

Identification of a localization wire tip in an occult breast lesion using a handheld magnetometer

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Conflict of interest

None declared

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Abstract

Background. The Sentimag hand-held probe detects the magnetic response from iron oxide particles trapped in a sentinel node.

Objectives. To investigate if an electromagnetic probe can be helpful in the identification of a hook wire tip located in an occult breast lesion.

Materials and methods. Forty-two patients undergoing lumpectomy without axillary procedure were enrolled. In all cases, suspicious non-palpable microcalcifications without mass were found, and a vacuum-assisted stereotactic biopsy was performed. On the day of surgery, a traditional localization wire (LW) was placed under imaging guidance. The Sentimag magnetometer was used to precisely detect the wire tip through the skin. Then, the skin incision was made and Sentimag was used again to guide the surgeon to the lumpectomy bed. The accuracy of excision was assessed with intra-operative specimen 3D tomography.

Results. Median lesion size was 16 mm (range: 4–38 mm) and median depth was 33 mm (range: 14–78 mm). In all cases, the wire tip was successfully identified. Neither wire displacement nor transection occurred. Intraoperative radiography demonstrated doubtful margin requiring selective cavity shaving in 6 patients (14%). The need for cavity shaving was significantly influenced by the lesion size and histology: median size 30 mm (range: 24–38 mm) compared to 15 mm (range: 4–28 mm) and histology of ductal carcinoma in situ (DCIS) compared to atypical ductal hyperplasia (ADH) and lobular neoplasia (LN). Tumors requiring cavity shaving tended to be deeper – they had a median depth of 43 mm (range: 17–78 mm) compared to 32 mm (range: 14–76 mm) in patients who did not need cavity shaving, but this parameter was statistically significant.

Conclusions. Intraoperative identification of the wire tip using Sentimag is a simple technique facilitating targeted excision without excessive removal of breast tissue. Since it is not associated with additional costs, it may be worth considering, particularly in developing countries.

Key words: breast cancer, minimally invasive biopsy, biopsy site indicator, magnetic tracer, occult lesion localization

Background

The Sentimag system is one of the recent promising alternatives to traditional sentinel node mapping using a ^{99m}Tc -radiolabelled nanocolloid.¹ In this technique, a hand-held magnetometer detects a magnetic response from superparamagnetic iron oxide (SPIO) nanoparticles trapped in a sentinel node.² Non-inferiority for Sentimag and SPIO over traditional isotope and blue dye has been demonstrated.^{3–8} As a radiotracer-independent method, it simplifies logistics, eliminates possible hazards to the patient and staff, provides a very comfortable timeframe, and offers benefits where nuclear medicine units are not available. Because of these advantages, paramagnetic mapping and SPIO-guided sentinel node biopsy have been introduced in our institution as a standard technique since 2017. However, since the magnetometer detects a magnetic response, it could also potentially allow for precise targeting of a localization wire (LW) placed into a non-palpable breast lesion.

Objectives

The aim of this study was to investigate if the Sentimag probe can be helpful in the identification of a LW tip and, therefore, to facilitate a targeted lumpectomy without excessive breast tissue excision.

Materials and methods

Patients

We retrospectively reviewed patients who underwent minimally invasive percutaneous biopsy of a non-palpable breast lesion, followed by LW-guided surgical excision, in our institution in the years 2018–2019. In 42 cases, a Sentimag probe was used to help the surgeon to identify the LW tip. All procedures were performed in accordance with institutional and national recommendations. The study was conducted according to the Declaration of Helsinki. In each case, informed consent was obtained for all diagnostic and surgical procedures, as well as for the collection and publication of their medical data. Since the study was a retrospective analysis and did not involve any experimental interventions, an independent ethics committee approval was not required. The Institutional Review Board reviewed and approved the study (approval No. NDBI/5/2019/KP).

Biopsy

All studied patients underwent a vacuum-assisted stereotactic biopsy of the non-palpable suspicious breast microcalcifications. Biopsies were performed by 1 breast-dedicated radiologist (P.K.) at the same breast care unit.

Procedures were performed under local anesthetic with 1% lidocaine using a two-step approach (superficially and deeply), and were completed under digital mammography guidance using a designated prone table unit (Mammotest Plus/S; Fisher Imaging, Denver, USA) with a 10-G needle (EnCore Enspire Breast Biopsy System; C.R. Bard Inc., Tempe, USA). Biopsy specimens were radiographed to confirm the presence of microcalcifications. In cases where there were no residual microcalcifications, a single biopsy clip (non-magnetic), visible on mammogram, was placed (Gel Mark Ultra, Breast Tissue Marker GMUEC10GSS; SenoRx Inc., Tempe, USA). Baseline characteristics are presented in Table 1.

Table 1. Baseline characteristics

| Characteristics | n (%) |
|--|------------------------------|
| Patients age [years] median, mean \pm SD, range | 52, 52.3 \pm 9.9, 32–75 |
| Side right left | 20 (48) 22 (52) |
| Lesion histology ductal carcinoma in situ atypical ductal hyperplasia lobular neoplasia | 22 (52) 14 (33) 6 (19) |
| Lesion size [mm] median, mean \pm SD, range | 16, 17.6 \pm 8.3, 4–38 |
| Localization wire target post-biopsy clip residual microcalcifications | 10 (24) 32 (76) |

Targeted surgery

On the day of surgery, a single hooked LW (Accura BLN 20G; Argon Medical Devices Inc., Frisco, USA) was inserted under stereotactic guidance to target the biopsy clip or residual microcalcifications. A bracketing technique with multiple wires was not used. Due to the absence of a concomitant mass neither preoperative nor intraoperative localization ultrasound were used. The procedure was performed by 3 board-certified breast-dedicated radiologists experienced in localization techniques of non-palpable breast lesions. To confirm successful localization, a two-view mammography (cranio-caudal and medio-lateral) was conducted (Fig. 1). Intraoperative LW tip localization was performed by the surgeon using the hand-held Sentimag magnetometer (Endomagetics Ltd., Cambridge, UK). Prior to skin incision, the probe was used to scan the area from the entry point, along the LW, detecting the transcutaneous magnetic signal with real-time audible and visual numeric feedback from the detector. As both numeric count and audio tone are related to the strength of the magnetic field, a continuous decrease of signal was observed along the LW, as its distance from the skin increased. A sharp discontinuation of the signal indicated

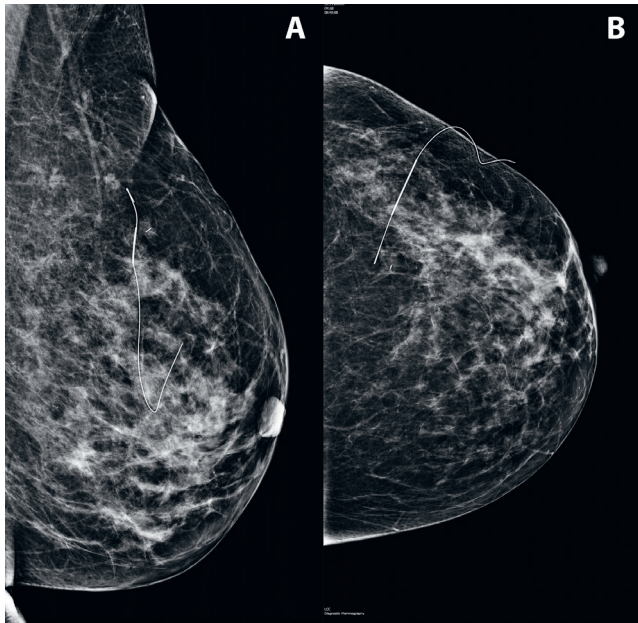


Fig. 1. Localization wire on mammography
A. medio-lateral view; B. cranio-caudal view.

the probable location of the LW tip (Fig. 2A). The skin incision was then made, and Sentimag was used again to guide the surgeon to the lumpectomy bed (Fig. 2B). After the excision was complete, the surgical specimen was properly

aligned by placing stitches to mark the sides (Fig. 3A). A 3D tomosynthesis radiogram was performed using the MO-ZART System (Kubtec Medical Imaging; KUB Technologies Inc., Stratford, USA) to confirm the LW had not been dislocated and to confirm that all the residual microcalcifications, or the biopsy clip, were excised (Fig. 3B). Excision was performed by 4 board-certified breast-dedicated surgical oncologists. The specimen was inked in the operating room and then sent to pathology. Cavity shaving was not routinely performed, only being utilized to remove doubtful margins shown on imaging. Due to possible bias caused by breast compression, the depth of lesion was not evaluated on a mammogram. Instead, the actual surgical depth was assessed intraoperatively using a disposable straightedge, taking measurements of the distance between the skin and the posterior margin of the cavity. All the procedures (biopsy, localization and surgery) were completed at the Division of Breast Imaging and the Division of Breast Surgery of the same Breast Unit, Wroclaw Comprehensive Cancer Center, Poland).

Statistical analysis

All clinical and pathological data was entered into a computer database. The median, range and mean with standard deviation (SD) values were calculated where appropriate. The correlation between categorical variables was

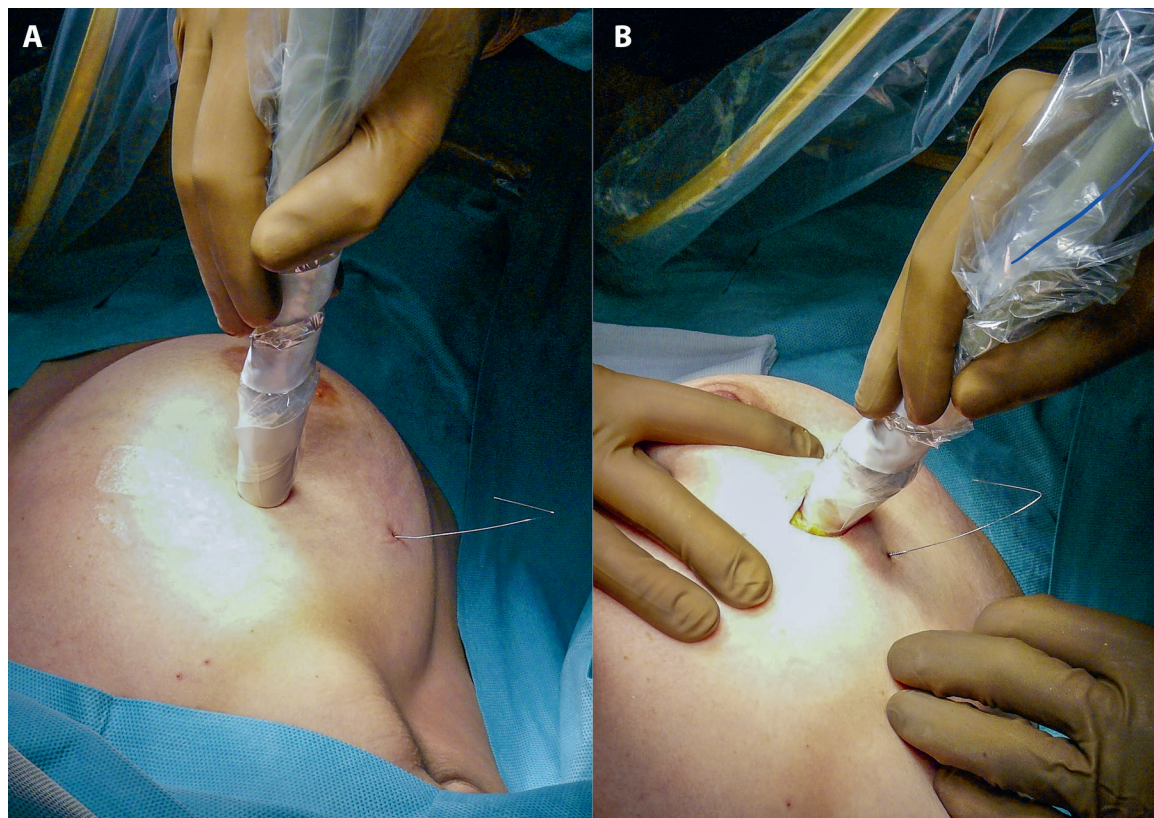


Fig. 2. Identification of the localization wire tip
A. transcutaneous scanning to find the tip; B. targeting the tip during lumpectomy.

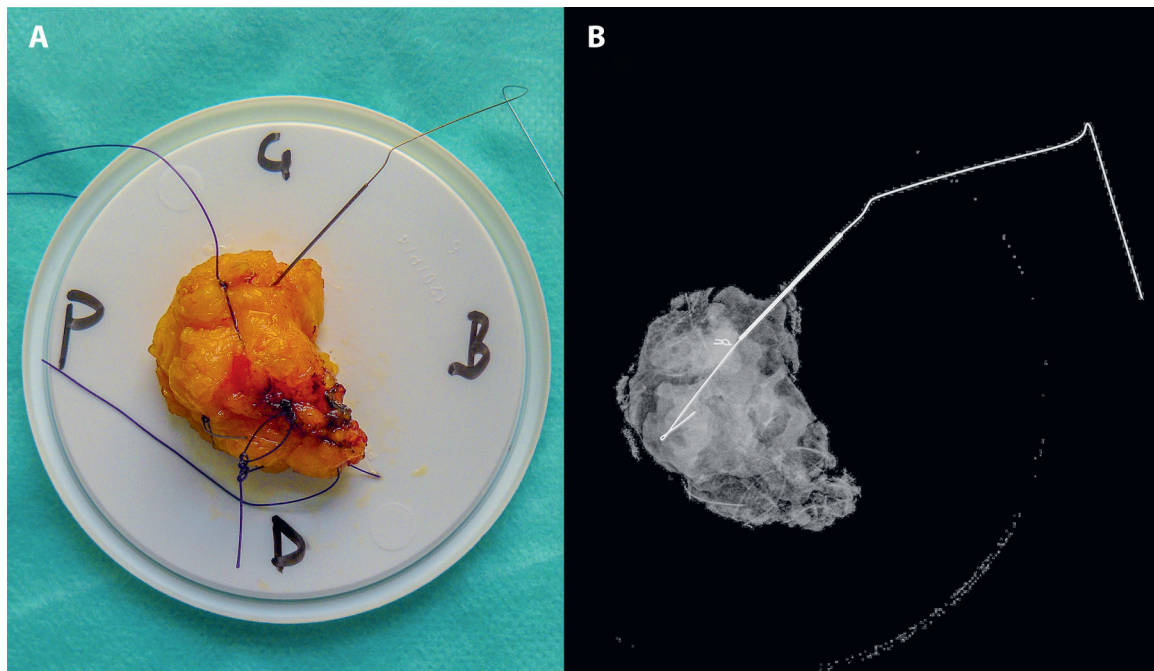


Fig. 3. Surgical specimen

A. specimen oriented with stitches, before inking; B. specimen radiography.

assessed using the χ^2 test with a Yates's correction, and correlation between continuous variables was assessed using the Mann–Whitney U test. Statistical significance was assumed at a p-value of less than 0.05.

Results

In all cases, the operation was completed without any difficulties. The LW tip was successfully identified, and the lesion with surrounding tissues was excised. Neither wire displacement nor transection occurred. Intraoperative specimen radiography demonstrated a doubtful margin in 6 cases (14%). Those patients underwent additional cavity shaving at the questionable margins. The postoperative pathologic report showed R0 resection in 40 cases (no ink on tumor), including primary margins in the 4 re-excised patients. In the remaining 2, the margin of the primary excision was microscopically positive; however, following cavity shaving, it was diagnosed as negative.

Lesions requiring cavity shaving were significantly larger than those not requiring such procedure (median; range; mean \pm SD): 30 mm; 24–38 mm; 30 \pm 4.9 mm compared to 15 mm; 4–28 mm; 15.6 \pm 6.9 mm (z-score = -3.52254 ; $p = 0.0004$). Lesion histology also significantly influenced the need for cavity shaving; all cases requiring cavity shaving were ductal carcinoma in situ (DCIS): 27% (6/22) compared to 0% (0/20) ($\chi^2 = 4.331$; $p = 0.037$), which did not require cavity shaving. Patients' age was similar (median; range; mean \pm SD): 53 years; 38–68 years; 52.5 \pm 9.8 years in patients who required cavity shaving compared to 52 years; 32–75 years; 52.3 \pm 10.1 years in patients who

did not require it (z-score = -0.08986 ; $p = 0.928$). Cavity shaving was not needed in any of the cases where the LW target was the biopsy clip: 0% (0/10) patients requiring cavity shaving compared to 19% (6/32) in the other group. Probably, due to the small sample size, the difference was not significant ($\chi^2 = 0.924$; $p = 0.336$). The posterior margin of the tumor cavity tended to be deeper in those requiring cavity shaving (median; range; mean \pm SD): 43 mm; 17–78 mm; 44.2 \pm 23.1 mm compared to 32 mm; 14–76 mm; 34.8 \pm 14.2 mm in those who did not need such procedure. However, the impact of lesion depth was not statistically

Table 2. Surgical findings

| Feature | n (%) |
|---|----------------------------|
| Cavity depth [mm] median, mean \pm SD, range | 33, 36.1 \pm 15.8, 14–78 |
| Radiological margin | |
| negative | 36 (86) |
| doubtful | 6 (14) |
| Cavity shaving | |
| required | 6 (14) |
| not required | 36 (86) |
| Microscopic margin before shaving | |
| negative | 40 (95) |
| positive | 2 (5) |
| Microscopic margin after shaving | |
| negative | 42 (100) |
| positive | 0 (0) |
| Risk factors for cavity shaving | |
| lesion size | $p < 0.001$ |
| lesion histology | $p < 0.050$ |
| cavity depth | not significant |
| patients age | not significant |
| localization wire target | not significant |

significant (z -score = -0.95252 ; $p = 0.342$). Due to the small volume of the removed glandular tissue, advanced oncoplastic techniques for breast reshaping were not required. In all patients, the surgical defect was closed with simple tissue undermining and re-approximation (level I oncoplasty). Surgical findings are presented in Table 2.

Discussion

Needle localization for non-palpable breast lesions was first described in 1965 by Dodd et al.⁹ A key modification of a LW, a self-retaining hooked tip at its distal end to anchor the wire at the intended target, was presented by Frank et al. in 1976.¹⁰ For decades, it remained the method of choice for non-palpable breast tumors requiring surgical excision. The LW has several drawbacks, most notably the necessity of performing its implantation the same day as the surgery, which complicates scheduling and can lead to delays in the operating theater as well as possible displacement of the wire.^{11,12} Other important disadvantages include: possibility of wire transection, an additional procedure adding to patient stress, a possibility that placement of surgical incision can be limited by the wire entry point, and common vasovagal episodes.^{13,14} In addition, pneumothorax, site-specific pain, retention of wire fragments, hematoma, bleeding, infection, adjacent tissue injury, hemoptysis, hemothorax, non-target tissue excision, and breast implant puncture can occur.¹⁵ However, because of its low cost, simplicity and effectiveness, as well as the important limitations of other methods, use of a LW remains the most widely adopted approach to non-palpable breast lesions. Moreover, it is the only localization technique that can be performed under imaging guidance using all modalities. Thus, some claim that a LW should be considered the gold standard, with new localization techniques randomized against it.¹⁶

Among the new alternatives, radio-guided occult lesion localization with injection of 99 Technetium (ROLL), seed of radioactive 125 Iodine (RIS), radiofrequency identification with microprocessor tag (RFID), SCOUT Radar using infrared light, and paramagnetic-based seeds have been investigated most extensively.^{12–17} Magnetic systems in particular are believed to be very promising because they overcome the disadvantages of both LW and radioactive techniques and potentially offer logistical benefits (easy deploying, comfortable scheduling, no operating theater delays). Magnetic-based localization has been demonstrated as a safe, accurate, efficient, and effective method, and supposedly demonstrates potential to replace the conventional approach.^{18–21}

During LW-guided excision, one of the common difficulties is the possible interference with the surgical approach.¹⁶ Moreover, to accurately discern the position of the wire tip intraoperatively may be a challenge.²² The entry point of the LW may be at some distance from the wire tip, making optimal incision placement a challenge, and

may lead to extensive dissection to remove the target lesion.²⁰ We have demonstrated that the Sentimag probe can detect the magnetic response of the LW in a similar way to the signature generated by Magseed. As the magnetic signal is weak, the LW tip can be precisely targeted. In Poland, it makes for a much less expensive alternative to the dedicated magnetic seeds.

The paramagnetic-based localization systems have some disadvantages. The hand-held magnetometer requires regular calibration during usage which extends the duration of surgery. Electrocautery can also interfere with the signal.¹⁷ Stainless steel surgical instruments, such as metal surgical retractors, are not compatible with Magseed. When it is in use, non-magnetic tools (titanium or polymer) must be used. This may add separate per-use fees in addition to the dedicated console and probe.¹⁵ However, none of our cases required the use of non-magnetic instruments as the Sentimag LW tip targeting and the step-by-step breast tissue dissection were performed in an alternating fashion. In cases of cancer, another possible limitation may be the potential overlapping of the magnetic signals of the sentinel node (SPIO) and the tumor located close to the axilla (Magseed). However, in the study of this entirely magnetic technique, that complication was not observed.²³ The Magseed manufacturer reports the sensing depth to be 3 cm, but notes that it is greater with palpation.¹⁴ Harvey et al. detected Magseed clips with a Sentimag probe at depths ranging from 3.5 mm to 30 mm as measured on ultrasound.²⁰ In a series by Hersi et al., the distance from the skin to the tumor reached up to 65 mm, but the magnetic signal was not detected before the skin incision in 6% of patients.²³ In such extremely deep lesions, some Magseed investigators used a traditional LW instead of a magnetic clip.²¹ Some others postulate that Magseed and Sentimag are effective at all depths, especially for posterior lesions in very large breasts.²⁰ This topic warrants further research.

The reported re-excision rate due to positive margins for non-palpable cancer following a LW-guided lumpectomy varies from 13–14% up to 47%.^{14,15} In contrast, we obtained clear margins in all patients in our series. This was probably due to both accurate LW placement and accurate excision bolstered by tip detection. On the other hand, it was also influenced by the availability of intraoperative imaging with 3D tomosynthesis and subsequent cavity shaving in patients with doubtful local control, identified by a radiologically close margin. In case of a higher budget, a bracketing technique employing multiple LW is worth considering, as it can significantly reduce the risk of positive margins and the need for re-excision, as well as reduce the volume of normal breast tissue removed.^{24,25}

Limitations

Our study has some important limitations. Firstly, it is just a preliminary observational report based on a case series. Secondly, it is not a multi-institutional study. Thus,

we cannot be sure that our findings will be repeatable by other radiological and surgical teams or in a different patient setting. Thirdly, due to the small sample size, the statistical power of comparison is low. No comparison with other localization methods was conducted. Moreover, the ratio of resected tumor tissue to healthy breast tissue was not calculated. Therefore, no definitive conclusions can be drawn. However, our findings demonstrate that the accessory application of the paramagnetic-based SentiMag hand-held probe is safe, effective and not associated with additional costs.

Conclusions

Our initial findings suggest that the simple technique of targeting the LW tip using the SentiMag detector is safe and promising. It should be considered for further investigations if it facilitates more selective and targeted excision, helps to avoid excessive removal of breast tissue and, consequently, improves surgical intervention and benefits the patient. We believe that it may be particularly worth considering in developing countries with a public health service functioning on a tight budget.

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