior extent (d). The X shaped clip is seen in the third specimen radiograph without the SAVI reflector (e). Negative final surgical pathology margins were documented.

guided biopsy at an outside institution. At the time of localization, the originally biopsied mass was no longer identified within the scattered fibroglandular density breast and only a hematoma remained. The SCOUT® reflector was placed under ultrasound guidance using the hematoma as the target. The signal was not detectable at the time of placement; however, it was detectable with the radiology console on the day of surgery, 13 days later, after the hematoma decreased in size from 4.2 cm to 3.2 cm.

The fourth and final case of SCOUT® failure relates to the surgical specimen. Ultrasound guided reflector placement targeted a clip that denoted the site of discordant pathology within the heterogeneously dense breast. The ultrasound images and the post-procedure mammogram demonstrate successful reflector placement at the clip and audible signal was confirmed in the radiology suite. The audible signal was reportedly used for localization in the operating room; however, the clip was not within the surgical specimen. Final excisional biopsy pathology demonstrated that the targeted biopsy site was within the surgical specimen but without the clip. Follow-up mammogram performed 1 year after surgery demonstrated the clip remained in the breast with lateral migration as compared to the post-placement mammogram. It is unclear if migration occurred after the post-procedure mammogram and prior to surgery, or if migration occurred during the surgery itself (Fig. 3).

Nineteen (15%) patients had > 1 reflector placed (Table 2) for bracketed, non-bracketed, and/or bilateral localizations (Table 3). The mean distance between two reflectors within the same breast was 7.9 cm (range: 2.2 to 17.8 cm). Audible signals obtained for individual reflectors were acquired in the radiology suite and operating room

irrespective of the distance between the reflectors.

No procedure-related or post-procedure complications occurred. We did not observe any vasovagal events during reflector placement, perhaps because the patients are able to eat and drink before the procedure. There were no reflector migrations observed on the post-procedure mammograms or reflector transections seen on the surgical specimens.

4. Discussion

Previous studies have demonstrated the SAVI SCOUT® system to be a reliable substitute for WL or RSL excision of non-palpable breast lesions with successful reflector placement under sonographic guidance (32.5 to 64%) or mammographic guidance (36% to 67.5%) [3–6, 11]. In our study, SCOUT® localization was 97% successful, similar to the 90–100% reported frequencies of successful localizations using wire, RSL, or SCOUT® [5–7, 12, 13]. Our study confirms the feasibility of placing up to 3 SCOUT® reflectors in one breast, as close as 2.2 cm apart. Mango et al. previously reported successful separate transcutaneous audible reflector signals from up to 3 reflectors in the same breast placed 2.6 cm apart [6]. More recently, Jadeja and colleagues demonstrated successful SCOUT® localizations in 183 patients, 42 of whom had multiple reflectors placed (up to 3 in one breast) with a mean distance of 4.2 cm between reflectors and as close as 2.2 cm apart [14].

In our study, we also report the feasibility of SCOUT® reflector placements into axillary lymph nodes. We routinely place biopsy clips into fine needle aspirated proven metastatic lymph nodes at the time of biopsy (utilizing on-site cytology) to facilitate targeted axillary

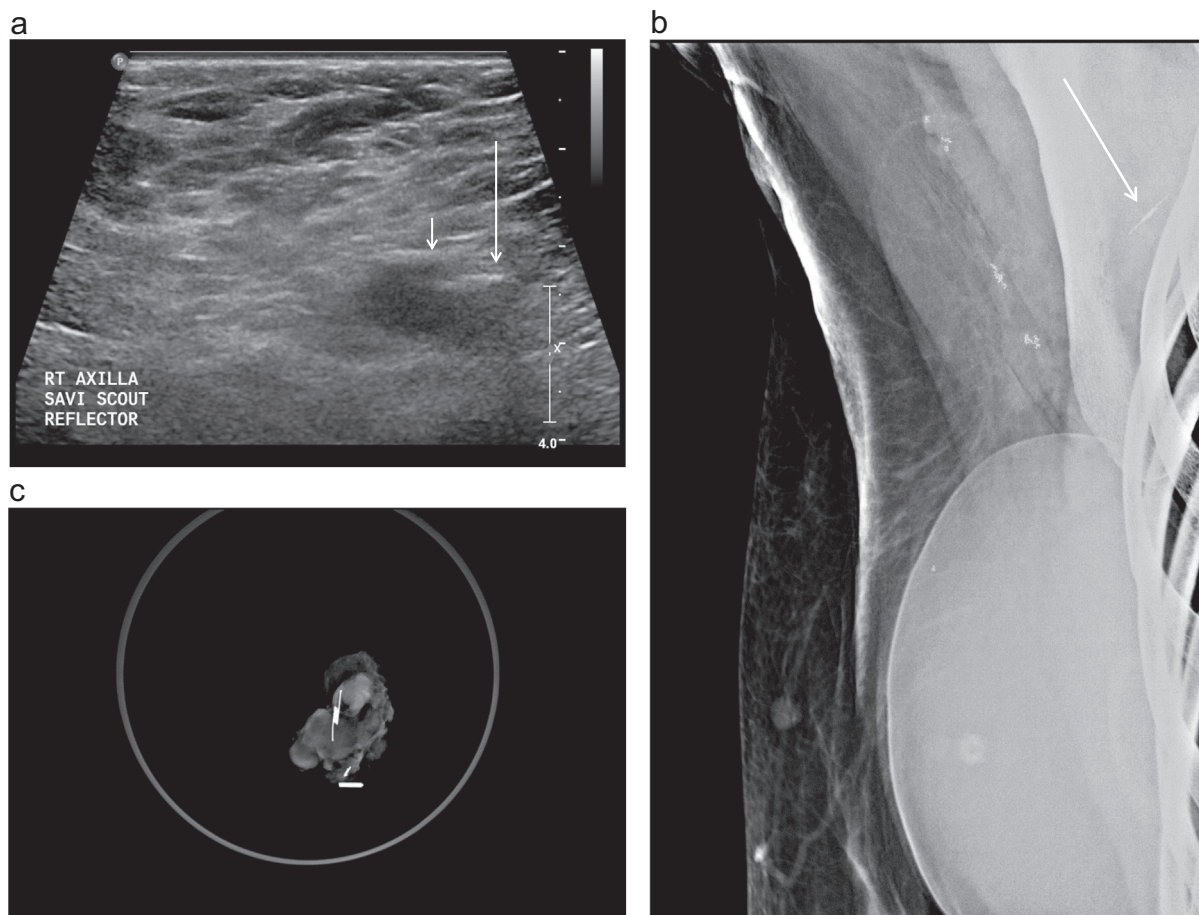


Fig. 2. A 56 year old female presented for ultrasound guided SAVI SCOUT localization of a biopsy-proven metastatic right axillary lymph node. Ultrasound image (a) of the right axilla demonstrates a lymph node (short arrow) with associated SAVI reflector (long arrow). No signal was obtained with the console in the radiology suite immediately following reflector placement. Post procedure mammogram (b) of the right axilla confirms SAVI reflector placement (arrow), which is 8 cm from the skin. On the day of surgery, audible signal was obtained with the surgery console in the radiology suite. Specimen radiograph (c) demonstrates successful excision of SAVI reflector and lymph node.

dissections. Neoadjuvant chemotherapy presents a unique setting in which the clip and/or lymph node may not be well visualized at the time of localization. Thus, in light of recent approval for life-long reflector implantation, the radiologist and surgeon may discuss reflector placement prior to initiation of neoadjuvant chemotherapy if targeted axillary dissection is planned.

Compared to wire localization, a cited potential disadvantage of the reflector is the inability to move or retrieve the reflector once deployed [15]; however, we did not encounter this problem, as all SCOUT® reflector placements in our study were reported successfully placed at the target site. Our challenging cases most often resulted from failure to obtain audible signal from the reflector in the radiology suite, as demonstrated by the cases that include a faulty reflector, an axillary lymph node, or hematoma.

The original SAVI SCOUT® console was approved to detect reflectors placed up to 5 cm in depth, and the next generation SAVI SCOUT® console is approved for 6 cm depth [16]. Although use of the next generation console may alleviate some cases of undetectable signal due to reflector placement depth, in our experience, depth was rarely the culprit. While the distance on post-biopsy mammography yielded measurements from target to skin beyond 5 cm, the measurements on ultrasound did not exceed 2.5 cm, which is well within the manufacturer's recommendation regarding maximal depth of placement. This difference highlights how patient positioning impacts distance from skin and may be exaggerated on mammography. When implementing a SCOUT® program, it is important to realize this distinction and not

confuse mammographic depth with the manufacturer's recommended depth.

Based on our experience, we developed the following algorithm for radiologists to utilize when they place a reflector but cannot acquire audible signal in the radiology suite. First, position the patient slightly differently and repeat the attempt to acquire reflector signal. The radiologist should move the console handpiece slowly to permit the radar signal adequate time to return from the reflector. When verifying signal in the radiology suite, many users will cover the console handpiece with sterile plastic for infection control purposes. Because certain plastics (e.g. sterile gloves) may adversely impact infrared transmission, the manufacturer suggests clear plastic. If reflector signal is still not heard despite proper probe coverage and changes in patient positioning, additional trouble shooting should be performed as follows.

Next, ensure that the reflector is not still in the needle. Because the deployment device requires unsheathing the reflector, rather than the more frequent end deployment of biopsy clip devices, operator error may occur. If the reflector remains in the needle, then repeat placement with a new device. The presence of air along the needle tract may obscure detail on ultrasound, therefore, if the reflector is not well identified, as the next step, post-procedure mammography should be obtained to verify that the reflector was successfully deployed.

We described a case where signal was not obtained in the radiology suite but was obtained with the operating room SCOUT® console. The consoles in radiology and the operating room may be different. The operating room console has enhanced technical capabilities that are

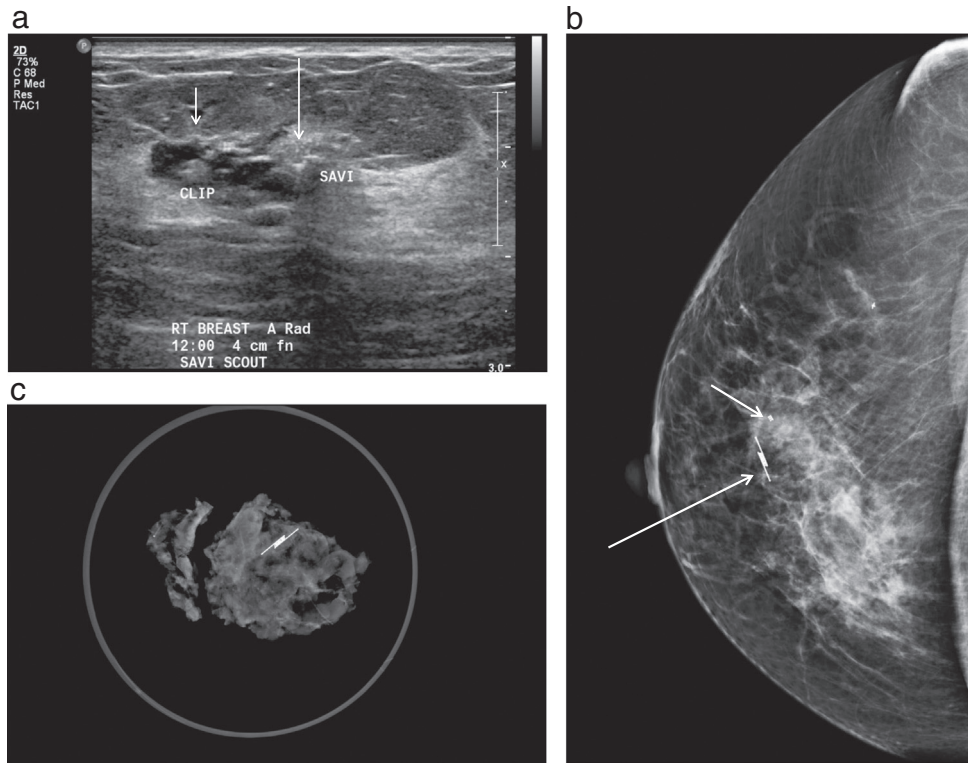


Fig. 3. A 52 year old female presented for ultrasound guided SAVI SCOUT localization of a biopsy clip in the right breast due to discordant histology. Ultrasound image (a) demonstrates post-procedure changes with clip (short arrow) and associated SAVI reflector (long arrow) within 1 cm. Right post procedure mammogram in the CC projection (b) demonstrates the SAVI reflector (long arrow) associated with the coil shaped biopsy clip (short arrow). Of note, an X shaped clip is also present from prior benign biopsy. The specimen radiograph (c) demonstrates the SAVI reflector but no coil clip. Follow-up mammogram performed 1 year after surgery in the CC projection (d) demonstrates absence of the SAVI reflector but migration of the coil clip laterally (arrow). Final surgical pathology revealed complex sclerosing lesion with previous biopsy changes.

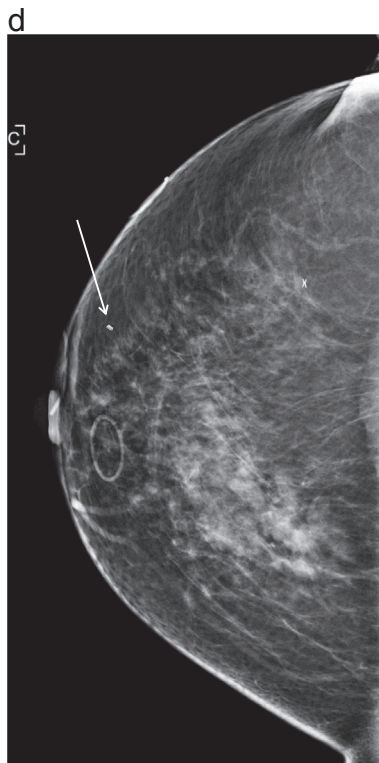


Fig. 3. (continued)

Table 2
Number of multiple reflector placements.

Number of reflectors	Number of patients (%) N = 129
1	110 (85)
2	15 (12)
3	4 (3)

Table 3
Types of multiple reflector procedures.

Procedure type	Number of patients (%) N = 19
Bracketed excision	7 (37)
Non-bracketed excision	3 (16)
Bilateral excision	6 (31)
Combination of 2 of the above ^a	3 (16)

^a Three patients had multiple reflectors due to multiple same day procedures, including two patients with bracketed excision and bilateral excision as well as one patient with non-bracketed excision and bilateral excision.

useful in the operating room but at an incremental cost increase beyond what may be routinely necessary for the radiology suite. If the consoles are different and reflector deployment has been confirmed on mammography, attempt to obtain audible reflector signal using the operating room SCOUT® handpiece and console.

The reflector signal may be dampened or obscured by dense objects overlying the reflector. Mango et al. evaluated 122 excised reflectors in 100 women and reported 2 cases of transcutaneous signal failure due to hematoma and 1 case of signal failure due to a densely calcified

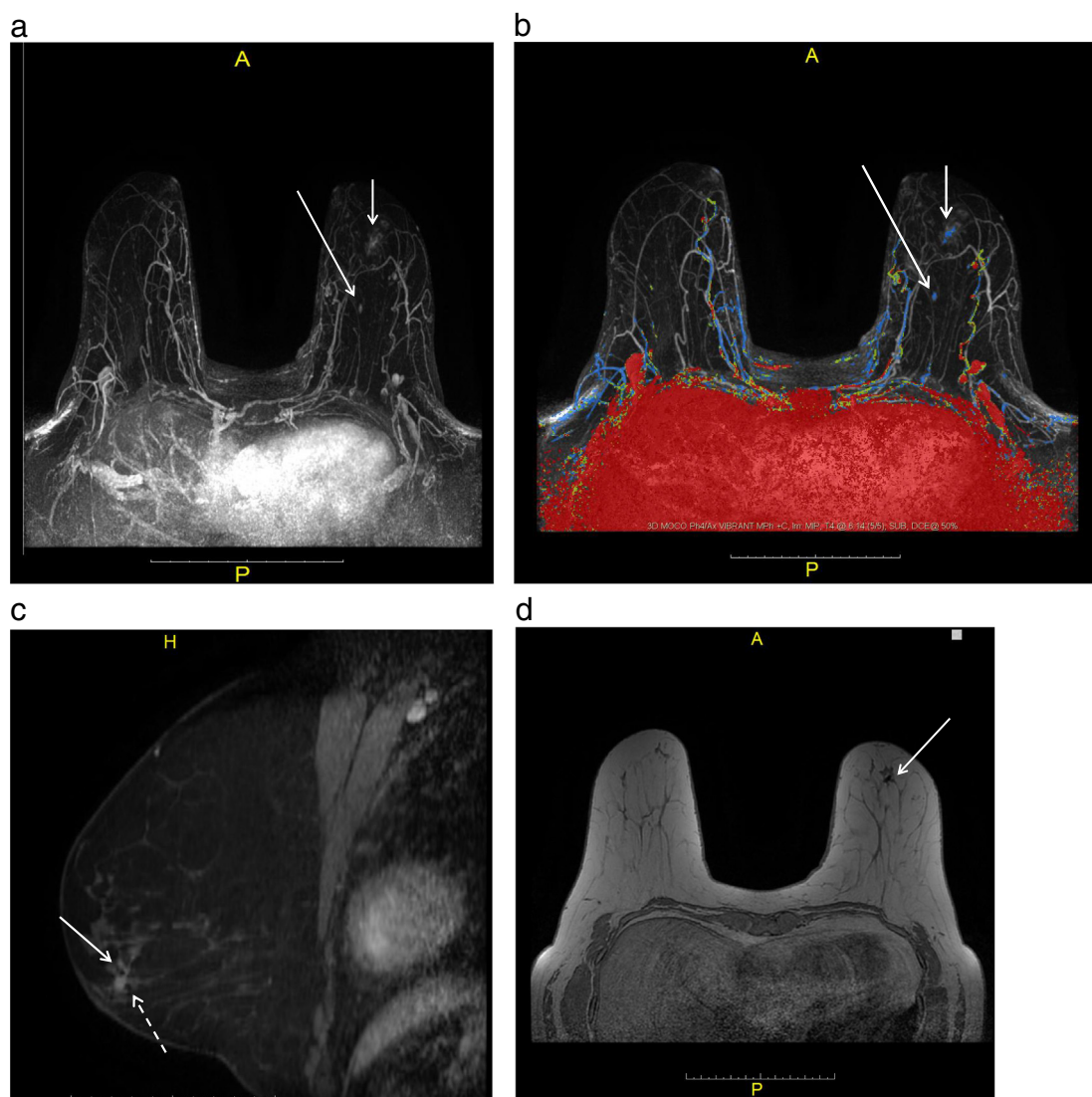


Fig. 4. A 72 year old female presented from an outside institution with ultrasound guided biopsy proven IDC with top hat clip in good position. Mammographic guided SAVI reflector localization of the top hat clip was performed prior to pre-operative MRI due to a scheduling issue. Subtracted post-contrast maximum intensity projection MRI images without color overlay (a) and with color overlay (b) demonstrates the site of biopsy proven IDC with SAVI reflector (short arrow) as well as an additional focal area of non-mass enhancement at a separate site (long arrow). A reformatted sagittal T1 post-contrast, fat suppressed MRI image (c) and axial T1 image (d) demonstrate signal void from reflector associated with the known malignancy (short arrow). Top hat biopsy clip signal void associated with the known malignancy is also demonstrated on the sagittal image (dashed arrow). Subsequent MRI guided biopsy of the separate focal area of non-mass enhancement revealed buckle shaped clip in expected position. On the day of surgery, mammographic guided wire localization of the buckle clip was performed. Left post procedure mammograms in the CC projection (e) and the 90 degree mediolateral projection (f) demonstrate successful wire localization of the buckle clip denoting ILC in the central left breast (long arrow), and the SAVI reflector at the 6 o'clock top hat clip denoting site of IDC (short arrow). A single specimen radiograph (g) from oncoplastic reduction demonstrates the biopsy clips, SAVI reflector and intact wire.

fibroadenoma; after skin incision, all 3 reflectors were audible [6]. The presence of a hematoma obscured transcutaneous signal in one of our patients at time of placement which was later detectable with decreased hematoma size. Therefore, a reflector should not be placed within or posterior to a hematoma. If lack of signal is thought to be due to hematoma, the patient can be brought back on the day of surgery to evaluate for decreased hematoma size and thus signal. If audible signal remains undetectable, a wire could then be placed. Similarly, wires anterior to the reflector may decrease the audible signal. Thus, in rare cases that have WL and SCOUT® reflector placements in the same breast, the wire should be placed posterior to the reflector (Fig. 4). In our experience, a biopsy clip does not impact SCOUT® signal. Furthermore, while dense breast tissue with a deep central target poses a theoretical barrier to obtaining signal, we did not identify any cases of breast density causing signal failure.

We present a case of MRI guided reflector placement. The reflector is MR conditional due to the presence of nickel and ferromagnetic properties based on non-clinical testing [10]. In our unique case, which represents a departmental effort to convert all localizations to SAVI® SCOUT, bracketing of multi-focal disease was achieved with MRI guided reflector placement at the anterior and posterior extent of disease. No complications were reported with the delivery system needle in the MRI environment. Margins were negative on final surgical pathology.

Our study has limitations. Our retrospective, single-institution study included all consecutive SCOUT® localization cases. However, cases that the surgeon or radiologists identified as challenging due to targeted lesion depth or position were not offered SCOUT® localization, resulting in selection bias. Some patients may have elected wire placement due to scheduling convenience (i.e., same day localization and surgery) or due

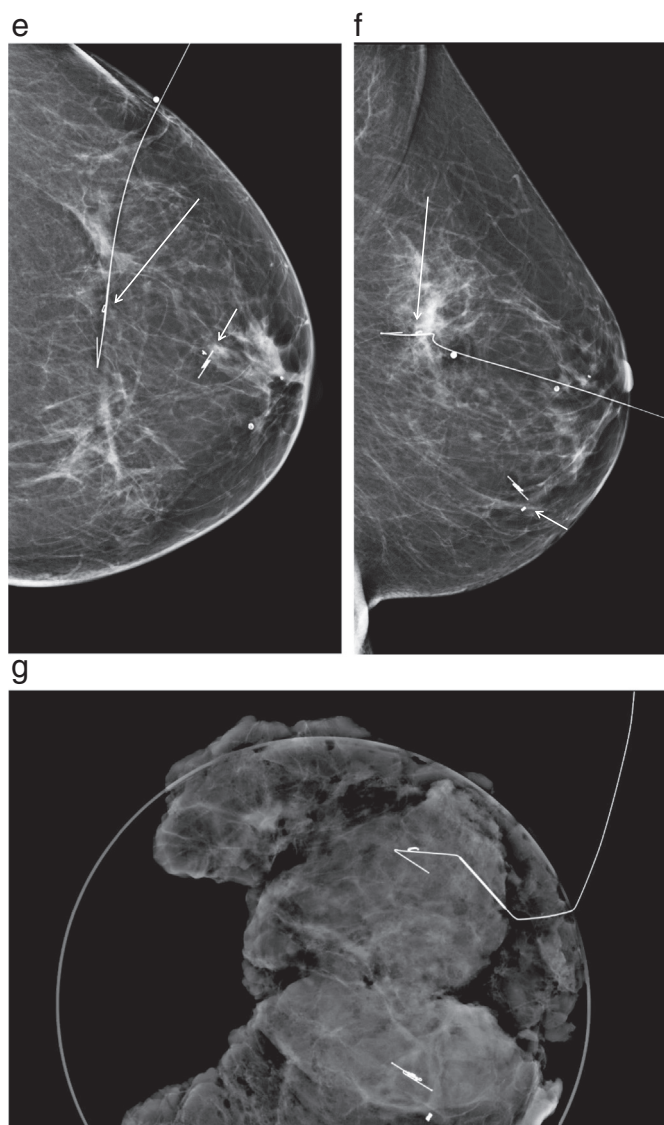


Fig. 4. (continued)

to anxiety associated with a new technology. We did not compare re-excision rates for WL and SCOUT® performed during the same time period. Patel and colleagues compared surgical outcomes of SCOUT® localizations to wire localizations in 42 matched patients and found no significant difference in median specimen volume, margin positivity rate, close margin rate and re-excision rate [11]. The authors report that their results are similar to prior studies comparing RSL and WL, which show comparable or improved performance [11, 13]. A SAVI SCOUT® pilot study performed by Cox et al. observed similar re-excision rates (7%) as reported for RSL and improved re-excision rates compared to WL (12–60%) [4, 6]. The author's subsequent multi-center, prospective study, however, demonstrated a slightly higher re-excision rate with SAVI SCOUT® (16.8%) than in the pilot study, yet still within acceptable limits as compared to WL [3]. Finally, we did not

perform a cost benefit analysis of SCOUT® and WL. The startup cost of the SAVI SCOUT® system needs to be evaluated in combination with the savings incurred by increased radiology and operating room efficiency, potential differences in localization reimbursement due to differential scheduling, and/or lack of need for radiation safety personnel and equipment at sites currently using RSL.

In conclusion, the SAVI SCOUT® system is a reliable, accurate, and convenient localization system for nonpalpable breast lesions that alleviates some of the disadvantages of WL and RSL. In addition, SCOUT® can be successfully used for bracketing breast lesions and localizing axillary lymph nodes. The SAVI SCOUT® system recently received clearance from the FDA for lifelong implantation, thus further decoupling localization and surgery scheduling [17].

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