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Review

Savi Scout® Radar Localisation of Non-palpable Breast Lesions: Systematic Review and Pooled Analysis of 842 Cases

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Abstract. *Background/Aim: With the increase in detection of non-palpable breast lesions through screening, wire-guided localisation (WGL) has long been the favoured method for preoperative localisation. However, this technique comes with several limitations. New methods have been developed, including several non-radioactive, wireless options. We aimed to assess the effectiveness of Savi Scout® localisation (SSL) through this pooled analysis and systematic review. Materials and Methods: A number of databases were searched for records reporting data on localisation and retrieval of SSL reflectors, as well as re-excision rate. We included our own data from 20 patients (22 reflectors) at our institution. Results: 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 SSL. A statistically significant difference in re-excision rate was found in a smaller pooled analysis conducted across four studies comparing SSL and WGL (12.9% and 21.1% respectively, p<0.01). Conclusion: The Savi Scout® localisation system is a safe and effective alternative to WGL. It facilitates flexible scheduling by decoupling radiology and surgery interventions and may reduce the need for re-excision procedures for positive surgical margins.*

The incidence of non-palpable breast cancer has been increasing with the widespread adoption of screening mammography and magnetic resonance imaging (MRI) and use of neoadjuvant systemic therapy (NST) (1). Precise surgical excision of such non-palpable breast lesions requires accurate pre-operative localisation. Since the first use of hooked-wire breast lesion marking (2), wire-guided localisation (WGL) has become the favoured method by which non-palpable breast lesions are localised for surgical excision. Surgeons have become well trained in using this technique and it is relatively affordable (3). However, a number of limitations are associated with its use. Several issues have been reported in the literature, such as wire transection (4), flaying (5) and migration (6). The risk of migration forces scheduling of WGL to occur within 24 hours of surgical excision, often on the same day of surgery. This results in scheduling restrictions since coordination between radiology and surgery departments must occur, often limiting which days procedures may be carried out. Increased patient anxiety (during an already stressful time) has been associated with the prospect of having two procedures on the same day (5). Moreover the protrusion of the wire from the chest wall causes increased patient discomfort and anxiety. Furthermore, incisional dissection for lesion excision is based on wire placement directionality and may potentially result in excessive removal of breast tissue and inferior cosmetic outcomes. Diathermy burns conducted through the wire to the skin surface, pericardial injuries and pneumothoraxes have also been reported (5). These limitations underscore the need for localisation techniques that overcome these issues and provide greater procedure satisfaction.

Radioactive seed localisation (RSL) was the first wireless alternative that evolved and, in this approach, a radioactive ^{125}I seed is placed at the site of the lesion up to 5 days prior to surgical excision (7). The location of the seed, and therefore the lesion, is accurately detected during surgery using a handheld gamma probe. Importantly, surgeons can make the incision they deem most appropriate, rather than having to follow the path of a localisation wire. In addition, recent research has suggested that RSL may be more time and cost efficient than WGL (8, 9). However, the use of a radioactive material also comes with its own practical

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constraints, since care is required when handling the seed. Significant regulatory requirements regarding training of personnel, oversight and seed handling must be met in any centre planning to use RSL (10, 11) – this is often associated with a prolonged programme start up time. Although rare, cases have been recorded whereby the seed has been transected during post-operative pathology slicing, requiring appropriate management and disposal procedures (4). Furthermore, the short duration permitted from the time of deployment to surgery is too short to allow placement at the time of biopsy. Moreover, the radioactive seed can potentially cause radiation injury to normal tissues and it always requires retrieval. It would therefore be preferable to utilise a wire-free localisation method that does not involve the use of radioactive material.

Several such techniques have emerged, namely the use of radiofrequency identification (RFID) tags (LOCalizer™; Hologic, Santa Carla, CA, USA) (12); magnetic seeds (Magseed®; Endomagnetics Inc., Cambridge, UK) (13); and infrared reflectors (Savi Scout®; Cianna Medical Inc., Aliso Viejo, CA, USA) (14). All three radiation-free wireless methods allow localisation to occur before the day of surgical excision, reducing the need for scheduling coordination. Furthermore, these markers can be inserted at the time of pre-operative biopsy thus potentially avoiding a second invasive procedure. This is of particular importance in patients who undergo NST. Limitations include the incapability to re-adjust the position of the device once inserted and unavailability of MRI compatible delivery systems (11, 15).

The current article will focus on the use of reflector-guided Savi Scout® localisation (SSL). The SSL system involves the insertion of a 12×1.6 mm electromagnetic wave reflector (Figure 1) into the target tissue using a sterile 16-gauge introducer needle delivery system (available needle lengths of 5, 7.5 and 10 cm) under mammogram or ultrasound guidance. The reflector is activated by infrared light impulses generated by the console probe and uses two antennas to reflect an electromagnetic wave signal back to the handpiece (Figure 2) (16). Modulation of the pulsating infrared light by the console ensures that the reflector returns a unique signal. This provides real-time directionality and proximity information to the detection probe. The signal is processed by the console to produce an audible and visual distance to target feedback to the operator, guiding the removal of the lesion throughout surgical dissection (17). Reflector localisation can be confirmed at the time of placement using the handpiece and/or using ultrasound or mammogram. Retrieval during surgery can also be confirmed using the handpiece and/or on specimen radiographs (Figure 3). Since the reflectors are not radioactive, they do not require specific disposal. The accurate detection range is up to 6 cm from the skin surface (18). The US Food and Drug Administration (FDA) first cleared the use of SSL for breast lesions in 2014 and was Council of Europe (CE) marked in 2020. The current licence allows implantation for an unrestricted length of time pre-operatively and includes axillary lymph nodes, thus facilitating targeted axillary dissection following NST (19, 20). We have recently published the first reported European evaluation of the Savi Scout® system based on the experience with our own patient cohort (20).

This systematic review and pooled analysis aimed to assess the efficacy of the Savi Scout® system for localisation of non-palpable breast cancer lesions. The pooled analysis focused on three aspects: successful placement of SSL 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. We also included our experience of 20 patients undergoing SSL at our centre from our recent publication (20).

Materials and Methods

Data sources and searches. Complete searches of the PubMed, Ovid, Google Scholar and Cochrane Library databases were conducted in order to identify and extract relevant publications and records. Search terms varied depending on database and included records published from 2010. Two PubMed searches were conducted: one on 27th April 2020 using the term 'Savi Scout' and one on 29th April 2020 using the search criteria 'reflector guided AND breast'. The Ovid search of 'Savi Scout' was performed on 29th April 2020 and used the Embase and Ovid MEDLINE(R) and Epub Ahead of Print, In-Process and Other Non-Indexed Citations, Daily and Versions(R) databases. The Google Scholar search used the term 'Savi Scout' and was conducted on 30th April 2020. Finally, the Cochrane Library search was performed on 2nd May 2020, also using the term 'Savi Scout'. One conference abstract was also identified via an external source.

In the present study, we have also included our own cohort of 20 patients (22 reflectors) who had undergone SSL at our centre (The London Breast Institute, The Princess Grace Hospital, London, UK). These results were included in our recently published evaluation (20).

Inclusion and exclusion criteria. Retrospective and prospective cohort studies were included. Publications needed to summarise findings when exploring the use of Savi Scout®/reflector-guided technology to localise non-palpable breast lesions in the abstract. 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 the Savi Scout® reflector, and
- The number of successful retrievals of the Savi Scout® reflector using SSL.

When available, data regarding re-excision rates were also included. If the publication detailed only margin positivity, this was assumed to indicate re-excision. References of assessed full-text publications were also screened for any relevant publications, as well as previously published reviews.

Abstracts were excluded when they clearly did not investigate the use of SSL for non-palpable breast lesions. Full-text/abstract publications were excluded from the pooled analysis when data regarding the successful placement and retrieval of reflectors from breast lesions was unclear or unavailable. However, publications comparing SSL to other localisation methods were also included – data regarding other methods were ignored for the purposes of our calculations, except where relevant to the smaller pooled analysis. Both full texts and abstracts were included in our analysis. The data were independently verified by both authors.

Data management. The authors extracted and combined data to calculate the overall rates of successful placement and retrieval from data sets of included studies. Some studies included patients who had multiple SSL reflectors placed for localisation. When no extra data were provided, it was assumed that the number of patients was equal to the number of reflectors placed. Mean values were calculated by combining data sets from each included study to give overall rates for successful placement/localisation, retrieval and re-excision. Retrieval rate was calculated using only reflectors, which had been successfully localised and subsequently retrieved using SSL guidance. Re-excision rate was computed using only cases which had malignancy in their preoperative biopsy or postoperative pathology and had successful reflector placement. A Chi-square test was used to analyse re-excision rate in studies directly comparing SSL against WGL.

Results

Literature search results and characteristics of the included studies. A total of 93 records were initially identified (24 from PubMed; 43 from Ovid; 25 from Google Scholar; 1 from the Cochrane Library). After removing duplicates, 56 publications were initially assessed for inclusion. A total of 43 were immediately excluded after screening their abstracts for eligibility. Many were reviews or studies investigating other localisation methods – these were examined for any relevant studies that could be included in our analysis. One conference abstract was added to our analysis through an external source.

Full texts (where available) were then examined for the 14 abstracts, which initially met the criteria for SSL efficacy analysis (16, 17, 21-32). In total, three of these publications were excluded from our calculations. One study was excluded because it assessed the use of SSL for sentinel lymph node biopsy rather than breast lesions (22). A second study was also excluded for including reflectors placed outside of the breast (27) – these could not be differentiated from reflectors placed within the breast in the study's data set. A final third publication's data (21) were excluded since its results were already a part of a larger study that is already included in our analysis (30). Therefore, 11 studies were used to calculate the rates of successful placement, successful retrieval and re-excision in the final pooled analysis (16, 17, 23-26, 28-32).

Of these eleven studies, four directly compared SSL to WGL. These were included in a smaller pooled analysis, which selectively investigated re-excision rates in the use of SSL in

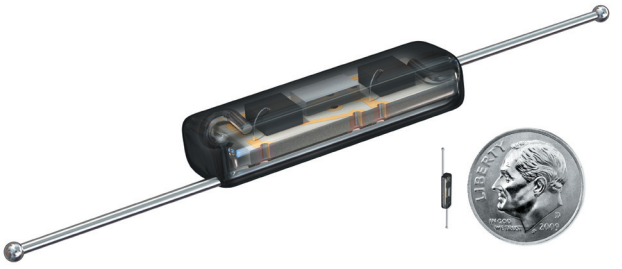

Figure 1. *An illustration of the size and scale of the Savi Scout® reflector relative to a coin. The reflector measures 12×1.6 mm.*

Figure 2. *The Savi Scout® guidance system consisting of a console and handpiece. The console is able to provide an audible sound and distance to target reading whilst localising the reflector.*

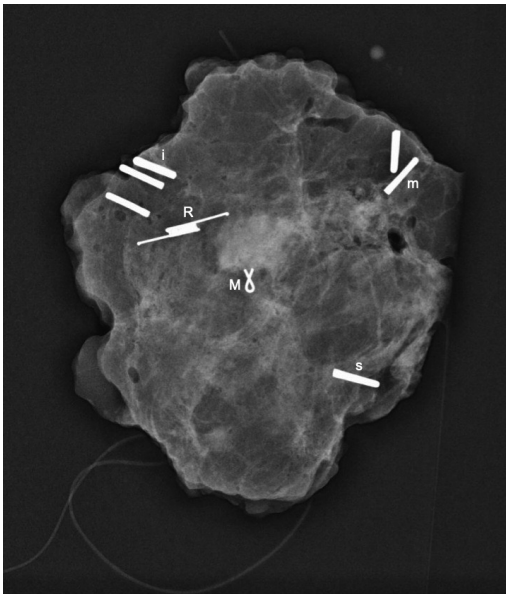

Figure 3. *A specimen radiograph demonstrating the Savi Scout® reflector (R) placed next to a tumour. The peripheral metallic clips (1 for superior (s); 2 for medial (m); 3 for inferior (i)) are used to orientate the specimen and the marker clip (M) within the specimen was previously deployed at the time of the biopsy.*

direct comparison to WGL (24, 25, 28, 29). A PRISMA (33) flowchart summarising these findings is shown in Figure 4.

Our patient cohort. To add to the data sets extracted from the identified studies, we included 20 patients (22 reflectors) from our centre who had undergone SSL for non-palpable breast lesions. Of these, 22 reflectors (100%) were successfully placed and 21 (95.45%) subsequently retrieved during surgery using SSL. Of the 17 malignant lesions localised, 1 (5.9%) was found to have positive margins and therefore required re-excision. These results were included in the large pooled analysis.

Results of pooled analysis. Across our own data and the 11 studies included in the analysis, 842 Savi Scout® reflectors were inserted. Of these, 839 were successfully placed and 836 were successfully retrieved using SSL. This gives a successful deployment rate of 99.64% and a successful retrieval rate of 99.64%. Of the 839 successfully placed reflectors, 624 were inserted in malignant lesions with 80 requiring re-excision. The re-excision rate was therefore 12.8%. These results are detailed in Table I.

Across the four studies directly comparing Savi Scout® to wire-guided localisation, 545 WGLs were performed and 264 reflectors were placed to localise malignant lesions. Of these, 115 WGLs required re-excision compared to 34 SSLs. This gives a re-excision rate of 21.1% for WGL and 12.9% for SSL. A chi-square test found this difference to be statistically significant (χ^2 with Yates' correction=7.4639, $p<0.01$). These results are detailed in Table II.

Discussion

Savi Scout® is an effective and safe alternative non-radioactive, wire-free system for the localisation of non-palpable 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.

Initially, we had hoped to include data from records that had clear successful placement criteria of localisation within 1 cm of the targeted lesion. However, publications differed in their definitions of successful placement, with many relying on reflector detection by the system console or visual confirmation on post-placement imaging. Furthermore, criteria for successful identification during surgery also differed. We therefore acknowledge that a limitation of our analysis is the inclusion of data from publications with differing experimental designs and patient inclusion criteria – the majority were retrospective studies. In addition, data sets included in our analysis represent a range of clinicians and institutions experience with the Savi Scout® technology. Differences in reported measures also hindered the ability to carry out further pooled analyses on key variables relating to localisation of non-palpable breast lesions, however some studies did include these data.

In studies directly comparing Savi Scout® (n=264) and wire-guided localisation (n=545), we found an overall re-excision rate of 21.1% for WGL. This figure is comparable to WGL margin positivity rates reported in large series studies of 16.4% to 20.8% (34-36). We found a significant difference ($p<0.01$) in re-excision rate between Savi Scout® (12.9%) and wire-guided localisation (21.1%) in the separate pooled analysis of the four applicable studies, yielding a relative risk of 0.61. This provides evidence supporting the Save Scout® system as a safer alternative to WGL and is achieved alongside several other recognisable benefits. This finding could have a significant impact on cost savings and oncological care of breast cancer patients. However, this observation should be validated in adequately powered randomised controlled trials.

Minimal Savi Scout® reflector migration was reported in individual studies (16, 27). This is supported by our own cohort results where we report 0% reflector migration (20). In contrast, wire migration is a recognised limitation of WGL due to its protrusion from the breast. Post-biopsy haematomas were often documented for the few cases where significant migration was observed (21, 30). However, the definition of migration was heterogeneous across studies, thus hindering accurate analysis. Nevertheless, the reflector design, as seen in Figure 1, has inherent anti-migration characteristics.

In relation to the surgical specimen size, the relevant publications reported no significant differences between WGL (24, 25) and RSL (25, 31). Within our patient cohort, the mean specimen weight for malignant cases was 21.1 g – this appears to be lower than previously reported specimen weights for WGL (37.4 g) (37).

Many other notable benefits of SSL over WGL exist. Surgeons are able to choose the most optimal surgical incision site, rather than be dictated by wire placement, thereby potentially allowing for preferable cosmetic outcomes. The ability to conduct reflector placement days in advance of surgery allows for great flexibility in radiology and surgery scheduling. This also provides a particular benefit for patients undergoing NST since the reflectors can be inserted at the time of biopsy with no limit on how long they can be placed within the breast tissue pre-operatively (18). Srour *et al*., (25) conducted an extensive time-specific variable analysis comparing the uses of SSL and WGL. They found that WGL involved significantly longer preoperative times and significantly longer delays to operation starting times on the day of surgery when compared to SSL within the hospital setting.

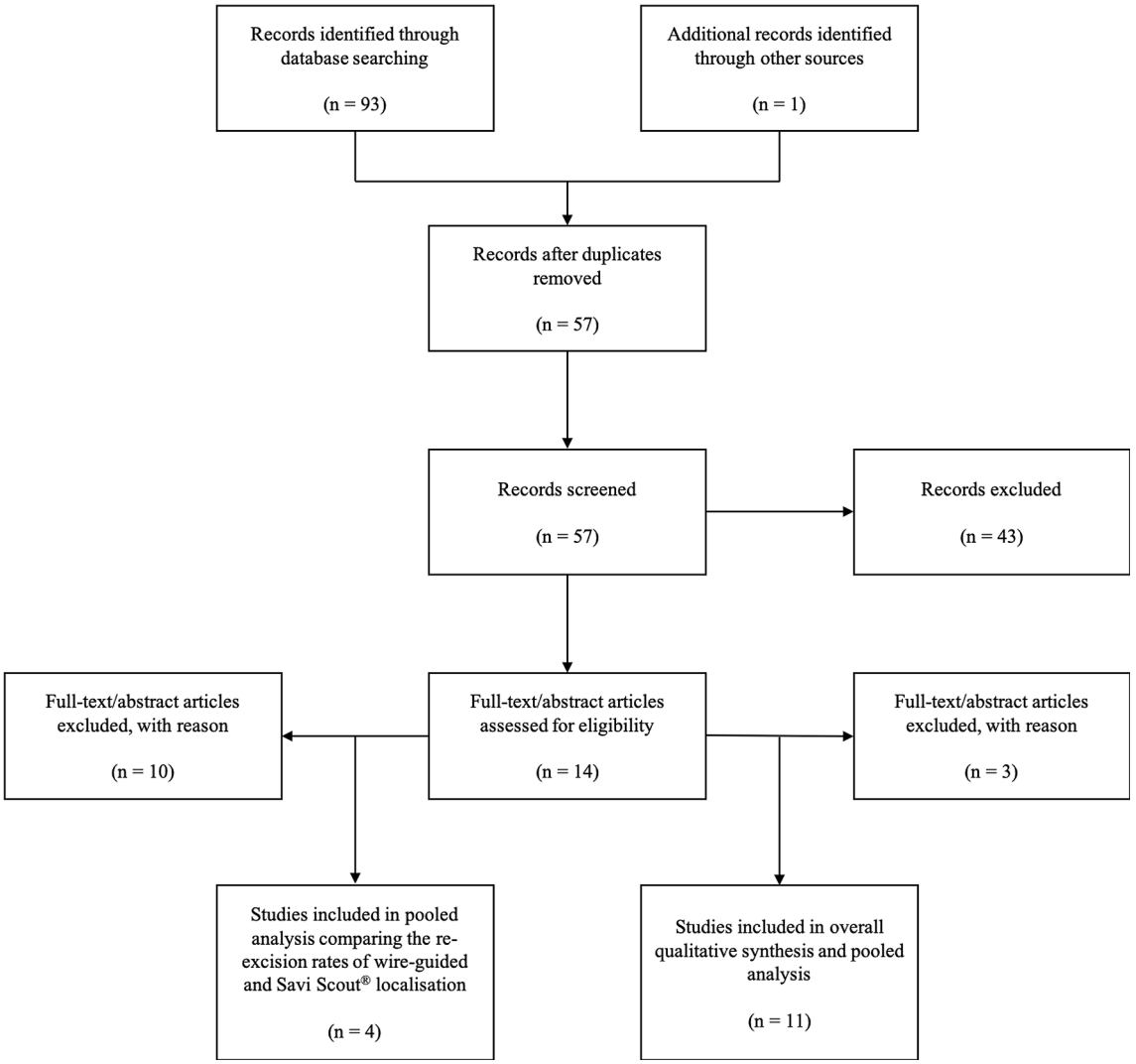

Figure 4. *A PRISMA flowchart summarising the results of data collection.*

These differences were largely attributed to WGL being performed on the same day of surgery and to delays in the radiology departments. We found the mean duration of reflector deployment to be 5.6 min, which is shorter than the 10 min reported for WGL wire placement (38). Despite the higher initial and recurrent costs of Savi Scout® compared to WGL, it is likely that the lower re-excision rate, reduced device deployment time, shorter operating delays and greater scheduling flexibility will translate to greater cost-effectiveness and indirect financial savings (3, 11). Facility providers can potentially save $4,721 per re-excision case avoided within the US healthcare setting (39). Moreover, switching from WGL to Savi Scout® was estimated to result in cost savings of $1,972 per case due to reduction in operating room waiting time (20).

Some complications with the Savi Scout® system were reported. An initial pilot study into SSL described one case of detection signal loss after an electrocautery device came into contact with the reflector (16). Although the manufacturer has since modified the reflector to overcome this, however this modification does not seem to completely eliminate this possibility (8). There is also a risk of reflector antenna transection during surgical dissection (8). However, these limitations may be of minimal consequence since reflector damage by electrocautery would suggest that the surgeon has reached the lesion and is therefore able to visualise and remove the reflector. Post-placement signal detection difficulties associated with the presence of post-biopsy haematoma (27, 30) and a calcified fibroadenoma between the reflector and the skin (30) have also been

Table I. *Details of studies included in overall pooled analysis*.

Study (reference)	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 (25)*	Srour *et al*.	2020	108§	108 (100%)	108 (100%)	16/79 (20%)
A new era of preoperative breast lesion localization (conference abstract) (23)	Khaiat *et al*.	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 (26)	Jadeja *et al*.	2018	90	90 (100%)	90 (100%)	4/39 (10%)
Reflector-guided breast tumor localization *versus* wire localization for lumpectomies: A comparison of surgical outcomes (28)*	Patel *et al*.	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) (29)*	Turk *et al*.	2018	127§	126 (99%)	126 (100%)	13/126 (10%)
Beyond wires and seeds: Reflector-guided breast lesion localization and excision (30)	Mango *et al*.	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) (24)*	Shirley *et al*.	2017	26	26 (100%)	25 (96%)	2/17 (12%)
A comparison of SAVI SCOUT radar to the radioactive I125 seed in the localization of non-palpable breast cancer (conference abstract) (31)	Rico *et al*.	2017	59§	59 (100%)	59 (100%)	8/59 (14%)
A comparison of the micro-impulse radar SAVI SCOUT to the radioactive I125 seed in localization of non-palpable breast cancer for breast conserving therapy (conference abstract) (32)	Nolano *et al*.	2017	35§	35 (100%)	35 (100%)	4/35 (11%)

Table I. *Continued*

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Study (reference)	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 (%)
Pilot study of a new nonradioactive surgical guidance technology for locating nonpalpable breast lesions (16)	Cox *et al*.	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 (17)	Cox *et al*.	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%)

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.

Table II. *Details of studies included in pooled analysis comparing re-excision rate between Savi Scout® and wire-guided localisation*.

Study (reference)	Author	Year	Savi Scout® reflectors successfully inserted and retrieved in malignant lesions using SSL	SSL cases requiring re-excision (%)	Wires successfully inserted in malignant lesions using WGL	WGL cases requiring re-excision (%)
Comparison of wire localization, radioactive seed, and Savi scout® radar for management of surgical breast disease (25)	Srour *et al*.	2020	79§	16 (20%)	79	16 (20%)
Reflector-guided breast tumor localization *versus* wire localization for lumpectomies: A comparison of surgical outcomes (28)	Patel *et al*.	2018	42	3 (7%)	42	4 (10%)
Is SAVI SCOUT localization as accurate as needle-localization in obtaining negative margins at time of breast conservation? A single institutional experience. (conference abstract) (29)	Turk *et al*.	2018	126§	13 (10%)	308	52 (17%)
Pilot study of SAVI SCOUT® to localize nonpalpable breast lesions to reduce re-excision (conference abstract) (24)	Shirley *et al*.	2017	17	2 (12%)	116	43 (37%)
		Overall	264	34 (12.88%)**	545	115 (21.10%)

SSL: Savi Scout® localisation; WGL: wire-guided localisation; §number of reflectors assumed from number of patients; **statistically significant difference in re-excision rate *versus* wire-guided localisation ($p<0.01$).

reported. Difficulties with haematomas may, however, be overcome by placing the reflector next to, rather than within, the haematoma with the appropriate information relayed to the operating surgeon (30). Further limitations include the inability to reposition the reflector once deployed (11) and lack of MRI compatible delivery systems (20). Although reflector failure was previously reported in the radiology suite (27) and after direct contact with electrocautery (16), we were the first to report a single case of failure where signal was detected in the radiology suite but could not be detected in the operating room after the patient was anaesthetised. We therefore modified our protocol to test for a reflector signal in the anaesthetic room prior to administering anaesthesia (20).

Detection at different depths of reflector placement was difficult to investigate since studies largely followed the manufacturer's guidelines at the time. Although use is currently recommended for up to 6 cm depth (14), one study detected reflectors up to 8 cm from the skin surface (17). However, reflector placement at excessive depths is not recommended since it is unreliable in the absence of studies examining this as a primary endpoint. One publication focussed specifically on the use of multiple Savi Scout® reflectors within the same breast (26), reporting comparable successful placement (100%), successful retrieval (100%) and re-excision (10.3%) rates to our overall pooled analysis. Despite the manufacturer's recommendation of an at least 2.5 cm distance between reflectors, we were able to detect distinct reflector signal when deployed as close as 1.7 cm apart (20). Successful placement and retrieval were demonstrated using up to three reflectors within the same breast (26).

It is important to note that several studies have reported the use of Savi Scout® system to successfully localise axillary lymph nodes (22, 27), including within our own patient cohort (20). Lack of sufficient available data prevented any meaningful analysis from being conducted as part of our pooled analysis.

A direct alternative to the Savi Scout® is the similar non-radioactive, wireless Magseed® localisation system. The marker of Magseed® is an inducible paramagnetic seed which is deployed through a sterile 18-gauge needle any time before surgery. It can be detected from the skin surface using a handheld probe up to a reliable depth of 4 cm (20). We recently conducted a similar analysis to this study on the use of Magseed® for the localisation of non-palpable breast lesions, reporting similar rates as SSL regarding successful placement (94.42%), successful retrieval (99.86%) and re-excision (11.2%) (15). In comparison to Savi Scout®, the Magseed® deployment system uses an introducer needle with a smaller diameter (18-guage needle *versus* 16-guage) and the seed itself is smaller in size than the Savi Scout® reflector (5×0.9 mm *versus* 12×1.6 mm). The Magseed® system may therefore be preferred for small, superficial lesions near the skin surface (15). The Savi Scout® system, however, has the advantage of measuring and displaying the distance between the handpiece and the reflector in mm, thus allowing a more accurate reorientation in real time whereas the current Magseed® system does not have this feature, although the audible signal and digital display seem to correlate with the distance from the probe to the target (15). Furthermore, the Magseed® detection probe is bulkier than that of SSL and all metal instruments need to be removed from the immediate surgical field when in the Magseed® detection probe is in use (3, 11). This can be tedious during surgery and the use of non-magnetic surgical tools may represent an additional indirect cost of Magseed® (11). Moreover, Magseeds® and RFID tags have a significant limitation of possible signal void artefacts on follow-up MRI scans – these may be as large as 4-6 cm and 2 cm, respectively (11). MRI signal artefacts may impede the detection of residual disease during progression monitoring after further cancer therapy (15). Importantly, the Savi Scout® reflector produces much more minimal MRI signal void artefacts (<5 mm) (11, 20), as demonstrated in Figure 5. This renders it a much more desirable system, particularly for deployment during diagnostic biopsy in patients with highly suspicious lesions (BIRADS-5), thus potentially reducing the need for a further invasive procedure.

One prospective analysis investigated clinician and patient experience with the Savi Scout® system (17). Cox *et al*. used a Likert scale to compare the use of SSL against WGL. On average, surgeons rated SSL better that WGL for ease of localisation, tissue removal and incisional site planning. These results are supported by anecdotes from other publications (16, 21), as well as by our own study whereby the surgeon rated Savi Scout® system as much better than WGL in all 23 cases (20). We also recorded strong positive feedback from radiologists. Physicians rated SSL as better for patient comfort, patient anxiety and overall patient experience, as well as clinician workflow in the study conducted by Cox *et al*. (17). Although a separate study (30) documented a case whereby patient distress during reflector placement necessitated the conversion to WGL, Cox *et al*. reported high overall patient satisfaction, with 97% of those surveyed recommending SSL to other patients. Of the patients surveyed within our cohort, a high mean satisfaction score of 9.8/10 was recorded (20).

Furthermore, the reflector is cleared for implantation for an unlimited length of time pre-operatively and SSL may be conducted at the time of diagnostic biopsy. This is likely to lead to greater patient satisfaction, and cost-effectiveness since it negates the need for a separate localisation procedure to be carried out. Clinically, this is important in patients who undergo NST, since Savi Scout does not compromise MRI used to monitor response to treatment. The avoidance of a

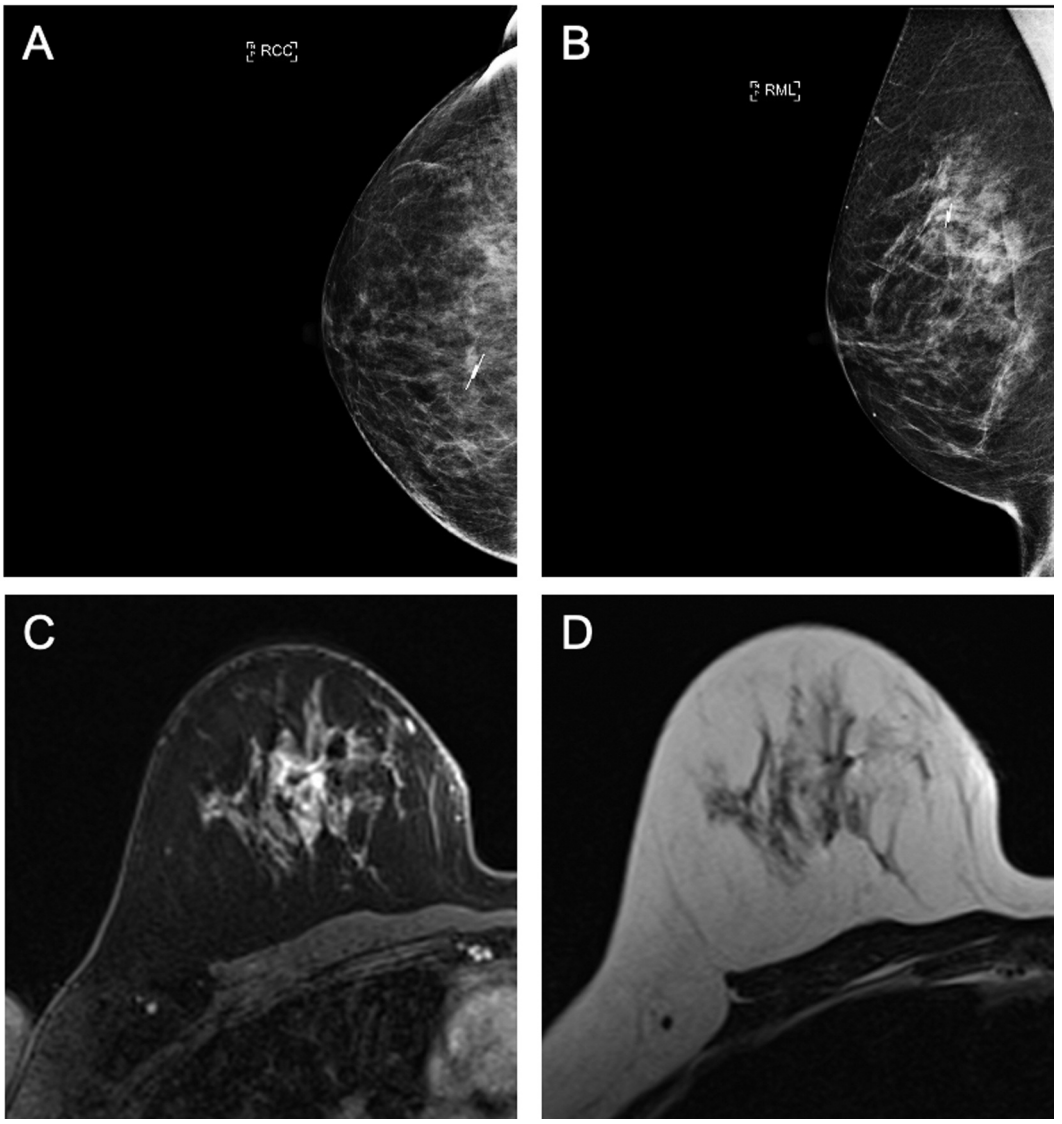

Figure 5. *Minimal MRI void signals at the site of reflector localising the tumour in the upper inner quadrant of the right breast. (A) Right craniocaudal mammogram view. (B) Right mediolateral oblique mammogram view. (C) T1 non-subtracted MRI image post contrast. (D) T2 MRI image showing minimal MRI signal void.*

separate localisation procedure will also contribute to the indirect financial savings of using the Savi Scout® system when compared to WGL.

Future Directions

It would be of interest to investigate SSL re-excision rate in the future preferably in the context of randomised trials including comparisons with not only WGL, but also other wireless technologies such as Magseed®. Since the Savi Scout® method is relatively new, inexperience may have adversely affected re-excision rate in these initial comparative studies due to a learning curve impact. Furthermore, detailed analysis into the cost-effectiveness of the Savi Scout® system in comparison to WGL should be conducted. In the present study, we highlighted many potential sources of indirect financial savings, however these could be further investigated.

Despite its many advantages, the Savi Scout® system would benefit from some improvements in order to make it a more preferable localisation option. Unlike wires, the current Savi Scout® reflector delivery system, like Magseed® and RFID tags, is not suitable for use under MRI guidance. Developments to the reflector itself would also be beneficial.

The current reflector is relatively long and therefore less suitable for smaller lesions. Furthermore, RFID tags each have a unique identification number that can be displayed on the detecting probe, allowing for distinction between multiple devices within the same breast, thus facilitating bracketing of extensive or multifocal lesions (12). Unique Savi Scout® reflectors with identification numbers or variable reflector designs, which can be distinguished both radiographically and by the detection console would be favourable. This would be particularly advantageous when bracketing extensive malignant microcalcifications within the same breast.

It is clear that no one technique fulfils all requirements and therefore an ideal localisation system does not exist. This pooled analysis was prompted by a lack of large clinical studies into SSL. There is an evident need for future randomised controlled trials comparing the Savi Scout® system against other localisation methods in order to obtain more accurate data for all measures.

Conclusion

Our findings show the Savi Scout® system to be a highly successful localisation technique, which is associated with lower re-excision rates than WGL. This is achieved whilst overcoming many of the recognised limitations of the latter, including minimal device migration, more optimal skin incisions and potentially smaller specimen sizes. Several other distinguishable benefits have also emerged, such as high patient and clinician satisfaction as well as decoupling of radiology and surgery scheduling. There is, however, much scope for future research into the use of the Savi Scout® localisation system.

Conflicts of Interest

This work carried no conflicts of interest.

Authors' Contributions

Kasem I and Mokbel K carried out the data search and analyses. Kasem I and Mokbel K wrote and reviewed the article.

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