scientific reports

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Magnetic surgical marker navigation for excision of non-palpable ultrasound visible breast lesions: first 200 cases in a French cancer center

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Wire guided localization is widely used as the standard method of pre-operative localization of breast lesions. The aim was to assess outcomes following the introduction of a novel non-wire guided, magnetic surgical marker navigation system. A prospective study between May 2022 and June 2023 established a data base of the first 200 procedures performed using the Sirius Pintuition GPS Detect magnetic marker. The primary outcome measures were the successful excision of the target lesion and retrieval of the magnetic marker. The primary lesion was excised and the magnetic marker was retrieved in all 200 procedures. In 17 procedures (8.5% of the total sample), the magnetic marker was dislodged during surgery; however, the primary lesion was still effectively excised with clear margins without the need for an additional procedure or radiologic assistance. The re-excision rate to achieve margin clearance was 9%. Insertion of the marker was classified as "easy" and "in contact with the target" by the radiologist in all cases (100%). This study has shown that surgical marker navigation reliably localizes lesions and is associated with low re-excision rates. We also perceived improvement in theater planning.

Keywords Non-palpable breast cancer, Magnetic marker surgical navigation, Safe procedure, Alternative to wire, Improvement in theater planning

Abbreviations

DCIS	Ductal Carcinoma in situ
LCIS	Lobular Carcinoma in situ
MRI	Magnetic Resonance Imaging
SD	Standard Deviation
BMI	Body Mass Index
HER 2	Human Epidermal Growth Factor Receptor 2
Ki67	Prognostic biomarker in invasive breast cancer
TNBC	Triple Negative Breast Cancer
IOUS	intra operative ultrasound localization

Breast cancer is the most diagnosed cancer in women in the European Union, with approximatively 400,000 new breast cancers cases diagnosed each year[1]. In developed countries, with breast screening programs, the estimated rates of non-palpable breast cancer diagnosed are from 30 to 50%[2]. These non-palpable cancers require appropriate pre-operative localization to guide the surgeon.

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Wire-guided localization was first described by Dood et al., in 1965. The technique was then modified with the addition of a hooked tip to the wires to limit the risk of their displacement prior to surgery[3]. Wire guided localization evolved further during the late 1980's, in the absence of better alternatives, to become the standard of care in non-palpable breast cancer.

This technique, although safe and accurate, is not without shortfalls; such as discomfort, hematomas, the need for bandages, pre- or intra-operative migration, and planning constraints. Wire insertion is usually carried out on the day of surgery, which can cause delays in the operating theater. Moreover, there must be good coordination between the radiologist and the operating room to facilitate this, which can cause organizational problems. Some have even described accidents of exposure to blood linked to the use of the wire.

In recent years, there has been a drive to develop alternative localization techniques which may optimize theater planning; including the use of radar techniques, radiofrequency based techniques, and radioactive seed localization[4]. Concerning radioactive seed localization, although this technique is discussed favorably in the literature, the regulatory barriers and the necessity for a nuclear medicine department on site circumvent this technique from being widely adopted[5].

Non-wire, probe-guided technologies using the power of magnetism have been developed recently as an interesting alternative[6]. One of the advantages of using magnetic power is the removal of the need for radioisotopes. Moreover, the magnetic signal does not decay over time. Magnetic-type markers are non-radioactive inert metallic objects, which are detected intraoperatively using a hand-held probe. In Europe, the Sirius Pintuition is one such marker. The Sirius Pintuition uses a permanent magnet which always has a magnetic field allowing for detection from any direction, even in fluids (https://www.sirius-medical.com/pintuition-marker). The Sirius Pintuition works by generating a magnetic field that is detected by the probe provided with the system. Furthermore, it can be inserted up to 180 days before the surgery (long-term placement is allowed in the USA). Post insertion control of the correct placement is performed using mammography or ultrasound detection.

The aim of this study was to assess outcomes following the introduction of such a magnetic surgical marker navigation system for pre-operative localization of non-palpable breast cancer lesions at our specialized French breast cancer center.

Methods

Patient selection

This was a monocentric, prospective study which included the first 200 patients who underwent magnetic surgical marker navigation in a specialized French breast cancer center between the 5th of May 2022 and the 28th of June 2023.

Only one of the radiologists was entitled to use the magnetic marker during the study. The others still used traditional wire guided localization. In contrast, patients could be operated by any of the nine surgeons of the breast unit.

Patient eligibility for pre-operative localization of breast lesion was decided upon by the surgeon at the pre-operative consultation. The patient was then scheduled with the radiologist who confirmed the patient's eligibility for surgery with the surgical marker navigation.

We used only non-palpable masses visible on ultrasound.

Patient inclusion criteria were: the presence of a nodular unifocal non-palpable confirmed diagnosis of invasive breast cancer, carcinoma in situ (DCIS or LCIS) or other high-risk features (atypical ductal hyperplasia, atypical lobular, hyperplasia, radial scar etc.), location of the lesion less than 50 mm under the skin (50 mm probe detection range according to the manufacturer), and visibility of the nodule on ultrasound for pre-operative identification under ultrasound guidance.

Patient exclusion criteria were: absence of visibility on ultrasound, i.e., calcifications alone, palpable lesion, bi or multifocality, location of the lesion more than 50 mm under the skin, absence of confirmed diagnosis of invasive breast cancer, carcinoma in situ or other high-risk features (atypical ductal hyperplasia, atypical lobular, hyperplasia, radial scar etc.). We did not include patients who had a marker placed during the biopsy for micro calcifications or distortions alone.

We excluded calcifications and distortions in order to have a homogeneous cohort in terms of means of localization, with markers placed only under ultrasound guidance.

Patient eligibility for breast conservative surgery with pre-operative localization of breast lesion was decided upon by the surgeon at the pre-operative consultation. Concerning non-palpable lesions, the patients selected were all from the french breast cancer screening program.

The patient was then scheduled with one of the departments radiologists. In the majority of cases, the patient was scheduled with our one full time radiologist dedicated to breast imaging, biopsy and pre-operative localization who performs the majority of the pre-operative localization at our unit. The radiologist then confirmed the patient's eligibility for surgery with the surgical marker navigation.

Technique

The magnetic surgical marker navigation system used in this study was the Sirius Pintuition GPS Detect™ (Sirius Medical Systems B.V., Eindhoven, The Netherlands). The magnetic marker is an inert metallic marker 5×1.6 mm in size. The marker surface is made of titanium. The marker insertion was performed by the radiologist. It was performed under local anesthesia, using ultrasound guidance, in every case. The marker was placed using the marker insertion device including a 14G pre-loaded needle with an ultrasound-enhanced tip. It was placed within the lesion, or just behind it if it was close to the skin (< 5 mm). The radiologist specified in the report for the surgeon the size of the lesion (length, width and height), its localization in relation to the nipple (radius, distance in centimeters) and the depth in relation to the skin. If the surgery was carried out the same day, we carried out

a skin marking. Once in place, all the placement of the permanent magnetic markers were confirmed in the correct position using 2-axis mammography (Fig. 1). The unilateral post-procedure control mammogram was performed on 2 orthogonal views in order to check the correct positioning of the marker and it was considered as correct if less than 1 centimeter between the lesion and the marker, as shown in Fig. 1.

Intraoperative localization of the magnetic marker was performed using the surgical marker navigation probe. This specific probe allows detection of the magnetic marker with millimeter precision transmitted to the surgical marker navigation base unit. The base unit provides the surgeon with visual feedback showing the distance in millimeters between the magnetic marker and the detector and also includes sound feedback, using an audible tone, which increases in pitch as the probe gets closer to the marker.
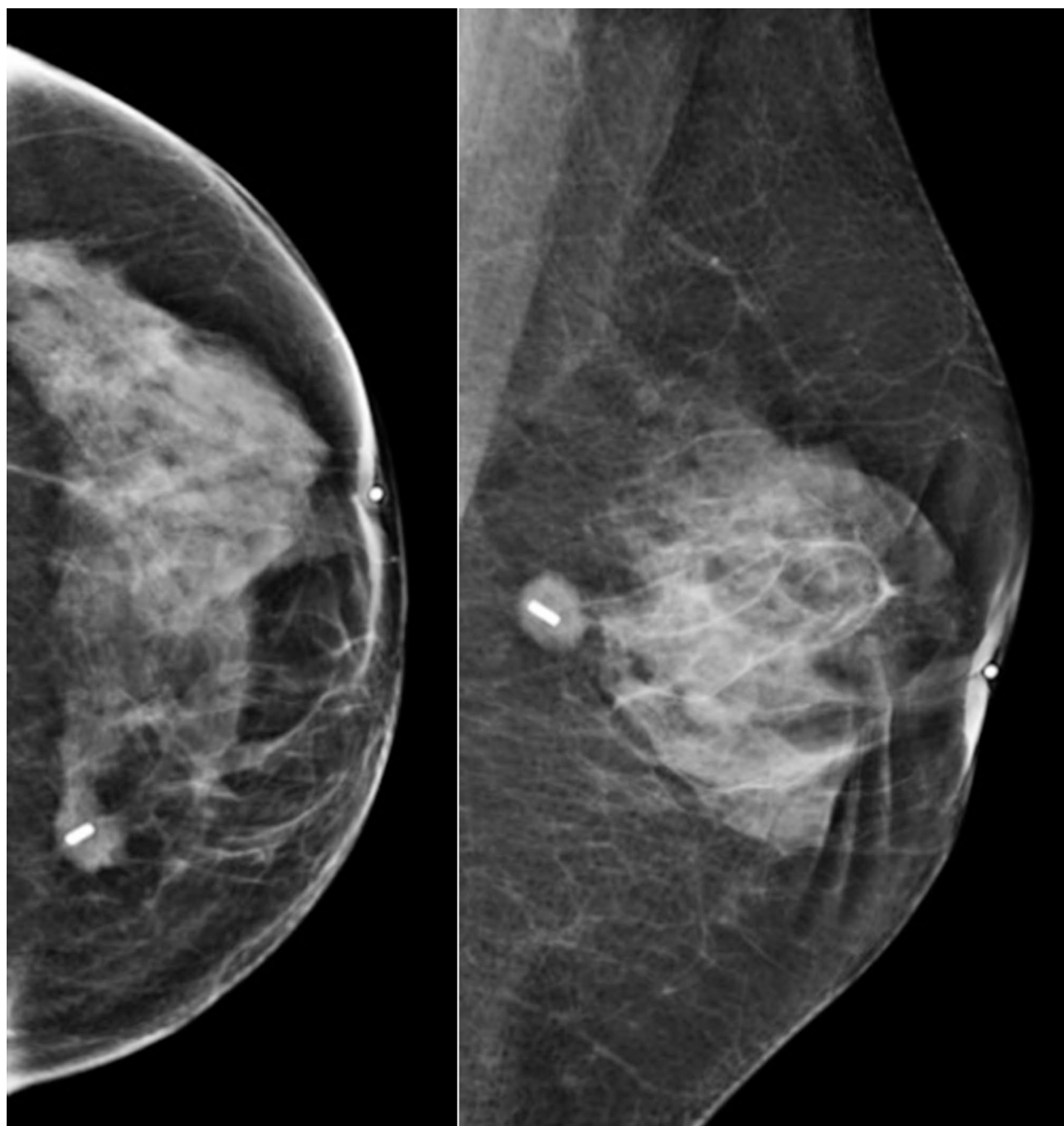
All surgeries were performed under general anesthesia.

Fig. 1. Pre-operative mammographic control of the magnetic marker. Sub clinical centimetric tumor at the union of the inner quadrants of the left breast, corresponding to a ductal invasive carcinoma, luminal A, without adenopathy.

During the procedure, the marker location was confirmed repeatedly by regular probe guidance. The magnetic marker and the tumor excision were verified in two steps. Firstly, the location of the marker was confirmed within the excised specimen using the probe, and secondly, a specimen X-ray was performed immediately in the radiology unit (Fig. 2). Shaving of the cavity margins was decided upon by the individual surgeon, following review of the specimen X-ray.

Margins were considered as "clean" if greater than 2 mm for ductal carcinoma in situ (DCIS) alone, and if there was no ink on the tumor in cases of invasive cancer alone or those associated with DCIS, according to the National Comprehensive Cancer Network (NCCN) guidelines breast cancer version 4.2024[7], Society of Surgical Oncology-American Society for Radiation Oncology-American Society of Clinical Oncology Consensus Guidelines[8,9], and actual French standards[10].

Data collection

Data was collected from a prospective database. The results of this clinical trial are registered according to French standards with the CNIL. The patient characteristics recorded were age, body mass index (BMI) and
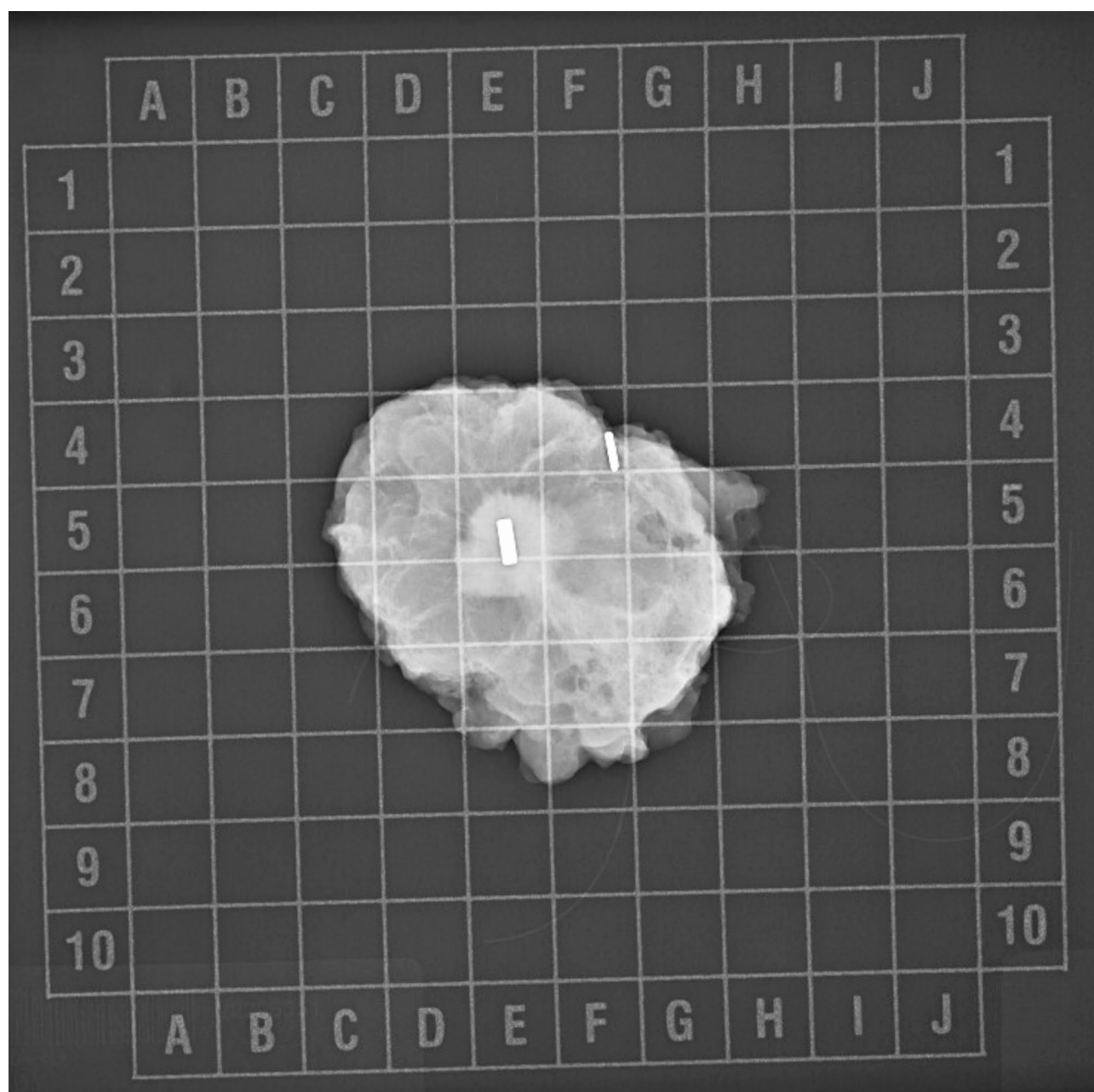

Fig. 2. Intra operative control of the excision of the tumor with the magnetic marker. The magnetic marker is correctly placed at the center of the tumor. A surgical clip is used on the 12o'clock axis to give the orientation of the tissue removed.

personal history of cancer. Data collection on the history of care included was: time of the first biopsy, time of insertion of the magnetic marker, number of magnetic markers inserted, time of the surgery, and details of the neoadjuvant chemotherapy (if performed). Pre-operatively, we recorded: localization, radiological size, MRI (if performed), ease of insertion, quality of the insertion (distance from the tumor), patient acceptance to pain and tolerance of the marker's insertion. Peri-operatively, we recorded: the pre-operative histological diagnosis, the type of surgery (standard, oncoplastic), axillary lymph node surgery (if performed), length of surgery, ease of the operative gesture, dislodgement of the marker during the procedure, dimensions of the lumpectomy, number of intra operative recut. Post-operatively, we recorded: margin status, the need for surgical revision, pathological size, receptor status, lymph node status, Ki67, and HER2 status.

According to French regulations and in line with the principles of the Declaration of Helsinki, all individual participants included in the study were informed of the research to be performed, and written informed consent was obtained. Approval was granted by the Ethics Committee of the Reims Unicancer Institute (Registration Number 19086206, date of registration 18/07/2024).

Outcome measures
The primary outcome measures were successful excision of the tumor and retrieval of the magnetic marker. The secondary outcomes analyzed were difficulty of insertion, localization accuracy, patient's tolerance/pain, and breast margin re-excision rate.

Statistical analysis
Quantitative parameters were described by their mean and standard deviation (SD), qualitative parameters by their frequency and percentage. Continuous variables were compared using Student's t-test. Categorical variables were compared using the chi-squared test. Statistical tests were performed at a significance level of 0.05. Analyses were performed using the R Development Core Team (2020) software[11].

Results
Patient characteristics
During the study period, 194 surgeries were performed on patients using the surgical marker navigation system. This accounted for 200 procedures, as 6 surgeries were bilateral. The patient characteristics are detailed in Table 1. The mean age was 60.7 ± 12.4; mean BMI was 26.9 ± 5 kg/m^2, 11% had a preexisting history of cancer, 37% underwent MRI evaluation before surgery, 19.7% of patients underwent neoadjuvant chemotherapy.

Tumor pre-operative characteristics
Table 2 summarizes the following tumor pre-operative characteristics as determined via ultra sound: localization of the tumor, size of the tumor (long axis, mean 12.6 mm +/- 8.3 standard deviation) and the depth in relation to the skin (mean 10.1 mm +/- 8.3 standard deviation); and histological type on the biopsy.

T1c (78 patients, 39%) and T2 (2 patients, 1%) lesions were non-palpable in relation to the breast volume, the deep localization and/or the histological type (DCIS, lobular).

Characteristics	Mean ± SD	N	%
Age, years	60.7 ± 12.4	200	100
< 40		11	5.5
40 ≤ age < 50		27	13.5
50 ≤ age < 60		48	24.0
60 ≤ age < 70		61	30.5
70 ≤ age < 80		42	21.0
> 80		11	5.5
Body mass index, kg/m²	26.9 ± 5.6		
< 20		9	4.5
20 ≤ BMI < 25		63	31.5
25 ≤ BMI < 30		77	38.5
30 ≤ BMI < 35		36	18.0
≥ 35		15	7.5
Breast density			
A		10	5
B		131	65.5
C		56	28
D		3	1.5
Preexisting cancer	–	22	11.0
Preoperative MRI	–	74	37.0
Neoadjuvant chemotherapy	–	36	19.7

Table 1. Patient characteristics. *MRI* magnetic resonance imaging, *SD* standard deviation.

Characteristics	Mean ± SD	N	%
Histologic sub type			
Invasive ± DCIS	–	181	90.5
DCIS	–	12	6.0
High-risk lesion	–	7	3.5
Tumor localization			
Outer quadrants	–	121	60.5
Inner quadrants	–	47	23.5
Central tumors	–	32	16.0
Tumor size, mm	12.6 ± 8.3		
T1a		33	16.5
T1b		87	43.5
T1c		78	39.0
T2		2	1.0
Tumor depth, mm	10.1 ± 4.1		
≤ 5 mm		27	13.5
≤ 10 mm		87	43.5
≤ 20 mm		81	40.5
> 20 mm		5	2.5

Table 2. Tumor pre-operative characteristics as determined via ultrasound. *DCIS* ductal carcinoma in situ, *SD* standard deviation.

Most patients underwent surgery for a pre-therapeutic diagnosis of invasive breast cancer with or without in situ carcinoma (181 patients, 90.5%). Twelve patients (6%) had DCIS alone, or high-risk lesions (7 patients, 3.5%).

Marker placement

All insertions of the magnetic markers were considered easy by the radiologist; which were cases that were without difficulty in locating the lesion, procedure duration of 10 to 15 minutes, and a simple insertion of the marker, without complications." In all cases no complications were reported during the insertion procedure. The position of the magnetic markers in non-palpable breast lesions was considered as optimal (< 1 cm from the tumor) in all procedures. There was no need in any procedure in this study to place a 2nd marker due to incorrect positioning of the first marker and no migration of the marker.

The patients reported no pain or a low intensity of pain (1 or 2 on a pain scale from 0 to 10) in 193 cases (93%). One hundred and twenty-one magnetic markers (60.5%) were placed on the day of surgery or the day before surgery. Seventy-nine magnetic markers (39.5%) were placed between 2 and 29 days before surgery, including 19% at least one week earlier ($n = 38$).

Peri operative data

The primary tumor and the markers were retrieved in all cases.

Standard lumpectomy was performed in 114 procedures (57%) (Table 3). In 85 cases (42.5%), an oncoplastic procedure was performed (reduction mastoplasty, external oncoplastic incision, Round Block mastopexy, Thorek reduction mastoplasty). In 1 case (0.5%), an immediate breast reconstruction with implant was performed. The mean duration of tumor removal was 16.1 min (time from incision to removal of the tumor).

Detection of the magnetic marker was considered as "easy" in almost all procedures (98.5%). In 17 procedures (8.5%), the marker was dislodged during the surgery and was found in 13 cases (76% of the dislodged markers) in contact with a metallic surgical tool, and free in contact with tissues in 4 cases (24% of the dislodged markers). There was no need for re–excision in these patients as the primary lesion was still effectively removed.

Dislodged markers were significantly more superficial (7.9 vs. 10.3 mm, $p = 0.02$). A peri-areolar incision was significantly associated with dislodged markers compared with a direct radiary incision ($p < 0.001$). Lumpectomy with oncoplasty was significantly less associated with dislodged markers ($p < 0.001$). There was a significant trend towards dislodged markers with higher BMI (24.5 vs. 27.1 kg/m^2, $p = 0.05$). The mean number of days between insertion and surgery (2.6 vs. 3.1 days, $p = 0.72$), as well as the size of the lesion (7.9 vs. 9.5 mm, $p = 0.2$), had no influence on dislodged markers.

Post-operative data

The overall rate of second procedure for positive margins was 7%, 9% for invasive cancer without neo-adjuvant chemotherapy (13 re-excision out of 145 procedures), 0% for invasive cancer after neo-adjuvant chemotherapy (0 re-excision out of 36 procedures), 8.3% for DCIS alone (1 re-excision out of 12 procedures).

The re-excision rate if surgery was the first treatment for invasive cancer was 8.2% for invasive cancer alone and 9.7% if invasive cancer was associated with DCIS. The re-excision rate when the marker was inserted the

Characteristics	Mean ± SD	N	%
Incision type			
Radiary	–	44	22.0
Peri-areolar		65	32.5
Infra mammary fold		5	2.5
Oncoplastic surgery		86	43.0
Oncoplasty type			
Reduction mastoplasty	–	22	11.0
Round Block mastopexy	–	25	12.5
External oncoplastic incision	–	29	14.5
Others	–	10	5.0
Magnetic marker easy to detect by surgeon		197	98.5
Marker dislodgment during surgery	–	17	8.5
Lenght of tumor removal, min	16.1 ± 7.4	–	–
Sentinel node biopsy		161	80.5
Axillary lymph node dissection		20	10.0

Table 3. Peri operative data. *DCIS* ductal carcinoma in situ, *SD* standard deviation.

	Mean ± SD	N	%
Diameter of the surgical piece removed, mm	69.2 +		
Volume of the surgical piece removed, cm3	155 ±		
Weight of the surgical piece removed, g	57.4 ±		
Size of invasive cancer, mm	12.6 ± 8.3		
Size of invasive cancer, mm (when no neo-adjuvant chemotherapy)	13.9 ±		
Size of invasive cancer, mm (after neo-adjuvant chemotherapy)	11.7 ±		
Histological type			
Ductal invasive carcinoma		148	74.0
Lobular invasive carcinoma		23	12.5
DCIS only		10	5.0
Other		19	9.5
SBR		181	
1		45	24.9
2		106	58.6
3		30	16.6
Sub type		181	
Luminal		148	81.8
TNBC		17	9.4
Overexpressed HER2		16	8.8
Ki67		181	
0 to 20%		136	75.1
20 to 100%		45	24.9
Node status		181	
Negative		151	83.4
Positive		30	16.6

Table 4. Histologic data. *DCIS* ductal carcinoma in situ, SBR: Scarf Bloom Richardson score, TNBC: Triple Negative Breast Cancer, HER 2: Human epidermal growth factor receptor.

day of the surgery or the day before was 9.1%. The re-excision rate when the marker was inserted at least 2 days ahead of the surgery was 7.6% ($p = 0.71$).

The mean diameter of the surgical piece removed was 69.2 mm (Table 4); with a mean volume of 155 cm³ (range 12.5–3669); and its mean weight was 57.4 g (range 5-1485).

The mean pathological size was 12.6 mm for invasive carcinoma (with ou without DCIS) and 15.6 mm for DCIS alone. The majority of tumors were ductal invasive carcinoma (74.5%) and luminal histological subtype (73.0%). DCIS was associated with invasive carcinoma in less than half of all cases (45.4%). 10 cases were DCIS alone. 17.8% of lymph node investigations were positive.

Discussion

In this series of 200 surgical marker navigation procedures performed in a French cancer center, a 100% of the tumors and the magnetic markers were removed, with a low re excision rate (9%). A recent multicenter prospective study evaluated 946 Magseed versus 1170 wire-guided localizations of impalpable breast lesions in a population of 2116 patients[12]. The Magseed is a stainless steel paramagnetic marker that is detected using a magnetic probe to detect the reflected signal (https://www.endomag.com/products/magseed/). Using the device the authors showed that there was no difference in the median closest margin ($p = 0.342$), or re-excision rate ($p = 0.574$). The authors subsequently concluded that Magseed demonstrated similar safety and efficacy to wire guided localization.

In this study, 183 permanent magnetic markers (91.5%) were retrieved within the tumor and dislodged in 17 cases (8.5%). Concerning the 17 procedures with dislodgment of the markers, these were found in 13 cases in contact with one of the metallic surgical tools, and in 4 cases the marker was dislodged during the handling of the surgical piece. The tumors were, regardless of the dislodged markers, well excised without further necessity for re-excision.

Placing a stitch using a large needle, when getting close to the marker, in order to fix it, is an option that is recommended.

In our study, marker dislodgment was significantly higher if the lesion was more superficial (7.9 vs. 10.3 mm, $p = 0.02$) and if the incision was not direct ($p < 0.001$). The placement of the marker by the radiologist is important to reduce this risk. If the lesion is close to the skin, it is advised to place the magnetic marker a little behind it. This way, the risk of marker dislodgment when the surgeon dissects under the skin is greatly reduced, especially for non-direct incisions.

The timing of marker deployment might be important as well: we suggest that the earlier the better, as the tissue would have time to heal and encapsulate the marker, if the marker is placed earlier. We suppose it might reduce the risk of marker dislodgement during surgery, linked to surgical manipulations allowing movement of the marker in the insertion pathway. On the other hand, there might be some degree of marker migration during the process of healing. It may be the subject of a future work to evaluate the optimal timing of the marker placement.

Although the surgeons and radiologists involved in the surgical marker navigation procedure found it very user friendly and easy to implement, there was a tendency towards more marker dislodgement in the first hundred cases (10 dislodgements) than in the second one hundred cases (7 dislodgements) ($p = 0.48$). Although not statistically significant, we feel there is possibly a learning curve for this technique of detecting sub-clinical lesions, however simple, straightforward, and more efficient it might seem.

Other studies reported a 100% retrieval rate of the Magseed within the specimen of their studies[13–16]. These reassuring rates of tumor removal and marker retrieval confirm the validity of the procedure as an alternative to wire guided excision. Similarly, there were no cases of marker migration (i.e., clinically significant movement of the marker from the original placement position before surgery) in the present study, as in the literature[13–16], regardless of the time of preoperative placement.

Theater planning was significantly easier, since the magnetic marker could be inserted a few days (at least 2) or weeks before the surgical procedure, if necessary. The re-excision rate for these procedures (7.6%) was not different to the rate of the procedures with the marker inserted the day of the surgery or the day before (9.1%). Although, it wasn't the main end point of this study, it seems safe to place the marker a few days or even weeks before the surgery, with apparently a low risk of migration of the marker.

According to the manufacturer, the magnetic marker can be inserted up to 180 days before surgery and could be inserted as soon as neoadjuvant chemotherapy is indicated. However, the use of MRI (Magnetic Resonance Imaging) for monitoring might be a contraindication, as it can lead to artifacts and misinterpretation of the response to treatment[17]. In any case, it is recommended to use a magnetic marker after MRI is used for initial staging of prior to surgical treatment following neoadjuvant treatment[18].

In this series, in cases of neo-adjuvant chemotherapy, standard radiological markers were usually used before the medical treatment. The magnetic marker was placed when neo-adjuvant chemotherapy and the MRI monitoring are complete, if conservative surgical treatment for non-palpable lesions is confirmed. An alternative option would be to use Contrast Enhance Mammography instead of MRI.

The re-operation rate using the Sirius Pintuition magnetic marker in our study (8.3% for invasive cancer alone and 9.7% if invasive cancer associated with DCIS) was quite low in comparison with published re-operation rates using standard wire-guided localization: 14.9 to 20.8% in literature review with pooled analysis[4] and meta analysis of randomized controlled trials[19,20]. As a reminder, we only included patients with masses visible on ultrasound (diagnosis of invasive breast cancer, carcinoma in situ (DCIS or LCIS) or other high risk features), excluding micro calcifications or distortions alone, whether or not a marker from the previous biopsy was placed.

Our re-operation rate is however similar to other non-wire localization methods including radioactive seed localization, 6.8 to 10.3%[4,20], Magseed, 11.25 to 13.44%[20–22], radar techniques, 5.3 to 8.6% (Savi Scout Surgical guidance System)[20] and radiofrequency based techniques, 13.9% (LOCalizer)[23]; each with its specific advantages and limitations[24].

Finally, the lowest re-operation rates seem to have been obtained using intraoperative ultrasound localization (IOUS), 4.8 to 7%[4,25]. The other advantage of IOUS is the smaller surgical specimen volume necessary to achieve oncologic result[26,27]. The limitations of this technique are non-visible ultrasound lesions, operator dependency, necessity of specific training, and availability of an ultrasound machine[24]. Intra operative ultrasound detected marker is, however, a method that could be used in cases of non-visible ultrasound lesions[24].

There was only one complication in the series. In that case, occult bleeding occurred during insertion of the marker, leading to the formation of a hematoma that was not immediately visible. As the marker was inserted

the day of the surgery, the hematoma was discovered during the surgery. The magnetic marker was free in the hematoma. Fortunately, the lesion was in contact with the hematoma, allowing the surgeon to find it and remove it safely. There has been no re–excision in this case.

There are limitations to the study. It is a single site, non-randomized study with only one radiologist entitled to insert the magnetic markers. On the other hand, nine surgeons were involved in the surgical procedures, showing the ease to adapt to this procedure for the surgeons. Furthermore, we excluded calcifications in order to have a homogeneous cohort in terms of means of localization, with markers placed only under ultrasound guidance.

There was a lot of additional benefits using this magnetic marker for guided breast surgery of non-palpable lesions, which have not been evaluated, such as: more comfort for the patient, more freedom for the surgeon to decide the best incision, the localization of the magnetic marker was easier than with the end of the wire, and there was a possibility to check the margin with the probe (i.e., distance between the margin and the marker). Restrictions on the initiation of this technique in the department have led to the management of unifocal lesions only. Two markers can be placed in the same breast without interference if they are at least 2 cm apart. They can also be placed in the positive lymph node identified prior to neo-adjuvant chemotherapy for targeted axillary dissection[28]. These additional analyses may be the subject of future work as well as a direct comparison of magnetic markers versus wire guided localization.

Conclusion

The Sirius Pintuition magnetic surgical marker navigation system for the removal of non–palpable breast lesions has been easily implemented, with significant improvement in theater planning, and low complication and re-excision for margin clearance rates. The procedure is very safe and can be used as an alternative to wire guided excision.

Further prospective and comparative analyses could be the subject of future studies.

Data availability

The data generated during the current study are available from the corresponding author upon reasonable request.

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Author contributions
Conceptualization: VC, LW, FR, JH; Acquisition of data: VC, LW, SM, TG, NG, LD, LP, EG, FR, BG, JH; Analysis of data: VC, BG, JH; Writing original draft: VC; Writing review and editing: CV, JH; Supervision: FR.Vivien Ceccato, Lauren Wallaert, Fabien Reyal and Judicaël Hotton contributed to the study conception and design. Material preparation and data collection were performed by Vivien Ceccato, Lauren Wallaert, Sophie Michel, Thomas Gaillard, Noémie Girard, Lauren Darrigues, Léa Pauly, Elodie Gauroy, Fabien Reyal, Beatriz Grandal and Judicaël Hotton.Analysis were performed by Vivien Ceccato, Beatriz Grandal and Judicaël Hotton.The first draft of the manuscript was written by Vivien Ceccato. Judicaël Hotton and Fabien REYAL commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

Declarations

Competing interests
The authors declare no competing interests.

Ethical approval
This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Godinot Institute, Reims (registration number 19086206, date of registration 18/07/2024).

Informed consent
Written consent from included patients.

Additional information
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