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Evaluation of Magseed marker in location of non-palpable breast lesions

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ABSTRACT:

Introduction: Currently, there is an increasing number of breast cancer cases detected at an early stage. Removal of the minimum tissue volume that is necessary ensures that the correct shape of the breast is preserved. On the other hand, it is important to maintain negative tissue margins.

Aim: The aim is to present our own experience with pre-operative breast tumor marking using the Magseed marker.

Material and methods: On the day before surgery, the Magtrace magnetic marker was placed to map the lymph nodes, together with the Magseed magnetic marker placed in the tumor under ultrasound guidance, and the site of the lesion was marked with the skin marker as the surgical site. Before skin incision, the lesion was located using intraoperative ultrasound and the Sentimag probe. After the tumor was cut out, the presence of the marker was confirmed within the specimen using the magnetic method and the compatibility of the ultrasound image before and after the procedure.

Results: The study group consisted of 23 patients. Radical surgery was achieved in 20 patients (87%). To assess the sample and tumor sizes, we used the formula for the volume of the ellipsoid published by Angarita et al. We assessed how much of the sample was occupied by the tumor marked with the Magseed marker. We compared the cohorts of 11 patients at the beginning and at the end of the group, showing a significant increase in this parameter. Along with the learning curve, it is possible to more precisely identify the tumor and save healthy breast tissue while improving the aesthetic effect of the breast.

Conclusions: The method of localizing non-palpable lesions in the breast using the Magseed marker is simple to use, and its high detection rate directly translates into a reduced rate of non-radical resection during breast-conserving surgery.

KEYWORDS: location of non-palpable breast lesions, Magseed

ABBREVIATIONS

ACR – American College of Radiologists
BIRADS – Breast Imaging-Reporting and Data System
BMI – body mass index
CT – computed tomography
DCIS – ductal carcinoma in situ
FDA – Food and Drug Administration
MRI – magnetic resonance imaging
ROLL – radio-guided occult lesion location
RSL – radioactive seed location
SLNB – sentinel lymph node biopsy
SSR – SCOUT SAVI radar
WL – wire-guided location

INTRODUCTION

Thanks to the technological progress in breast imaging and popularization of screening, more and more cases of breast cancer are detected at an early stage, making breast-conserving surgery possible. Due to the prevalence of breast cancer (which is the most common malignant tumor in women in Poland – in 2019 there were 19,620 new cases [1]) and social expectations regarding the quality of life (effective oncology treatment with a good aesthetic effect after surgery), the most precise marking of the tumor before surgery is an important issue. Removing the least volume of the breast tissues ensures proper shape of the breast, but this should not be at the expense of non-radical resection. Many location methods are currently employed. In addition to the wire-guided location (WL) method, which has been used for the longest time, detection of ionizing radiation (radioactive seed location – RSL, or radio-guided occult lesion location – ROLL), magnetic field (Magseed), infrared radiation (Savi Scout) or radiowaves (LOCalizer chip) can all be used.

AIM

The aim of this study is to present our own experience with the use of pre-operative breast tumor location with the Magseed marker.

MATERIAL AND METHODS

The study group consisted of successive 23 breast cancer patients with oncologic indications for breast-conserving surgeryof non-palpable lesions. Each patient had been qualified for the procedure according to the oncology standards following the decision of the multispecialty team. Before the surgery, all patients underwent breast ultrasound and mammography according to the guidelines, as well as coarse-needle biopsy. In patients with confirmed cancer, abdominal ultrasound and chest X-ray were obtained as well.

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Tab. I. ???

NUMBER	RADICALITY	STAGING
1.	Yes	T1c No
2.	Yes	T1bNo
3.	Yes	T1bNo
4.	Yes	T1bNo
5.	No	T1cNo
6.	Yes	T1bNo
7.	Yes	T2No
8.	No DCIS, FEA	T1cN1a
9.	Yes	T1bNo
10.	No DCIS	T1cNo
11.	Yes, after chemotherapy	T3No
12.	Yes, two foci	T1bNo
13.	Yes	T1cNo
14.	Yes	T2No
15.	Yes	T1bNo
16.	Yes	T1cNo
17.	Yes	T1bNo
18.	Yes	T1No
19.	Yes	T1cNo
20.	Yes	T1bNo
21.	Yes	T1bNo
22.	Yes	T1cNo
23.	Yes	T2No

The study had the following exclusion criteria: pregnancy or lactation, presence of metal implants near the marker application site, previous implantation of the pacemaker, contraindications for breast-conserving surgery (inability to completely remove the primary tumor, inability to reach a good aesthetic effect, previous breast radiotherapy, connective tissue disease).

As part of the study, the following patients were qualified for breast-conserving surgery: women who had palpable breast lesions, confirmed cancer or lesions assigned BIRADS 4 or 5 on ultrasound, when previous biopsy was inconclusive, and who required open biopsy. Before the surgery, the lesion planned for excision was located using ultrasound. Then, the magnetic marker Magseed by Endomagnetics Ltd was placed in the lesion under ultrasound guidance. The location of the lesion was additionally marked with the skin marker as the surgical site. This procedure was performed on the day before surgery and was combined with magnetic marker placement for sentinel lymph node mapping. In several cases, when the sentinel node biopsy was not performed, the procedure was performed on the day of the procedure.

Before the skin incision, the tumor was again located using intraoperative ultrasound and the Sentimag probe. After the lesion was excised, the presence of the marker was confirmed in the specimen using the magnetic method, and the ultrasound image of the sample was compared with the pre-operative image. The specimen, after standard marking with threads, was submitted for pathology study. The bed of the excised tumor was marked with clips. Further treatment of the patients was conducted in accordance with the oncology standards (radiotherapy, possible hormone therapy and chemotherapy).

Tab. II. ???

NUMBER	TUMOR SIZE (CM)	SPECIMEN SIZE (CM)	RATIO OF TUMOR TO SPECIMEN VOLUME %
1.	1.2 × 1 × 1.3	4 × 4.5 × 2.5	1.8
2.	0.6 × 0.5 × 0.6	5.5 × 4.5 × 4.5	0.08
3.	1.1 × 0.9 × 0.9	7 × 4 × 3	0.55
4.	0.7 × 0.8 × 0.8	5.5 × 3.5 × 6.2	0.19
5.	1.5 × 1.3 × 1	9.5 × 7 × 3	0.51
6.	0.7 × 0.6 × 0.8	4 × 3.5 × 4	0.32
7.	1 × 1.8 × 4.5	11.5 × 7.5 × 2.5	1.9
8.	2 × 2.2 × 1.6	2.3 × 5 × 5	6.4
9.	0.7	8.5 × 3 × 8.5	0.08
10.	1.6 × 1.1 × 0.8	2 × 6 × 6.5	0.95
11.		8.5 × 9 × 3	
12.	0.5 × 0.6 0.8	8 × 6 × 5	0.05
13.	1.5 × 1 × 1.5	8.5 × 6 × 3	0.77
14.	3 × 2.3 × 3	9 × 12 × 4.5	2.2
15.	0.7	4.5 × 5 × 2.5	0.32
16.	1.2 × 1.1 × 0.9	2 × 6.5 × 4.5	1.07
17.	0.6	12 × 7 × 2.5	0.05
18.	1.2 × 1.2 × 1.5	3.5 × 5.5 × 2.5	2.3
19.	1.5 × 1 × 1.5	8.5 × 6 × 3.5	0.66
20.	0.8 × 1 × 1.2	8 × 6.5 × 3.5	0.27
21.	1.8 × 2.2 × 2.5	7.5 × 5 × 3	4.6
22.	1.5 × 1 × 1	4 × 4.5 × 2	2.2
23.	2 × 0.9 × 2.3	7 × 2.5 × 5	2.4
Mean 1–23	1.35		
Mean 1–12	1.17		
Mean 13–23	1.53		

Statistical analysis

The average age of patients in the studied group was 60 years (ranging from 44 to 77). The average BMI (Body Mass Index) was 28.37; two patients had morbid obesity (BMI >35), while three patients had BMI above 30. Only one patient was treated with pre-operative chemotherapy. In the vast majority (96%), the treatment was performed using oncoplastic techniques. Radical resection was achieved in 20 patients (87%). Among three patients requiring re-operation, the cause of non-radical resection in two patients was focal DCIS (ductal carcinoma in situ) at the specimen margin (Tab. I.). For the evaluation of the sample and tumor sizes, the formula for the volume of the ellipsoid published by Angarita et al. [2] was applied ($V = 4/3\ \pi\ a/2\ b/2\ c/2$, where a, b, c are the dimensions of the tumor in three planes). Then, it was assessed which part of the specimen was occupied by the tumor, using the Magseed marker. We also compared the cohorts of eleven patients at the beginning and end of the study group, showing a significant increase in this parameter (Tab. II.). According to the author, with experience in the use of this method (the learning curve), it is possible to identify the tumor much more precisely and, consequently, spare the healthy breast tissue while improving the aesthetic effect of the breast.

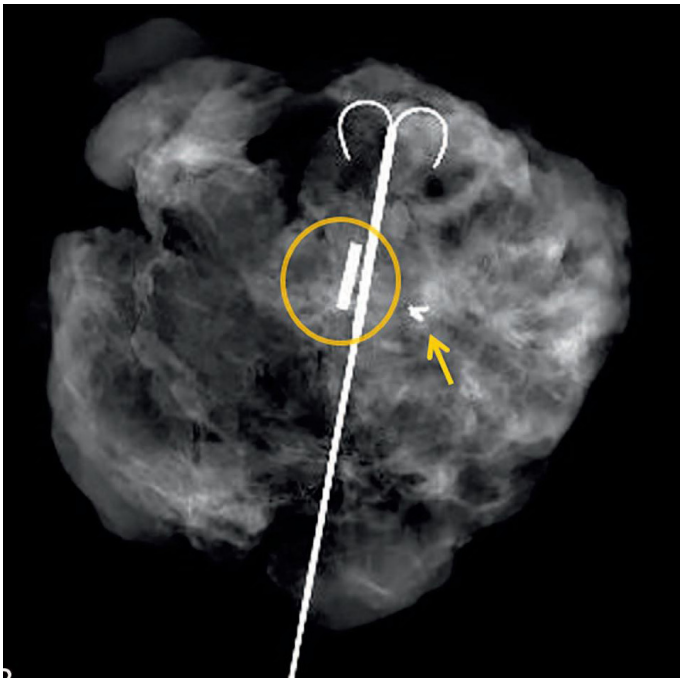

Fig. 1. Comparison of tumor location using anchor and marker.

Fig. 2. Marker used in ROLL method.

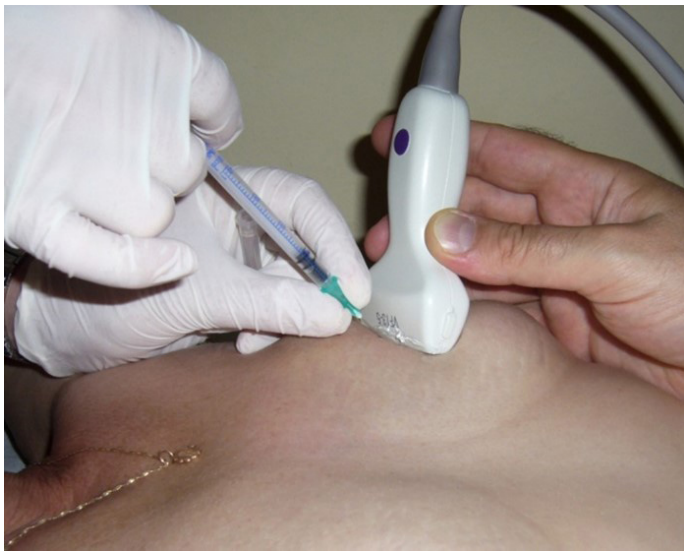

Fig. 3. ROLL method – marker implantation.

DISCUSSION

The first method of location was introduced in the early 70s of the 20th century, and it was based on tumor marking with an anchor, most often a metal wire (WL) [3]. The wire is placed in the tumor area on the day of surgery by the radiologist. In order to correctly mark the lesion, most commonly used is ultrasound, less often mammography, MRI, or CT (but it should always be a method in which the tumor is well visible – radiological control of the excised sample with the anchor is still valid) (Fig. 1.). The patient is then transferred to the surgical unit where the surgeon cuts out the marked area. It is mandatory to mark the boundaries of the specimen in a way that allows spatial location (usually with threads or clips) [4]. The margins of the tumor bed are also marked with clips to precisely plan radiation therapy with an increased dose to the area of the bed.

However, the use of the needle method to locate non-palpable lesions has some disadvantages. The need for precise needle insertion required an effective organization of work in the hospital and additional personnel (the surgeon adapts to the radiologist who introduces the needle) [5–7]. For technical reasons (the best ultrasound image is produced at a wave reflection angle close to 90 degrees), the wire is introduced at a certain distance from the lesion. This results in the need to cut out additional tissues around the inserted anchor. The needle method makes it difficult to use oncoplastic techniques (the needle insertion site does not correspond to the planned skin cuts) and can damage the aesthetic effect. The wire protrudes from the patient's skin, so it can move, which is an important problem, especially when for logistical reasons the patient waits long for the operation. In the studies, the presence of positive margins for this method was found ranging from 20% to even 70% [8]. An additional negative aspect is the patient's discomfort and pain. Despite those disadvantages, the location of the needle in many institutions remains the standard technique, due to its low cost and easy availability.

The natural way of searching for new location methods was to use a radioisotope, which was a consequence of numerous experiments on sentinel node biopsy, where the radiopharmaceutical method is routinely used. Before surgery, the radiologist places the radioactive marker at the site of the suspected breast lesion together with the radioisotope for the sentinel node mapping. There are two varieties of this method with either solid markers (RSL) or a suspension of radiocolloid (ROLL) (Fig. 2.). In the first method, the lesion is marked using the titanium markers with radioactive iodine isotope I-125 placed under the visual guidance as well, most often with ultrasound. In ROLL, the colloid of Tc-99m-labeled albumin is administered (Fig. 3.). Then, during the operation, the breast area showing the highest radioactivity on gamma camera is excised. The correct location is confirmed by the lack of radiation from the remaining breast tissues.

Those methods overcome many disadvantages of marking the lesion with an anchor, primarily by reducing the risk of accidental wire displacement. Tc -99m as well as I-125 can be introduced into the tumor earlier than on the day of surgery. Radioisotope techniques have been proven to cause less pain and greater total comfort to the patient [9]. However, the use of those markers requires a strict regime related to protection against ionizing radiation, which is a major restriction in the use of those methods in hospitals. RSL has an advantage over ROLL because the marker is visible on mammography or ultrasound (visible metal clip in addition to the

Fig. 4. Magseed magnetic marker.

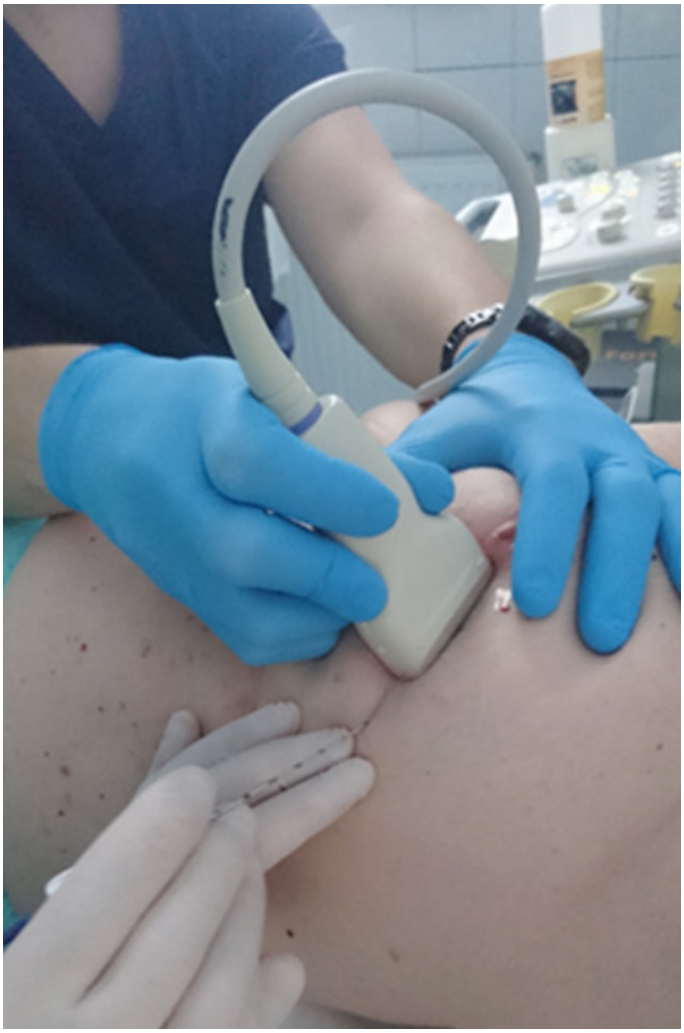

Fig. 5. Placing the Magseed marker under ultrasound guidance.

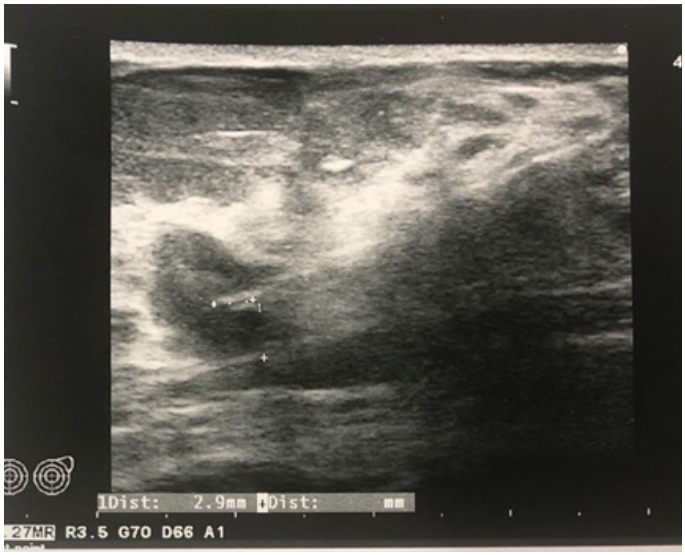

Fig. 6. Ultrasound image during Magseed marker implantation.

Fig. 7. Sentimag probe.

gamma camera), and it is easier to plan surgery because of the longer I-125 half-life (60 days) compared to the TC-99m radioisotope, which requires the administration to the tumor up to 24 hours before surgery [3]. However, this is also a disadvantage because the marker must be retrieved from the postoperative specimen, and then properly disposed of. In the studies, the rate of tumor-free margins after tumor excision ranges from 73% to 92.8% for RSL compared to 54% to 87% for WL and 89.1% for ROLL [4, 10–12]. Langhans et al., in their study analyzed 390 cases of RSL and WL patients, and noted a significantly higher number of positive margins when DCIS is present outside the area of invasive cancer [4]. Angarita et al. in a large study (747 patients undergoing WL and 577 RSL) showed that in the case of radioactive methods, the volume of the excised tissues is smaller while maintaining the oncologic radicality [2]. In the group of patients operated on by Horwood et al., the duration of treatment was significantly longer for the RSL method (104 minutes *vs*. 82 minutes) [13]. The authors explained this difference by the learning curve. According to Tran et al., with a comparable low rate of positive margins (3% RSL and 2.8% WL respectively), RSL significantly facilitates the use of oncoplastic techniques [14].

Two new technologies have now been introduced that do not use radioisotope to mark non-palpable breast lesions [15]. SCOUT SAVI (Cianna Medical, Viejo Aliso, California) uses a special marker, which serves as a reflector of infrared waves. The reflected wave is recorded by the receiver. The reflector is 12 mm in size and it is placed under the skin under visual guidance (ultrasound or mammography) up to seven days before surgery. Mango et al. in their pilot study on a group of 13 patients achieved a 100% rate for free-margin resection [16]. The re-operations' rate since the initial publication of the SCOUT SAVI technique (SSR) ranges from 0% to 18.5%. The disadvantage of this technique is the limited depth of marker placement to 45 mm due to the penetration of the

infrared waves – there is a risk of non-detection of the reflector after insertion (2.0–2.5%) [16, 17].

Magseed (Endomag, Austin, TX) is a 1 × 5 mm magnetic metallic marker (Fig. 4.) that is placed using a 18G sterile needle under mammography or ultrasound guidance up to 30 days before surgery (according to the product registration information). The procedure is performed under local anesthesia (Fig. 5.). Immediately after the marker is placed, the correct placement can be confirmed on imaging studies (it is echogenic on ultrasound and, at the same time, clearly visible on mammography) (Fig. 6.). The marker is detectable with the Sentimag probe (Fig. 7.) in the same way as with the Magtrace magnetic indicator in the sentinel node biopsy. It can be located from any direction, regardless of the orientation of the marker. The Sentimag probe produces a variable magnetic field that temporarily magnetizes the iron oxide particles inside Magseed. The probe displays a numerical value and produces an acoustic signal that is associated with the magnetic field strength and depends on the distance of the marker in the tumor from the detector probe. Therefore, more than one lesion can be marked at the same time, provided that the markers are scattered more than 10–20 mm from each other. The marker is cylindrical, smooth, has no moving parts, and cannot be damaged during implantation. The main advantage of Magseed and SCOUT SAVI is the lack of radioactivity, so they do not require compliance with restrictions specified in the nuclear law, and it is safer for the patient and the environment. Some authors even suggest that the use of a magnetic marker may be the preferred location technique in centers without a nuclear medicine unit [18]. In the animal model, no differences were found in the accuracy and duration of the procedure compared to methods using the gamma camera [19]. Srour et al. compared 293 patients in the study group and did not find any differences between WL, RSL, and SSR with respect to the rate of positive margins, specimen volume, or complications over a period of 30 days [20].

Since the FDA (Food and Drug Administration) approved the Magseed marker in 2016, there have been reports from many centers around the world about its use. In the published papers, the authors emphasize the oncologic efficacy comparable with other techniques and relatively simple implementation of this technique in new centers [21]. The effectiveness of finding the marker during surgery reaches 100% [22, 23]. In his article, Zacharioudakis compared the Magseed technique with the needle location and pointed out the reduced volume and mass of the specimen when using the magnetic location method, but the difference was not statistically significant [24]. In our own experience of using the Magseed marker (between July 2019 and February 2020 on 23 patients), we showed high compatibility of the intraoperative ultrasound image and location using the Sentimag probe. We did not find any cases of marker displacement earlier reported in individual cases published by other authors [22]. Magseed was placed in our facility on the day before or on the day of the surgery. In the study by Žatecký et al., the average period from marker placement to treatment was 9.5 days [22]. Similarly, McCamley reported an interval of a couple of days from the implementation of the marker (median 7 days), although in individual cases this period was significantly longer [18]. Fung et al. reported implantation from 6 to 56 days prior to surgery with no marker migration in 9 cases [25]. The longest interval described in the literature is 183 days, which significantly exceeds the time suggested in the product characteristics (30 days) [18]. According to the surgeons performing this procedure, it is easy to learn his method and very precisely locate the marked lesion. Similar conclusions on the short learning curve for this new technique were also presented by other authors [22, 23]. Singh reported that almost all markers were placed by the radiologist the first time; also the use of the Sentimag probe by the surgeon did not significantly affect the duration of the operation during the learning curve [23]. The signal from the probe is no longer received at a distance of 1–2 cm from the position of the marker. It also confirms the presence of a magnetic signal source in the material taken for pathology study. The published papers highlight the precision in lesion location using Magseed – Singh placed 100% of the markers at a distance of less than 1 cm from the lesion, and McCamley reported that 90% of the time it was no more than 5 mm [18, 23]. During the surgery in our patients, we had no difficulty with transcutaneous location of Magseed in the breast – the Sentimag probe received a signal 100% of the time before making the skin incision even in lesions located near the fascia of the pectoralis muscle. The depth of the marker position specified by the manufacturer is 30 mm. However, Hayes in his article defines it as 4 cm, and Žetecky et al. reported the maximum depth of insertion of the marker to be 50 mm [22, 26]. It is a little more challenging to properly interpret the signal when the tumor is located in the upper outer quadrant of the breast and the magnetic method is used simultaneously to map the sentinel node. Such a situation requires an appropriate modification, i.e. administration of a liquid marker to identify sentinel lymph nodes in another place at an appropriate distance from the tumor. As a potential hindrance, the authors from the Czech Republic report the need for frequent recalibration of the Sentimag probe [22]. However, in our experience, this did not significantly affect the course of the operation – the signal of the metal marker is much stronger than the liquid paramagnetic suspension used for mapping of SLNB (sentinel lymph node biopsy).

A completely new method is to use a chip emitting radiofrequency signals detected by a special probe for the pre-operative mapping. By 2019, the data were published on 121 cases of application of this method worldwide [27]. The patented method uses LOCalizer™ chip by the American company Faxitron (Hologic, Inc., Marlborough, MA, USA). The implantation method is similar to the previously described methods, i.e. the marker is introduced into the lesion under imaging guidance, either ultrasound or mammography. The difference is the size of the wave emitter; the chip is 2 mm × 10.6 mm, which is about twice as large as the clips used in other methods. This means a slightly greater discomfort for the patient and is more difficult if the breast is mainly fibroglandular and dense (type 3 and 4 by the American College of Radiologists (ACR)). For this reason, it is not suitable for marking small lesions (less than 5 mm in size). However, it works well in large calcifications as in DCIS. It could also be helpful in planning surgical incisions during mastectomy with one-step reconstruction in patients with non-palpable masses. The advantage is also easy visualization of the chip in the specimen, because it is visible even without special imaging techniques [28–31].

CONCLUSIONS

The method of location of non-palpable lesions in the mammary gland using the magnetic Magseed marker is simple to apply, and its high detection rate directly translates into a limited rate of non-radical resection in the case of breast-conserving surgery. Its additional advantage is the use of equipment that is used routinely for sentinel node biopsy.

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