



SAVI SCOUT® RADAR LOCALIZATION OF NON-PALPABLE BREAST LESIONS: SYSTEMATIC REVIEW AND POOLED ANALYSIS OF 842 CASES

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AIM

To evaluate the effectiveness of Savi Scout® localisation for non-palpable breast lesions through pooled analysis of placement, retrieval, and re-excision rates, including comparison with wire-guided localisation.

INTRODUCTION

With the increase in detection of non-palpable breast lesions through screening, precise surgical excision of such lesions requires accurate pre-operative localisation. Wire-guided localisation (WGL) has long been the favored method for preoperative localisation. Clinicians are very familiar with the technique and it is relatively affordable. However, this methods comes with several limitations including wire flaying, migration and transection. Surgeons are compelled to follow the direction of wire placement during surgical dissection, potentially resulting in inferior cosmetic outcomes. In addition, WGL must occur within 24 hours of surgical excision, posing significant constraints on scheduling. This, combined with the protrusion of the wire from the chest wall, causes increased patient anxiety and discomfort.

Wireless alternatives have been developed, including radioactive seed localisation. However, this technique comes with complexities and limitations associated with the use of radioactive material. Several non-radioactive, wireless methods have emerged, including Savi Scout®, Magseed® and LOCALizer™. Savi Scout® localisation (SSL) involves the insertion of an electromagnetic wave reflector into the target tissue (Figure 1) under mammogram or ultrasound guidance. The reflector is activated by infrared light impulses generated by the console probe and uses antennas to reflect a signal back to the handpiece. This provides real-time directionality and proximity information to the detection console which produces an audible and visual distance to target feedback to the operator. This guides the removal of the lesion throughout surgical dissection. Reflectors are licensed for implantation for an unrestricted length of time preoperatively.

This pooled analysis and systematic review aimed to assess the effectiveness of SSL. The pooled analysis focused on three aspects: successful placement of reflectors, successful retrieval of reflectors and re-excision rates. A second smaller analysis focused on re-excision rates in studies directly comparing SSL to WGL.

MATERIALS AND METHODS

Data sources and searches

Searches of the PubMed, Ovid, Google Scholar and Cochrane Library databases were conducted in order to identify and extract relevant publications and records. Databases were searched during April and May 2020 for records dating back to 2010. Different search terms were used depending on the database. Two PubMed searches were conducted using the search terms ‘Savi Scout’ and ‘reflector guided AND breast’. The search term ‘Savi Scout’ was used for the Ovid, Google Scholar and Cochrane Library searches. We also included our own cohort of patients who had undergone SSL at our centre.

Inclusion and exclusion criteria

Retrospective and prospective cohort studies were included. In the full text, the following raw data were required to be included:

- The total number of patients undergoing Savi Scout® localisation,
- The number of successful localisations/placements of reflectors, and
- The number of successful retrievals of the Savi Scout® reflector using SSL.

When available, data regarding re-excision rates were also included. Fulltext/ abstract publications were excluded from the analysis when data regarding successful placement and retrieval of SSL reflectors was unavailable or unclear. Studies directly comparing SSL to WGL were included in the smaller pooled analysis of re-excision rates. Re-excision rate was computed using only cases which had malignancy in their preoperative biopsy or postoperative pathology.

RESULTS

Literature search results and data

Ninety-three records were initially identified across the databases searched. After accounting for duplicates, 56 studies were initially assessed for inclusion. 13 abstract were identified as relevant to our analysis and their full-texts were further assessed for eligibility. Three of these studies were eventually excluded and one additional conference abstract was also identified via an external source. Therefore 11 studies were included in our pooled analysis. Of these eleven, 4 directly compared SSL to WGL and were included in the smaller pooled analysis investigating re-excision rates in the use of SSL in direct comparison to WGL.

This data was combined with results from our own cohort of twenty patients (22 reflectors). Results of the studies included, and our own data, are detailed in Table I.

Results of pooled analysis

A total of 842 reflectors were inserted across eleven studies and our own data. Pooled analysis revealed an overall successful deployment rate of 99.64% and a successful retrieval rate of 99.64% using the Savi Scout® system (Table I). The overall re-excision rate was found to be 12.8%.

Across the four studies directly comparing Savi Scout® to wire-guided localisation, 264 reflectors were placed and 545 WGLs were performed to localise malignant lesions. A statistically significant difference in re-excision rate was found between SSL (12.9%) and WGL (21.1%) (χ^2 with Yates' correction=7.4639, $p<0.01$).

CONCLUSIONS

Savi Scout® is an effective and safe alternative nonradioactive, wire-free system for the localisation of nonpalpable breast lesions, as demonstrated by the high successful insertion/localisation rate of 99.64% and successful retrieval rate of 99.64% found in our pooled analysis of data on 842 Savi Scout® reflectors. We report an overall re-excision rate of 12.8%, making SSL a safe alternative to WGL while overcoming most of its limitations.

In studies directly comparing Savi Scout® (n=264) and wire-guided localisation (n=545), we found overall re-excision rates of 12.9% and 21.1%, respectively. This yields a relative risk of 0.61 and provides evidence supporting the Savi Scout® system as a safe alternative to WGL. This is achieved alongside other recognizable benefits including minimal device migration, superior patient comfort and shorter operating delays. Furthermore, the ability to conduct reflector placement days in advance of surgery allows for flexible scheduling by decoupling radiology and surgery interventions.

Some complications of the system were recorded. These include a risk of reflector antenna transection during surgical dissection; however, this is of minimal consequence since it would indicate to the surgeon that they have reached the lesion. Post-placement signal detection difficulties associated with post-biopsy haematomas and calcified fibroadenomas were also reported. Further limitations include the inability to reposition the reflector after deployment and the lack of MRI compatible delivery systems. Other nonradioactive, wire-free options such as LOCALizer™ radiofrequency identification tags and Magseeds®, are associated with a significant limitation of possible signal void artefacts on follow-up magnetic resonance imaging (MRI). These may be as large as 2 cm and 4-6 cm, respectively. Such interferences may impede the detection of residual disease during progression monitoring after further cancer therapy. Conversely, the Savi Scout® reflector produces much more minimal signal void artefacts (<5 mm) and is therefore a much more desirable system.

Limitations and future directions

We acknowledge that a limitation of our analysis is the inclusion of data from publications with differing experimental designs, as well as differing criteria for successful placement and retrieval. In addition, data sets included in our analysis represent a range of clinicians and institutions experience with the Savi Scout® technology. It would therefore be of interest to investigate SSL in the context of randomised trials, including direct comparisons with WGL and other wireless technologies such as a LOCALizer™ and Magseed®.

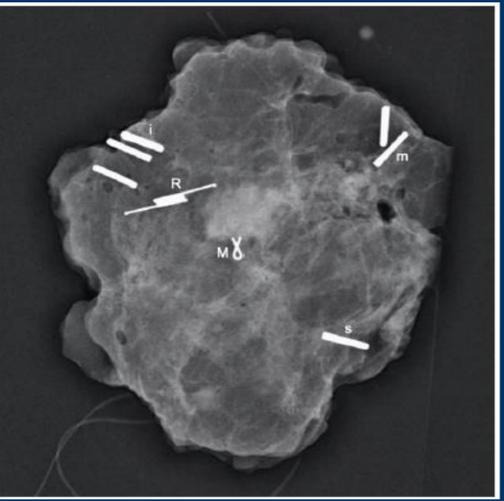


Figure 1. A specimen radiograph demonstrating the Savi Scout® reflector (R) placed next to a tumour. Marker (M) and peripheral metallic (s, m, i) clips can also be seen.

REFERENCES

Please refer to Table I for studies included in our analysis.

Study	Author	Year	Total Savi Scout® reflectors	Reflectors successfully inserted / localised (% of total reflectors)	Reflectors successfully retrieved using SSL (% of reflectors inserted)	Malignant lesions requiring re-excision (%)
Comparison of wire localization, radioactive seed, and Savi scout® radar for management of surgical breast disease. *	Strour <i>et al</i>	2020	108 §	108 (100%)	108 (100%)	16 / 79 (20%)
A new era of preoperative breast lesion localization. (conference abstract)	Khalaf <i>et al</i>	2018	6 §	6 (100%)	6 (100%)	0 / 6 (0%)
Utilization of multiple SAVI SCOUT surgical guidance system reflectors in the same breast: A single-institution feasibility study.	Jadeja <i>et al</i>	2018	90	90 (100%)	90 (100%)	4 / 39 (10%)
Reflector-guided breast tumor localization versus wire localization for lumpectomies: A comparison of surgical outcomes. *	Patel <i>et al</i>	2018	42	42 (100%)	42 (100%)	3 / 42 (7%)
Is SAVI SCOUT localization as accurate as needle-localization in obtaining negative margins at time of breast conservation?: A single institutional experience. (conference abstract) *	Turk <i>et al</i>	2018	127 §	126 (99%)	126 (100%)	13 / 126 (10%)
Beyond wires and seeds: Reflector-guided breast lesion localization and excision.	Mango <i>et al</i>	2017	123	122 (99%)	122 (100%)	4 / 54 (7%)
Pilot Study of SAVI SCOUT® to Localize NonPalpable Breast Lesions to Reduce Re-excision. (conference abstract) *	Shirley <i>et al</i>	2017	26	26 (100%)	25 (96%)	2 / 17 (12%)
A comparison of SAVI SCOUT radar to the radioactive 125 seed in the localization of non-palpable breast cancer. (conference abstract)	Rico <i>et al</i>	2017	59 §	59 (100%)	59 (100%)	8 / 59 (14%)
A comparison of the micro-impulse radar SAVI SCOUT to the radioactive 125 seed in localization of non-palpable breast cancer for breast conserving therapy. (conference abstract)	Nolano <i>et al</i>	2017	35 §	35 (100%)	35 (100%)	4 / 35 (11%)
Pilot Study of a New Nonradioactive Surgical Guidance Technology for Locating Nonpalpable Breast Lesions.	Cox <i>et al</i>	2016	50	50 (100%)	50 (100%)	3 / 41 (7%)
A Prospective, Single Arm, Multi-site, Clinical Evaluation of a Nonradioactive Surgical Guidance Technology for the Location of Nonpalpable Breast Lesions during Excision.	Cox <i>et al</i>	2016	154	153 (99%)	152 (99%)	22 / 109 (20%)
Our Cohort	-	-	22	22 (100%)	21 (95%)	1 / 17 (6%)
OVERALL			842	839 (99.64%)	836 (99.64%)	80 / 624 (12.82%)

Table I. Details of studies included in overall pooled analysis. SSL: Savi Scout® Localisation; *study included in smaller pooled analysis comparing Savi Scout® and wire-guided localisation; §number of reflectors assumed from number of patients.