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Title Page

Multi-centre evaluation of magnetic technology for localisation of non-palpable breast lesions and targeted axillary nodes.

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Multi-centre evaluation of magnetic technology for localisation of non-palpable breast lesions and targeted axillary nodes.

ABSTRACT:

Purpose: Magseed technology is a recently introduced localisation technique for impalpable breast lesions with possible advantages over traditional techniques. These include improved theatre logistics, flexibility in incision placement and improved patient experience. This multicentre study evaluates the experience of introducing Magseed technology into routine surgical practice.

Methodology: A prospective multicentre study of Magseed localised procedures was performed. Insertion data was recorded by the Radiologist including lesion characteristics and Magseed insertion accuracy. The surgical team recorded time from insertion to operation, operating time and surgical satisfaction. Pathology results were reviewed for specimen weight and margins.

Results: Between February 2019 and June 2020, 100 patients were enrolled. Magseed localised procedures included 18 excisional biopsies, 23 wide local excisions (WLE), 50 WLE with axillary surgery and 4 cases of Magseed localised breast WLE with Magseed localised axillary surgery. There were 3 therapeutic mammoplasties and 2 cases of Magseed localised targeted axillary node dissection alone. 90% of Magseeds were radiologically placed within 5mm of the target lesion/node. Time between incision and specimen removal was 17 minutes (range 6 – 40mins). All breast and axillary Magseeds were successfully identified and retrieved during surgery. The target lesion was identified in the specimen in all cases. 10% of cases required further surgery for pathologically positive margins. Overall, surgeons reported that Magseed localisation was “easy” or “very easy” in 77% of cases.

Conclusion: Magseed is a reliable, safe and accurate surgical technique that provides logistical advantages and flexibility of surgical approach. The method was well-accepted by all users.

INTRODUCTION:

Breast cancer is the most commonly diagnosed cancer in Australian women, affecting over 19,000 individuals in 2019 (1). Early diagnosis and treatment of breast cancer improves survival outcomes (1), reduces treatment intensity (2) and widespread screening programs have increased the diagnosis of impalpable breast cancers and other breast lesions (1,3–5). As a result, surgical excision of impalpable lesions is a common procedure. Various approaches to localisation have been used (4,5).

The traditional strategy of hookwire localisation (HWL) is a readily available technique commonly utilised in breast conserving surgery (3,6). However HWL may cause time delays due to coordination of radiology and theatre on the day of surgery and suboptimal skin incisions (3,5–9). While the risk of significant complications are low (6,7), wire displacement is an inherent risk of the HWL technique, resulting in potential for incomplete excision (3,7,8).

Carbon tracking (CT) is an alternative to HWL (10). The CT can be placed many weeks prior to surgery and thereby allows decoupling of radiological insertion and theatre, reducing anxiety on the day of surgery and avoiding theatre delays. However, carbon is not visible on imaging and the CT defines the surgical approach, thus limiting surgical incision placement options (10). Additionally, the entire CT must be excised to avoid granuloma formation, which can mimic malignancy on future imaging (6).

Radioactive localisation techniques, including seeds or tracers have been introduced to allow localisation prior to the day of surgery (7). These technique can avoid delays in theatre, allow the surgeon choice of incision and are associated with improved patient comfort levels compared to HWL (6,7,9,11,12). These techniques also utilise the gamma probe which is routinely available for sentinel lymph node biopsies, therefore avoiding purchase of additional equipment. However, radioactive localisation techniques are limited by the availability of Nuclear Medicine services which may preclude regional/rural centres and are under strict Government regulations (6,8,13–17),which can be cumbersome and prescriptive.

Magseed technology is an evolving localisation strategy for impalpable breast lesions with possible advantages over other localisation techniques, including the decoupling of radiology and theatre, flexibility in incision placement and improved patient experience (13,18). Thus, magnetic technology may have the advantages of radioactive seeds without the radiation safety issues. In 2016, Magseed® (Endomagnetics Ltd, Cambridge, UK) was FDA approved for localization of breast lesions. Additional approval was granted Magseed for use in localisation of lymph nodes.

A Magseed is a 5x1 mm paramagnetic steel and iron oxide seed that is readily visible on mammogram and ultrasound (3,5). Magseeds are inserted preoperatively under ultrasound or stereotactic guidance. Intraoperatively, Magseeds® are detected using the Endomag Sentimag® probe (Endomagnetics Ltd, Cambridge, UK) that generates an alternating magnetic field turning the seed transiently into a magnet (3–5,17). The use of the Sentimag® probe is comparable to the gamma probe, displaying a numerical count and producing a graded audio tone to guide the continuous location of the seed (13,19).

This multicentre study aimed to evaluate the Australian experience of introducing Magseed technology into routine surgical practice for localisation of impalpable breast lesions and axillary lymph nodes. The study was approved by HREC ethics committee (reference # LNR/51418/PMCC-2019).

METHOD:

All adult female patients requiring radiological localisation of an impalpable breast lesion or a marked axillary lymph node were eligible for the study. All patients were discussed at a Breast Multidisciplinary Meeting (MDM) involving Radiologists, Pathologists and Surgeons. A consecutive series of selected patients were included in the study. Patients were eligible for Magseed insertion if neoadjuvant therapy (NAT) was recommended and a target clip was inserted into the lesion/lymph node prior to commencing NAT. Magseed was not performed if the patient was likely to require magnetic resonance imaging (MRI) following localisation.

The primary outcome of the study was successful excision of the targeted lesion. Secondary outcome measures included accuracy of seed placement, weight of total breast specimen, operation time, need for intra-operative shavings, margin status, re-operation rates and surgeon satisfaction assessed using a Likert scale.

METHOD: Radiology

The Magseeds were inserted under local anaesthetic by Interventional Breast Radiologists, using a preloaded 18-gauge deployment needle. Ultrasound or stereotactic guidance aimed to insert the seed in the centre of the target lesion. Multiple seeds per case could be used if bracketing was required, maintaining a distance of at least 2cm in between seeds. Lesion depth was assessed on ultrasound. A post deployment two-view mammogram was taken after seed insertion to measure the distance between the seed and the target lesion in order to evaluate accuracy of seed placement. Insertion of the Magseed was planned within 30 days of surgery according to Australian TGA guidelines.

Radiological lesion size and appearance, location of lesion (including depth), accuracy and modality of Magseed insertion and complications were recorded.

METHOD: Surgery

The operations were performed by experienced Breast Surgeons. Intraoperative Magseed® localization was performed using the Sentimag® probe and non-metallic surgical instruments were used to avoid signal interference. Both scanning of the specimen with Sentimag® and a specimen X-ray were performed to confirm the removal of Magseed®.

Clinical data recorded included patient age, use of neoadjuvant chemotherapy, time between Magseed insertion and surgery, procedure performed and intraoperative time from incision to Magseed removal. Intra-operative shaves were performed at the discretion of the operating Surgeon and documented. Surgical complications and need for re-excision was recorded. Surgeon experience was described utilising a five-point Likert scale from “very difficult” to “very easy”.

METHODS: Pathology

Pathological information including biopsy result, surgical pathology and margin status was recorded. A negative margin was defined as no tumour on ink for invasive cancer and >2mm from margin for DCIS (20).

RESULTS:

A total of 100 patients were enrolled in the study between February 2019 to July 2020. Overall, the average patient age at time of operation was 58 years (range 27 to 80).

Magseed localised procedures included 18 excisional biopsies, 23 wide local excisions (WLE) and 54 WLE with axillary surgery. Therapeutic mammoplasties were performed in three cases. Magseed localised targeted axillary node dissection (TAD) was performed in 6 cases (see table 1).

BREAST

Ninety eight patients had breast surgery with Magseed localisation. The majority of localisation procedures were performed by ultrasound (68%). Mammographic stereotactic localisation was performed in 32%. There were a variety of abnormalities targeted for localisation, including calcifications (8 cases), calcifications & clip (10 cases), clip (18 cases), mass (32 cases) and mass & clip (30cases). A single breast lesion was localised in 95 cases and two breast lesions localised in three cases. Bracketing was performed in four cases.

Magseed insertions were performed by Breast Radiologists. It was noted that ultrasound insertion of Magseeds was difficult during the learning curve due to the deployment system. Feedback from Radiologists suggest that it was a quick, efficient procedure that was well tolerated by patients. However improvements to the delivery system and needle sharpness were recommended.

The most common location for the breast lesion was in the upper outer quadrant (40%) and upper inner quadrant (27%). On average the lesion was 4cm from the nipple (range 0 to 13cm). Magseeds were inserted within 5mm of the target lesion or clip in 90% of cases. Seed displacement occurred in 3 cases (discussed in “Complications” section below). No radiology-related adverse events (eg syncope, haematoma) were reported. The median time from Magseed insertion to surgery was 7 days (range 0-183days). Decoupling of radiology and theatre occurred in 95% of cases with only five patients requiring localization on the day of surgery. One case had Magseed inserted prior to NAT (see “Case of Note”). Despite the prolonged time insitu, Magseed localisation was performed without additional localisation and the surgery was uncomplicated. When this case was excluded from the data, the average time from insertion to operation was 9.8days. NAT was completed in 9 patients.

A periareolar incision was used in 43% of operations. In other cases, a curvilinear incision over the tumour along Kraissl’s or Langer’s line was performed, with exception of therapeutic mammoplasties which were performed by a wise pattern technique (n=3). Magseeds were removed in all cases, with 96% of Magseeds located within the main specimen (see Image 1). Cavity shaves were performed by the Surgeon as clinically indicated intra-operatively. Cavity shaves were completed at the discretion of the Surgeon and occurred in 34% of operations.

Median time between incision and specimen removal was 15 minutes (mean 17minutes, range 6 – 40mins). Overall, surgeons reported that Magseed localisation was “easy” or “very easy” in 77%, “neutral” was reported in 15% and was not reported in 4%. Cases described as “difficult” are described below. There were no cases described as “very difficult”.

Overall the average specimen weight was 27grams (range 2-229grams). Average weight of the mammoplasty specimen was 118grams (range 86 – 229grams), and average specimen weight of WLE specimens was 21grams (2 - 66grams).

Complications:

There were three cases of Magseed migration during the study. Two cases had migration of the Magseed along the insertion track that was recognised pre-operatively and required HWL for surgery. Intraoperatively the HWL lesion and also the Magseed were removed. The two cases were described as “neutral” and “easy” by the operating Surgeons and no re-excision was required. One case required additional Magseed insertion due to Magseed displacement on insertion. Intraoperatively, the case was described as “easy” by the operating Surgeon and both Magseeds were removed without difficulty with no interference between the two Magseeds experienced. The patient required re-excision due to positive margin of in-situ disease.

Complications occurred in two cases which included one post-operative haematoma and one post-operative infection. Two of these cases were described as “easy” by the operating Surgeon, with the Magseed located within the main specimen. The case described as “difficult” experienced post-operative infection and is discussed below.

“Difficult cases”:

Four cases were described as “difficult” by the operating Surgeon. In one case the surgery was made difficult by the choice of periareolar incision for an upper inner quadrant tumour. There were no radiological or surgical complications, the specimen was removed within 21minutes and the Surgeon still preferred Magseed to HWL or CT. The second case described as “difficult” had the specimen removed within 20minutes, was uncomplicated and no re-excision was required. Despite the case being described as difficult, Magseed was still the preferred localisation technique. The third case described as difficult was due to displacement of the Magseed intraoperatively. The Surgeon removed the Magseed within the main specimen and completed two shavings. No further surgery was required and there were no complications. Magseed was preferred over HWL and CL for this case. The fourth case described as difficult was due to the deep lesion location and unavailability of deep non-metal surgical instruments. The specimen was removed within 19 minutes, the Magseed was found within the main specimen and margins were negative. The surgery was complicated by post-operative infection. The Surgeon would have preferred HWL in this case due to availability of retractors.

AXILLARY NODE LOCALISATION

Magseed localised targeted lymph node dissection (TAD) was performed in six cases. Four of these cases were combined with breast localisation with Magseed and one case was combined with Magtrace localisation of a sentinel node.

The majority of cases had NAT and it was pre-determined at MDM that TAD was appropriate management. These NAT patients had the positive lymph nodes clipped prior to systemic treatment. Following NAT, patients completed restaging and were found to have a good clinical and radiological response to treatment. Following MDT, TAD was deemed appropriate surgical management.

Pre-operative insertion of Magseed to the axilla was performed by ultrasound (100%). There were no failures of insertion or complications. Median time from Magseed insertion to surgery was 6 days (range 3 – 183days). One case had a Magseed inserted prior to NAC (183days prior to surgery, see “Case of Note”) and when this case was excluded, the average time from Magseed insertion to surgery was 8 days (range 3 – 18days).

The surgeries were all performed without complication and the Magseeds were retrieved in all cases. The average time from incision to removal of targeted node was 16.5mins (range 10 to 21mins). Surgeons described the procedure as “easy” in 100% of operations, with no preference for HWL or CT.

The Magseed was found intra-nodally in 4 cases and extranodal location in 2 cases. Pathology results showed nodal fibrosis in 5 cases (range of lymph node size 3mm - 14mm). In one case macrometastatic disease (8mm metastatic deposit) was found within a 35mm lymph node. The remaining lymph nodes were clear of disease.

CASES OF NOTE:

In one case, due to a communication failure, Magseeds were inadvertently inserted prior to NAT resulting in the breast and axillary Magseeds insitu for a prolonged period. MRI was performed with breast and axillary Magseeds insitu. Whilst there was no impact upon the patient's treatment or outcome, the resulting MRI showed significant artefact (see Image 2). This artefact has been previously described as a "bloom" effect and is documented to occupy 4cm of the imaging sequences (13). This interference impacts upon the imaging, especially for monitoring of response to NAT.

DISCUSSION:

Traditional HWL techniques for non palpable breast lesions have significant limitations which has resulted in evolution of technology. Our experience of Magseed localisation demonstrated that the technique is accurate and safe for impalpable breast lesions and for targeted axillary dissection following NAT. Our study achieved 96% surgical excision of the Magseed within the main surgical specimen and a 100% retrieval rate. A total of 34 % of cases involved additional intra-operative cavity shaves, which were performed at the discretion of the operating surgeon.

A high level of surgeon satisfaction was reported with this new technique. The Magseeds allowed for decoupling of radiology from surgery with cases to able to be performed first on morning operating lists. The Magseed technique is also ideal for centres without access to onsite interventional breast radiology services for hookwire localisation or nuclear medicine for radioactive seeds.

A recent observational trial compared HWL with Magseed technology in 168 cases (21). Both techniques were found to be radiologically highly accurate and surgical re-excision rates were similar between the groups. Interestingly, this study found Magseed specimen weights were significantly lower and lesions were more centrally placed on pathological examination than HWL cases, suggesting improved accuracy of lesion position intraoperatively with Magseeds. Results also showed radiologists and surgeons preferred Magseeds over HWL. Of particular note, patient reported less anxiety with Magseeds, however no difference in patient discomfort was found.

RADIOLOGICAL INSERTION

Our experience is comparable to international studies. Price (et al 2018) reported on the introduction of Magseeds into their routine breast surgery practice (19). This study examined Magseed localisation in 64 patients, with results displaying a high accuracy of Magseed insertion with 70% of Magseeds placed within 1mm of the target lesion. Insertion was most frequently with MMG localisation and was performed within 30days of surgery. Our study was comparable with 77% of Magseeds placed either within the target lesion or within 1mm, however our study had predominantly US-guided insertion. Similarly high insertion accuracy has been described by other authors (14,19). Published cohort series have described an average of 7.5minutes for insertion of Magseed (17). Our study did not examine this parameter. However average time for surgical removal, (measured from incision to specimen removal) was included in our study and found to be 17minutes. International studies reported average operative time for specimen removal to be

13.5minutes (17) and 8minutes (3,5). These reported shorter operating times may be related to the small study cohorts and case selection.

Recently, a systematic review study of 1559 Magseed procedures was published (13). This study examined the accuracy of placement, successful retrieval and localisation rate as well as re-operation rates. The analysis found a highly accurate “successful” Magseed placement rate of over 99%, however the definition of “successful” was highly variable between studies and therefore unable to be standardised (13).

No complications were reported within the Manchester group study (14). In our study no cases of radiological complications were experienced (eg syncope, haematoma), however Magseed migration was noted in 3 cases (3%) that required further localisation.

Deeply situated lesions are a potential limitation of the Magseed technology, with transcutaneous detection being limited to 4cm (Price 2018). However other authors have reported depth of lesion is not a limiting factor of Magseed technology (13,14,22). Our experience did not include lesions beyond 29mm depth and further studies are required to determine the limit of detection using Magseed technology.

SURGERY

A recent study examining Surgeon experience of Magseed surgery found that Surgeons described the procedure as “easy” or “very easy” in 80% of cases (23). This is comparable to our study which found 76% of Surgeons described the breast localisation as “easy” or “very easy”. Studies have suggested that the learning curve of this procedure is short (5,21). Our series included six axillary lymph node localisation procedures, all of which were described as easy. Surgeon satisfaction with the axillary technique has also been reported in overseas studies (3,24). Studies have shown the technique to be safe and efficient in targeted axillary dissection (24).

Interestingly, there was no correlation between cases reported as “difficult”, surgical complications or re-operation rate for positive margins. In only one “difficult” case was Magseed not the Surgeon-preferred localisation technique.

International studies have described a 100% operative retrieval success rate for both impalpable breast lesions and axillary nodes (19,25,26). These results are consistent with our study and reflects the accuracy of the Magseed technique.

PATHOLOGY

Our study demonstrated 10% of cases with biopsy showing malignancy required further surgery for positive margins (refer to Table 2). This re-excision rate is less than the 19.5% overall re-operation rate following breast conserving surgery published by one of the participating institutions prior to the use of Magnetic technology (27) Our re-excision rate is similar to recently published Australian studies (28,29), including a study comparing the re-excision rate of HWL and radioactive seeds for non-palpable breast cancers. Results of this study showed the re-excision rate of HWL was 18.9% and radioactive seeds 13.9%. This indicates that Magseeds are comparable to these modalities (29). Results are also comparable to a recent systemic review of 16 studies, which found the overall re-excision rate was 11.25% (13).

COST OF INTRODUCTION

Current cost of the Magseed equipment is $62,500 for purchase of the Sentimag probe ($2000 monthly rental, $700 daily rental). Magseed cost is $560/seed, with 7cm and 12cm introducers available. Due to the interference of standard surgical instruments with the magnetic signal, non-metallic surgical instruments (eg. retractors) are also required for the technique and are an additional cost. The cost savings for Magseed technology include radiological insertion as an outpatient and improved theatre efficiency by decoupling theatre and radiology. Recent data has shown Magseeds are safe to remain insitu for an unlimited time (13,30) which further decouples radiology from surgery and allows NAT.

This study did not assess the cost effectiveness of Magseed technology. The Magseeds are more expensive than the consumables associated with hookwire localisation ($560/seeds compared with $40/hook wire), however the avoidance of delays on the day of surgery due to decoupling of the localisation procedure and the day of surgery potentially saves substantial costs. In particular for those patients on a morning list, surgical efficiency is greatly enhanced Further studies are required to confirm this (3).

Future research

To investigate the non-inferiority of Magseeds, a Swedish open-labeled randomised control trial examining Magnetic localisation for DCIS or invasive cancer is currently recruiting (MAGTOtal trial) (31). The study aims to recruit 200 patients and will investigate Magnetic technology compared to hook wire localisation.

Breast localisation technology will continue to evolve. Scout Radar is a technique that utilises infra-red to localise breast lesions and has similar advantages to Magseeds, including decoupling of radiology and theatre (6). Whilst this strategy is rarely used in Australia, its characteristics provide a competitive profile to Magseeds. Further local studies are needed to compare different localisation techniques including radioactive seeds, scout radar, hookwire and Magseeds.

CONCLUSION:

In Australia, the need for localisation strategies for non-palpable breast lesions that decouple radiology and surgery is real, especially in centres without onsite radiology services. Our study found the introduction of Magseed location was well received by radiologists and surgeons. Our results show accuracy of both radiological insertion and surgical removal of the target lesion. A low re-excision rate for malignant lesions was found, indicating that Magseed is an effective technique. We found that Magseeds provide logistical benefits of decoupling of radiology and theatre, facilitating streamlined operating lists. The technique was easily performed by Breast Surgeons familiar with the gamma probe technique and overall satisfaction was high. Our study demonstrates that Magseed is a reliable, safe and accurate surgical technique that provides logistical advantages and flexibility of surgical approach. s the techniques for localisation of non-palpable lesions continue to evolve, future studies are needed to compare Magseeds with other localisation techniques including Scout Radar and radioactive seeds.

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Image 1: Magseed localised WLE (specimen Xray)

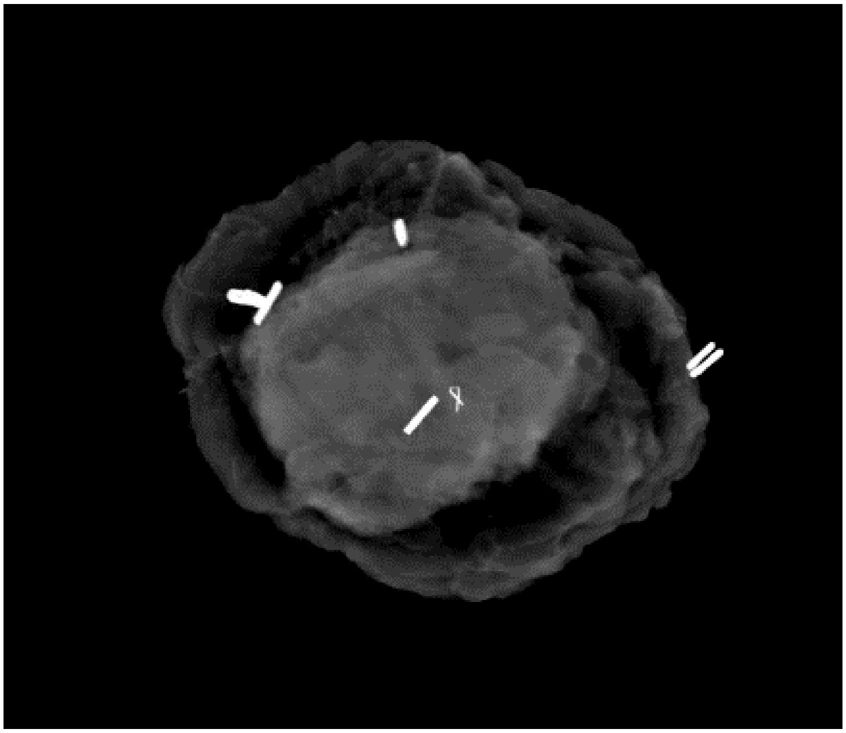

Image 2 Magseeds and MRI

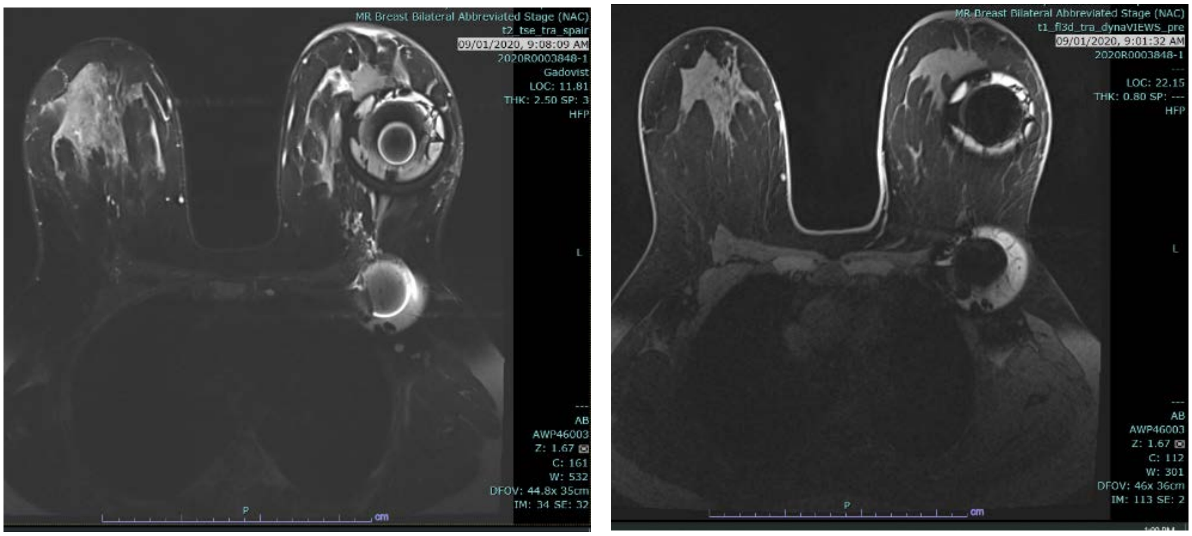

Table 1 Magseed localisation procedures

Table 1: Magseed localisation procedures		
Magseed Patients	**Procedure**	**N**
Breast lesion localisation		**94**
	Excisional biopsy	18
	WLE*	23
	Therapeutic mammoplasty	3
	WLE and SLNB **	46
	WLE and ALND ***	4
Breast lesion and axillary lymph node localisation	**WLE and TAD**** **	**4**
Axillary lymph node localisation	**TAD**	**2**

* WLE = wide local excision

** SLNB = sentinel lymph node biopsy

***ALND = axillary lymph node dissection

**** TAD = targeted axillary dissection

Table 2: Positive Margins for Biopsies with Malignancy

Malignant Biopsy	(n)	Positive Margin (n)
IDC NST	46	3
IDC NST and DCIS	6	1
ILC	5	0
Papillary cancer	1	0
Mucinous cancer	1	
DCIS	21	4
TOTAL	80	8