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A prospective, single-arm, multicentre clinical evaluation of a new localisation technique using non-radioactive Magseeds for surgery of clinically occult breast lesions☆

D. Thekkinkattil [a,*], M. Kaushik [b], M.M. Hoosein [b], M. Al-Attar [b], S. Pilgrim [b], A. Gvaramadze [a], L. Hyklova [a], A. Jibril [a]

[a] Department of Oncoplastic Breast Surgery, Lincoln County Hospital, United Lincolnshire Hospitals NHS Trust, UK
[b] Department of Oncoplastic Breast Surgery, University Hospitals of Leicester NHS Trust, UK

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AIM: To evaluate the safety, usefulness, and outcome of Magseed localisation for surgery of non-palpable breast lesions in a non-experimental setting.

MATERIALS AND METHODS: An audit was undertaken of a prospectively maintained database of patients who had undergone breast surgery under Magseed guidance in two high-volume institutions in the UK. Patients were selected for Magseed localisation depending on service convenience. Wire localisations were used in other patients in accordance with previous normal practice. One hundred and thirty-nine Magseed localisaton procedures were performed between September 2017 and March 2019. Data were collected on age, body mass index, size, bra cup size, weight of specimen, surgery, histology, re-excision rate, and time and mode of insertion of seeds.

RESULTS: A total of 137 patients had Magseed localisation with a total of 139 seeds. Sixteen patients had a diagnostic procedure and 121 had therapeutic surgery. The distribution of procedures were similar between the two institutes (n=63 and n=74). Mean age was 60 (range 28–81) years. The majority of seeds were placed under ultrasound guidance (n=112) and 25 lesions were targeted under stereo guidance. Mean size of the lesions was 15.2 (range 1–85) mm. The mean weight of the specimen was 75.5 (range 2–1,900) g. The mean body mass index was 30.56 (range 18.1–48.3). All Magseeds and index lesions were retrieved. The re-excision rate for patients who underwent therapeutic surgery was 14.8% (n=18).

CONCLUSION: The Magseed localisation technique of non-palpable breast lesions is a safe, easy procedure, and comes with the advantage of better utilisation of theatre and radiology resources. The re-excision rate in this series is lower than the national average.

Introduction

Breast cancer is the most common cancer in women all over the world.[1] Many countries have a national population-based screening programme.[2–5] This has

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* Guarantor and correspondent: D. Thekkinkattil, Department of Oncoplastic Breast Surgery, Lincoln Breast Unit, Lincoln County Hospital, Greetwell Road, Lincoln, Lincolnshire LN2 5QY, UK. Tel.: +441522597583.
E-mail address: drdiku@gmail.com (D. Thekkinkattil).

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helped to reduce mortality by 25–31%.[2,6] Since its inception, the National Health Service Breast Screening Programme continues to improve its quality of performance in the UK and now diagnoses about 50% of new cancers. More than 50% of screen-detected invasive cancers are <15 mm. As a consequence, there is increased need for surgery on non-palpable cancers that require preoperative localisation. Breast-conservation surgery is gaining wider acceptance as there is evidence to confirm that there is no survival advantage for mastectomy.[7,8] Preoperative localisation is mainly achieved by placing a wire into the lesion under image guidance. Some of the disadvantages include wire displacement, retained fragments, and extra procedures on the day of surgery leading to increased patient anxiety and stress.[9] The need for placement of wire prior to surgery limits the flexibility and can lead to less efficient utilisation of theatre resources. Migration can lead to missing the lesion or resection of excess tissue.[10] Another limitation is the site of insertion, which is mainly determined by ease of access by the radiologist and optimal visualisation by targeting imaging and not based on the ease of access or by cosmetic considerations by surgeons. The surgeon also faces the challenge of planning the surgical approach from mental reconstructions in the non-compressed breast based on information from mammographic images obtained by compressing the breast tissue.[11] These factors can contribute to difficulty or failure to locate the lesion. Hence there has been much effort to improve localisation procedures such as radio-guided occult lesion localisation (ROLL), SAVI SCOUT radar localisation, and iodine seed localisation.[12–16] Iodine seed localisation has been shown to reduce re-excision rates[14] and with better patient satisfaction; however, the logistical and regulatory challenge of managing radioactive seeds has been the main barrier in gaining wider acceptance and popularity. The use of the non-radioactive Magseed system (Endomagnetics, Austin, TX, USA) secured US Food and Drug Administration in 2016 for localisation surgery, and early experience has been promising in addressing many of the drawbacks of existing localisation techniques.[17–19] At the time of the present study, Magseeds were approved (CE marked) for placement up to 30 days prior to surgery.

The aim of the present study was to evaluate the clinical safety and utility of this new localisation system in a non-experimental real-world hospital practice in the UK.

Materials and methods

A review of prospectively maintained database of all patients who underwent Magseed localisation at two institutions in the UK (both institutions treat in excess of 650 new breast cancers per annum each) was carried out. Magseeds were placed under both ultrasound and mammographic guidance. Data were collected on patient demographics such as age, body mass index (BMI), bra cup size, weight of resection specimen, type of surgery, mode of insertion, time of insertion, histology, re-excision rate, and details any perioperative complications.

All surgeons (n=12) had varying amounts of experience in performing surgery for clinically occult breast lesions, but all met the UK screening guidance of minimum cases annually.

Approval from the Clinical Audit and Governance Departments was secured from both institutions for this study. Both institutions approved the adoption of Magseed localisation to routine clinical practice for surgery for non-palpable breast lesions.

Patient selection

Patients (mean age 60 years; range 28–81 years) were allocated for Magseed localisation depending on service convenience, such as those patients whose surgery was scheduled as first on the operation list or those who were having their surgery in the peripheral hospital without radiology support on the day of surgery for wire insertion. Wire localisations were used in other patients in accordance with previous normal practice. The reason for limiting Magseed localisation to these patients was due to the significant benefit of the new localisation technique in this subset of patients.

Technique

The Magseeds are stainless steel pellets measuring 5×1 mm in size. They do not possess any inherent magnetic activity; however, they can be induced to become magnetic under the influence of a detector (Sentimag probe, Endomagnetics). The seeds were introduced with a 18 G preloaded with 7 or 12 cm needles under local anaesthesia. All the seeds were introduced done prior to surgery under either ultrasound or mammographic guidance and check mammograms were performed afterwards. No additional check ultrasound or mammograms were performed to assess the position of the seeds on the day of surgery. Some patients also had the lesion surface marked on the skin, depending upon the preference of the surgeon. The Magseeds were inserted only after discussion and confirmation of surgical procedure with the patient and none were inserted at the time of initial biopsy. During surgery, the Magseeds were localised with the help of the Sentimag probe and specimen radiographs were undertaken to confirm adequate excision of the lesion with Magseeds (Fig 1). Further cavity shaves were taken if indicated after specimen radiography.

Results

A total of 137 patients (63 patients from one institute and 74 from the second) underwent Magseed-localised surgery during the period September 2017 to March 2019 in two centres in the UK and both centres treat >650 new cancers per annum. Two patients had two Magseeds: in one patient there were two foci of cancer and the second patient had neoadjuvant chemotherapy for T3 cancer and the seeds were used to bracket the marking coils. Four patients had two adjacent lesions marked by one Magseed in the middle

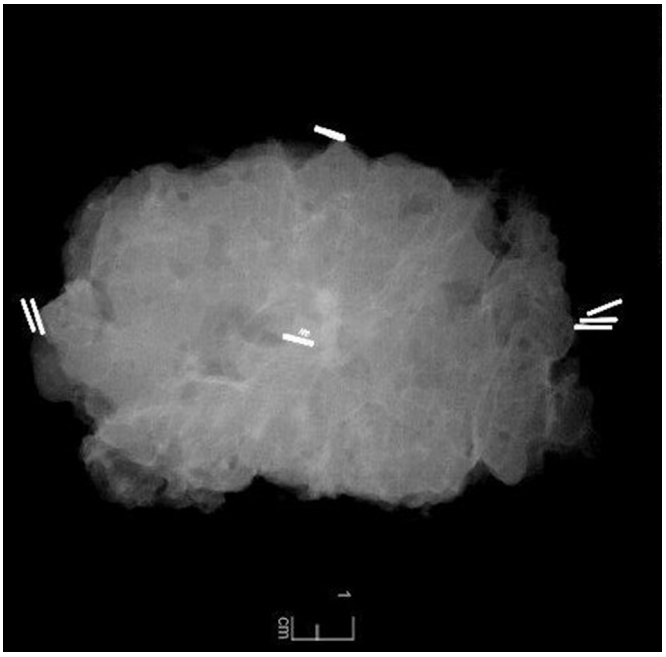

Figure 1 Specimen radiograph showing the Magseed and marker clip in the centre.

of the two lesions. Altogether 139 Magseed localisations were performed in 137 patients.

The majority of Magseeds were placed under ultrasound guidance (n=112) and 25 lesions were targeted under stereo mammographic guidance. Sixteen patients underwent the localisation procedure to facilitate a diagnostic biopsy. The rest of the patients underwent breast-conservation surgery, which included wide local excisions and therapeutic mammoplasties. The majority of Magseeds were placed prior to the day of surgery (mean 7 days, range 0–30 days). There was no migration of seeds and all seeds were retrieved with index lesions.

Mean size of the index lesions was 15.2 mm with a range 1–85 mm. The mean weight of the excision specimen ranged from 2–1,900 g with a mean of 75.5 g. The mean BMI of these patients was 30.56 (range 18.1–48.3). Of 137 patients, information on bra cup size was reported by 100 patients. The distribution of bra size is detailed in Table 1.

Table 1
Distribution of bra cup size.

Bra cup size	No. of patients (n=100)
A	8
B	20
C	27
D	23
DD	9
E	5
F	1
FF	1
G	2
GG	3

In the present series where surgery was carried out with therapeutic intent, the re-excision rate was 14.8% (n=18). All these re-excisions were carried out for ductal carcinoma in situ with or without an invasive component. Re-excisions are carried out when margins are <1 mm from nearest in situ or invasive disease in accordance local unit policy. Table 2 lists the histology details. Most of the patients had invasive cancer and excision margins were clear for invasive components in all patients.

Sixteen patients had the localisation to facilitate diagnostic biopsy procedures. Mean weight of diagnostic biopsy specimen were 14.73 (range 2–48) g. Table 3 lists the details of the radiological abnormality and postoperative histology in patients who underwent diagnostic biopsy.

All the participating surgeons and radiologists and consultant mammographers filled out a custom-made satisfaction questionnaire for the first 10 Magseed procedures and found the procedure easier than conventional wire localisation procedure. The radiologists found the Magseed insertion was easier and quicker than wire insertion. All lesions were localised accurately and the distance of Magseeds from the index lesions were within recommended guidelines. In most patients, the seeds were within the index lesions (n=100) and of those outside the lesion, the range was 1–10 mm.

Discussion

Magseed localisation is a relatively new procedure for localising clinically occult breast lesions. This procedure is gaining popularity quickly as the technique is simple and logistically less demanding. Moreover, it comes with the advantage of avoidance of another procedure on the day of surgery with the added benefit of better patient experience. This also gives flexibility for effective utilisation of theatre time and radiology resources.

Wire insertion procedures are known to be associated with a number of practical issues. The challenges with wire localisation include migration and remote point of insertion of wire necessitating unnecessary tissue dissection. No migration of magnetic seeds was noted in the present series.

Magseed localisation is similar to radio-iodine seed localisation without the logistical challenges and risks of storage, handling, and retrieving radioactive seeds. Milligan *et al.* has shown that radioactive iodine seed localisation is associated with significant lower weight resection

Table 2
Distribution of histology.

Histology	No. of patients (n=137)
Benign	11
DCIS	24
Invasive ductal cancer	60
Invasive ductal cancer + DCIS	27
Invasive lobular cancer	10
Invasive tubular cancer	3
Mixed invasive cancer	2

Table 3
Radiological abnormalities and post-operative histology in patients who underwent diagnostic biopsy.

Radiological abnormality	Postoperative histology
Asymmetric density	Papillary lesion
Microcalcification	Benign calcification
Asymmetric density	Invasive ductal cancer
Asymmetric density	Atypical ductal hyperplasia
Mass lesion	Myofibroblastoma
Asymmetric density with calcification	Papillary lesion
Asymmetric density	Papilloma
Asymmetric density	Intermediate DCIS
Mass	Haemangioma
Microcalcification	Low-grade DCIS
Microcalcification	Amyloidosis
Microcalcification	Benign calcification
Mass	Complex sclerosing lesion
Mass	Fibroadenoma
Microcalcification	Atypical ductal hyperplasia
Mass	Sclerosing adenosis

specimens in comparison with wire localisation procedures[20]; however, in the present series a number of patients underwent various therapeutic mammoplasty procedures, which will influence the specimen weight.

Magseed also enabled better utilisation of theatre slots at peripheral hospital sites without the need for availability of a radiologist to place the wire on the day of surgery. This again helped to enhance patient experience as they were able to undergo surgery closer to their home.

To the authors' knowledge, the present series has the highest number of patients undergoing Magseed localisation. Similar to other series.[19] It is very reassuring that seed migration did not occur, even when seeds were placed on the day of surgery, as some of the patients had the seeds placed on the morning of their surgery.

The present series involved 12 surgeons with varying amounts of surgical experience in removing clinically occult lesions. The surgeons involved reported that the technique was very easy to learn as it is analogous to sentinel node localisation using a gamma probe. Likewise, a number of consultant radiologists and consultant mammographers (n=10) placed the Magseeds. Hence, the present series reflects safety and outcomes in a non-experimental setting and can be replicated in real clinical practice in various hospitals rather than in a trial setting. It is reassuring that all seeds along with index lesions were successfully removed in the present series with a re-excision or repeat surgery rate of 14.8%, which is well below the national average of re-excision rate in the UK during the period of 2016–2017.[21] The placement of seeds was very accurate and is well within the National Breast Screening guidelines.

Another concern about Magseed localisation is the limitation of sensing depth for the probe (30 mm); however, in the present series, the bra cup size ranged from A to GG cup. Although it is acknowledged that bra cup size is not the best method to objectively assess breast size, it does give a rough gauge of breast size. In addition, the BMI ranged from 18.1 to 48.3 with a mean of 30.56. In our experience, the signal can be picked up even in bigger breasts by pushing the probe against the chest wall. Secondly, lesions in the periphery of larger ptotic breasts did not pose any challenge to identify the signal, as the sensing depth in the periphery of the breast is rarely >30 mm.

The major limitation of the present study is the lack of data on cost effectiveness. Most of the cost savings with new technique is indirect. Indirect cost-savings vary from institution to institution depending upon the location of theatre, admission wards, radiologists' workloads, structure of clinics, and the cancer workload. Secondly, in the present series patient satisfaction was not assessed objectively. It is logical to assume that avoidance of an additional visit to another department for an invasive procedure just before their cancer surgery will be associated with less patient stress and higher patient satisfaction. Anecdotally all patients found the localisation process an easy procedure. A comparative study addressing this issue is not easy, if not impractical, as the same subset of patients would not have experience with wire localisation and Magseed localisation at the same time to compare their satisfaction with either procedure. Thirdly, the duration of the procedure was not calculated. This again was not done as patients had a range of procedures from simple wide local excision to complex therapeutic mammoplasty procedures.

In conclusion, Magseed localisation is a safe, easy technique to facilitate surgery for clinically occult breast lesions. This has a very short learning curve and gives greater flexibility for surgeons to effectively utilise theatre resources with better patient satisfaction. The technique also comes with the added benefit of efficient utilisation of radiology resources; however, a larger, multicentre study would be beneficial to validate the cost-effectiveness of the procedure in various clinical settings.

Conflict of interest

The authors declare no conflict of interest.

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