# A Novel Surgical Marker Navigation System to Localise and Remove Non-Palpable Breast Lesions: A Dutch Centre Experience

Linda Stengs<sup>1</sup>, Suzanne van Veen<sup>2</sup>, Gisela Moormann<sup>1</sup>

<sup>1</sup>Departments of Surgery, <sup>2</sup>Radiology, Red Cross Hospital (RKZ), Beverwijk, The Netherlands

> lumpectomy with wire-guided localisation (WGL). Materials and Methods: This retrospective, single-centre study evaluated surgical margin status, complications, lump weight and re-excisions in patients who underwent lumpectomy of nonpalpable breast lesions with SMN using Sirius Pintuition (n = 85) and with WGL (n = 52). Statistical Analysis: Chi-square and T tests were conducted for group comparisons. **Results:** Surgical outcomes in the patients undergoing lumpectomy with SMN were not significantly different from those in the WGL group. Overall clear margin rates were 97.4% in patients with invasive carcinoma, and 90.0%in patients with ductal carcinoma in situ. This led to a total of five re-excisions (3.6%). Complications were mostly mild. SMN was easily implemented and the radiologists and surgeons were satisfied with using Pintuition. Conclusion: SMN with Pintuition is feasible and safe, with similar surgical outcomes in comparison to wire-guided localisation in this single centre. The opportunity to separate radiology and surgery with SMN is advantageous for hospital planning and logistics. The surgeons found lumpectomy with Pintuition more intuitive and less complex than WGL. Given these results, we are now exploring localisation of lymph nodes in the axilla, multifocal breast tumours and other soft tissue lesions.

**Keywords:** Lumpectomy, non-palpable breast lesions, pintuition, surgical marker navigation, wire-guided localisation

Context: For non-palpable tumours and early-stage breast cancer, surgeons

can perform breast-conserving surgery guided by localisation technologies to

find and remove lesions. Aims: The present study describes the implementation

and clinical experience with Sirius Pintuition, a novel non-wire surgical marker navigation (SMN) technology. Settings and Design: Surgical outcomes were evaluated and compared to a cohort of patients who had undergone

**KEY MESSAGES:** Surgical marker navigation with Pintuition is feasible and safe, with similar surgical outcomes in comparison to wire-guided localisation. The surgeons found lumpectomy with Pintuition more intuitive and less complex than wire-guided localisation. Given these results, we are now exploring localisation of lymph nodes in the axilla, multifocal breast tumours and other soft tissue lesions.

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# INTRODUCTION

O f all breast cancer cases,  $33\%^{[1]}$  to  $44\%^{[2]}$  are nonpalpable at the time of diagnosis. For early-stage breast cancer, the first treatment of choice is usually surgery where small and non-palpable breast tumours

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can be completely removed while preserving healthy breast tissue. The goal is to excise the tumour to negative

Address for correspondence: Gisela Moormann, MD, Vondellaan 13, 1942 LE Beverwijk, The Netherlands. E-mail: gmoormann@rkz.nl

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Figure 1: Left: Pintuition marker and Pintuition Needle. Right: Pintuition detector consisting of the Pintuition probe (front) and base unit delivering auditory and visual feedback to guide seed detection

margins, stage the axilla, and provide satisfactory cosmetic results.<sup>[3]</sup> A multidisciplinary approach is indispensable to achieve this. The radiologist performs the preoperative, image-guided localisation of the non-palpable breast tumour and axillary lesion and evaluates the surgical specimen to confirm its removal by the surgeon. The pathologist investigates the lump and determines the tumour type, and the free margins around the lesion. With these results, further therapy can be planned.

Localisation technologies have been developed to optimise curative, breast-conserving surgery. Wireguided localisation (WGL) has been widely applied, where the radiologist implants a metal wire under imaging guidance, that traverses the breast from the surface into the lesion. After the operation is scheduled, the surgeon creates a pathway following the wire and removes the tissue around the tip. The patient is left with a wire protruding from the breast until surgery, which is generally more painful than the alternative techniques.<sup>[4,5]</sup> In some cases, the wire migrates, dislodges or fractures.<sup>[6]</sup> The linkage in scheduling between radiology and surgery can stress the hospital workflow because the time to surgery should be reduced to 1 day at most.<sup>[7]</sup> Furthermore, the predetermined entry position and pathway of the wire inside the breast can restrict the surgeon in determining the ideal surgical trajectory. In short, WGL comes with some disadvantages for the patient, the surgeon, as well as for hospital logistics.

More recently, non-wire localisation alternatives have been approved for long-term implantation with the intent to remove them at a later date: radioactive seeds, radar reflectors, magnetic seeds, and radiofrequency identification tag localisers (see review<sup>[8]</sup>). Each technique for surgical marker navigation (SMN) has its pros and cons and the choice depends on cost, workflow efficiency, hospital resources, physician preference, and ease of use. These devices are used for localising smaller lesions of the breast and axillary lymph nodes as well as for bracketing larger lesions, and can be

50

deployed before neoadjuvant chemotherapy.<sup>[9]</sup> As the surgical tissue excision is not restricted by a predefined pathway, this bears the potential to decrease lump volumes and to improve cosmetic results.<sup>[10]</sup> Patients undergoing lumpectomy with magnetic seeds were less anxious between localisation and surgery than those with a wire, while surgeons reported higher ease of use. Both radiology and surgical staff were more satisfied with using a magnetic seed than a wire.<sup>[11]</sup> Moreover, non-wire techniques allow for more flexibility in patient scheduling than wire-guided techniques.<sup>[10]</sup> We therefore decided to introduce SMN to our clinic.

The present study aims to describe the implementation and clinical experience with Pintuition, a novel nonwire surgical marker navigation, in a single centre that had previously been using WGL. This is supported by a retrospective analysis of a case series of patients with non-palpable breast lesions. Surgical outcomes were evaluated in cohorts of patients that underwent tumour excision using WGL, and in patients using SMN with Pintuition.

# SUBJECTS AND METHODS

#### **Study design and patients**

This retrospective, observational study was conducted in a case series of non-palpable breast cancer patients. For the analysis, a local patient database was used that had been developed for quality auditing purposes by the surgery department of the Red Cross Hospital (RKZ) in Beverwijk in The Netherlands. Consecutive patients receiving the Pintuition marker between November 2020 and May 2022 were identified as well as a comparable group of patients undergoing wireguided lumpectomy from 2019 to 2020. The medicalethical review board of the hospital was informed about the study and expressed no objections.

#### Localisation

During wire-guided localisation, the radiologist inserts a metal wire with an anchor tip inside or near the lesion guided by imaging. In the operating room, the surgeon removes the tissue near or surrounding the anchor tip, guided by the wire and any previous images obtained of the lesion and implantation report of the radiologist.

The Pintuition system for non-wire SMN is manufactured by Sirius Medical (Eindhoven, The Netherlands). It comprises a tiny  $(5 \times 1.6 \text{ mm})$  magnet in a biocompatible titanium encasing, delivered in a preloaded and sterile 14G hollow positioning needle, and a detection probe with a monitor [Figure 1].

The Pintuition marker is indicated for pre-operative percutaneous implantation into soft tissue, such as glandular, fibrous, or fatty tissue of the breast, lymph nodes in the axillary and inguinal region, subcutaneous tissue and skeletal muscle tissue. The marker is intended for the temporary marking (<180 days in Europe) of a tissue (e.g., tumour or a suspected lesion) that is, indicated for surgical removal. It can be deployed under ultrasound or mammographic guidance.

The Pintuition detector is designed to detect the presence and proximity of the implanted magnetic marker. It comprises a table-top base unit and a cable-connected reusable probe. The detector can be used before and during breast surgery to plan the surgical approach and to guide the excision. The multi-sensor probe and GPSDetect<sup>™</sup> software (Sirius Medical, Eindhoven, The Netherlands) provide navigational guidance with audio and visual feedback towards the Pintuition marker.

Other wireless localisation devices such as Magseed from Sentimag® differ from the Pintuition marker in that the Pintuition software provides a 360° directional guidance as well as the true distance from the tip of the probe to the marker. The marker detection range for Pintuition is 5cm compared to 3cm for Magseed. In addition Sentimag® needs to be calibrated more than once during the surgical procedure whilst Pintuition requires just a single initial calibration. The Magseed magnetic marker is indicated for the long-term use in any soft tissue, whereas Pintuition is indicated for temporary marking (<180 days) of soft tissues. Both localisation techniques operate under the principle of magnetism yet the two technologies differ significantly. The Sentimag® probe operates similarly to a metal detector hence the limitation of use with metallic surgical instruments and the need to use plastic instruments.

# **Radiology and surgery**

Two senior surgeons and three senior radiologists with extensive experience in wire-guided surgery and radiology procedures were involved in the localisation and lumpectomies.

Start-up phase and learning curve: A technical representative of the manufacturer trained the team

of surgeons and radiologists beforehand on the use of the Pintuition marker and its navigational audio and visual feedback by using phantom breasts. During surgery of the first two patients, the radiologist and the technician were also present in the operation room. The surgeon identified the previously positioned Pintuition marker with the probe. This was then confirmed by the radiologist using ultrasound, after which the surgery was performed. The next 18 cases undergoing SMN with the Pintuition marker were patients with invasive tumours that were slightly palpable. During surgery, the palpable lesion served as an extra verification of the position of the Pintuition marker. These first twenty procedures were excluded from the present analysis. They were considered as our learning curve to become fully familiar with this novel SMN technique.

SMN with Pintuition: Leading up to surgery, the radiologist placed the Pintuition marker in or nearby the lesion under ultrasound guidance after administration of local anaesthesia. The surgeon started with planning the ideal trajectory based on previous imaging and the report of the radiologist where the marker was positioned relative to the lesion. Surgery was performed under general anaesthesia. The incision was planned starting from the ideal entry site for optimal aesthetic results. The probe was applied for the transcutaneous detection of the Pintuition marker, which was marked on the skin.

After the incision had been made, the skin was mobilised. While dissecting the surgical path, the probe was entered inside the breast and dynamically maneuvered to repeatedly determine the distance and direction towards the marker. In this way, the desired pathway was repeatedly confirmed by using the probe. The surgeon excised the tissue surrounding the marker and removed the lump, which was checked with the probe to confirm the presence of the marker. The specimens were marked with sutures to indicate orientation, and transferred to the radiology department. After re-confirming marker retrieval by an X-ray of the lump, the specimen was stored in formalin and sent to the pathology department for macroscopic and microscopic evaluation.

Wire-guided procedure: Before surgery, but on the same day, the radiologist placed the ultrasound-guided hook wire localisation (Duo System Premium, 20-Gauge puncture cannula, Somatex, Berlin, Germany). Patients received local anaesthesia before wire placement. The wire protruded externally through the skin and was taped to the breast to prevent movement and pain. Patients awaited their surgery on the ward. Patients received general anaesthesia. The surgeon planned the incision for an optimal approach to the wire, after which the wire was cut and the incision performed. Following the trajectory of the wire while making the surgical pathway, the surgeon dissected the tissue surrounding the hook. The wire with hook and the lump attached were retracted from the breast. The specimen was marked with sutures to indicate orientation, transferred to the radiology department for confirmation by X-ray of the retrieval of the lesion, stored in formalin and sent to the pathology department for macroscopic and microscopic evaluation.

# Outcomes

The main endpoints of the analysis were the clear margin rate, re-excision rates, lump weight, and complications. We used the margin definitions as stated in the Dutch pathology guidelines. Clear margins indicate that there is no tumour in the inked plane. In focally positive margins, the tumour touches the inked plane over a length of maximally 4mm. In extensive positive margins, the tumour touches the inked border over a length of more than 4mm. Guidelines for re-excision differ between ductal carcinoma in situ (DCIS) and invasive carcinoma. Re-excision of DCIS was performed when positive margins were found. In the case of invasive carcinoma, re-excision was performed only in case of extensive positive margins.

The time between placement of the wire or the Pintuition marker and surgery was also reported, as well as postoperative pathology assessments, comprising tumour grading (Bloom Richardson), lump weight, and the diameters of invasive and *in situ* components.

#### Usability

A brief customised usability questionnaire was completed by the three radiologists and two surgeons who had performed the procedures with the wires as well as SMN with the Pintuition marker. They retrospectively evaluated overall complexity of the procedure and their general satisfaction with the devices. Complexity and satisfaction were rated on a 5-point scale (Complexity; 1: not at all complex; 2: slightly complex; 3: moderately complex, 4: very complex, 5: extremely complex. Satisfaction; 1: Very dissatisfied, 2: Dissatisfied, 3: Not dissatisfied/not satisfied, 4: Satisfied, 5: Very satisfied). Other questions [Table 3] could be answered with Yes, No, or Other. All questions had open fields for optional comments.

# **Analysis**

52

For baseline characteristics, means and ranges were reported. Statistical testing was performed to compare clear margins, re-excision, complication rates, infection rates and lump weight. Chi-square tests or Fisher Exact Tests were performed on frequency data, and *T* tests for normally distributed continuous data (lump weight).

# RESULTS

#### **Patients and demographics**

Our hospital had been performing WGL before our implementation of SMN with Pintuition in November 2020. Since then, we have applied Pintuition exclusively to patients with unifocal breast tumours. A suitable comparator group was selected among patients who underwent WGL between January 2019 and December 2020. Multiple wires had been used for cases with multifocal and large breast lesions. For reasons of comparability between the groups, only patients with unifocal breast lesions and single wires were selected.

Between 2019 and 2022, a total of 661 new patients presented to our department. Our surgical database included data from 573 patients who underwent surgery in the Red Cross Hospital between January 2019 and May 2022. For the current analyses, we only selected patients with non-palpable breast cancer (n = 224) who were operable (n = 223), underwent lumpectomy, and were seen during post-operative follow-up visits at our hospital with most data complete (n = 204). Excluded were patients who underwent ablation (n = 41) and patients with 2 wires (n = 23) or 3 wires (n = 3). This resulted in a selection of 137 patients, who underwent single wire-guided lumpectomy (n = 52) or via SMN with the Pintuition marker (n = 85). Table 1 shows the baseline characteristics of both groups.

#### **Surgical outcomes**

Table 2 lists the surgery-related outcomes in both groups. The average time between the placement of the Pintuition marker and surgery was on average 8.9 days. Placement of the wire at the radiology department and the lumpectomy was on the same day in all patients.

The overall clear margin rate of the invasive component was 97.4% (in all patients with invasive carcinoma with or without DCIS; n = 114). In all patients with DCIS (with or without invasive carcinoma; n = 70), the clear margin rate of the *in situ* component was 90.0%. Clear margin rates were not significantly different between the groups.

In the total group (n = 137) the lumpectomy of the invasive component had positive margins in two patients (2.9%), and extensive positive margins in another two patients. The resection of the DCIS resulted in positive margins in eight patients (5.8%). This led to an overall re-excision in five patients (3.6%). Re-excision rates were not significantly different between the groups.

Ta	able 1: Baseline characteristics	
	Pintuition $(n = 85)$	Wire $(n = 52)$
Age (mean years, range)	65.2 (41-82)	62.3 (44-80)
Histology ( <i>n</i> )		
Invasive	41 (48.2%)	26 (50.0%)
in situ (DCIS)	15 (17.6%)	8 (15.4%)
Invasive + DCIS	29 (34.1%)	18 (34.6%)
pTNM ( <i>n</i> )		
T1	65 (92.9%)	36 (81.8%)
T2	5 (7.1%)	6 (13.6%)
Т3	0 (0%)	0 (0%)
T4	0 (0%)	0 (0%)
Diameter lesion (mean mm, range)		
Invasive	11.8 (1-32)	12.5 (5-30)
in situ	13.3 (3-62)	12.1 (1-50)
Grade (Bloom Richardson)		
Invasive <sup>1</sup> $(n)$		
1	25 (35.7%)	15 (34.1%)
2 3	40 (57.1%)	24 (54.5%)
3	5 (7.1%)	5 (11.4%)
$DCIS^{2}(n)$		
1	6 (13.6%)	6 (23.1%)
2	25 (56.8%)	10 (38.5%)
3	9 (20.5%)	8 (30.8%)
Hormone receptor-positive ( <i>n</i> )	63 (74.1%)	41 (78.8%)
Triple-negative ( <i>n</i> )	6 (7.1%)	3 (5.8%)
HER2-neu positive ( <i>n</i> )	3 (3.5%)	3 (5.8%)
Neo-adjuvant chemotherapy ( <i>n</i> )	4 (4.7%)	2 (3.8%)
Lymph node metastasis ( <i>n</i> )	12 (14.1%)	9 (17.3%)

DCIS, ductal carcinoma in situ; Diameters before neoadjuvant therapy, if applicable; Grade: Bloom Richardson.

<sup>1</sup>: Patients with Invasive tumour with or without *in situ* component;

<sup>2</sup>:Patients with *in situ* component with or without invasive tumour. Diameter *in situ* component: 1 case missing where the DCIS was not found in the lump

Table 2: Surgery-related characteristics					
N = 137	Pintuition $(n = 85)$	Wire ( <i>n</i> = 52)			
Time device implanted till surgery (days)	8.9 (0-32)	0			
Mean weight lump <sup>1</sup> (g)	33.6 (6-101)	32.1 (9-93)	P = 0.744		
Median weight <sup>1</sup> lump (gr)	30	26			
Missing weight	26 (30.6%)	14 (26.9%)			
Lump with breast reduction	1 (1.1%)	2 (3.8%)			
Transcutaneous detection	100%	100%			
Retrieval rate	100%				
Invasive tumour <sup>2</sup> clear margin	67 (95.7%)	44 (100.0%)	P = 0.158*		
In situ lesion <sup>3</sup> clear margin	40 (90.9%)	23 (88.5%)	$P = 0.665^*$		
Invasive tumour <sup>2</sup> positive margin	2 (2.9%)	0			
Invasive tumour <sup>2</sup> extensive positive margin	2 (2.9%)	0			
DCIS <sup>3</sup> positive margin	3 (6.8%)	2 (7.7%)			
DCIS <sup>3</sup> extensive positive margin	0	1 (3.8%)			
Re-excision	3 (3.5%)	2 (3.8%)	P = 1.00*		
Complications	5 (5.8%)	3 (5.8%)	P = 0.644		

DCIS, ductal carcinoma in situ; <sup>1</sup>Single case with a breast reduction lump of 174 g was dropped from the weight analyses

<sup>20</sup>/<sub>0</sub> is relative to all cases with invasive components (with or without DCIS)

<sup>30</sup>/<sub>20</sub> is relative to all cases with DCIS (with or without invasive tumours). For all cases with the lump excised in a breast reduction, lump weight was not analyzed

\*Fisher exact test

Table 3: Usability						
Surgeons	1	2				
Some surgeons say that wire-guided lumpectomy is more	Yes	Yes@				
complex compared with using the Pintuition marker. Would you agree?						
How would you rate the complexity <sup>1</sup> of the surgery with						
the wire	Very complex	Very complex				
Pintuition	Slightly complex	Slightly complex				
Is wire-guided lumpectomy more difficult to teach to new surgeons compared to using pintuition? <sup>2</sup>	Yes	Yes				
Some surgeons say that lumpectomy with the Pintuition marker is more intuitive compared to lumpectomy with the wire. Would you agree? <sup>2</sup>	Yes	Yes				
How satisfied <sup>3</sup> are you with using:						
the wire	Not satisfied, not dissatisfied	Dissatisfied				
Pintuition	Very satisfied	Satisfied				
RADIOLOGISTS	1	2	3			
How would you rate the complexity <sup>1</sup> of the procedure with:						
the wire	Not at all complex	Slightly complex	Not at all complex			
Pintuition	Not at all complex	Not at all complex	Not at all complex			
Is the procedure more complex to perform with the wire compared to Pintuition? <sup>2</sup>	No	Yes	No			
Is the procedure with the wire more difficult to teach to	No	Yes	No			
new radiologists compared to Pintuition? <sup>2</sup>						
How satisfied <sup>3</sup> are you with using:						
the wire	Very satisfied	Satisfied	Very satisfied*			
Pintuition	Very satisfied	Very satisfied	Very satisfied#			

Usability questionnaire with responses from 2 surgeons and 3 radiologists

<sup>15</sup> point scale: not at all complex/slightly complex/moderately complex/very complex/extremely complex

<sup>2</sup>No/equally difficult/yes/other, namely: [free text field]

<sup>3</sup>Very dissatisfied/dissatisfied/not dissatisfied, not satisfied/satisfied/very satisfied

Remarks: \*"easy to perform and very good visibility with ultrasound"; # "easy to perform, the only disadvantage is the visibility of the seed is quite bad with ultrasound after placement"; @"orientation and depth of the wire make it more complex"

Complications were documented in a total of eight patients (5.8%): in the Pintuition group, there were three cases with post-operative bleeding and two cases of wound dehiscence. In the wire-guided group there was one case of nipple necrosis, one case of wound dehiscence, and one case of wound infection that was treated with antibiotics. All the cases of dehiscence were resolved by wound irrigation with saline. Two cases with postoperative bleeding required a re-operation. Complication rates were not significantly different between the groups.

There were no cases reported with Pintuition marker or wire migration or dislodgement. In one case, a second wire had to be placed because the first wire was not optimally positioned.

#### Usability

54

Three radiologists and two surgeons completed a brief usability questionnaire evaluating the complexity of the procedures using Pintuition versus the wire [Table 3].

Overall, the surgeons were satisfied with using the Pintuition marker and less satisfied with using the wire.

They found wire-guided lumpectomies more complex to perform compared to using the marker. They rated the procedure with the wire as "very complex", as opposed to "slightly complex" with the marker. The surgeons found surgery more intuitive with the marker than with the wire, and easier to teach to new surgeons.

The radiologists are satisfied to very satisfied with using the wire, and also very satisfied with the Pintuition marker. Two out of three radiologists did not find it more difficult to teach the wire-guided procedure to new radiologists and did not find the procedure with the wire more complex than with the marker. All radiologists rated the marker procedure as "not at all complex", and two out of three rated the wire procedure as "not at all complex".

# DISCUSSION

After always having performed wire-guided lumpectomies, the RKZ hospital has introduced a non-wire, magnetic marker for surgical navigation (Pintuition) in non-palpable breast masses. Although the surgeons obtained good results with the wire-guided procedure, they deemed it rather patient-unfriendly. The wire protruding externally through the breast between placement at the radiology department and surgery was causing discomfort for the patient. Also, hospital planning and logistics were stressed by the coupling of radiology and surgery. To reduce patient discomfort, the logistics were changed to ensure that the patient was operated on the same day as wire placement. The option of using iodine seeds was also explored but proved to be not feasible due to regulations and logistics. In November 2020, surgical marker navigation with the Pintuition marker was introduced.

Following the lumpectomies in 137 patients, overall clear margin rate was 97.4% in patients with invasive carcinoma and 90.0% in patients with DCIS. The 5 re-excisions (3.6%) were slightly lower than in previous reports.<sup>[5,8]</sup> We found similar clear margin and re-excision rates in the SMN group versus the WGL group. Complication rates were equal in both groups (5.8%). There was one case where an additional wire had to be implanted because the first wire could not be positioned optimally. We found no cases of wire dislodgment or migration as was seen in previous reports (0%–1.8%).<sup>[8]</sup> This is probably due to our long experience with WGL and the fact that our centre had changed hospital logistics to ensure that patients undergoing lumpectomy had the wire placed on the same day. Over recent years, we have conducted more oncoplastic operations to ensure breast-conserving therapy. A dedicated plastic surgeon reconstructs the breast immediately after the lumpectomy within the same operation. In these cases flap techniques are used for oncoplastic closure such as the Grisotti or the lateral intercostal artery (LICAP) flap reconstruction. In the case of large breast volumes the lumpectomy is performed in combination with a breast reduction. In the present patient sample due to the small lesions only breast reductions were performed. This results in more extensive surgery and larger wounds which may explain the cases of post-operative bleeding and wound dehiscence.

Lump weight and volume have been reported as an outcome in the comparison of non-wire techniques versus WGL, with contradicting results. In the present study, lump weights for the Pintuition (30g) and WGL (26g) groups were similar. The registration of lump weight is not standard practice in our centre, hence the missing weights in about a third of our patients. A previous study<sup>[5]</sup> also reported similar weights and volumes for magnetic seed localisation (MaMaLoc; 36g and 39.5 cc) versus WGL (39g and 42.9 cc). While

Micha *et al.*<sup>[11]</sup> reported lower lump weights using magnetic markers versus WGL, others did not find such differences relative to several non-wire devices.<sup>[8,12]</sup> Also reported were slightly higher specimen weight<sup>[13-15]</sup> and volume in wireless devices. Whether lump weight or its dimensions is relevant for the cosmetic satisfaction of the patient remains to be investigated.

In our experience, a low lump weight is not always a relevant surgical outcome. This also depends on breast size and patient preference. In some of our patients, a relatively large part is excised from the skin down to the fascia since the wound closes more favourably with this technique. It prevents the accumulation of fluids in the wound cavity that we see with the excision of a round lump. This can cause adverse effects in response to radiotherapy. Moreover, a smaller lump is not necessarily cosmetically better, and some patients (3 in the present sample) prefer to combine the lumpectomy with a breast reduction. Also, the lump is excised more liberally in some patients with large breast sizes. A relatively larger lump volume may be preferable to the patient or for the sake of reducing aesthetically adverse effects after radiotherapy.

Wire-guided localisation and surgical marker navigation both have their advantages and disadvantages. The excision with Pintuition gives the surgeon more freedom to plan the incision from an esthetical perspective. During WGL, on the contrary, the surgical pathway is primarily determined by the predefined position of the wire. As the breast is pushed down and compressed during wire placement, a sharp curve is sometimes imposed on the trajectory of the wire when placed under fluoroscopy and sometimes also when placed under ultrasound guidance. This can make wire-guided surgery more complex. The Pintuition marker did not easily show on ultrasound in a single case during placement but was readily identified during our standard confirmation by X-ray. An advantage of SMN is the opportunity to separate the radiology and surgery procedures during hospital logistics and planning. Overall, the radiologists were very satisfied with Pintuition and did not find the wire procedure more complex. The surgeons found surgery with WGL more complex to perform compared with Pintuition. They were (very) satisfied with Pintuition, found the procedure more intuitive to perform, and easier to teach to new surgeons compared to WGL.

Limitations of the present retrospective study were that record keeping was not controlled, which resulted in missing values such as for lump weight. Randomised-controlled studies may be designed to conduct a head-to-head comparison between different

**<**55

surgical localisation techniques. For future studies, we recommend evaluating breast size in relation to lump volume and patient-reported outcomes such as cosmetic satisfaction.

Now that we have introduced SMN in our clinical practice, we are also exploring other applications such as localisation of lymph nodes in the axilla, multifocal breast tumours, and other soft tissue lesions. Future applications may also include bracketing, where multiple non-wire markers can be placed on opposing sides of large nonpalpable lesions.<sup>[8]</sup> In conclusion, it is feasible and safe to position the Pintuition marker and remove non-palpable breast lesions with surgical outcomes similar to wire-guided surgery. The implementation of SMN went smoothly in our centre and its use is considered very satisfactory by the radiologists and surgeons.

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#### **Conflicts of interest**

There are no conflicts of interest.

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56

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