

Efficacy and patient/physician satisfaction using US-guided preoperative SAVI SCOUT® surgical guidance system for intraoperative guidance to non-palpable breast lesions: preliminary data of prospective multi-institutional clinical evaluation

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BACKGROUND: PREOP LOCALIZATIONS METHODS RESULTS

- Nonpalpable breast lesions are routinely localized for surgery using percutaneous needle or wire localization (WL).
- WL requires patients to undergo the mammo or US-guided wire placement earlier the same day as the scheduled surgery.
- The wire protrudes from the breast until removed with the targeted lesion. Several hours between localization and excision is typical.
- Relatively newer alternative of radioactive seed localization (RSL) can be done several days in advance of surgery. Hence its main advantage is the uncoupling of the tight co-scheduling needed with WL.
- However, wider adoption has been hindered by the considerable regulatory requirements for the handling and monitoring of radioactive materials at each step of the process, from storage to placement to excision and eventual disposal.

- Initial 50-patient pilot study to determine safety
- IRB-approved, HIPAA compliant
- Prospective single-arm
- Multiple institutions
- Nonpalpable breast lesions, benign and nonbenign
- Reflector placement under US-guidance
- Primary study endpoints: successful reflector placement, intraoperative localization (detection), and retrieval
- 3/2015 - 11/2015
- 89 radar reflectors in 89 patients under US guidance
- Scouts placed ≤7 days prior to surgery
- 11 sites, 17 surgeons
- Satisfaction ratings by surgeons: 1/2 < WL, 3 = WL, 4/5 > WL
- Satisfaction ratings by patients: 1 = not satisfied, 2 = somewhat unsatisfied, 3 = neutral, 4 = somewhat satisfied, 5 = very satisfied

Table 1. Patient Enrollment

Institution	Radiologists	Surgeons	Patients Enrolled	Patient Age (years) Average	Range
USF Breast Health Program	3	1	2	69.5	62 – 77
Morton Plant Hospital	4	2	0	-	-
Nashville Breast Center	1	1	20	66.9	45 – 89
Pink Lotus Breast Center	0	1	13	54.2	36 – 75
Cancer Centers of Colorado	1	2	14	55.9	42 – 75
UC Irvine Health	1	2	13	51.4	35 – 64
NYU Langone Medical Ctr	5	3	8	51.0	29 – 69
Medical Center of Plano	1	1	9	59.6	44 – 70
Baylor Regional at Plano	2	1	1	69.0	69 – 69
Texas Breast Specialists	0	1	4	53.8	46 – 61
Hackensack University	2	1	5	65.0	55 – 80
All Cases	20	16	89	65.0	29 – 89

Table 2. Reflector Placements.

	USF Breast Health	Morton Plant Mease	Nashville Breast Center	Pink Lotus Breast Center	Cancer Centers of Colorado	UC Irvine Health	NYU Langone Medical Ctr	Medical Center of Plano	Baylor Regional at Plano	Texas Breast Specialists	Hackensack University	All Cases
Completed Cases												
Ultrasound Guidance	2	0	20	13	14	13	8	9	1	4	5	89
Reflector distance from skin (cm)												
Average	1.1	-	1.5	2.2	2.0	1.0	0.8	3.5	1.0	1.6	2.0	1.8
Range	1.0 – 1.2	-	0.6 – 2.5	0.7 – 7.5	1.0 – 3.7	0.4 – 1.6	0.4 – 1.3	1.5 – 5.0	1.0 – 1.0	1.3 – 1.8	1.2 – 4.8	0.4 – 7.5
Reflector distance from target (mm)												
Average	3.6	-	0.3	1.7	1.5	1.0	0.8	2.4	0.0	0.8	0.0	1.1
Range	0.2 – 7.0	-	0 – 3.0	0 – 10.1	0 – 4.0	0 – 8.0	0 – 6.0	0 – 5.0	0 – 0	0.1 – 1.7	0 – 0	0 – 10
Success of Reflector Placement												
Reflector Placed Successfully	2/2	-	20/20	13/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Reflector Detection Verified	2/2	-	20/20	13/13	12/14	13/13	8/8	9/9	1/1	4/4	5/5	87/89
Patient Satisfaction												
Patient Satisfaction Score*	5.0	-	NA	4.0	4.6	4.7	4.3	4.2	4.0	NA	4.2	4.4

* Satisfaction scale: 1 = not satisfied, 2 = somewhat dissatisfied, 3 = neutral, 4 = somewhat satisfied, 5 = very satisfied, NA = not answered.

Table 3. Reflector Localizations and Excisions.

	USF Breast Health	Morton Plant Mease	Nashville Breast Center	Pink Lotus Breast Center	Cancer Centers of Colorado	UC Irvine Health	NYU Langone Medical Ctr	Medical Center of Plano	Baylor Regional at Plano	Texas Breast Specialists	Hackensack University	All Cases
Days Reflector Placed Prior to Excision												
Average	2.5	-	0.0	0.4	3.1	1.3	3.4	0.7	1.0	0.0	1.4	1.2
Range	1 – 4	-	0 – 0	0 – 4	0 – 7	0 – 7	0 – 6	0 – 1	1 – 1	0 – 0	0 – 3	0 – 7
Reflector Excision												
Reflector Detected Pre-Excision	2/2	-	20/20	12/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Reflector Localized Post-Excision	2/2	-	20/20	12/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Reflector Successfully Removed	2/2	-	20/20	13/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Reflector Detected in Spec Rad	2/2	-	20/20	13/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Reflector Intact	2/2	-	20/20	13/13	14/14	13/13	8/8	9/9	1/1	4/4	5/5	89/89
Surgeon Evaluation												
Ease of Localization**	5.0	-	5.0	5.0	4.4	4.6	4.1	4.0	4.0	3.8	5.0	4.6
Ease of Removal**	5.0	-	5.0	5.0	4.5	4.5	3.0	4.1	5.0	3.8	5.0	4.5

** Compared to WL, scale of 1-5 where 3 = same as WL, <3 is worse than WL, >3 is better than WL

Table 4. Surgical Pathology.

	Excisional Biopsies*	Lumpectomies*	All Cases
Number of Cases with Complete Pathology			
USF Breast Health	1	1	2
Morton Plant Hospital	0	0	0
Nashville Breast Center	0	20	20
Pink Lotus Breast Center	4	9	13
Cancer Centers of Colorado	4	10	14
UC Irvine Health	6	7	13
NYU Langone Medical Ctr	4	4	8
Medical Center of Plano	4	5	9
Baylor Regional at Plano	1	0	1
Texas Breast Specialists	0	4	4
Hackensack University	2	3	5
All Cases	26	63	89
Final Diagnosis			
Benign	19/26	2/63	21/89
DCIS only	3/26	12/63	15/89
Invasive Cancer only	3/26	19/63	22/89
DCIS + Invasive Cancer	1/26	30/63	31/89
Tumor Size (cm)			
Average	1.3	1.7	1.6
Range	0.1 – 2.4	0.2 – 7.0	0.1 – 7.0
Amount of Tissue Excised (cm³)			
Average	39.3	146.8	112.5
Range	3.3 – 283	6.0 – 652	3.3 – 652
Margin Status			
All Margins Clear	25/26	53/63	78/89
Positive Margin	1/26	10/63	11/89
Close Margin (1 mm)	3/26	6/63	9/89
Required Re-Excision	3/26	11/63	14/89

* Cases without a pre-op dx of cancer were classified as an excisional biopsy; the rest were classified as a lumpectomy



Figure 1. SAVI SCOUT System Components

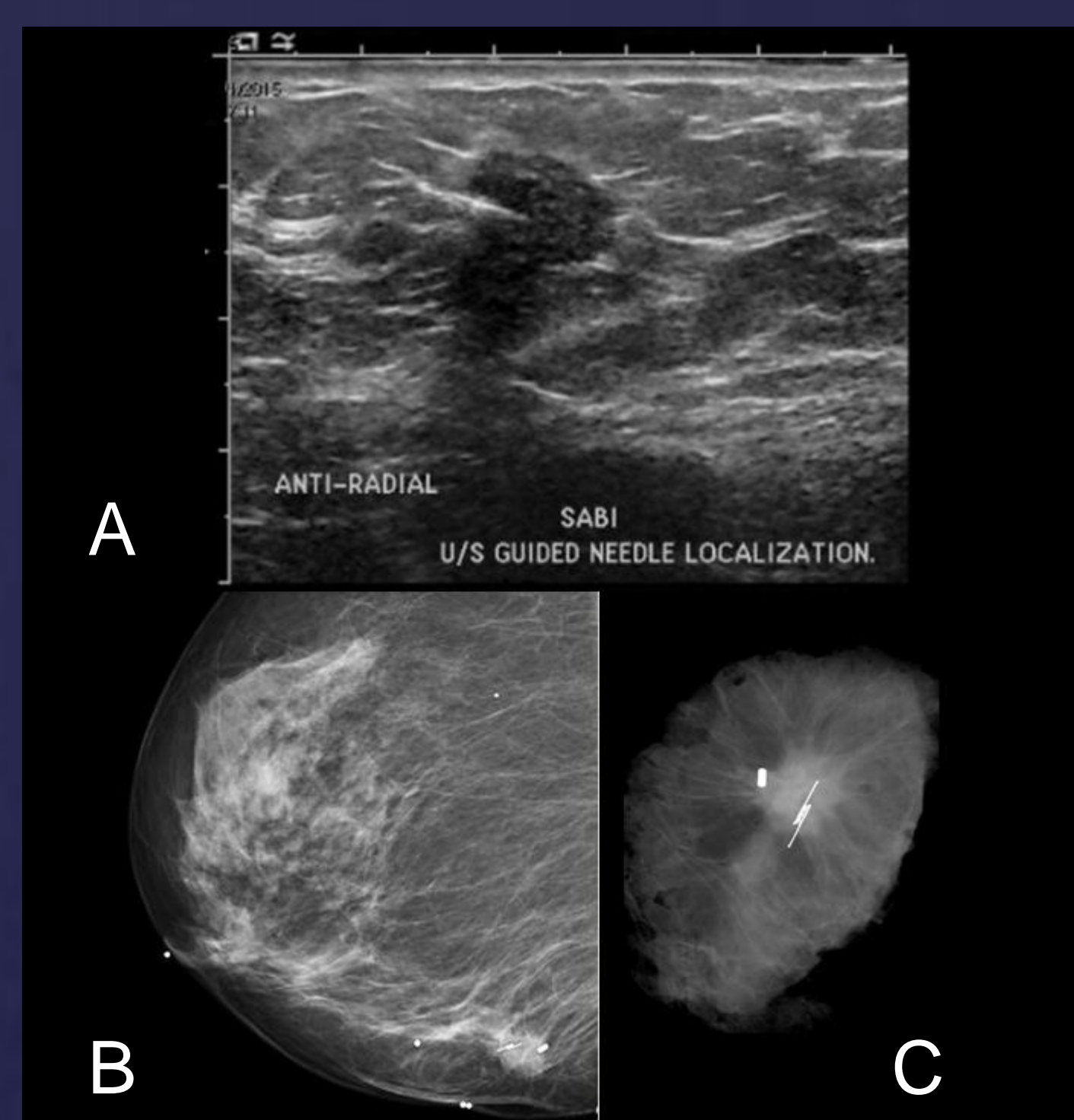


Figure 2. A: US image of reflector delivery system placed into target, B: after successful placement of reflector, C: specimen radiograph showing successful removal of reflector

LIMITATIONS

- US-guided SAVI SCOUT® placement is straightforward for radiologists facile with percutaneous procedures. Reflector placement technique is similar to steps involved in wire localization approach and biopsy clip placement.
- Relative limitation: learning curve for surgeons for discerning reflector location and adjusting surgical approach
- Not all patients may be eligible for this procedure

CONCLUSIONS

- US-guided preop SAVI SCOUT® system is an accurate and convenient alternative to WL and RSL for nonpalpable breast lesions.
- Early data shows high rates of technical and clinical efficacy in image-guided reflector placement, intraoperative retrieval, and surgical success rates.
- This user-friendly system has been well-received by many radiologists and surgeons and is reproducible across diverse institutions. High rates of patient and physician satisfaction have been reported.
- Logistical/system-wide advantages include decoupling of the localization and the surgery dates.
- From the patients' and staffs' perspective, the non-radioactive technology and simplified scheduling have potential for enhanced satisfaction.

CLINICAL RELEVANCE

- The SAVI SCOUT® surgical guidance system is a novel, safe, and accurate alternative for surgical guidance of non-palpable lesions using no wires or radioactive materials. Attractive additional advantage of decoupling the reflector placement and surgery dates increases all-around satisfaction (patient, surgeon, and radiologist) and improves workflow efficiency.
- After initial learning curve, technical efficacy and clinical satisfaction rates should be reliably high.

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