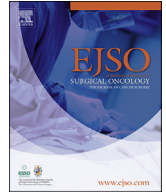




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## Results of shared learning of a new magnetic seed localisation device – A UK iBRA-NET breast cancer localisation study



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### ABSTRACT

**Introduction:** Shared learning is imperative in the assessment and safe implementation of new health-care interventions. Magnetic seeds (Magseed®) potentially offer logistical benefit over wire localisation for non-palpable breast lesions but few data exist on outcomes comparing these techniques. A national registration study (iBRA-NET) was conducted to collate device outcomes. In order to share learning, thematic analysis was conducted to ascertain early clinical experiences of Magseed® and wire guided localisation and explore how learning events may be applied to improve clinical outcomes.

**Methods:** A qualitative study of 27 oncoplastic surgeons, radiologists and physicians was conducted in January 2020 to ascertain the feasibility and challenges associated with Magseed® versus wire breast localisation surgery. Four focus groups were asked to discuss experiences, concerns and shared learning outcomes which were tabulated and analysed thematically.

**Results:** Three key themes were identified comparing Magseed® and wire localisation of breast lesions relating to preoperative, intraoperative and postoperative learning outcomes. Percutaneous Magseed® detection, instrument interference and potential seed or wire dislodgement were the most common issues identified. Clinician experience suggested Magseed® index lesion identification was non-inferior to wire placement and improved the patient pathway in terms of scheduling and multi-site insertion.

**Conclusions:** Prospective shared learning suggested Magseed® offered additional non-clinical benefits over wire localisation, improving the efficiency of the patient pathway. Recommendations for improving

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breast localisation technique, appropriate patient selection and clinical practice through shared learning are discussed that may aid other surgeons in the adoption of this relatively new technique.

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## 1. Introduction

Wire-localisation of impalpable screen-detected breast lesions is the current standard for surgical localisation. With more advanced, more sensitive imaging and the increasing availability of screening there has been an increase in the need to operate on non-palpable lesions that led many to develop novel methodologies for surgical localisation [1–7]. Incident and event reporting through shared learning is imperative in the assessment and implementation of novel healthcare interventions [8]. Shared learning is recommended by decision makers, including the National Institute for Health and Care Excellence (NICE), and correlates with improved clinical outcomes [9] and a reduction in adverse or ‘never’ events [10]. The iBRA-NET Study Group is a UK national group of breast and oncoplastic surgeons, allied health professionals and patients, designed to prospectively audit outcomes of breast surgical interventions [11]. Its objective is to evaluate the safety and efficacy of new breast device technologies within a structured framework, including the appraisal of breast localisation technologies such as Magseed® (Endomag).

Magseed® is a new breast localisation technique for impalpable lesions, utilizing magnetic seeds, without the use of radionuclides. The technique has been described elsewhere in detail [12]. Magseed® are 5 × 1 mm paramagnetic steel and iron oxide seeds which are inserted prior to surgery and can be visualised using mammography or ultrasound to confirm their position. The magnetic signature is detected perioperatively by a probe which generates an alternating magnetic field to display a numerical count and audio tone, correlating with the strength of the magnetic field, and hence distance from seed to probe. The feasibility and safety of Magseed® localisation has been validated in two-centre cohort studies in the United Kingdom for breast lesions [13] and the USA [14,15]. The wider results of the larger prospective iBRA-NET study comparing wire and Magseed® localisation have also recently been reported elsewhere [16].

Magseed® may potentially offer logistical benefit over conventional wire breast localisation [12,13]. However, little is known about clinical experiences, potential complications and learning used to overcome perioperative challenges changing from wire to a Magseed® device. Qualitative feedback is necessary to inform prospective clinical trials, improve clinical practice and facilitate the implementation of new breast localisation devices through collective shared learning.

The aim of this study was to ensure that clinicians using new Magseed® technology as part of the national iBRA-NET localisation study could share early experiences and learning.

## 2. Methods

This study formed part of a national prospective Phase 2a/2b study conducted by the iBRA-NET Localisation Study Group that aimed to evaluate the safety and efficacy of Magseed® for women undergoing breast conserving surgery, with the full methods reported elsewhere [17]. Shared learning was either captured prospectively as part of the registry study between January 2019–March 2020, or face-to-face as part of a qualitative focus group. Each online case report form included an optional section on

shared learning, with a prompt (yes/no) relating to whether there was an event/experience in that case that the collaborator wanted to share, and whether this shared learning related to; device insertion, localisation prior to anaesthetic induction or intra-operative surgical dissection. There was a free text box in which to elaborate on the event and lessons learned. All participating surgeons contributing to the iBRA-NET localisation study were required to complete the shared learning domain on the case report form and were encouraged to report any unanticipated complication or procedural modifications that occurred.

Prospective, anonymised clinical and demographic data were collected and managed using REDCap electronic data capture tools hosted at the Kennedy Institute of Rheumatology, University of Oxford [18,19]. REDCap (Research Electronic Data Capture) is a secure web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; a 4) procedures for data integration and interoperability with external sources.

Qualitative focus groups were formed with oncoplastic breast surgeons, breast radiologists and allied clinicians to ascertain the potential benefits and risks associated with Magseed® versus wire localisation in non-palpable breast lesions. All healthcare professionals attending the UK Interdisciplinary Breast Cancer Symposium in Birmingham were invited by email to attend a breast localisation group discussion session on 27<sup>th</sup> January 2020. This was advertised as an open opportunity to present and discuss any shared learning experiences from inserting or using wire or Magseed® breast localisation techniques for surgical excision. All clinicians entering data in the iBRA-NET localisation database were invited to attend. Clinicians with experience of using either localisation technique were purposively selected for interview [20].

Data were gathered from four focus group discussions conducted during the session. Focus groups were specifically chosen over individual interviews to allow for more in-depth discussion of learning outcomes and exploration of experiences between members from different units [21]. The focus group discussions were facilitated by four members of the iBRA-NET localisation shared learning initiative. The session was split into four sub-sections:

1. **Introduction:** Attendees were briefed on the iBRA-NET localisation study aims, methods and recruitment.
2. **Example of shared learning:** Summaries of the radiological and surgical experiences from UK breast units were presented as examples of shared learning practice.
3. **Breakout and focus groups:** Attendees were asked to share their own experiences of different breast localisation techniques, including any learning points or challenges, related to both wires and Magseed®. Participants were split into four focus groups to facilitate the discussion. Each focus group was asked to summarise their findings.
4. **Consolidation and discussion:** Further discussion with an emphasis on shared learning was sought from the whole group to consolidate the major themes and suggestions for practice.

Data were collected until saturation of themes [22] and no further

learning outcomes were raised in the focus group discussions. All data were managed using Microsoft® Word v2016 and NVivo v11 software. Thematic analysis was applied to systematically identify, analyse and report trends within the data [23]. Learning outcomes from the focus group discussions were noted alongside illustrative experiences. Themes were initially coded independently by three researchers (HB, JH and RD) to ensure consistency in the major outcomes derived. These were reviewed by the iBRA-NET shared learning panel (HB, JH, RD) in order to refine the final themes and ensure concordance in recommendations. A summary of the shared learning outcomes was disseminated to the iBRA-NET membership for clarification to ensure an accurate and valid interpretation of focus group discussions had been conducted [24].

The shared learning research was undertaken as part of the iBRA-NET localisation study (North West Research Ethics NW/16/0092) and verbal consent was sought from all participants. No financial incentive was provided. Results are reported against Consolidated criteria for Reporting Qualitative research (COREQ) [25] and Standards for Reporting Qualitative Research (SRQR) [26] guidelines, in keeping with good qualitative research practice (Supplementary Tables 1 and 2).

### 3. Results

Thirty-five UK breast units took part in the study between January 2019 and March 2020. A total of 1981 patient records were entered into the REDCap database during the study period, of which 50 (2.5%) included a shared learning event.

Four focus groups were held including a total of 27 healthcare professionals, of which 24 (88.9%) were oncological breast surgeons and 3 (11.1%) were breast radiologists. The focus groups were all conducted at the same time and lasted for 57 min. Sample characteristics for the online and focus groups are given in Table 1.

#### 3.1. Thematic analysis

Three major themes were identified by thematic analysis of the

**Table 1**  
Demographics for each shared learning sample.

Characteristic	Online database N (%)	Focus groups N (%)
Total number of shared learning records	50 (100)	27 (100)
<b>Breast units:</b>		
North West England	10 [20]	6 [22]
Yorkshire and Humber	1 [2]	2 [7]
West Midlands	0 (0)	3 [11]
East Midlands	9 [18]	3 [11]
South West England	0 (0)	5 [19]
Oxford and South East	27 (54)	2 [7]
Scotland	3 [6]	5 [19]
Wales	0 (0)	1 [4]
Used surgical innovation (Magseed®)	30 (60)	20 (74)
Used standard care (wire-guided)	20 (40)	27 (100)
Male	12 [24]	14 (52)
Female	38 (76)	13 (48)
<b>Speciality experience:</b>		
Surgeon	26 (52)	23 (84)
Radiologist	0 (0)	3 [12]
Junior doctor trainee	22 (44)	1 [4]
Allied health professional	2 [4]	0 (0)
<b>Shared learning themes:<sup>a</sup></b>		
Technical efficacy or modification	21 (42)	13 [28]
Advantages of new device	14 [28]	15 (56)
Disadvantages of new device	16 [32]	6 [22]
Patient outcomes and limitations	10 [20]	18 (67)
Future application and evidence	13 [26]	7 (33)

<sup>a</sup> Note: Cumulative totals exceed 100% as some learning events included multiple themes.

data relating to preoperative, intraoperative and postoperative shared learning outcomes. Table 2 summarises the major themes and shared learning experiences identified in each category. Both methodologies provided complementary data on shared learning events. Participants were more likely to detail learning events related to the limitations of the device in a focus group setting compared to online (30.5% of all shared learning experiences vs 20.0%), whereas the online reporting featured more events related to technical efficacy (42.0% vs. 22.0%).

The focus groups also provided many more shared learning events per individual participant (59 events from 27 participants; with a mean of 2.19 events per participant) and more depth of data. Comparatively, only 2.5% of entries on REDCap contained a shared learning entry (52 events from 98 participants and 1981 entries; with a mean of 0.5 events per participant), however the online system was able to capture data from more participants with significantly less time and cost.

#### 3.1.1. Shared learning in the preoperative setting

Preoperative shared learning primarily focused on considerations likely to reduce adverse events. Appropriate patient selection was deemed the most important preoperative consideration, regardless of breast localisation technique. Most issues associated with insertion and detection correlated with patient factors and comorbidities, including the number, location and size of the index lesion and patient-clinician preference. Magseed® was considered to be more difficult to localize in a bigger breast or at depth. Bracketing with wires was preferred for multiple and larger (>30 mm) breast index lesions because of the potential for cross-signal interference observed with multiple Magseed® insertions. Magseed® was preferable in breast units with remote radiology, particularly in women with less dense breast tissue, due to the potential for placement in advance and lower risk of preoperative displacement when transporting patients.

No focus group reported a significant adverse event related to insertion of Magseed®. Magseed® insertion was feasible and required little adjustment of technique compared with standard wire insertion or core biopsy under radiological guidance. Three clinicians reported incidents where a Magseed® had been inserted 10–20 mm outside of the target lesion, although this phenomenon was also similarly observed using wires. Multi-disciplinary consensus felt that provided Magseed® orientation had been adequately documented, it did not adversely affect surgical margins. No unit reported a major event from a grossly misplaced Magseed® insertion, but secondary wire correction was sometimes used in such cases.

A final preoperative outcome highlighted was the importance of scheduling localisation around neoadjuvant chemotherapy cycle imaging. Magseed® artefact was an issue in one patient due to insertion prior to final neoadjuvant chemotherapy review magnetic resonance imaging (MRI). Shared learning practice suggested that this could be avoided through planning device insertion around MRI, if needed, and regular discussion between oncological, radiological and surgical services in the breast multi-disciplinary meeting on what imaging is required post neoadjuvant chemotherapy.

#### 3.1.2. Shared learning in the intraoperative setting

Device dislodgement during surgical dissection was deemed the most important intraoperative adverse event reported, but was considered uncommon. The most common intraoperative event reported was difficult percutaneous detection. Three surgeons reported an event where they were either unable to detect a Magseed® signal until an incision was made or where no signal was elicited at all. Difficult percutaneous detection was primarily

**Table 2**  
Shared learning themes.

THEME	EXAMPLE OF SHARED LEARNING
<b>Preoperative learning outcomes</b>	
Patient selection	<ul style="list-style-type: none"> <li>• Wire-guided localisation was more appropriate in some clinical circumstances, e.g. posteriorly located index lesions or large dense breasts</li> <li>• Patient choice or pre-existing health issues affected eligibility and surgical approach.</li> <li>• Bracketing with wires for multiple ipsilateral breast cancers (&lt;25 mm apart) prevented cross-signalling issues observed with multiple Magseed® clips.</li> </ul>
Insertion	<ul style="list-style-type: none"> <li>• The Magseed® was placed &gt;20 mm inferior to the lesion. It was left in situ, with suggestion of further wire localisation on the day of surgery.</li> <li>• Difficult to assess confirmation of Magseed® position on specimen xray where multiple clips were used simultaneously.</li> </ul>
Scheduling	<ul style="list-style-type: none"> <li>• Magseed® artefact on neoadjuvant chemotherapy magnetic resonance imaging was minimal but could have been avoided.</li> <li>• Magseed® localisation worked even better in units with multiple site radiology departments as patients could not be safely transported with wires in situ.</li> <li>• Advance placement with Magseed® improved patient flow on the day of surgery and reduced delays in theatre between cases.</li> </ul>
<b>Intraoperative learning outcomes</b>	
Percutaneous detection	<ul style="list-style-type: none"> <li>• Difficulty locating any magnetic signal percutaneously in large volume breast tissue, dense breast tissue or in posteriorly located index lesions.</li> <li>• A minority of cases experience no Magseed® signal identification until after initial skin incision was made</li> <li>• A few experiences nationally reported if no Magseed® signal being present so a wire guided localisation was subsequently performed.</li> </ul>
Interference	<ul style="list-style-type: none"> <li>• The machine count was triggered by use of diathermy and forceps and required regular recalibration.</li> <li>• = Incorrect handling of probe, metal retractors and wedding ring interference commonly affected the Magseed® probe signal.</li> <li>• Magseed® and Magtrace® signals were indistinguishable. Additional localisation with skin marking was required to locate tumour.</li> <li>• During operation Magseed® probe giving very erratic readings with no consistency and throughout entire breast..</li> </ul>
Dislodgement	<ul style="list-style-type: none"> <li>• Wire dislodgement during dissection was more common than Magseed® surgery due to the lack of tension on the wire during dissection.</li> <li>• Dissection made through the middle of the index mass, exposed the Magseed® and this was removed by the surgeon.</li> </ul>
<b>Postoperative learning outcomes</b>	
Adverse events	<ul style="list-style-type: none"> <li>• Re-excision of margins was observed in Magseed® and wire wide local excision specimens.</li> <li>• No immediate post-operative reaction or adverse events reported following wire or magnetic seed placement.</li> </ul>
Training	<ul style="list-style-type: none"> <li>• Technically straightforward to insert (comparable to core biopsy and wire)</li> <li>• Little additional training required</li> <li>• Small learning curve among surgeons familiar with sentinel node isotope probe</li> </ul>
Application	<ul style="list-style-type: none"> <li>• Targeted axillary node dissection</li> <li>• Business case may be necessary and dependent on clinical trials in smaller units</li> </ul>

associated with posteriorly located breast index lesions and women with dense or large volume breast tissue. No unit had to abandon breast conserving surgery or reschedule further localisation, however poor initial percutaneous signal did incur intraoperative delay.

Magnetic trace interference was another learning event, with magnetic count recalibration necessary after diathermy, forceps and metal retractor use during surgical dissection. Other interference occurred between the Magseed® and probe itself from surgeon-related factors (e.g. metallic wedding rings, incorrect handling of the probe) and patient- and procedure-related factors (e.g. dual iron agent procedures, using both Magtrace® and Magseed®, or where two Magseed® clips were used in the same breast). Cross-signal interference from multiple Magseed® clips was felt to be less common when index lesions were >25 mm apart.

### 3.1.3. Shared learning in the postoperative setting

No immediate adverse postoperative complications were reported. Surgical re-excision of margins was required in some cases but this was no more common compared to wire-guided wide local excision based on the experiences of those attending the discussion. One unit discussed the potential postoperative use of targeted axillary dissection with Magseed® after positive percutaneous lymph node biopsy but limited numbers of cases had been performed to validate this approach.

Focus groups described improved patient flow and satisfaction associated with the advanced placement of Magseed®, and discussed the potential for reduced theatre delay, provided percutaneous Magseed® detection was adequate. There was agreement that Magseed® implementation would require some initial training experience and might be limited in smaller breast units with lower funding availability.

## 3.2. Suggestions for practice

The following suggestions were developed to facilitate clinical

practice:

- **Patient selection:** Seek early multi-disciplinary team involvement to allow appropriate patient selection and scheduling around neoadjuvant chemotherapy imaging, based on local protocols and experience.
- **Complex index lesion:** For ipsilateral, multiple breast lesions (especially if < 25 mm apart), large breast lesions (>30 mm) and patients with large volume or dense breast tissue, where signals may be compromised or cross-signal interference may occur, wire-guided localisation may be considered during the learning phase of Magseed®.
- **Scheduling:** Units with offsite radiology/operating theatres should consider advanced scheduling with Magseed® where patients are suitable.
- **Preoperative checklist:** Preoperative confirmation of signal could be documented in the breast surgical checklist before induction of anaesthesia. This should include radiological confirmation of correct placement of the device in the target lesion. Confirm availability of additional instrumentation (e.g. non-metal retractors) and radiology accessibility to identify issues prior to surgery in the learning phase.
- **Percutaneous detection:** Skin marking was considered a useful adjunct if percutaneous Magseed® signal is likely to be limited (e.g. high breast density, macromastia, BMI >30, posterior index lesion).
- **Surgical approach:** Manual breast fixation and deeper probe compression where felt by some to improve signal and may help to distinguish the index lesion during dissection. Imaging should also be used to guide dissection intraoperatively.
- **Interference:** Regular recalibration, correct probe handling technique and removal of metal wear in close proximity to the probe (e.g. wedding rings, mobile phones, retractors) may decrease magnetic interference. Consider appropriateness of dual iron agents if the target lesion is located close to the axilla to prevent cross-signal interference.

- **Application:** Consider whether Magseed® localisation may be of benefit in patients requiring remote surgical incision, nodal or targeted axillary dissection.

#### 4. Discussion

This study has applied prospective shared learning to identify the benefits and challenges associated with Magseed® localisation in non-palpable breast lesions and provides a timely contribution to the literature given the paucity of data comparing Magseed® and wire-guided localisation methodology. Studies comparing Magseed® localisation with wire localisation for breast conserving surgery have shown it is non-inferior [7,15,16] and that displacement during surgical excision is less frequent among Magseed® cases [7,16]. Qualitative analysis of shared learning also suggested Magseed® was non-inferior to wire-guided localisation in terms of insertion and lesion excision, and offered additional benefit from advanced preoperative scheduling and multi-site working.

Magseed® breast localisation did incur additional intra-operative challenges specific to magnetic signal tracing. Difficult percutaneous magnetic seed detection and signal interference were highlighted as potential barriers to localisation in previous studies comparing breast cancer localisation techniques [14,15]. Shared learning demonstrated that appropriate patient selection, early involvement of relevant multi-disciplinary team members, intra-operative breast compression and correct positional probe handling may mitigate these adverse events and improve surgical practice.

Ultimately, the localisation approach applied is likely to consider multiple clinical resource and other local factors, however utilizing shared learning practice and prior awareness of potential complications may improve surgical outcomes in both groups. An analysis comparing consecutive re-excision rates for wire-guided and radio-active seed breast lesion excisions [27], demonstrated better margin clearances following sharing of expertise and clinical experience. By sharing learning outcomes associated with localisation techniques in this analysis, it is hypothesised will shorten the learning curve and potential for adverse events, although further empirical evidence is necessary to validate this.

A major strength of this analysis is the ability to formulate clear suggestions which may be applied by clinicians in their daily practice. Incident reporting of any harm and quality improvement is encouraged in all healthcare interventions [28]. Shared learning practice has been utilised to improve patient outcomes and compliance with national guidelines in pancreatic cancer surgery [9] and acute surgical ambulatory care [10,29] previously. This study complies with guidance on shared learning methodology [30,31] and highlights comparable shared learning practices that could be applied to localisation procedures in other surgical disciplines.

Early identification of perioperative challenges may potentially improve clinical outcomes, patient experience and surgical practice [32]. Whilst this study does offer guidance to facilitate radiological and surgical practice, empirical data are required to ascertain the precise impact of these suggestions on breast cancer and patient outcomes. The experiences were limited to clinicians who were likely more knowledgeable about Magseed® and may not reflect the experiences observed in all breast surgical units. The outcomes of the study also reflect those in the early phase of learning with Magseed, shared learning performed after several years of unit use may produce different learning themes.

There were advantages and disadvantages to each method of data collection, but the combination of both meant that a greater variety and number of themes were collected. This complimentary approach should be recommended for similar future studies to

allow the full variety of shared learning events and examples to be collected. Focus groups, whilst costly from both time and resource perspective may provide insight into the best way to collect and categorise learning events, thereby improving REDCap data collection. Focus group methodology also allows for in-depth discussion between learners about potential solutions to problems that had arisen, which is not possible with the online format. The online format is likely to under-report shared learning events as many of the data entries were collated by a third party within the study centre, not present in all of the surgeries. To improve shared learning, a contemporaneous approach of recording the learning events at the time of the event would be ideal but would require far more resource. The authors would therefore advise a combined approach to capturing shared learning events for future similar studies, with focus groups being utilised early in the process to enable adaptation and improvement of online data collection forms. Improved methods of contemporaneous shared learning data capture would likely be beneficial to users' learning experience.

#### 5. Conclusion

In conclusion, a mixed methods approach to shared learning data collection is to be recommended for studies designed to evaluate the safety and efficacy of new breast cancer technologies within a structured framework. This analysis of shared learning events suggests Magseed® is a feasible alternative method of breast localisation surgery and may provide additional benefit over wire localisation from advanced scheduling and improved patient and surgical flow. Potential challenges associated with Magseed® versus wire localisation include difficult percutaneous detectability, magnetic interference and instrument recalibration.

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#### Declaration of competing interestCOI

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Mr James Harvey: I have been Chief Investigator for a previous industry funded study funded by Endomagnetics. I have also been an external consultant for Endomagnetics. Mr Rajiv Dave: I have received honoraria from Roche and Endomagnetics, but I do not deem these as competing interests for this paper. Mr Yazan Masannat: I have not personal COI to declare in relation to this paper, but I think it's worth mentioning that I run the iBreastBook website and webinars and some events have been sponsored by the industry to include Endomag, Avatar Medical, KUBTEC, SPERCTROS and STRYKER. That sponsorship is for iBreastBook project to support the ongoing expenses.

#### CRedit authorship contribution statement

**Jenna L. Morgan:** Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Hannah L. Bromley:** Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review and editing. **Rajiv V. Dave:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – review and editing. **Yazan Masannat:** Investigation, Methodology, Writing – review & editing. **Tahir**

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejso.2022.07.014>.

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