Learning Curve for the SAVI SCOUT Breast Localization and Surgical Guidance System

Savya C Shukla, MD; Steven C Shivers, PhD; Anne Mattingly, MD; Scott Russell, MS; Ankur Mehindru, BS; Ebonie Carter, BS; Charles E Cox, MD

Morsani College of Medicine at the University of South Florida (USF), Tampa, Florida, USA

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BACKGROUND & OBJECTIVES

The gold standard for localizing non-palpable breast lesions for surgical excision is wire localization (WL). Multiple disadvantages for WL include complicated scheduling and migration of the wire after placement. Radioactive seed localization (RSL) mitigates these disadvantages, but regulatory requirements regarding radiation limit more universal adoption. The SAVI SCOUT surgical guidance system (an FDA cleared medical device) eliminates the drawbacks of WL without the regulatory requirements of RSL. SCOUT utilizes electromagnetic wave technology and infrared light to provide intraoperative guidance during surgical excision. The purpose of this study is to describe the learning curve associated with adoption of this new technology.

METHODS

An IRB-approved prospective, single-arm, multi-site trial enrolled women with non-palpable breast lesions requiring localized surgical excision. After informed consent, a radiologist or surgeon used imaging guidance to implant the SCOUT reflector into the target lesion. Intraoperatively, the surgeon used SCOUT for localization of the reflector and removal of the target lesion. We evaluated the association of several independent variables with respect to successful localization and surgical excision including: tumor side, tumor quadrant, distance of reflector from the skin, and the number of SCOUT localized breast excisions performed by operating surgeon up to the first five cases. We studied the relationship between these independent variables and the following dependent variables: reflector detection post-placement, reflector detection pre-incision, and reflector localization post-incision. Statistical analysis utilized the z-test to perform a two-sided test of equality at an alpha level of 0.05 with adjustment for multiple comparisons by the Bonferroni method. T-tests were used to perform two-sided tests of equality for numeric variables.

Figure 1. SAVI SCOUT System Components.

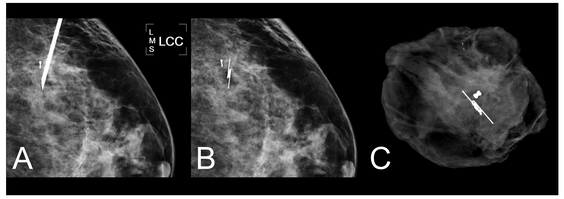

Figure 2. **A:** mammographic image of reflector delivery system placed into target, **B:** after successful placement of reflector, **C:** specimen radiograph showing successful removal of reflector

RESULTS

Across 11 institutions, SCOUT reflectors were successfully placed into 154 patients, however one case was converted to a standard WL because the reflector was too far away from the lesion. Subsequently, 16 surgeons performed a total of 153 surgical excisions using SCOUT guidance. Overall success rates of reflector detection pre-incision and post-incision were 98% (150/153) and 99% (151/153), respectively. The reflectors were successfully removed in 100% (153/153) of cases. Difficulty with reflector detection immediately post placement was significantly associated with reflectors more than 4 cm or 5 cm from the skin, or the procedure being the first SCOUT case by the operating surgeon. Operating surgeons performing their first SAVI localization procedure were significantly associated with difficult reflector detection post-incision. Subsequent procedures, up to the first five SCOUT localizations, noted no significant difficulty with reflector detection.

Table 1. Patient Enrollment.

Institution	Radiologists	Surgeons	Patients Enrolled	Patient Age (years) Average	Range
USF Breast Health	3	1	15	59.5	41 - 77
Morton Plant Hospital	4	2	22	62.8	38 - 83
Nashville Breast Center	1	1	23	66.1	42 - 89
Pink Lotus Breast Center	0	1	13	54.2	36 - 75
Cancer Centers of Colorado	1	2	16	56.9	42 - 75
UC Irvine Health	1	2	14	50.6	35 - 64
NYU Langone Medical Ctr	5	3	18	52.6	29 - 73
Medical Center of Plano	1	1	19	58.6	39 - 75
Baylor Regional at Plano	2	1	4	63.0	53 - 69
Texas Breast Specialists	0	1	4	53.8	46 - 61
Hackensack University	2	1	6	62.9	49 - 80
All Cases	**20**	**16**	**154**	**58.8**	**29 - 89**

Table 2. Reflector Placements, Localizations and Excisions by Institution.

	USF Breast Health	Morton Plant-Mease Hospital	Nashville Breast Center	Pink Lotus Breast Center	Cancer Centers of Colorado	UC Irvine Health	NYU Langone	Medical Center of Plano	Baylor Regional at Plano	Texas Breast Specialists	Hackensack University	All Cases
Completed Cases	**15**	**22**	**23**	**13**	**16**	**14**	**18**	**19**	**4**	**4**	**6**	**154**
Mammography Guidance	13	22	3	0	2	1	10	10	3	0	1	65
Ultrasound Guidance	2	0	20	13	14	13	8	9	1	4	5	89
Reflector distance from skin (cm)												
Average	3.2	3.1	1.7	2.2	2.2	1.0	2.5	4.0	3.7	1.6	2.6	2.6
Range	1 - 6.9	1.5 - 4.5	0.52 - 5.3	0.65 - 7.5	1 - 4	0.2 - 1.6	0.4 - 6	1.1 - 8	1 - 7	1.3 - 1.78	1.2 - 5.3	0.2 - 8
Reflector distance from target (mm)												
Average	2.3	5.5	1.2	1.7	4.2	1.2	0.9	3.9	7.0	0.8	0.3	2.8
Range	0 - 7	1 - 20	0 - 20	0 - 10	0 - 25	0 - 8	0 - 10	0 - 15	0 - 17	0.1 - 1.7	0 - 2	0 - 25
Reflector Placement												
Success of Reflector Placement	15/15	22/22	23/23	13/13	15/16	14/14	18/18	19/19	4/4	4/4	6/6	153/154
Reflector Detection Verified	15/15	22/22	23/23	13/13	13/16	14/14	16/18	18/19	3/4	4/4	6/6	147/154
Localizations & Excisions	**15**	**22**	**23**	**13**	**15**	**14**	**18**	**19**	**4**	**4**	**6**	**153**
Excisional Biopsies	7	9	0	0	4	6	11	0	0	0	3	40
Lumpectomies	8	13	23	13	11	8	7	19	4	4	3	113
Days Reflector Placed Prior to Excision												
Average	1.3	3.6	0.1	0.4	3.1	1.3	3.8	0.9	1.0	0.0	2.0	1.8
Range	0 - 4	1 - 7	0 - 2	0 - 4	0 - 7	0 - 7	0 - 6	0 - 3	1 - 1	0 - 0	0 - 5	0 - 7
Reflector Excision												
Reflector Detected Pre-Incision	15/15	22/22	23/23	12/13	15/15	13/14	17/18	19/19	4/4	4/4	6/6	150/153
Reflector Localized Post-Incision	15/15	22/22	23/23	12/13	15/15	14/14	17/18	19/19	4/4	4/4	6/6	151/153
Reflector Successfully Removed	15/15	22/22	23/23	13/13	15/15	14/14	18/18	19/19	4/4	4/4	6/6	153/153
Reflector Detected in Spec Rad	15/15	22/22	23/23	13/13	14/15	13/14	18/18	18/19	3/4	4/4	6/6	149/153
Reflector Intact	15/15	22/22	23/23	13/13	15/15	14/14	18/18	19/19	4/4	4/4	6/6	153/153

Table 3. Comparison of Column Proportions (z-tests) for Categorical Variables.

		Reflector Detected Post-Placement		Reflector Detected Pre-Incision		Reflector Localized Post-Incision		Any Detection Problem	
		No	Yes	No	Yes	No	Yes	no	yes
Tumor Side	Left	4	71	1	74	1	74	71	4
	Right	2	76	2	76	1	77	74	4
Tumor Quadrant	LIQ	0[1]	11	0[1]	11	0[1]	11	11	0[1]
	LOQ	1	18	**2**	**17**	2[1]	17	17	2
	UIQ	1	39	0[1]	40	0[1]	40	39	1
	UOQ	4	78	1	81	0[1]	82	77	5
Guidance	Mammography	4	60	1	63	1	63	60	4
	Ultrasound	2	87	2	87	1	88	85	4
Reflector Target	Biopsy Marker	4	63	2	65	1	66	62	5
	Lesion	2	84	1	85	1	85	83	3
Reflector more than 3 cm from skin	no	2	101	1	102	0[1]	103	100	3
	yes	4	46	2	48	2[1]	48	45	5
Reflector more than 4 cm from skin	no	***3***	***123***	2	124	1	125	121	5
	yes	***3***	***24***	1	26	1	26	24	3
Reflector more than 5 cm from skin	no	***4***	***139***	2	141	***1***	***142***	***137***	***6***
	yes	***2***	***8***	1	9	***1***	***9***	***8***	***2***
First Case	no	***4****	***135****	2	137	***1****	***138****	133	6
	yes	***2****	***12****	1	13	***1****	***13****	12	2
First Two Cases	no	4	123	2	125	1	126	121	6
	yes	2	24	1	25	1	25	24	2
First Three Cases	no	3	112	2	113	1	114	110	5
	yes	3	35	1	37	1	37	35	3
First Four Cases	no	3	100	2	101	1	102	98	5
	yes	3	47	1	49	1	49	47	3
First Five Cases	no	3	90	2	91	1	92	88	5
	yes	3	57	1	59	1	59	57	3

Note: Values in bold are significantly different at p< .05 in the two-sided test of equality for column proportions. Tests assume equal variances.
* Values marked with an asterisk are also significantly different at p< .05 by Fisher's Exact Test (two-sided).
1. This category is not used in comparisons because its column proportion is equal to zero or one.
2. Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

RESULTS, Cont.

Table 4. Comparison of Column Means (t-tests) for Continuous Variables.

	Reflector Detected Post-Placement		Reflector Detected Pre-Incision		Reflector Localized Post-Incision		Any Detection Problem	
	No	Yes	No	Yes	No	Yes	No	Yes
Days Reflector Placed	1	2	0	2	1	2	2	1
Mammo Compression Thickness	5.88	5.96	6.30[1]	5.95[2]	6.30[1]	5.95[2]	5.96	5.88
Ultrasound Chestwall Distance	4.5	3.51	1.32	3.59	1.20[1]	3.56[2]	3.57	2.91
Reflector Distance from Target	2.02	2.55	2.67	2.53	0	2.57	2.53	2.51
Reflector Distance from Skin	**4.32**	**2.46**	3.45	2.51	4.65	2.5	**2.46**	**3.78**
Case Index	5	7.54	5.67	7.47	5.5	7.46	7.53	5.75

Note: Values in bold are significantly different at p< .05 in the two-sided test of equality for column means. Tests assume equal variances.
1. This category is not used in comparisons because the sum of case weights is less than two.
2. This category is not used in comparisons because there are no other valid categories to compare
3. Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

CONCLUSIONS

As previously reported, the final data from this prospective, multi-site study showed that real-time surgical guidance with SCOUT is an accurate technique for directing the removal of non-palpable breast lesions and is reproducible at multiple clinical sites (Table 1). The study yielded 99.3% surgical success (Table 2) with a re-excision rate of 14.9% (data not shown) for patients with cancer, which is in line with those reported for RSL and intraoperative ultrasound (IOUS). The data suggest that SCOUT is a safe and effective tool for the localization of non-palpable breast lesions and a viable alternative to WL.

Although not part of the original study design, this abstract examined the relationship between the failure to detect and localize the SCOUT reflector at specific points throughout the procedure and various clinical variables.

1. Reflector detection problems were found to be possibly associated with tumor in the lower outer quadrant (LOQ) of the breast and cases in which the reflector was placed more than 4 cm from the surface of the skin (Table 3). The LOQ association was not confirmed by a more stringent analysis using the Fisher's Exact Test. However, reflector distance from skin as a continuous variable was found to be associated with the ability to detect the reflector immediately after placement (Table 4).
2. Reflector detection problems were *not* found to be associated with tumor side, type of placement guidance (mammography vs. ultrasound) or reflector target (biopsy marker vs. lesion). There was also no association found with the number of days between reflector placement and localization (up to 7 days), mammo compression thickness, ultrasound to chestwall distance or reflector to target distance (Table 4).
3. Reflector detection problems were more strongly associated with the first case for each surgeon and this association was also detected by the Fisher's Exact Test. Difficulty with reflector detection was not noted after the surgeon's first SCOUT procedure. Thus, it appears that the learning curve for reflector placement and localization for non-palpable breast lesions is relatively short.
4. Due to the low incidence of the observed failures and the ad hoc nature of this analysis, we strongly suggest that these relationships need to be further examined in future studies.

The options for the surgical excision of non-palpable breast lesions have expanded with the FDA's clearance of the SCOUT radar localization (RL) system, a zero-radiation, wire-free approach to breast tumor localization and surgical guidance during lumpectomies and excisional biopsies. SCOUT offers several benefits over current localization methods including non-radioactive technology, simplified scheduling, improved surgical planning and guidance and the potential for enhanced patient satisfaction.

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