Results of a Phase I, Prospective, Non-randomized Study Evaluating a Magnetic Occlusion Localization Instrument (MOLLI) for Excision of Non-palpable Breast Lesions
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Introduction

- Common contemporary approaches for localizing breast lesions are wire and radioactive seed localization (RSL).
- Wire localization causes significant patient discomfort and health systems inefficiencies due to the coupling of implantation procedure with same day surgical excision. Radioactive seed localization requires significant administrative infrastructure due to handling of radioactive sources. Other commercially available products for localization also have shortfalls.

- Sunnybrook Odette Cancer Centre has developed a non-radioactive wireless localization system Magnetic Occlusion Lesion Localization Instrument (MOLLI), designed to be accurate, easy to use, compatible with conventional metal OR equipment, robust, and cost-effective.
- This phase I first-in-human trial establishes clinical feasibility for localizing solitary non-palpable breast lesions with MOLLI

![Figure 1: A photograph highlighting the components of the MOLLI system. The MOLLI introducer consists of a pre-loaded 8 & 12 cm needles, designed for single-handed implantation procedures. The MOLLI marker is a 3.2 mm long magnetic marker. The MOLLI wand detects the local magnetic field from the MOLLI marker to provide real-time feedback in the form of auditory and distance feedback to the surgeon on the MOLLI tablet.](image)

Methods

- Design: Single arm phase I non-randomized first-in-human trial (N=20)
- Intervention: Use of RSL and MOLLI for breast lesion localization

- Primary Outcome: Successful retrieval of MOLLI marker

- Secondary Outcomes:
  - User satisfaction of surgical oncologists, radiologists and pathology staff using 5-point Likert scale questionnaires

![Figure 2: Flowchart representation of the clinical trial protocol.](image)

- Non-palpable breast lesions with lumpectomy using the MOLLI guidance system from August 2018 to January 2019
- Co-localization with magnetic and radioactive markers up to 3 days before lesion excision by a dedicated breast radiologist under ultrasound guidance
- Dedicated intraoperative probes for RSL and MOLLI

Results

- Table 1: Demographic data of enrolled patients. MOLLI marker was successfully removed in all patients. There were no positive margins requiring re-excision.

- Abbreviations: DCIS = Ductal Carcinoma in-Situ, ER = Estrogen Receptor, IDC = Invasive Ductal Carcinoma, PR = Progesterone receptor, E + = Standard Error

![Figure 3: (A) Post implant mammogram of a typical patient enrolled in the trial. Image illustrates the radiographic appearance of the MOLLI marker with respect to an implanted biopsy clip and the radioactive seed. (B) Post implant ultrasound image of the MOLLI marker beside a radioactive marker.](image)

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Clinical Implications / Future Directions

- MOLLI is a feasible, safe, accurate & intuitive alternative for non-palpable breast lesion localization
- Future directions include further validation in centers within and outside of Canada for usability and cost effectiveness.

![Figure 4: Results from the Likert scale satisfaction questionnaires.](image)