

Evaluation of the SAVI SCOUT Surgical Guidance System for Localization and Excision of Nonpalpable Breast Lesions: A Feasibility Study

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OBJECTIVE. The purpose of this study is to evaluate the feasibility of the SAVI SCOUT surgical guidance system, which uses a nonradioactive infrared-activated electromagnetic wave reflector, to localize and excise nonpalpable breast lesions. We evaluated the system's use in 15 nonpalpable breast lesions in 13 patients.

CONCLUSION. Image-guided placement was successful for 15 of 15 (100%) reflectors. The final pathologic analysis found that lesion excision was successful, including five malignancies with negative margins. No patients required reexcision or experienced complications. SAVI SCOUT is a feasible method for breast lesion localization and excision.

Excision of nonpalpable breast lesions using preoperative image-guided wire localization (WL) is effective, but its disadvantages include patient discomfort, a movable external component, possible wire transection, limited scheduling flexibility that decreases operating room (OR) efficiency, lack of a point source for reorientation during surgery, and suboptimal incision placement due to wire location [1–6]. As a result, numerous institutions have replaced WL with ¹²⁵I-radioactive seed localization (RSL) [7, 8]. However, the use of radiation and its associated safety precautions limit the widespread adoption of RSL [8].

The SAVI SCOUT (Cianna Medical) surgical guidance system received 510(k) U.S. Food and Drug Administration approval in December 2014. SAVI SCOUT involves implanting a nonradioactive infrared (IR)-activated electromagnetic wave reflector into the breast under mammogram or ultrasound guidance. Our goal is to evaluate the feasibility of SAVI SCOUT for localization and surgical excision of nonpalpable breast lesions.

Materials and Methods

This study was an institutional review board–approved HIPAA-compliant retrospective review with the need for patient informed consent waived. We evaluated cases for which the SAVI SCOUT system was used at our institution, from June 2015 through October 2015, for localization and surgical excision of 15 nonpalpable breast lesions in 13 women (mean age, 52.5 years). Patients were selected by a single

breast surgeon, after image review, on the basis of target visibility and depth. Initial cases were ultrasound visible in case the surgeon needed to use intraoperative ultrasound for additional guidance. Exclusion criteria included age younger than 18 years, lesion depth greater than 4 cm, and known nickel allergy, because the reflector contains nickel.

The reflector is 12 mm long and includes two antennae, an IR light receptor, and a transistor switch (Fig. 1). Percutaneous image-guided reflector placement was performed by one of three breast radiologists (with 4–27 years' experience) using a sterile single-use preloaded 16-gauge needle (5, 7.5, or 10 cm long), using a procedure similar to that used for preoperative WL. Mammography-guided localization used an alphanumeric grid with needle insertion and reflector deployment (Fig. 2). Ultrasound-guided reflector placement was performed similarly (Fig. 3).

Postprocedure mammogram images assisted with operative planning. In the OR, the surgeon used a sterile detector handpiece on the skin connected to a console emitting IR light and an electromagnetic wave signal. The IR light receptor in the reflector receives the IR light pulse from the handpiece, which closes the transistor switch connected to the antennae, resulting in a reflected electromagnetic wave signal back to the handpiece. Dissection is directed by continuous audible feedback from the console, enabling reorientation around a point source. Target and reflector removal was verified with handpiece specimen examination, specimen radiography, and pathologic analysis. Pathologic results, complications, and reexcision rates were recorded.

Keywords: breast cancer, electromagnetic wave, infrared activated, localization

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TABLE 1: Fifteen Nonpalpable Breast Lesions Successfully Excised With the SAVI SCOUT (Cianna Medical) Surgical Guidance System

Case No.	Size (cm)	Imaging Findings	BI-RADS Category	Image-Guided Biopsy Pathologic Findings ^a	Final Surgical Pathologic Finding	Target Depth (cm) ^b
1	1.2	Mass	5	ILC	ILC	3.0
2	0.9	Mass	4	Papillary carcinoma	Papillary carcinoma	2.9
3	1.0	Mass	4	ALH	ALH	1.8
4	1.1	Mass and calcifications	4	Papilloma	Papilloma with atypia	2.0
5	0.6	Mass	4	DCIS	IDC and DCIS	3.1
6	0.7	Mass	4	ADH focal DCIS	DCIS	1.2
7	0.6	Mass	4	Papilloma	Papilloma	2.6
8	1.0	Calcifications	4	DCIS	DCIS	2.6
9	1.1	Mass	4	ALH	ALH	3.5
10	0.9	Calcifications	4	ADH	Fibrocystic change with calcifications; biopsy site	1.2
11	0.5	Enhancing mass (MRI only)	4	DCIS (0.5 cm)	Fibrocystic change, healing scar, and biopsy site	2.5
12	0.5	Calcifications	4	ADH	Columnar cell change calcifications; biopsy site	3.7
13	0.6	Mass	4	Papilloma	Benign proliferative breast tissue with columnar cell hyperplasia; biopsy site	1.7
14	0.8	Calcifications	4	Papilloma	Papilloma	1.2
15	1.1	Mass (vague)	4	Normal breast tissue (discordant with imaging)	Fibrocystic change; biopsy site	2.3

Note—ILC = invasive lobular carcinoma, ALH = atypical lobular hyperplasia, DCIS = ductal carcinoma in situ, IDC = invasive ductal carcinoma, ADH = atypical ductal hyperplasia.

^aLesion excision was indicated because of malignancy or high-risk pathologic finding on preoperative image-guided biopsy, except for case 15, which was excised after benign results on initial biopsy were deemed to be discordant with imaging findings.

^bTarget depth from skin surface measured on mammogram.

Results

Fifteen of 15 (100%) reflectors were successfully placed within the breasts of 13 women under image guidance (mean target-to-reflector distance on mammogram, 0.2 cm; range, 0–1.0 cm) 0–6 days before surgery (mean, 2 days). One patient had two reflectors placed in the same breast, and another patient had one placed in each breast. Eight of 15 cases used ultrasound guidance for mass localization (six containing clips), and seven of 15 cases used mammogram guidance for clip localization.

Fifteen of 15 (100%) targets and reflectors were successfully excised. The final surgical pathologic analysis revealed five malignancies (0.5–1.2 cm; one invasive ductal carcinoma, one invasive lobular carcinoma, two ductal carcinomas in situ, and one papillary carcinoma) all with negative margins, five high-risk lesions (two atypical lobular hyperplasias and three papillomas), and five benign results (Table 1). No patient required reexcision.

Fourteen of 15 (93%) specimen radiographs showed a distance between the target and reflector within 0.3 cm compared with postprocedure mammogram obtained the day of reflector placement. One of the 15

(7%) specimens showed a 2.7-cm increased target-to-reflector distance on specimen radiograph compared with postprocedure mammogram, where the reflector was placed within a large postbiopsy hematoma. The mean reflector depth from the skin on mammogram was 2.4 cm (range, 1.2–3.7 cm).

Specimen radiographs showed no reflector damage or transection. No procedural or related postoperative complications were identified.

Discussion

Reflector placement and target and reflector excision were 100% successful in this feasibility study of 15 nonpalpable breast lesions. Five malignancies excised had negative margins, and no patients required reexcision, which supports the feasibility of the SAVI SCOUT technique.

The radiologists had varying experience levels, yet all of them found this device easy to use, given its procedural similarities to WL, with the added benefit of optimizing the localization approach independently of the surgical approach. Reflectors were accurately placed, with a mean target-to-reflector distance on postprocedure mammogram of 0.2 cm (range, 0–1.0 cm). This is comparable to

RSL studies showing a mean target-to-seed distance of 0.1 cm (range, 0–2.0 cm) [8]. A comparison of postprocedure mammograms to specimen radiographs showed no substantial reflector migration in 14 of 15 (93%) cases; a postbiopsy hematoma case was the exception. Caution is warranted in patients with hematoma, but this is also true for WL and RSL and is not unique to this device.

The surgeon reported no difficulties with the SAVI SCOUT system, with operative times equal to those of WL after the first five cases. Intraoperative ultrasound was not needed to assist in localization. Preliminary observations based on these initial cases that warrant future study include no WL-related OR delays, continuous intraoperative reorientation with target centering in the specimen, decreased removal of nontargeted tissue, and a cosmetic advantage, because surgical tunneling is done via a hidden incision (i.e., periareolar, axillary, or inframammary crease) rather than along a wire.

The SAVI SCOUT has numerous advantages over WL. The lack of an external component limits the possibility of displacement or transection. The U.S. Food and Drug Administration approves it for placement up to 7 days preoperatively, which decouples ra-

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diology and surgery scheduling. There is no inherent reflector expiration at 7 days; thus, earlier placement is likely possible and is an area warranting further study. SAVI SCOUT shows many of the advantages of RSL, but because the reflector is nonradioactive, one can bypass radiation safety precautions.

Cost is a potential disadvantage of SAVI SCOUT because its use requires an initial capital purchase and single-use reflector and handpiece purchases. Although it is significantly more expensive than WL (with the exact price negotiated by the institution), the expected OR cost savings by eliminating WL-related delays likely counterbalance the device's expense. We plan a complete cost analysis in a future study after additional data collection.

SAVI SCOUT's limitations include limited reflector repositioning once deployed. Withdrawing the release button, rather than pushing forward, deploys the reflector to avoid antennae bending, and attempts to reposition may cause damage and malfunctioning. In addition, a reflector deeper than 4.5 cm may not produce a detectable signal, although mam-

mogram depth may overestimate lesion depth compared with supine surgical positioning. The needle delivery system is not MRI compatible; however, the reflector is MRI conditional. Patients can be scanned safely (at 3 T or less) immediately after placement.

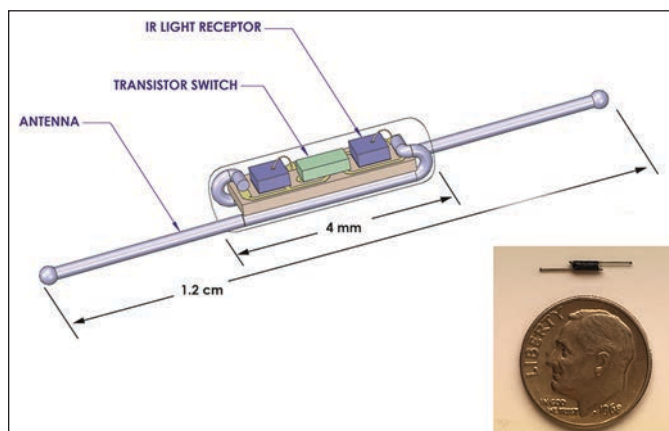
Two reflectors were placed 7 cm apart in one breast. Further research is needed to determine the minimum distance required to differentiate two separate reflectors percutaneously.

This study is also limited by the fact that it is a single-institution retrospective study involving one breast surgeon and a limited number of selected patients with a few relatively small cancers. Larger randomized studies are warranted for further investigation.

In conclusion, the SAVI SCOUT surgical guidance system is a feasible method to localize and excise nonpalpable breast lesions and appears to overcome many WL- and RSL-related limitations. Further study is necessary to validate these results.

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A



B

Fig. 1—SAVI SCOUT surgical guidance system. (Images courtesy of Cianna Medical, Inc.; reprinted with permission)

A, Diagram of reflector. SAVI SCOUT reflector is placed into breast under ultrasound or mammogram guidance, measures 1.2 cm, and consists of two antennae, infrared (IR) light receptor, and transistor switch. Photograph in inset shows reflector next to dime for size comparison.

B, Photographs of system. Handpiece and console system (*top*) emit IR light and electromagnetic wave signal, which are reflected back by reflector, providing localization and target proximity information to surgeon. System also enables radiologist to confirm reflector is placed and functioning day of reflector placement. Preloaded 5-, 7.5-, or 10-cm 16-gauge needle (*bottom*) enables percutaneous reflector placement under image guidance. Reflector (*black arrow*) is deployed by engaging and sliding release button (orange component of handle) proximally (*white arrow*).

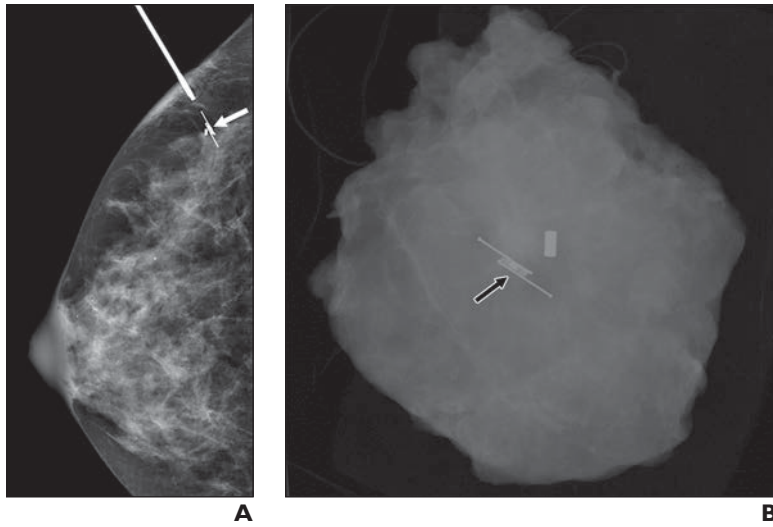


Fig. 2—52-year-old woman with left upper outer breast calcifications that underwent stereotactic biopsy with clip placement. Pathologic analysis found atypical ductal hyperplasia. Mammogram-guided localization of clip with SAVI SCOUT (Cianna Medical) reflector was performed.

A, Orthogonal craniocaudal view shows deployed reflector (*arrow*) adjacent to targeted clip, with needle partially withdrawn.

B, Specimen radiograph shows that target and reflector (*arrow*) have been excised and are well centered within specimen.

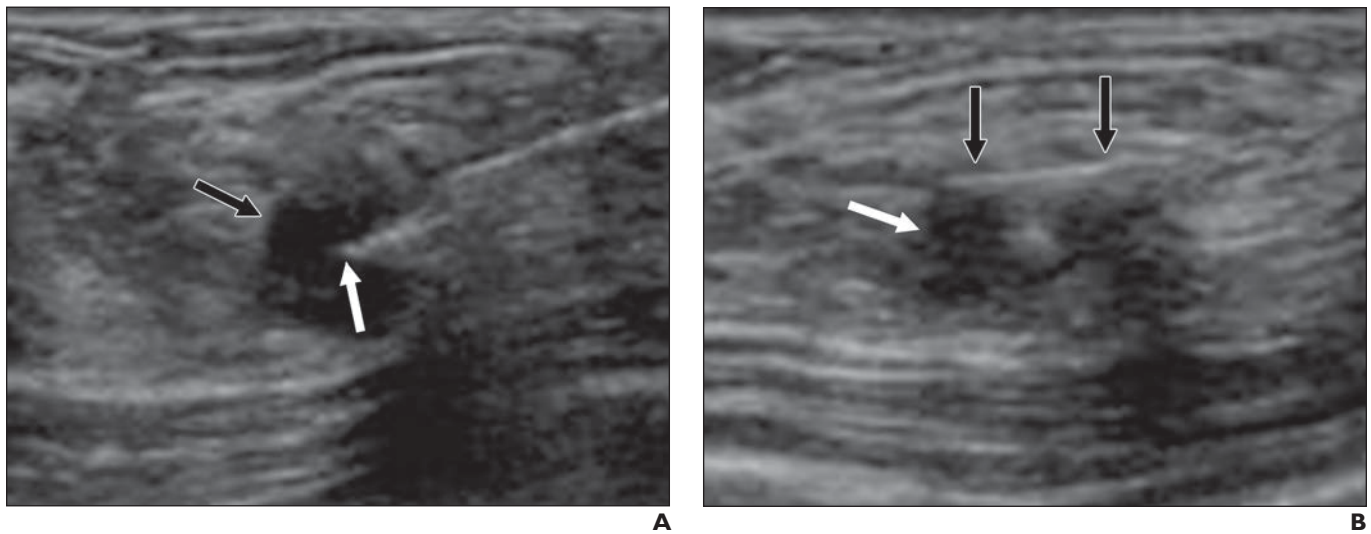


Fig. 3—42-year-old woman with 0.7-cm mass in 9 o'clock position in right breast detected on screening mammogram with ultrasound correlate. Biopsy found papillary carcinoma. Ultrasound-guided SAVI SCOUT (Cianna Medical) reflector placement was performed.

A, Ultrasound-guided reflector placement targeting mass (*black arrow*) was performed using preloaded needle (*white arrow*).

B, Postplacement ultrasound documents echogenic reflector (*black arrows*) within mass (*white arrow*).