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Research Article

Magnetic Seed Localisation for Non-Palpable Breast Lesions: A Comparison with Hooked-Wire

Dehaene A[1,2], Smeets A[1,2], Vos H[1,2], Van Ongeval C[2,3], Neven P[2,4], Laenen A[4,5], Schops L[6], Prevos R[2,3], Thywissen T[2,3], Keupers M[2,3] and Nevelsteen I[1,2]*

[1]Department of Surgical Oncology, University Hospitals Leuven, Belgium

[2]Multidisciplinary Breast Centre, University Hospitals Leuven, Belgium

[3]Department of Radiology, University Hospitals Leuven, Belgium

[4]Department of Gynecology and Obstetrics, University Hospitals Leuven, Belgium

[5]Department of Biostatistics and Statistical Bioinformatics Centre, Catholic University of Leuven, Belgium

[6]Multidisciplinary Breast Centre, Noorderhart Maria Ziekenhuis Pelt, Belgium

***Corresponding author:** Nevelsteen I, Department of Surgical Oncology, University Hospitals Leuven, Herestraat 49, B-3000 Leuven, Belgium

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Abstract

Introduction: Screening programs and improved imaging result in higher frequency of non-palpable breast lesions, requiring preoperative localisation. Several localisation methods have been developed, with Magseed® among the more recent techniques. This observational study registered safety, effectiveness and surgeon satisfaction of Magseed® localisation. Data were compared with hooked-wire procedure.

Methods: Data regarding safety, effectiveness and surgeon satisfaction of 100 patients who underwent Magseed® localisation were prospectively collected between September 2018 and April 2019, and compared with retrospectively collected data of 91 patients who underwent hooked-wire localisation between March 2018 and September 2018.

Results: In total, 103 seeds and 102 wires were included. All magnetic seeds were placed under ultrasound guidance, with a median of two days preoperative. Complication rate did not significantly differ between Magseed® and hooked-wire (2.97% *vs*. 2.13%; p = 1.000). 94.06% of the seeds were detected with Sentimag®, with a retrieval rate of 100%. Positive margin rate was lower for Magseed®, although not significant (4.76% *vs*. 10.39%; p = 0.233). Due to positive margins, 1 additional mastectomy was performed, in contrast with 3 mastectomies and 1 additional re-excision in the hooked-wire group. Surgeons scored 81% of the Magseed® procedures as 'easier than hooked-wire'.

Conclusion: Rate of positive margins and re-excision/mastectomy showed a tendency to be lower with Magseed® localisation compared to hooked-wire localisation. Complication rate was equal. Moreover, high surgeon satisfaction and logistical advantages designate Magseed® as preferable over hooked-wire.

Keywords: Breast cancer; Non-palpable lesion; Localisation; Magseed®; Hooked-wire; Sentimag®

Introduction

Breast Cancer (BC) is the most frequently diagnosed type of cancer in women [1]. BC screening and high-resolution imaging result in approximately 25-35 % of breast cancers being non-palpable at diagnosis [2]. Randomised trials in the early 2000s showed that Breast Conserving Surgery (BCS) followed by irradiation is the treatment of choice in most of these cases [3,4]. Several preoperative localisation methods have been developed, of which hooked-wire localisation is the gold standard in many institutions. Although hooked-wire is established to be the default technique for many surgeons, it is associated with well-known disadvantages including scheduling difficulties (same day procedure), impaired patient comfort, limited incision flexibility and relatively high positive surgical margin rates varying from 14% to 47%, compared to other localisation techniques [2]. Recently, the concept of magnetic susceptibility has emerged as an alternative. Magseed® (Endomagnetics Inc., Cambridge, UK, CE-labelled class IIa medical device) is a 5 x 1 mm stainless steel seed which is preoperatively placed under radiographic, ultrasound or CT guidance. The seed is detectable with the Sentimag® probe (Endomagnetics Inc., Cambridge, UK) guiding the surgeon to the lesion. The seed's safety and feasibility have been proven by Harvey et al. in a two-centre open-label cohort study in which all seeds were placed with a median of five days before surgery without migration and intact removal [5]. Neither seed placement nor surgery gave rise to complications. Subsequently, Price and colleagues published their data [6]. They concluded that Magseed® is an effective and accurate method for preoperative lesion localisation. In addition, Zacharioudakis et al. performed a comparative study, concluding that Magseed® localisation is as reliable and effective as hooked-wire localisation with additional surgical and logistical advantages [7]. A pilot trial with Magseed® including nineteen patients with non-palpable tumours was conducted in our centre in October 2017. Additionally, Magseed® became the standard of care in our centre since September 2018 as an alternative to hooked-wire. The main objective of this observational study was to identify the added clinical and logistic value of Magseed® in BCS of non-palpable breast lesions without compromising oncological safety, by collecting data regarding safety, effectiveness and surgeon satisfaction.

Methods

Patient inclusion

A retrospective and subsequent observational prospective study

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$$V_{tumour} = \frac{4}{3}\pi\,(r_{ML} * r_{CC} * r_{AP})$$

Equation 1. *Tumour volume based on an ellipsoid model with preoperative assessed tumour dimensions*

$$ORV = \frac{4}{3}\pi[(r_{ML} + 10) * (r_{CC} + 10) * (r_{AP} + 10)]$$

Equation 2. *Optimal resection volume based on an ellipsoid model with preoperative assessed tumour dimensions*

$$TRV = \frac{4}{3}\pi\left(r_{ML} * r_{CC} * r_{AP}\right)_{initial} + \frac{4}{3}\pi(r_{ML} * r_{CC} * r_{AP})_{additional}$$

Equation 3. *Volume of the specimen based on an ellipsoid model with specimen dimensions assesed during pathological examination*

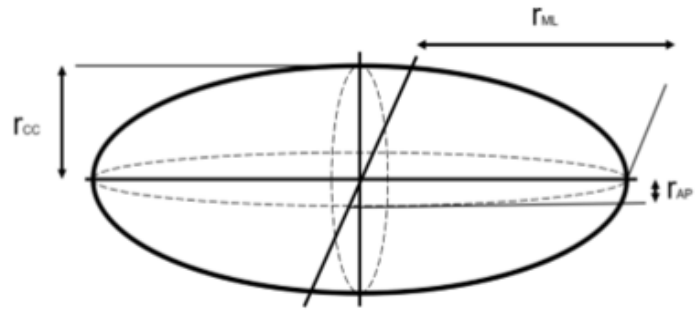

Figure 1: Formula to calculate tumour volume, optimal resection volume and volume of specimen.

was performed, comparing hooked-wire and Magseed® localisation in patients with a non-palpable breast lesion scheduled for BCS. For the retrospective part, patients were selected from the Multidisciplinary Breast Centre clinico-pathological database based on the following criteria: BCS with hooked-wire localisation, surgery in UZ Leuven between March 2018 and September 2018 and complete medical file available. Subsequently, data of patients who underwent BCS for a non-palpable breast lesion between September 2018 and April 2019 were prospectively collected after obtaining their informed consent. This combined prospective and retrospective study was approved by the Ethics Committee of UZ Leuven (NCT03988777).

Preoperative localisation procedure

All Magseed® markers were inserted under ultrasound guidance, with a maximum of 26 days prior to surgery. The seeds were deployed with an 18G needle under local anesthesia with confirmation of appropriate placing by mammogram. In 3 Magseed®-cases, the target lesion was radiographically not clearly visible, therefore a hooked-wire was placed under ultrasound or mammographic control before inserting Magseed®. The wire was retracted afterwards, leaving only the magnetic marker behind, of which correct placement was subsequently confirmed on mammogram. Breast volume was calculated on mammogram, using Volpara™ software.

Surgical procedure

Before skin incision, the magnetic seed was localised with the Sentimag® probe set at medium sensitivity level (level 2). During excision, repeated measurements with Sentimag® were performed to localise Magseed®. After excision, the specimen was examined *ex vivo* with the probe to confirm the presence of Magseed®. Subsequently, macroscopic margins were assessed with specimen radiography. In case of insufficient margins, an additional peroperative excision was performed.

Surgeon satisfaction

After the procedure, surgeons were asked to score the Magseed®-procedure as 'easier' than hooked-wire, 'same technicality' or 'more challenging' than hooked-wire.

Histopathology and microscopic examination

Afterwards, the specimen was examined at the department of pathology according to the applicable standards for breast cancer tissue specimens. Surgical margins were 'negative' as 'no ink on tumour' was present, for invasive tumors as well as for DCIS. Tumour volume, optimal resection volume and total resected volume were calculated, based on the consideration of tumour and resection specimen being ellipsoid (Figure 1).

Data handling and analysis

Statistical analysis was performed by an expert statistician using SAS software (version 9.4 of SAS System for Windows). Group comparisons were performed using the Fisher exact test for categorical variables or the Mann-Whitney U test for continuous variables. A multivariable logistic regression model was performed to test the effect of group on positive margin rate, correcting for ratio of specimen volume to breast volume. All reported p-values are two-sided. P-values of 0.05 or less are defined as significant.

Results

Hundred patients were prospectively included, of which 3 patients received two Magseeds®, resulting in 103 seeds. In the retrospective study, data from 91 patients who received a hooked-wire between March 2018 and September 2018 were collected. Eleven patients received 2 hooked-wires, resulting in 102 retrospective hooked-wires. There were no significant differences in baseline patient nor tumour characteristics between both groups (Table 1 and 2).

Preoperative localisation

As shown in Table 3, all Magseeds® and hooked-wires were placed under ultrasound guidance. In three cases, a hooked-wire was used to guide the Magseed® insertion and retracted afterwards. Magseed® was placed with a median of 2 and a maximum of 26 days pre-operatively. The median depth of Magseed® placement, measured on ultrasound, was 12.0mm with a maximum depth of 45.0mm. Two patients received two Magseeds®, indicating the outer margins of a single lesion.

Ninety-nine out of 103 Magseeds® were placed within 5 mm distance from the target, resulting in an accuracy rate of 96.12%. Similarly, 98.04% of the hooked-wires were accurately placed (measured from the tip of the hooked-wire and/or placement of the wire through the lesion). The maximum distance from Magseed®

Table 1: Baseline patient characteristics of Magseed® and hooked-wire group.

	Magseed®	Hooked-wire	*p*-value
Age in years[1]	59.5 [52.0 – 66.0]	60.0 [53.0 – 65.0]	0.523
Body mass index[1]	24.8 [21.8 – 29.3]	25.8 [23.2 – 30.0]	0.201
Menopausal status			1
Premenopausal (%)	22 (22)	20 (21.98)	
Perimenopausal (%)	3 (3)	2 (2.20)	
Postmenopausal (%)	71 (71)	66 (72.53)	
Unknown (%)	4 (4)	3 (3.29)	
Breast volume (cm^3)[1]	644.4 [403.0 – 982.5]	783.7 [480.7 – 1184.7]	0.063
Neoadjuvant treatment	10	8	0.809

[1]Data are shown as median [interquartile range].

Table 2: Baseline preoperative tumour characteristics for Magseed® and hooked-wire group.

	Magseed®	Hooked-wire	*p*-value
Maximal radiographic measurement (mm)[1]	12.0 [10.0 – 17.0]	14.0 [9.0 – 23.0]	0.161
Tumour volume (cm^3)[1]	0.5 [0.3 – 1.3]	0.6 [0.2 – 2.2]	0.434
cT[2]			0.752
Tis (%)	14 (13.86)	17 (18.09)	
T1 (%)	53 (52.48)	43 (45.74)	
T2 (%)	12 (11.88)	12 (12.77)	
yT0 (%)	3 (2.97)	5 (5.32)	
yT1 (%)	5 (4.95)	2 (2.13)	
yT2 (%)	1 (0.99)	1 (1.06)	
Not applicable (%)	12 (11.88)	12 (12.76)	
Unknown (%)	1 (0.99)	2 (2.13)	
cN[2]			0.722
N0 (%)	76 (75.25)	67 (71.28)	
N1 (%)	2 (1.98)	5 (5.32)	
N2 (%)	0 (0.00)	0 (0.00)	
N3 (%)	1 (0.99)	0 (0.00)	
yN0 (%)	8 (7.92)	7 (7.45)	
yN1 (%)	1 (0.99)	1 (1.06)	
Not applicable (%)	12 (11.88)	12 (12.76)	
Unknown (%)	1 (0.99)	2 (2.13)	
cM[2]			1
M0 (%)	78 (77.23)	72 (76.60)	
M1 (%)	1 (0.99)	0 (0.00)	
yM0 (%)	9 (8.91)	8 (8.51)	
Not applicable (%)	12 (11.88)	12 (12.76)	
Unknown (%)	1 (0.99)	2 (2.13)	
Histology (based on core needle biopsy)			
Malignant invasive (%)	75 (74.26)	63 (67.02)	0.31
Malignant *in situ* (%)	15 (14.85)	20 (21.28)	1
Uncertain malignant potential (%)	8 (7.92)	11 (11.70)	0.578
Benign (%)	3 (2.97)	0 (0.00)	

[1]Data are shown as median [interquartile range].

[2]'Not applicable' includes benign lesions and lesions with uncertain malignant potential. 'Unknown' means that the cTNM staging could not be retrieved from the patient's medical file.

Table 3: Data concerning placement of Magseed® or hooked-wire.

	Magseed®	Hooked-wire	*p*-value
Number of patients			
Magseed®/hooked-wire	99	86	
Magseeds®/hooked-wires	2	8	
Modality of placement			1
Ultrasound (%)	103 (100)	102 (100)	
Accuracy of placement			0.683
≤ 5mm from target (%)	99 (96.12)	100 (98.04)	
> 5mm from target (%)	4 (3.88)	2 (1.96)	
Depth (mm)[1]	12.0 [9.5 – 17.0]	-	
Days before surgery[1]	2.0 [1.0 – 7.0]	-	
Adverse events during placement			1
No (%)	98 (97.03)	92 (97.87)	
Yes (%)	3 (2.97)	2 (2.13)	

[1]Data are shown as median [interquartile range].

Table 4: Data concerning execution of wide local excision after Magseed® or hooked-wire localization.

	Magseed®	Hooked-wire	*p*-value
Cutaneous marking			
Yes (%)	41 (40.59)	84 (89.36)	
No (%)	59 (58.42)	-	
Uncertain (%)	1 (0.99)	10 (10.64)	
Sentinel node localisation			0.296
Yes (%)	69 (68.32)	57 (60.64)	
No (%)	32 (31.68)	37 (39.36)	
Percutaneous signal[1]			
Yes (%)	95 (94.06)	-	
No (%)	1 (0.99)	-	
Aberrant (%)	3 (2.97)	-	
Not applicable (%)	2 (1.98)	-	
Peroperative re-excision			0.718
Yes (%)	21 (20.79)	17 (18.09)	
No (%)	80 (79.21)	77 (81.91)	
Re-excision based on			
Peroperative RX (%)	10 (47.62)	14 (82.35)	
Sentimag® (%)	5 (23.81)	-	
Inspection, palpation (%)	2 (9.52)	3 (17.65)	
Unknown (%)	4 (19.05)	0 (0.00)	
Peroperative complications			0.354
Yes (%)	1 (0.99)	3 (3.19)	
No (%)	100 (99.01)	91 (96.81)	
Retrieval (%)	103 (100)	102 (100)	1
Retrieved in first resection (%)	100 (97.09)	102 (100)	0.246
Visible on peroperative imaging (%)	102 (99.03)	101 (99.02)	1

[1]'Not applicable' involves patients in which Magseed® was not retrieved with Sentimag® but with an additional hooked-wire or palpation.

Table 5: Data concerning pathological examination of the specimen.

	Magseed®	Hooked-wire	*p*-value
Specimen weight (g)[1]	28.0 [18.0 - 38.0]	30.0 [19.0 - 48.0]	0.337
Total resected volume (cm^3)[1]	30.4 [19.3 - 43.1]	31.8 [17.7 - 46.9]	0.873
Percentage resected breast volume	4.5 [3.1 - 6.0]	3.7 [2.9 - 5.8]	0.049
Margin status			0.233
Negative (%)	80 (95.24)	69 (89.61)	
Positive (%)	4 (4.76)	8 (10.39)	

[1]Data are shown as median [interquartile range].
[2]'Not applicable' includes benign lesions and lesions with uncertain malignant potential. 'Unknown' means that the pTN staging could not be retrieved from the patient's medical file.

or hooked-wire to the target lesion was 10 and 9 mm respectively. Complications encompass a procedural hematoma.

Surgical procedure

Surgical procedure data are shown in Table 4. Percutaneous detection with the Sentimag® device was unambiguously at 94.06%. In three cases, the percutaneous signal was aberrant, including a diffuse signal, an extremely low signal and impression of two foci of high signal. In one case, the Magseed® was only detectable after incision. None of the abovementioned deviations led to positive margins.

The need for additional peroperative excision (based on macroscopic, radiological and/or Sentimag® findings) was similar for Magseed® and hooked-wire (20.79% *vs.* 18.09%; p = 0.718). All implanted seeds could be surgically retrieved. Three Magseeds® could not be retrieved at first sight but were successfully removed in a second attempt. The only observed complication was an allergic reaction to patent blue (used for sentinel node biopsy) which occurred in both groups.

Pathological examination

Table 5 shows the pathological outcome. Median specimen weight and volume do not show a significant difference between Magseed® or hooked-wire localisation. The median ratio excised of specimen volume to initial breast volume is 4.5% after Magseed® localisation, compared to 3.7% with hooked-wire localisation (p = 0.049). Although not statistically significant, the rate of positive margins was higher with hooked-wire compared to Magseed® (10.39% *vs.* 4.76% resp.; p = 0.233). After correcting for the ratio of specimen volume to breast volume, this remained in the advantage of Magseed, though non-significant (odds ratio 0.493, 95% confidence interval 0.126; 1.925, p=0.3085). Even after propensity score adjustment, the result remained unchanged, showing a non-significant advantage for Magseed. Regarding specimen volume/breast volume ratio, the higher ratio for Magseed became non-significant after correction. In the Magseed® group, two cases of positive margins were attributable to pre- and postoperative discordancy in case of invasive lobular carcinoma. Regarding policy in case of positive margins (based on multidisciplinary decision), one completion mastectomy in the Magseed® group was performed and 3 additional mastectomies in the hooked-wire group. One case could be solved with a second wide local excision. Adjuvant therapy was subsequently at the discretion of the treating physician.

Surgeon satisfaction

During the first two months, less than 70% of the operations were scored as 'easier than hooked-wire' by the surgeons, but this scoring exceeded more than 80% by the end of the study.

Discussion

Breast cancer screening and advances in breast imaging have led to more breast lesions being non-palpable at diagnosis. Several alternatives to the gold standard hooked-wire technique have become available. Since September 2018, Magseed® localisation has become the standard of care for localising non-palpable breast lesions in UZ Leuven. In this prospective observational study, the oncological safety, the clinical safety and surgeon satisfaction of Magseed® localisation in breast cancer surgery have been prospectively assessed during a period of seven months.

Critical reflection

Placement of the device: All 103 Magseeds® and 102 hooked-wires were placed under ultrasound guidance, with Magseed® being implanted at a median of two days preoperatively. Regarding hooked-wire, a same day procedure is standard whereby dislocation might occur after mammographic control when placed in (large) fatty breast tissue. Occurrence of hematoma during placement was comparable between Magseed® and hooked-wire.

Detection of Magseed® with Sentimag®: Except for one case, a percutaneous signal was present in all patients. Regarding this unique case, several possible explanations have been postulated. First, a possible link with recent pregnancy leading to a larger breast volume and breast density? Patient's breast volume falls within the third quartile of all breast volumes, but density exceeded the third quartile. However, Harvey et al. showed that Magseed® is detectable in all breast sizes [5,9]. Secondly, Magseed® was placed at a depth of 22mm, which is still within the 30mm detection range and even the seed that was placed at a depth of 45mm could be percutaneously detected. Although all precautions were considered and measurements were performed repeatedly, a final explanation might be overlooking interfering factors.

Resected breast volume: In this study, resected volume after Magseed® or hooked-wire localisation does not show a significant difference. These results correspond with a comparative study performed by Zacharioudakis et al. [7] although with specimen volumes being three times as high as volumes in the current study. Hersi et al. report a median specimen volume of 41.75cm^3 with Magseed® localisation, which resembles more our data [10].

Our data show a significant difference in specimen volume to breast volume ratio with a lower percentage breast volume excised with hooked-wire localisation. Although statistically significant, these results need to be viewed with nuance. As shown in Table 5, specimen volumes between the Magseed® and hooked-wire group do not show a meaningful difference. In contrast, the estimated breast volume was considerably larger in the latter. Since there was no patient selection, this can be completely assigned to randomity. The combination of a comparable specimen volume but lower breast volume, might explain this difference. Regarding cosmesis after BCS, Cochrane et al. showed that 83.5% of the patients were very satisfied if excised volumes was less than 10% [11]. Another study used an even more stringent threshold of 7.2% at which excellent cosmesis could be achieved [12].

Surgical margins: A positive margin rate of 10.39% was reported in our historical hooked-wire series, which is lower than in literature. Positive margin rate with Magseed® is considerably lower in our study, even after correcting for ratio of specimen volume to breast volume. Literature reports positive margin rates with Magseed® localisation from 0% to 16% [6,10,13-15].

Clinical implementation and use of Magseed®

The implementation of a new methodology in clinical care always implies some trial-and-error in finding a new workflow. Although placing Magseed® up to 26 days pre-operatively was considered as a logistical advantage, it also involved (logistic) reorganisation between surgeons, radiologists and nurses.

Learning curve: Both radiologists and surgeons experience a short learning curve. For our radiologist, insertion of Magseed® was similar to the insertion of other tissue markers with comparable challenges regarding characteristics of the tissue. Magseed® and Sentimag® were generally described as 'peroperatively easier than hooked-wire' by surgeons, although some refinements could be formulated. Auto-calibration of the probe when not in use, would overcome the need for recurrent calibration. In addition, a wireless probe would also ameliorate clinical use of Sentimag®.

Applicability: In some cases, Magseed® did not seem applicable e.g. when tumour tissue was considered too firm for Magseed® implantation. Later, these hurdles were overcome by placing the Magseed® near the tumour instead of intralesional. Since Magseed® signal can be detected over 2cm, nearby-planted seeds can easily guide the surgeon towards the lesion. Furthermore, BCS for a papillary lesion was performed with a hooked-wire because of the loose nature of papillomata. Preference might also be given to hooked-wire in case of multifocality, because inserting more than 1 Magseed® would rise the cost and could result in an unclear Sentimag® signal. However, the most important indication wherein a hooked-wire was preferred over Magseed® was a linear configuration of microcalcifications. The wire could be used as a real guide throughout the zone of microcalcifications to be resected. Lastly, one patient was not suitable for Magseed® because of an implantable cardioverter defibrillator which is an absolute exclusion criterion for use of Sentimag®. Other limitations for the clinical integration of Magseed® include a larger signal void artifact on MRI than caused by other tissue markers and increased cost when compared to hooked-wire. Specifically, the initial start-up cost plus the additional costs for the nonferromagnetic instruments make Magseed® more expensive than hooked-wire localisation. However, this increased cost is compensated by more efficient and less time-consuming perioperative scheduling.

Limitations and Strengths of this Study

Limitations are mainly related to the monocentric set-up and partly retrospective data collection. The monocentric set-up and limited timeline implie a rather small number of patients, potentially lowering the study power. However, monocentricity can be justified by UZ Leuven being the first hospital in Belgium to adopt Magseed® as localisation method. Regarding the historical hooked-wire group, the effect of different approaches and practices is probably minimal since the limited number of surgeons, radiologists and pathologist involved in both studies. Secondly, except for the pilot study in October 2017, no formal training program took place, resulting in sporadically suboptimal use of the technique. Data from first experiences with Magseed® are also included in this study, while the hooked-wire technique was already well-mastered in all included cases. This could slightly distort our data. Lastly, calculating breast volume on craniocaudal view, using Volpara™ often leads to underestimation of the breast volume and might also influence the final result. Nonetheless, the use of an objective software tool also increases the reproducibility of the study and provides more reliable results.

Further strengths are the use of two comparable groups during a comparable time period. No patient selection took place when retrospectively collecting the hooked-wire data. Moreover, surgical experience and techniques are similar because both BCS with Magseed® and hooked-wire localisation were performed by the same small group of surgeons.

Future Perspectives

Future research might enclose larger and more powered studies to confirm the observed tendency in favour of Magseed® e.g. tendency to lower positive surgical margins. In addition, objective assessment of patient satisfaction and cosmetic outcome after Magseed® localisation is desirable, as these topics were currently not investigated. Regarding the latter, obtaining patient derived data is thus crucial in evaluating aesthetics. Furthermore, European approval for long-term placement of Magseed® was obtained, enabling implantation before neoadjuvant therapy. Placing Magseed® before start of systemic therapy offers the advantage of avoiding a second invasive procedure since Magseed® can be placed instead of the standard clip. However, the large signal void artefact on MRI impedes this application in case when BCS is considered, depending on the response to therapy.

Moreover, Magseed® may have further clinical applications beyond preoperative localisation of non-palpable breast lesions. Magseed® was also CE approved for the use in any soft tissue, including its use in lymph nodes, lung and thyroid tissue [16]. To explore the feasibility and safety of Magseed® in targeted axillary dissection and resection of metastases, clinical studies are highly advisable. Furthermore, exploring the extension of Magseed®'s clinical applicability in other pathologies would also be valuable.

Conclusion

This prospective observational study of Magseed® localisation compared oncological safety, clinical safety and surgeon satisfaction with a historical serie of hooked-wire localisations for non-palpable breast lesions. In terms of oncological safety, a trend for lower positive surgical margins with Magseed® was observed, leading to fewer re-excisions and less need for completion mastectomies. A comparable aesthetic outcome, based on resected breast volume, can be expected since specimen volumes were similar between both groups. In respect of clinical safety, all Magseeds® could be placed under ultrasound guidance with comparable (low) bleeding events. Regarding perioperative scheduling, Magseed® offers different logistics advantages compared to same-day hooked-wire procedure. In addition, surgeon and radiologist satisfaction with Magseed® as well as patient comfort are very high. Overall, these results are encouraging to continue using Magseed® in preoperative breast localisation as well as to explore and broaden its applicability in surgical oncology.

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