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Image-Guided Pre-Operative Magnetic Seed Localization of Breast Lesions: Experience of a Northern Ontario Hospital with the Magnetic Occult Lesion Localization Instrument (MOLLI)

Zacharie Gagné[a], Yasmine Sallam[b], Shaista Riaz[b,c], Amr Elnayal*[b]

[a]*Northern Ontario School of Medicine, Sudbury (ON), Canada*

[b]*Department of Radiology, Health Sciences North, Northern Ontario School of Medicine, Sudbury (ON), Canada*

[c]*University Institute of Radiological Sciences and Medical Imaging Technology, Faculty of Allied Health Sciences, The University of Lahore, Lahore, Pakistan*

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ABSTRACT

Background: Breast cancer remains one of the leading malignancies among Canadian women. Lumpectomies have been increasing in number over total mastectomies due to comparable survival and lower reoperation rates. While wire localization has been the traditional method for the localization of non-palpable breast lesions, it presents logistical and patient comfort challenges. Magnetic localization systems, such as the Magnetic Occult Lesion Localization Instrument (MOLLI), offer an alternative with potential advantages.

Methods: A retrospective review was conducted, examining the outcomes of 145 patients who underwent MOLLI seed localization between December 2023 and October 2024. A total of 154 seeds were placed, with localization performed predominantly via sonographic guidance. The primary outcomes were placement success, retrieval rates, margin status of the surgical specimens, and the number of days between seed placement and surgical excision.

Results: The mean patient age was 62 years. MOLLI seeds were successfully placed in 100% of cases, with 76% within or adjacent to the lesion. Of the excised lesions, 70.3% were malignant, with a positive margin rate of 17.3%, which was defined as invasive carcinoma or ductal carcinoma in situ (DCIS) being less than 2 mm from the margins. The MOLLI seeds were successfully retrieved in 100% of cases.

Conclusion: The MOLLI localization system demonstrated high accuracy and retrieval success, offering a viable alternative to traditional wire localization. The findings suggest MOLLI and other magnetic localizers may improve lesion localization and excision while also improving patient comfort. As this was a retrospective single-center study, further large-scale trials are needed to confirm generalizability.

INTRODUCTION

Breast cancer continues to be one of the most common malignancies in Canada, accounting for 25% of all newly diagnosed cancers in women.[1] Among the treatment options for breast cancer, patients must often choose between a total mastectomy and a lumpectomy. While total mastectomies have historically been the preferred approach, recent trends indicate a reversal, with the number of lumpectomies increasing significantly in part due to the decreasing rates of reoperation following these procedures.[2,3] Furthermore, new

***Address for correspondence:**
Dr. Amr Elnayal, MD,
41, Ramsey Lake Road, Sudbury, Ontario, Canada.
Email: aelnayal@hsnsudbury.ca

research indicates that lumpectomies are an adequate, and in some cases a superior treatment option compared with total mastectomy in terms of survival rates and patient satisfaction, particularly in early-stage breast cancers.[4–7] One of the challenges posed during lumpectomy procedures is the localization of non-palpable breast lesions. Since its popularization in the 1970s, pre-surgical wire localization has become the most commonly used system to assist in the excision of suspicious lesions. However, wire localization does have some limitations and challenges.[8] Primarily, wire localization possesses logistical difficulties, as it needs to be placed on the day of the scheduled procedure, requiring coordination between the radiology and surgical departments.[9,10] Additionally, once the wire is placed, the external portion protrudes outward from the skin, which can be uncomfortable for patients and increase the risk of the wire becoming displaced before the excision.[10,11]

To overcome these issues, other localization techniques have been developed. In the early 2000s, radioactive seeds using iodine-125 emerged as an alternative, offering several advantages over wire localization, including the ability to place them up to five days before surgery, thereby improving schedule flexibility.[9,10] Additionally, radioactive seeds can be placed in the same manner as wire localization, either by ultrasound or mammography, but have the advantage of not protruding from the skin, thereby reducing the risk of displacement. They do, however, possess their own drawbacks, including radiation exposure to both the patient and staff.[9,10] While the level of radiation exposure is minimal, about the equivalent of a two-view mammogram, decreasing any level of unnecessary radiation exposure is advantageous.[12] For this reason, among others, a non-radioactive alternative was developed using magnetic localization.

Magnetic seeds were first approved for use in Canada in April 2014, and several institutions have since adopted the system in favor of wire localization and radioactive seed localization. Magnetic seed localization possesses many of the same advantages as radioactive seeds, with the added benefit that these seeds can be placed many weeks in advance, as opposed to only five days, further increasing schedule flexibility.[9] This added flexibility is largely due to the magnetic seed's ability not to lose their signal intensity over time, which also allows for longer than planned neoadjuvant therapy if required.[9] Additionally, patients and staff have the advantage of not being exposed to excess radiation throughout the procedure. Currently, the biggest disadvantages of magnetic seeds are the higher associated cost of the devices as well as their ability to cause significant artifacts in MRIs, which can affect their use in neoadjuvant therapy.[9,13–15] In this article, we describe our institution's experience so far using magnetic seeds for non-palpable breast lesions, specifically the Magnetic Occult Lesion Localization Instrument (MOLLI) seed product. The goal of the current study is to evaluate the efficacy of the MOLLI seed product at our institution since making the switch from wire localization. To the best of our knowledge, this is the largest study evaluating the efficacy of the MOLLI seed system.

METHODS

This was a descriptive cross-sectional study with a convenience sampling method. Electronic medical records and PACS systems were used to identify patient age, localization features, histological features, as well as surgical outcomes. Patient charts were reviewed from December 7, 2023, which marked the start date of the magnetic seed localization program at our local hospital, to October 10, 2024. All data were anonymized before analysis to ensure patient confidentiality. The decision to transition from wire localization to MOLLI seed localization was made jointly between the radiology department and breast surgeons, with all parties implementing the change on December 7, 2023. All patients who underwent MOLLI seed localization for a lumpectomy over this period were included in this study. In total, 145 patients were treated over this period and included in the study, with a total of 154 MOLLI seeds being placed. Among the 145 patients, 4 had one seed placed in the breast and one in a lymph node, 3 had two seeds placed in the same breast for separate lesions, one had two seeds placed in the same breast for the same lesion, and one patient had one seed placed in each breast. The MOLLI seeds were primarily placed using sonographic guidance (N = 146), with only a small number requiring mammographic guidance (N = 8), based on patient characteristics and radiologist preferences. Hydromark biopsy clips were used, which create a hydrogel halo around the respective area, rendering them easily visible under sonographic guidance. Following MOLLI seed insertion, all patients underwent a post-procedure mammogram, which is standard practice at our institution to ensure proper seed placement in relation to the target lesion.

MOLLI seed system

The MOLLI seed system consists of a 1.6 mm × 3.2 mm neo-dynamic magnet that comes pre-loaded in the MOLLI introducer. The marker is introduced via a 14-gauge needle with a beveled tip and 1-cm depth indicators. The introducers come in 8-cm and 12-cm lengths to accommodate different breast sizes

and densities. The marker is implanted percutaneously using either ultrasound or mammographic guidance. Once introduced, it produces a continuous magnetic field, which is detected using a handheld probe that utilizes magnetometers to sense the direction and strength of the magnetic field created by the marker. The handheld wand localizes the marker in both the planar position (x-y coordinates) and depth (z coordinates), which allows it to localize the marker in 3D. The signal from the handheld probe is then visualized on the tablet, which provides real-time visual and auditory feedback regarding the distance and direction of the marker.

The MOLLI markers can be introduced up to 30 days before surgical excision and do not lose their signal strength over this period. The marker and introducer devices are disposed of following use; however, the handheld probes can be sterilized and used multiple times. An example of the MOLLI seed insertion process is shown in Figure 1.

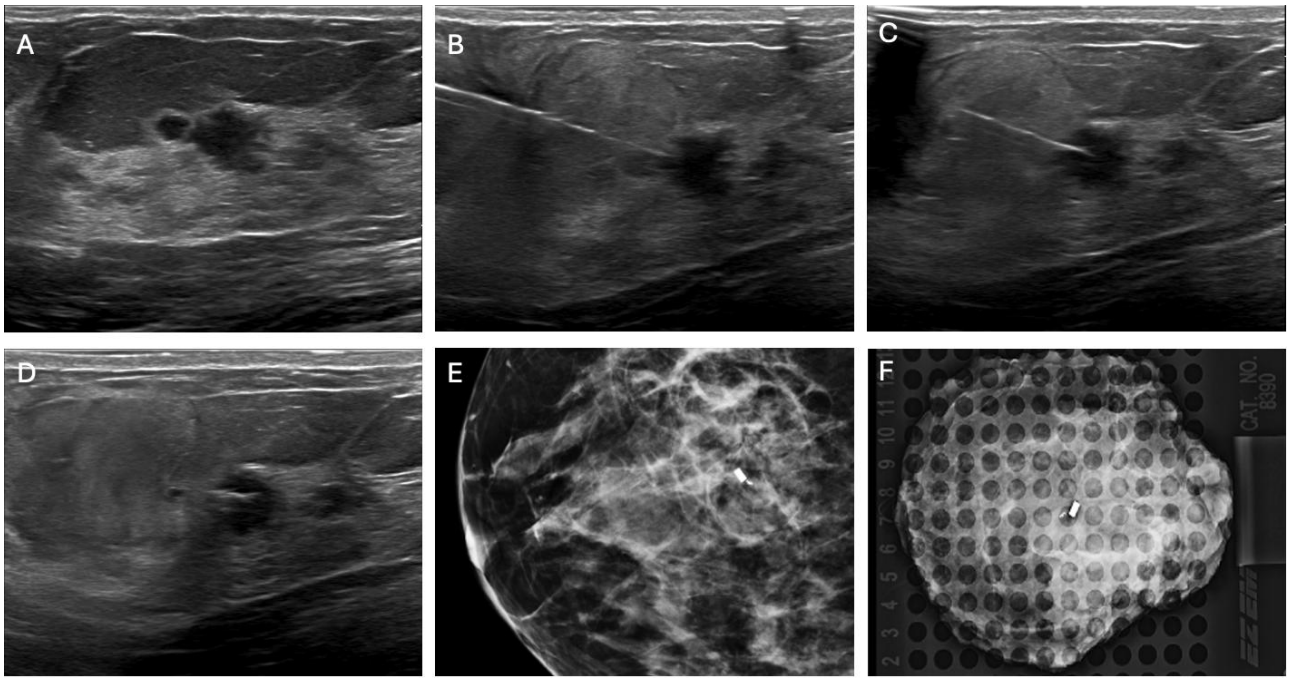

Figure 1. MOLLI Seed Insertion. A, displays a hypoechoic lesion. B, shows advancement of the 14-gauge needle into the hypoechoic lesion. C, demonstrates the deployment of the MOLLI seed, with D, showing the MOLLI seed in a good position within the hypoechoic lesion. E, shows a post-insertion mammogram with the MOLLI seed in proper position within the lesion. F, shows the post-lumpectomy X-ray to confirm the removal of the MOLLI seed.

RESULTS

The mean age of patients receiving MOLLI seed localization was 62 years (range: 32–98 years). Most patients who received MOLLI seed localization were scheduled for surgery on the same day (N = 105), with the longest wait between placement and surgery being 13 days. Localization features are detailed in Table 1.

The MOLLI seeds were successfully placed in all cases (154/154), defined as within 10 mm of the target lesion. In one case, two MOLLI seeds were placed for single-site localization, one seed within the lesion, and the second seed just adjacent to the lesion within an area of additional calcification. Additionally, in 4 cases, MOLLI seeds were placed within lymph nodes, with 2 testing positive for malignancy and 2 testing negative. There was a single case in which the MOLLI seed was placed 15 mm from the target lesion. This placement was intentional as there was an area of calcification approximately 30 mm from the lesion; therefore, a decision was made to place the MOLLI seed midway at 15 mm, with instructions to excise a wide margin around the MOLLI seed. Despite being placed further than 10 mm from the target lesion, this localization was considered successful. The MOLLI seeds were successfully retrieved in all cases (154/154).

The histological characteristics of the lesions are detailed in Table 2. Of the lesions excised using the MOLLI seed localization, 104 (70.3%) were malignant, with 18 (17.3%) lesions having positive margins. For this study, a positive margin was defined as the presence of invasive carcinoma or ductal carcinoma in situ (DCIS) within less than 2 mm of any margin as per the American Society of Breast Surgeons.

In three cases, the lesion was completely excised, but there was some DCIS involving one of the margins.

Table 1. Localization Features

Localization features	Number of lesions (%)
Guidance modality	
Ultrasound	146 (94.8)
Mammogram	8 (5.2)
Target appearance	
Mass with clip	89 (57.8)
Clip only	30 (19.5)
Mass	23 (14.9)
Calcifications	4 (2.6)
Calcifications with clip	4 (2.6)
Lymph node	2 (1.3)
Lymph node with clip	2 (1.3)
Placement success	
< 1 mm	117 (76)
1–6 mm	30 (19.5)
6–9 mm	6 (3.9)
>9 mm	1 (0.6)
Retrieval success	154 (100)

The remaining 15 cases had either invasive carcinoma or DCIS within less than 2 mm of one of the margins, but not in contact with the margin.

Table 2. Histological Characteristics

Histological characteristics	Number of lesions (%)
Lesion malignancy	
Malignant	104 (69.8)
Benign	45 (30.2)
Benign lesion characteristics	
Papilloma	15 (10.0)
Fibroadenoma	6 (4.0)
Pathologic complete response in patient after neoadjuvant therapy	5 (3.4)
Atypia (atypical ductal hyperplasia, atypical lobular hyperplasia)	5 (3.4)
Fibrocystic change	5 (3.4)
Biopsy site changes	4 (2.7)
Lobular carcinoma in situ	3 (2.0)
Fibromatosis	1 (0.7)
Benign phyllodes tumor	1 (0.7)
Malignant lesion characteristics	
Invasive ductal carcinoma	74 (49.7)
Ductal carcinoma in situ	15 (10.0)
Invasive lobular carcinoma	9 (6.0)
Papillary carcinoma	3 (2.0)
Invasive mucinous carcinoma	2 (1.3)
Invasive tubular carcinoma	1 (0.7)
Nottingham grade of malignant lesions	
Grade 1	22 (21.3)
Grade 2	63 (61.2)
Grade 3	18 (17.5)
Margin status of malignant lesions	
Positive	18 (17.3)
Negative	86 (82.7)

Among the 15 cases, 13 had DCIS within 2 mm of the margin, 1 case had invasive carcinoma within 1 mm of the margin, and 1 case had both invasive carcinoma within 1 mm of the margin and DCIS within 2 mm of the margin. There were no reported complications during MOLLI seed placement or excision in any of the cases.

DISCUSSION

The experience of our center so far with the MOLLI seed system has shown that it serves as a viable alternative to the wire localization method. At our center, the MOLLI seed localization system had a 100% retrieval rate and a high placement success rate, with 76% of the MOLLI seeds either located in the lesion or adjacent to it. The remaining seeds were all located within 9 mm of the lesion, except for one that was intentionally placed at a distance of 15 mm. To date, only one other study has specifically examined the MOLLI seed system, with a cohort of only 20 patients.[16] The study by Hong *et al.* reported that all 20 seeds were successfully placed within the lesion and retrieved following excision.[16] While these results are difficult to extrapolate given the small sample size, the results from our study are in line with research reports on other magnetic localization methods, such as Magseed, which found a successful placement rate (less than 10 mm from lesion) ranging from 94.42% to 100%.[14,15,17,18] Previous research also supports our findings of a high retrieval rate, with the lowest reported retrieval rate in the literature being 95% for the Magseed localization method.[14,15,17–20] If a magnetic seed is not retrieved, the surgeon would be notified by the radiologist, who would then use the magnetic probe to locate the seed.

The positive margin rate at our center was 17.3% (18/104), with 3 samples having DCIS involving one of the margins, and 15 having either invasive carcinoma or DCIS within 2 mm of a border. The study by Hong et al. using the MOLLI seed method had no positive margins, albeit with only 20 patients in their sample. Other magnetic localization systems, such as the Magseed, Sirius Pintuition, and TAKUMI, have shown positive margin rates ranging from 6.1% to 24.5%.[9,14,15,18–22] The positive margin rate of 17.3% observed at our center seems to be consistent with other studies using the magnetic localization technique. It is also important to note that while most studies use the positive margin rate of less than 1 mm for invasive carcinomas and 2 mm for DCIS, some use different thresholds. For example, Redfern et al. classified a positive margin as having the invasive carcinoma within 2 mm from an inked margin, while others such as Kelly et al. and Liang et al. classified a positive margin as either having the invasive carcinoma 0 mm from an inked margin or DCIS within less than 2 mm of an inked margin. These variations reflect differences in institutional

definitions, which can affect reported positive margin rates. Since no large-scale studies have evaluated the MOLLI seed system, it remains unclear whether the MOLLI system is superior in reducing the rate of positive margins. Further large-scale research investigating the newer localization systems, such as the MOLLI system, is currently needed.

When compared to wire localization, few large-scale studies or meta-analyses have demonstrated a clear superiority of magnetic localization. Research to date suggests that magnetic localization is either superior or non-inferior in certain respects to wire localization, while also having some limitations. One of the most recent studies by Dave et al. investigating the Magseed method showed that compared to wire localization, Magseed led to a higher rate of indexed lesion removal (99.8% vs 99.1%, P = 0.048), fewer failed localizations (1.64% vs 1.98%, P = 0.032) and a lower risk of dislocation (0.4% vs 1.4%, P = 0.039). Regarding re-excision rates, most studies to date have shown no significant difference between magnetic localization and wire localization, including a pooled analysis by Gera et al. and Shirazi et *al.*[14,19,22–25] However, Shirazi et al. did note in their pooled analysis a close to significant result (P = 0.0534) showing that magnetic localization had lower re-excision rates (13.44% vs 15.42%). Furthermore, there have been a few studies[26,27] that have shown a lower re-excision rate using the magnetic localization method compared to wire localization, including a pooled analysis by Ontario Health (11.3% vs. 15.4%).[28] Findings on total specimen volume are mixed, with some studies showing magnetic localization leading to a lower specimen volume[18,23,24,29], and others reporting no significant difference.[25,30] Similarly, studies have found no significant difference in positive margin rates between magnetic localization and wire localization.[18,24,27,29,30] No study to date has shown an increased risk of complications with magnetic localization compared to wire localization. One notable advantage of magnetic seeds is higher patient satisfaction, with multiple studies supporting that patients prefer magnetic localization over wire localization.[18,30] Currently, the two biggest limitations of the magnetic localization are their ability to cause significant artifacts in MRIs, which restricts their use in adjunct therapy, and their cost. It is estimated that the cost of each wire-free, non-radioactive localizer is $773.67 CAD, which is more than double the cost of radioactive localizers at $381.84 CAD and triple the cost of wire localization at $204.27 CAD.[28] As a result, Ontario Health estimates transitioning to wire-free, non-radioactive methods will cost an additional 7.73 million over 5 years.[28]

Our research has some limitations, primarily because it was conducted at a single center, which can limit the generalizability of results. This study did not assess the post-operative complication rates or the rate of re-excision due to incomplete removal of the lesion or close margins. The goal of this study was to assess the success rate of the MOLLI seed localization at our center following the transition from wire localization. Early results show that the MOLLI seed system is a viable alternative to wire localization; however, larger studies are needed to evaluate post-operative complication rates and the rate of re-excisions using the MOLLI seed system.

CONCLUSION

The initial experience at our center is in line with others, showing that magnetic localization is a safe and effective method for non-palpable breast lesions. The findings of our study indicate that the MOLLI seed system achieved a high success rate for placement and retrieval without increasing the rate of positive margins in the surgical specimens. While the cohort size of this study is the largest known to date using the MOLLI system, there is still some ambiguity regarding its effectiveness compared to wire localization. While further large-scale studies are needed to investigate the effectiveness of the MOLLI system, these results support the integration of the MOLLI seed system in routine clinical practice, particularly in practices that value flexible scheduling and enhanced patient comfort.

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CONFLICT OF INTEREST

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author upon reasonable request. Due to ethical and privacy

considerations, certain restrictions may apply to the availability of patient-related data. Aggregated or de-identified datasets may be shared in compliance with institutional and regulatory guidelines.

ETHICAL CONSIDERATIONS

The study received approval from the Research Ethics Board (REB) with the need for consent waived due to the retrospective nature of the review.

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