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CLINICAL STUDY

Radar reflector guidance system in breast surgery: A single-institution feasibility study

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ABSTRACT
Mammography breast cancer screening programs and continuing improvements in early diagnosis of the disease have led to more frequent detection of nonpalpable breast lesions. The commonly used technique in guiding the surgical removal of these lesions is hook wire-guided localization (WGL). However, the WGL procedure has been criticized for the last years. Key disadvantages of WGL are possible wire transection, wire migration before or during surgery, patient discomfort and pneumothorax. Over the last decade, alternatives to wire localization have emerged. In this study the authors present their initial experience with a wireless, nonradioactive, wave reflection implant system that enables surgeons to safely and accurately remove breast lesions *(Tab. 2, Fig. 4, Ref. 20)*. Text in PDF *www.elis.sk*
KEY WORDS: breast cancer, breast surgery, nonpalpable lesions, preoperative localization.

Introduction

Widespread use of screening mammography results in the detection of increasing numbers of non- palpable breast lesions. Such lesions represented over one-half of the detected cancers in recent screening projects. The extensive availability of mammography-breast cancer screening programs and continuing improvements in this area have led to more frequent detection of clinically occult breast lesions. The commonly used technique in guiding the surgical removal of these occult breast lesions is wire-guided localization (WGL). Hook wires with self-retaining tip are placed into the occult lesion under ultrasound, X-ray mammographic stereotaxy, or magnetic resonance guidance.

However, the WGL procedure has been criticized for the last years (1, 2). Key disadvantages of WGL are possible wire transection, wire migration before or during surgery, patient discomfort and pneumothorax. Another significant disadvantage of WGL is that the guide-wire does not provide a clear 3D perspective on the tumour (3). Over the last decade, alternatives to wire localization have emerged.

Garzotto et al (1) in their recently published systematic review and meta-analysis of clinical outcomes of innovative methods concluded that preoperative localization of nonpalpable breast lesions with non-wired techniques may improve clinical outcomes as re-operation rate, cosmetic outcome and contribute to organizational aspects improvement in breast conserving surgery. The SCOUT surgical guidance system (*Merit Medical Systems, Inc., South Jordan, Utah, USA*) is a wireless, nonradioactive, wave reflection implant system that enables surgeons to safely and accurately remove breast lesions (Fig. 1). It employs micro-impulse radar and infrared light technology to determine the location of the reflector, which is placed into the soft tissue during a prior procedure. Reflector remains in place passive until activated by the SCOUT handpiece. The console provides the micro-impulse radar signal to the handpiece along with power for the infrared light sources. The handpiece delivers the micro-impulse radar signal and infrared light into the soft tissue and in turn receives signals reflected back from the reflector. The SCOUT console processes the reflected radar signals to provide the surgeon with reflector proximity and location information via audible and visual feedback. The numeric display provides real-time distance (in mm) between the handpiece

Fig. 1. The SCOUT surgical guidance system (Merit Medical Systems, Inc., South Jordan, Utah, USA).

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Fig. 2. The SCOUT radar reflector (Merit Medical Systems, Inc., South Jordan, Utah, USA).

and reflector. The audible feedback produced by the console increases in cadence as handpiece is placed in closer proximity to the reflector. The console provides a maximum detection range of 60 mm from the handpiece to the reflector. Excision of the lesion is then performed using standard surgical technique. The SCOUT reflector (Fig. 2) is intended to be placed percutaneously in soft tissue (> 30 days) to mark a biopsy site or a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or mammography).

Materials and methods

Study design

Twenty patients were enrolled in this prospective, single-institutional, cohort study between November 2022 and April 2023 at the Breast Unit of the 2nd Department of Gynaecology and Obstetrics, Comenius University, Bratislava, Slovakia. Written informed consent was obtained from all patients. Enrolled were patients with non-palpable breast lesions eligible for surgery. Sixteen patients had a core biopsy-proven early breast invasive carcinoma (cT1-2 N0). The remaining subgroup of patients had a preoperative biopsy proven B3 lesions intended for surgical excision.

Localization procedures

Twenty-three SCOUT reflectors (Merit Medical Systems, Inc., South Jordan, Utah, USA) in twenty patients were inserted through 16-gauge needle deployment system under local anaesthesia into the centre of the target lesions under ultrasound guidance on the day prior to surgery. Ipsilateral two-view mammography (mediolateral and craniocaudal views) was performed immediately after each localization procedure to confirm the position of the reflector (Fig. 3). One patient had bilateral reflector placement, and two patients had two reflectors placed in the same breast.

Surgical procedures

Lymphatic mapping and sentinel lymph nodes detection through magnetic method (we described it elsewhere) were the initial surgical procedures. All SLNs were examined during an intraoperative frozen section consultation. In patients with metastases into > 2 SLNs, an axillary level 1+2 lymphadenectomy was performed. Prior to making the initial breast incision, the reflected radar signals were measured to find the position of the reflector. The skin incision and further breast tissue preparation were done under repeated

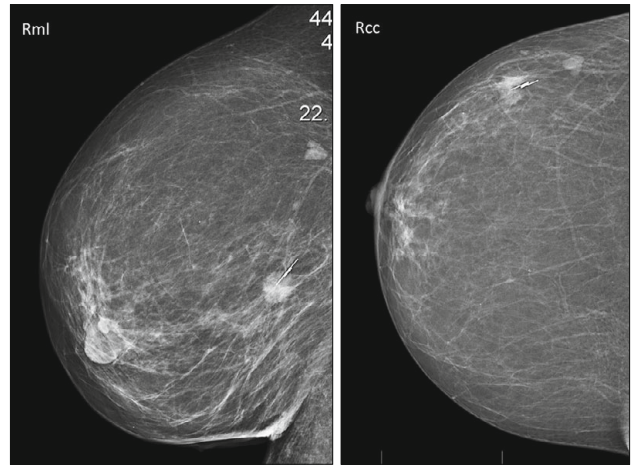

Fig. 3. Ipsilateral two-view mammography (mediolateral and craniocaudal views) was performed immediately after each localization procedure to confirm the position of the reflector.

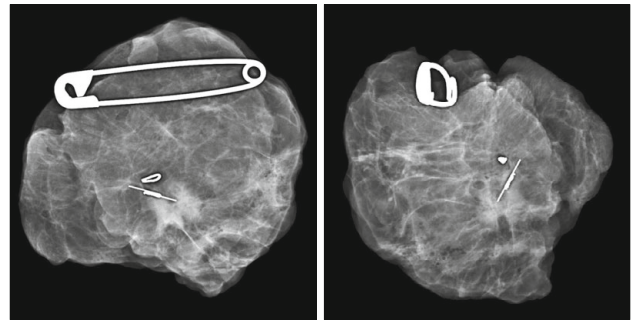

Fig. 4. Intraoperative two-view specimen radiography (mediolateral and craniocaudal view) provided confirmation of complete tumour resection and reflector presence in the specimen.

SCOUT handpiece monitoring. The lesions, together with healthy margins of breast tissue, were excised in an effort to get tumour-free surgical margins. After resection of the tumour, the reflector was confirmed to be present in the excised tissue using the SCOUT handpiece. Simple tools were used for specimen labelling. Two-view specimen radiography (mediolateral and craniocaudal view) provided confirmation of complete tumour resection and reflector presence in the specimen (Fig. 4). Breast-saving therapy or radical mastectomy were applied according to established criteria (4).

Pathology

All SLNs were examined intraoperatively by frozen section. SLNs with clearly presented metastases were determined as positive. All lymph nodes were than postoperatively evaluated in formalin-fixed embedded serial sections using hematoxylin/eosin staining and immunohistochemistry with cytokeratin AE1/AE3 stains. The surgical specimens were coated with ink and fixed in 10 % neutral-buffered formalin for 24 h. The fixed specimens were examined through serial sectioning. The sections were then stained with hematoxylin/eosin. Immunohistochemistry was used for evaluation of estrogen, progesteron and HER2 receptors, Ki67 proliferation index and myoepithelial cells integrity assessment.

Tab. 1. Tumour characteristics according to the American Joint Committee on Cancer (AJCC) Staging Manual, 8th Edition, 2016.

Patient	Tumour typing	pTNM stage	Grade	Molecular subtype	Prognostic stage (AJCC)
1	IDC-NST	pT1c N0 M0	2	luminal A	IA
2	IDC-NST	pT1b N0 M0	2	luminal A	IA
3	IDC-NST	pT2 N1a M0	2	HER2-enriched	IIB
4	ILC	pT2 N0 M0	2	luminal A	IIA
5	IDC-NST	pT1b N0 M0	2	luminal A	IA
6	IDC-NST	pT1c(m) N0 M0	3	luminal B	IA
7	IDC-NST	pT1b N0 M0	2	luminal B	IA
8	2x IDC-NST	pT2(m) N1a M0	2	luminal B	IIIA
9	lymph node	pT2 N1a M0	2	HER2-enriched	IIB
10	IDC-NST	pT1c N0 M0	3	luminal A	IA
11	IDC-NST	pT1b N0 M0	2	HER2-enriched	IA
12	2x IDC-NST post NAC	ypT0 N0 M+ (pCR)	3	HER2-enriched	IV
13	ILC	pT1c(m) N0 M0	2	luminal A	IA
14	IDC-NST	pT1b N0 M0	2	luminal A	IA
15	IDC-NST	pT2(m) N1a M0	2	luminal A	IIB
16	IDC-NST	pT2(m) N0 M0	3	HER2-enriched	IIB
17	phyllodes tumour	N/A	N/A	N/A	N/A
18	radial scar	N/A	N/A	N/A	N/A
19	2 fibroepit. lesions	N/A	N/A	N/A	N/A
20	ADH	N/A	N/A	N/A	N/A

IDC-NST = invasive ductal carcinoma of no special type, ILC = invasive lobular carcinoma, ADH = atypical ductal hyperplasia, NAC = neoadjuvant chemotherapy, HER2 = human epidermal growth factor receptor 2, N/A = not applicable

The intensity score for HER2 was defined in scale of 0 to 3 (for absent, weak, moderate or strong staining, respectively). In cases with HER2 score 2+ (equivocal), an additional evaluation through silver DNA *in situ* hybridization (SISH) was used for ultimate positive or negative results. According to histopathology results, the tumours were categorized as to intrinsic subtypes and pathologic prognostic stage groups. Histological grade of tumours was evaluated by the Elston-Bloom and Richardson systems (5). Specimens with no ink on tumour were evaluated as specimens with negative surgical margins, according to the current guidelines (6).

Results

The mean age of our group of patients was 58.1 years (range 41–72 years). Tumour characteristics of all surgically treated breast lesions are shown in Table 1. Infiltrating ductal carcinoma of no special type (IDC-NST) was the most common tumour; in two patients it was infiltrating lobular carcinoma. From the point of view of molecular subtypes, the carcinomas were classified in eight cases as luminal A, in three cases as luminal B and five patients had HER2-enriched breast carcinomas. In one patient (No. 12) two ipsilateral residual lesions were localized after six cycles of neoadjuvant chemotherapy. Pathologic complete remission (pCR) in the breast was confirmed in the surgical specimen. Four patients had benign breast lesions: one phyllodes tumour, one atypical ductal hyperplasia, one radial scar, and one patient had two fibroepithelial lesions in the same breast. Breast-saving therapy was performed in most patients, only two of them being submitted to radical mastectomy because of multicentric lesions (Tab. 2). The most often used surgical procedure was lumpectomy with sentinel lymph nodes biopsy. Axillary dissection was done in two patients because of ≥ 3 positive sentinel nodes. All tumours were removed with safe surgical margins through the first operation and no additional re-excision of margins was needed. Only one patient underwent a secondary mastectomy four months after primary surgery because of early recurrence of a high-grade HER2-enriched tumour.

Tab. 2. Types of surgical procedures.

Surgical procedure	No of patients
lumpectomy	12
quadrantectomy	6
radical mastectomy	2
sentinel lymph nodes biopsy	14
axillary dissection	2

Discussion

In 2018 and 2019, we reported about our initial experience with the wire-free localization of breast lesion through magnetic seeds (Magseed) in combination with lymphatic mapping and SLNs detection with superparamagnetic iron oxide nanoparticles (Magtrace), both detected with a magnetic handheld probe (Sentimag) (7, 8). This study reports about first Slovak experience with the SCOUT radar reflector guidance system in breast surgery.

The first feasibility studies with SCOUT technology were published in 2016 by Cox et al (9, 10) and by Mango et al (11). Both pilot studies demonstrated the system to be a safe and effective tool for tumour localization. In 2020, Srour et al (12) published the results from a comparison of three types of localization devices used in breast conserving surgery: wires (126 patients), radioactive seeds (59 patients), and SCOUT system (108 patients). They concluded that non-wire localization devices are associated with reduced overall perioperative time compared to wire localization and with few complications. In the same time, Tingen et al (13) referred the single-institution retrospective review of 512 patients that had their breast localized trough SCOUT system (320 patients) or hook-wires b (175 patients). In their series, the SCOUT system resulted in a lower rate of positive margins, reoperations, and surgical site occurrence. These data suggest that SCOUT localization is a reasonable replacement to wire localization for breast lesions and might produce superior results. Baker et al (14) prospectively evaluated in their pilot study the feasibility of localizing the metastatic lymph nodes with a SCOUT reflector prior to neoadjuvant

chemotherapy for targeted removal at surgery. In the preliminary results of the trial (NCT03411070) they referred that SCOUT reflector is feasible for targeted axillary dissection after neoadjuvant therapy (14). Their results have been confirmed by Weinfurtner et al (15) and Sun et al (16). SCOUT receives CE Mark approval in 2020 and the first reported European evaluation of the system was referred in the same year by Tayeh et al (17) and by Kasel et al (18), both from the London Breast Institute. There was a concern about possible artifacts in the breast MRI examination of patients in whom the SCOUT reflector was inserted. The official information from the manufacturer is that SCOUT reflector is MRI conditional. A patient with this device can be scanned safely under static magnetic field of 1.5 and 3 Tesla, only. Recently, Wazir et al (19) mentioned in their study that in six patients who had breast MRI after the deployment of the reflector, the MRI void signal was < 5 mm.

In February 2023, Banys-Paluchowski et al (20) discussed all available localization techniques and presented the MELODY study (NCT05559411), a multinational prospective intergroup cohort study which enrols breast cancer patients undergoing breast-conserving surgery using imaging-guided localization. The aim of the study is to investigate their safety, with a focus on patient, surgeon, and radiologist preference.

Conclusions

In 2022, SCOUT was approved by the Slovak State Institute for Drug Control. Our study is the first experience about SCOUT radar reflector guidance system in breast surgery in Slovak republic. From our initial experience we can confirm that SCOUT technology can increase the success rate of safe tumour excision with tumour-free margins as well as improve patients and surgeons' comfort.

References

1. Garzotto F, Comoretto RI, Michieletto S, Franzoso G, Lo Mele M, Gregori D, Bonavina MG et al. Preoperative non-palpable breast lesion localization, innovative techniques and clinical outcomes in surgical practice: A systematic review and meta-analysis. Breast 2021; 58: 93–105. DOI: 10.1016/j.breast.2021.04.007.

2. Cheang E, Ha R, Thornton CM, Mango VL. Innovations in image-guided preoperative breast lesion localization. Br J Radiol 2018; 91 (1085): 20170740. DOI: 10.1259/bjr.20170740.

3. Kapoor MM, Patel MM, Scoggins ME. The wire and beyond: Recent advances in breast imaging preoperative needle localization. Radiographics 2019; 39 (7): 1886–1906. DOI: 10.1148/rg.2019190041.

4. National Comprehensive Cancer Network® (NCCN) guidelines on breast cancer. Version 4.2023. https: //www.nccn.org/professionals/physician_gls/pdf/breast.pdf.

5. Christgen M, Länger F, Kreipe H. Histologisches Grading beim Mammakarzinom [Histological grading of breast cancer]. Pathologe 2016; 37 (4): 328–336. German. DOI: 10.1007/s00292-016-0182-8.

6. Brouwer de Koning SG, Vrancken Peeters MTFD, Jóźwiak K, Bhairosing PA, Ruers TJM. Tumor resection margin definitions in breast-conserving surgery: Systematic review and meta-analysis of the current literature. Clin Breast Cancer 2018; 18 (4): e595–e600. DOI: 10.1016/j.clbc.2018.04.004.

7. Pohlodek K, Sečanský P, Haluzová I, Mečiarová I. Localization of impalpable breast lesions and detection of sentinel lymph nodes through magnetic methods. Eur J Radiol 2019; 120: 108699. DOI: 10.1016/j.ejrad.2019.108699.

8. Pohlodek K, Foltín M, Mečiarová I, Ondriaš F. Simultaneous use of magnetic method in localization of impalpable breast cancer and sentinel lymph nodes detection: Initial experience. Nanomedicine (Lond) 2018; 13 (24): 3075–3081. DOI: 10.2217/nnm-2018-0220.

9. Cox CE, Garcia-Henriquez N, Glancy MJ, Whitworth P, Cox JM, Themar-Geck M, Prati R et al. Pilot study of a new nonradioactive surgical guidance technology for locating nonpalpable breast lesions. Ann Surg Oncol 2016; 23 (6): 1824–1830. DOI: 10.1245/s10434-015-5079-x.

10. Cox CE, Russell S, Prowler V, Carter E, Beard A, Mehindru A, Blumencranz P et al. A prospective, single arm, multi-site, clinical evaluation of a nonradioactive surgical guidance technology for the location of nonpalpable breast lesions during excision. Ann Surg Oncol 2016; 23 (10): 3168–3174. DOI: 10.1245/s10434-016-5405-y.

11. Mango V, Ha R, Gomberawalla A, Wynn R, Feldman S. Evaluation of the SAVI SCOUT surgical guidance system for localization and excision of nonpalpable breast lesions: A feasibility study. AJR Am J Roentgenol 2016; 207 (4): W69–W72. DOI: 10.2214/AJR.15.15962.

12. Srour MK, Kim S, Amersi F, Giuliano AE, Chung A. Comparison of wire localization, radioactive seed, and Savi scout® radar for management of surgical breast disease. Breast J 2020; 26 (3): 406–413. DOI: 10.1111/tbj.13499.

13. Tingen JS, McKinley BP, Rinkliff JM, Cornett WR, Lucas C. Savi Scout radar localization versus wire localization for breast biopsy regarding positive margin, complication, and reoperation rates. Am Surg 2020; 86 (8): 1029–1031. DOI: 10.1177/0003134820939903.

14. Baker JL, Haji F, Kusske AM, Fischer CP, Hoyt AC, Thompson CK, Lee MK et al. SAVI SCOUT® localization of metastatic axillary lymph node prior to neoadjuvant chemotherapy for targeted axillary dissection: a pilot study. Breast Cancer Res Treat 2022; 191 (1): 107–114. DOI: 10.1007/s10549-021-06416-z.

15. Weinfurtner RJ, Leon A, Calvert A, Lee MC. Ultrasound-guided radar reflector localization of axillary lymph nodes facilitates targeted axillary dissection. Clin Imaging 2022; 90: 19–25. DOI: 10.1016/j.clinimag.2022.07.007.

16. Sun J, Henry DA, Carr MJ, Yazdankhahkenary A, Laronga C, Lee MC, Hoover SJ et al. Feasibility of axillary lymph node localization and excision using radar reflector localization. Clin Breast Cancer 2021; 21 (3): e189–e193. DOI: 10.1016/j.clbc.2020.08.001.

17. Tayeh S, Muktar S, Heeney J, Michell MJ, Perry N, Suaris T, Evans D et al. Reflector-guided localization of non-palpable breast lesions: The first reported European evaluation of the SAVI SCOUT® system. Anticancer Res 2020; 40 (7): 3915–3924. DOI: 10.21873/anticanres.14382.

18. Kasem I, Mokbel K. Savi Scout® radar localisation of non-palpable breast lesions: Systematic review and pooled analysis of 842 Cases. Anticancer Res 2020; 40 (7): 3633–3643. DOI: 10.21873/anticanres.14352.

19. Wazir U, Kasem I, Michell MJ, Suaris T, Evans D, Malhotra A, Mokbel K. Reflector-guided localisation of non-palpable breast lesions: A prospective evaluation of the SAVI SCOUT® system. Cancers (Basel) 2021; 13 (10): 2409. DOI: 10.3390/cancers13102409.

20. Banys-Paluchowski M, Kühn T, Masannat Y, Rubio I, de Boniface J, Ditsch N, Karadeniz Cakmak G et al. Localization techniques for non-palpable breast lesions: Current status, knowledge gaps, and rationale for the MELODY study (EUBREAST-4/iBRA-NET, NCT 05559411). Cancers (Basel) 2023; 15 (4): 1173. DOI: 10.3390/cancers15041173.

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