Article:
Morgan, J.L., Bromley, H.L., Dave, R.V. et al. (14 more authors) (2022) Results of shared learning of a new magnetic seed localisation device – A UK iBRA-NET breast cancer localisation study. European Journal of Surgical Oncology, 48 (12). pp. 2408-2413. ISSN 0748-7983

https://doi.org/10.1016/j.ejso.2022.07.014

Results of Shared Learning of a new Magnetic Seed Localisation Device – a UK iBRA-NET breast cancer localisation study

Authors:

Jenna L Morgan [a], Hannah L Bromley [b], Rajiv V Dave [b,c], Yazan Masannat [d], Tahir Masudi [e], Senthurun Mylvaganam [f], Suzanne Elgammal [g], Nicola Barnes[b], Sue Down [h], Chris Holcombe [i], Shelley Potter [j,k], Matthew D Gardiner [l,m], Anthony J Maxwell [b,n], Santosh K Somasundaram [o], Amtul Sami [p], Cliona Kirwan [b,c], James Harvey [b,c], on behalf of the iBRA-NET Localisation Study Group

Author affiliations:

a) Department of Oncology and Metabolism, University of Sheffield Medical School, Sheffield, United Kingdom.
b) Nightingale Breast Centre, Manchester University NHS Foundation Trust, United Kingdom
c) Division of Cancer Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, United Kingdom.
d) Aberdeen Royal Infirmary, Aberdeen, United Kingdom
e) Rotherham NHS Foundation Trust, Rotherham, United Kingdom
f) New Cross Hospital, Royal Wolverhampton Hospitals NHS Trust, United Kingdom
g) University Hospital Crosshouse, NHS Ayrshire and Arran, United Kingdom
h) James Paget University Hospital, Great Yarmouth, United Kingdom
i) Breast Unit, Royal Liverpool University Hospital, United Kingdom
j) National Institute for Health Research Bristol Biomedical Research Centre, University Hospitals Bristol and Weston NHS Foundation Trust, Bristol, United Kingdom
k) Bristol Breast Care Centre, North Bristol NHS Trust, United Kingdom
l) Department of Plastic Surgery, Frimley Health NHS Foundation Trust, Slough United Kingdom
m) Kennedy Institute of Rheumatology, University of Oxford, Oxford, United Kingdom
n) Division of Informatics, Imaging & Data Sciences, Faculty of Biology, Medicine and Health, University of Manchester, United Kingdom
o) Royal Lancaster Infirmary, University Hospitals of Morecambe Bay, United Kingdom
p) Lincoln County Hospital, United Lincolnshire Hospitals NHS Trust, United Kingdom

Corresponding author:

Mr James Harvey

- ORCID: [0000-0002-1359-2186]

Nightingale Breast Centre, Wythenshawe Hospital, Manchester M23 9LT, United Kingdom
Email: james.harvey@mft.nhs.uk

Funding: This research was undertaken as part of the iBRA-NET Localisation study supported by the Association of Breast Surgeons.

Competing interests: None to declare.

Article type: Original research

Key words: Breast cancer, localisation, Magseed, wire, wide local excision, lumpectomy

Word count: /3000 words

Abstract (243/250)

Introduction: Shared learning is imperative in the assessment and safe implementation of new healthcare 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 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.

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, utilising magnetic seeds, without the use of radionuclides. The technique has been described elsewhere in detail (12). Magseed® are 5x1mm 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.

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 27th 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 & 2).

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 oncoplastic breast surgeons and 3 (11.1%) were breast radiologists. The focus groups were all conducted at the same time and lasted for 57 minutes. Sample characteristics for the online and focus groups are given in Table 1.

Thematic analysis

Three major themes were identified by thematic analysis of the 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.

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 (>30mm) 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 10-20mm 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.

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 associated with posteriorly located breast index lesions and women with dense or large volume breast tissue. No unit had to abandon breast conservating 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 >25mm apart.

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.

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 <25mm apart), large breast lesions (>30mm) and patients with large volume or dense breast tissue, where signals may be compromised or cross-signal interference may occur, wire-guided localization 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.

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 sislodgment 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 intraoperative 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, intraoperative breast compression and correct positional probe handling may mitigate these adverse events and improve surgical practice.

Ultimately, the localization 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.

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.

Tables

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)
Breast units:		
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)
Speciality experience:		
Surgeon	26 (52)	23 (84)
Radiologist	0 (0)	3 (12)
Junior doctor trainee	22 (44)	1 (4)
Allied health professional	2 (4)	0 (0)
Shared learning themes:*		
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)

*Note: Cumulative totals exceed 100% as some learning events included multiple themes

Table 2: Shared learning themes

THEME	EXAMPLE OF SHARED LEARNING
Preoperative learning outcomes	
Patient selection	• Wire-guided localisation was more appropriate in some clinical circumstances, e.g. posteriorly located index lesions or large dense breasts • Patient choice or pre-existing health issues affected eligibility and surgical approach. • Bracketing with wires for multiple ipsilateral breast cancers (<25mm apart) prevented cross-signalling issues observed with multiple Magseed® clips.
Insertion	• The Magseed® was placed >20mm inferior to the lesion. It was left in situ, with suggestion of further wire localisation on the day of surgery. • Difficult to assess confirmation of Magseed® position on specimen xray where multiple clips were used simultaneously.
Scheduling	• Magseed® artefact on neoadjuvant chemotherapy magnetic resonance imaging was minimal but could have been avoided. • Magseed® localisation worked even better in units with multiple site radiology departments as patients could not be safely transported with wires in situ. • Advance placement with Magseed® improved patient flow on the day of surgery and reduced delays in theatre between cases.
Intraoperative learning outcomes	
Percutaneous detection	• Difficulty locating any magnetic signal percutaneously in large volume breast tissue, dense breast tissue or in posteriorly located index lesions. • A minority of cases experience no Magseed® signal identification until after initial skin incision was made • A few experiences nationally reported if no Magseed® signal being present so a wire guided localisation was subsequently performed.
Interference	• The machine count was triggered by use of diathermy and forceps and required regular recalibration. • Incorrect handling of probe, metal retractors and wedding ring interference commonly affected the Magseed® probe signal. • Magseed® and Magtrace® signals were indistinguishable. Additional localisation with skin marking was required to locate tumour. • During operation Magseed® probe giving very erratic readings with no consistency and throughout entire breast..

Dislodgement	• Wire dislodgment during dissection was more common than Magseed® surgery due to the lack of tension on the wire during dissection. • Dissection made through the middle of the index mass, exposed the Magseed® and this was removed by the surgeon.
Postoperative learning outcomes	
Adverse events	• Re-excision of margins was observed in Magseed® and wire wide local excision specimens. • No immediate post-operative reaction or adverse events reported following wire or magnetic seed placement.
Training	• Technically straightforward to insert (comparable to core biopsy and wire) • Little additional training required • Small learning curve among surgeons familiar with sentinel node isotope probe
Application	• Targeted axillary node dissection • Business case may be necessary and dependent on clinical trials in smaller units

References

1. Moreira IC, Ventura SR, Ramos I, Fougo JL, Rodrigues PP. Preoperative localisation techniques in breast conservative surgery: A systematic review and meta-analysis. Surg Oncol. 2020;35:351-73.
2. Rose A, Collins JP, Neerhut P, Bishop CV, Mann GB. Carbon localisation of impalpable breast lesions. Breast. 2003;12(4):264-9.
3. Haloua MH, Volders JH, Krekel NM, Lopes Cardozo AM, de Roos WK, de Widt-Levert LM, et al. Intraoperative Ultrasound Guidance in Breast-Conserving Surgery Improves Cosmetic Outcomes and Patient Satisfaction: Results of a Multicenter Randomized Controlled Trial (COBALT). Ann Surg Oncol. 2016;23(1):30-7.
4. Kasem I, Mokbel K. Savi Scout(R) Radar Localisation of Non-palpable Breast Lesions: Systematic Review and Pooled Analysis of 842 Cases. Anticancer Res. 2020;40(7):3633-43.
5. Lowes S, Bell A, Milligan R, Amonkar S, Leaver A. Use of Hologic LOCalizer radiofrequency identification (RFID) tags to localise impalpable breast lesions and axillary nodes: experience of the first 150 cases in a UK breast unit. Clin Radiol. 2020;75(12):942-9.
6. Schermers B, van der Hage JA, Loo CE, Vrancken Peeters M, Winter-Warnars HAO, van Duijnhoven F, et al. Feasibility of magnetic marker localisation for non-palpable breast cancer. Breast. 2017;33:50-6.
7. Zacharioudakis K, Down S, Bholah Z, Lee S, Khan T, Maxwell AJ, et al. Is the future magnetic? Magseed localisation for non palpable breast cancer. A multi-centre non randomised control study. Eur J Surg Oncol. 2019;45(11):2016-21.
8. Parmelli E, Flodgren G, Fraser SG, Williams N, Rubin G, Eccles MP. Interventions to increase clinical incident reporting in health care. The Cochrane database of systematic reviews. 2012;8(8):CD005609-CD.

9. Roberts KJ. A model of fast-track surgery for pancreatic cancer to implement the NICE guideline recommendations for the management of operable patients. Birmingham: University Hospitals Birmingham; 2019.
10. NHS England. Shared Learning Event: Meeting the London Quality Standards for adult acute medicine and general emergency surgery services. London; 2015.
11. Association of Breast Surgery. iBRA-net study group Manchester, United Kingdom: iBRA-net; 2020 [cited 2020 2 April]. Available from: https://www.ibranet.co.uk/.
12. Zacharioudakis K, Down S, Bholah Z, Lee S, Khan T, Maxwell AJ, et al. Is the future magnetic? Magseed localisation for non palpable breast cancer. A multi-centre non randomised control study. European Journal of Surgical Oncology. 2019;45(11):2016-21.
13. Harvey JR, Lim Y, Murphy J, Howe M, Morris J, Goyal A, et al. Safety and feasibility of breast lesion localization using magnetic seeds (Magseed): a multi-centre, open-label cohort study. Breast cancer research and treatment. 2018;169(3):531-6.
14. Lovrics PJ, Goldsmith CH, Hodgson N, McCready D, Gohla G, Boylan C, et al. A multicentered, randomized, controlled trial comparing radioguided seed localization to standard wire localization for nonpalpable, invasive and in situ breast carcinomas. Annals of surgical oncology. 2011;18(12):3407.
15. Price ER, Khoury AL, Esserman LJ, Joe BN, Alvarado MD. Initial clinical experience with an inducible magnetic seed system for preoperative breast lesion localization. American Journal of Roentgenology. 2018;210(4):913-7.
16. Dave R, Barrett E, Morgan J, Chandarana M, Elgammal S, Barnes N, et al. Wire- and magnetic-seed-guided localization of impalpable breast lesions: iBRA-NET localisation study. British Journal of Surgery. 2022;109(3):274-82.
17. Bromley H, Dave R, Holcombe C, Potter S, Maxwell A, Kirwan C, et al. A Novel Mixed-Methods Platform Study Protocol for Investigating New Surgical Devices, with Embedded Shared Learning: Ibra-net Breast Lesion Localisation Study. International Journal of Surgery: Protocols. 2021;25(1):26–33.
18. Harris P, Taylor R, Minor B, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: Building an international community of software partners. J Biomed Inform. 2019.
19. Harris P, Taylor R, Thielke R, Payne J, Gonzalez N, Conde J. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(22):377-81.
20. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. Adm Policy Ment Health. 2015;42(5):533-44.
21. Braun V, Clarke V. Successful qualitative research: A practical guide for beginners: sage; 2013.
22. Morse J. Data were saturated…. Qualitative Health Research. 2015;25(5):587-8.
23. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis: Striving to Meet the Trustworthiness Criteria. International Journal of Qualitative Methods. 2017;16(1):1609406917733847.
24. Carter N, Bryant-Lukosius D, DiCenso A, Blythe J, Neville AJ, editors. The use of triangulation in qualitative research. Oncology nursing forum; 2014.
25. Tong A SP, Craig J.,. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. . International journal for quality in health care. 2007;19(6):349-57.
26. O'Brien BC HI, Beckman TJ, Reed DA, Cook DA.,. Standards for reporting qualitative research: a synthesis of recommendations. Academic Medicine. 2014;89(9):1245-51.

27. Pieri A, Milligan R, Critchley A, O'Donoghue JM, Sibal N, Peace R, et al. The introduction of radioactive seed localisation improves the oncological outcome of image guided breast conservation surgery. Breast (Edinburgh, Scotland). 2017;36:49-53.
28. Anderson JE, Kodate N, Walters R, Dodds A. Can incident reporting improve safety? Healthcare practitioners' views of the effectiveness of incident reporting. International journal for quality in health care : journal of the International Society for Quality in Health Care. 2013;25(2):141-50.
29. Kreckler S, Catchpole K, McCulloch P, Handa A. Factors influencing incident reporting in surgical care. Quality & safety in health care. 2009;18(2):116-20.
30. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004;141(10):781-8.
31. Fowler AJ. A Review of Recent Advances in Perioperative Patient Safety. Annals of Medicine and Surgery. 2013;2(1):10-4.
32. Mahajan RP. Critical incident reporting and learning. BJA: British Journal of Anaesthesia. 2010;105(1):69-75.

Supplementary materials

Supplementary Table 1: ***Consolidated criteria for reporting qualitative studies (COREQ) checklist***

No. Item	**Guide questions/description**	**Reported**
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the focus group?	JH, SE, SM, RD
2. Credentials	What were the researcher's credentials?	FRCS, PhD, MBChB
3. Occupation	What was their occupation at the time of the study?	Oncoplastic surgeon
4. Gender	Was the researcher male or female?	Female and male
5. Experience and training	What experience or training did the researcher have?	HB had qualitative research experience

Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	IBRA-net study group members
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Role and purpose made explicit
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Experience with IBRA-net stated in limitations section
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study?	Thematic analysis
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Purposive via email
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Email
12. Sample size	How many participants were in the study?	27
13. Non-participation	How many people refused to participate or dropped out? Reasons?	Nil
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Conference session
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	No
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Demographics provided (Table 1)
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Session outline described in methods
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	No
20. Field notes	Were field notes made during and/or after the interview or focus group?	Yes

21. Duration	What was the duration of the interviews or focus group?	57 minutes total (FG 25-30 minutes each)
22. Data saturation	Was data saturation discussed?	Yes
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	A summary of the themes was sent
Domain 3: analysis and findings		
Data analysis		
24. Number of coders	How many data coders coded the data?	3
25. Description of coding	Did authors provide a description of the coding tree?	May be requested
26. Derivation of themes	Were themes identified in advance or derived?	Derived from data
27. Software	What software was used to manage the data?	NVivo and Microsoft® Word
28. Participant checking	Did participants provide feedback on the findings?	Yes
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?	Not applicable
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Relationship to existing empirical
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes, in results
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes, in discussion

Supplementary Table 2: Standards for Reporting Qualitative Research (SRQR) checklist

	Standards for Reporting Qualitative Research (SRQR)*	**Reported?**
Title and abstract		
	Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	✓
	Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	✓

Introduction		
	Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	✓
	Purpose or research question - Purpose of the study and specific objectives or questions	✓
Methods		
	Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., post positivist, constructivist/ interpretivist) is also recommended; rationale**	✓
	Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	✓
	Context - Setting/site and salient contextual factors; rationale**	✓
	Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	✓
	Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	✓
	Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	✓
	Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	✓
	Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	✓
	Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	✓
	Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	✓

	Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	✓
Results/findings		
	Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	✓
	Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	NA
Discussion		
	Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	✓
	Limitations - Trustworthiness and limitations of findings	✓
Other		
	Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	✓
	Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	NA