# Results of a Phase I, Prospective, Non-randomized Study Evaluating a Magnetic Occult Lesion 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 nonradioactive wireless localization system; Magnetic Occult 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

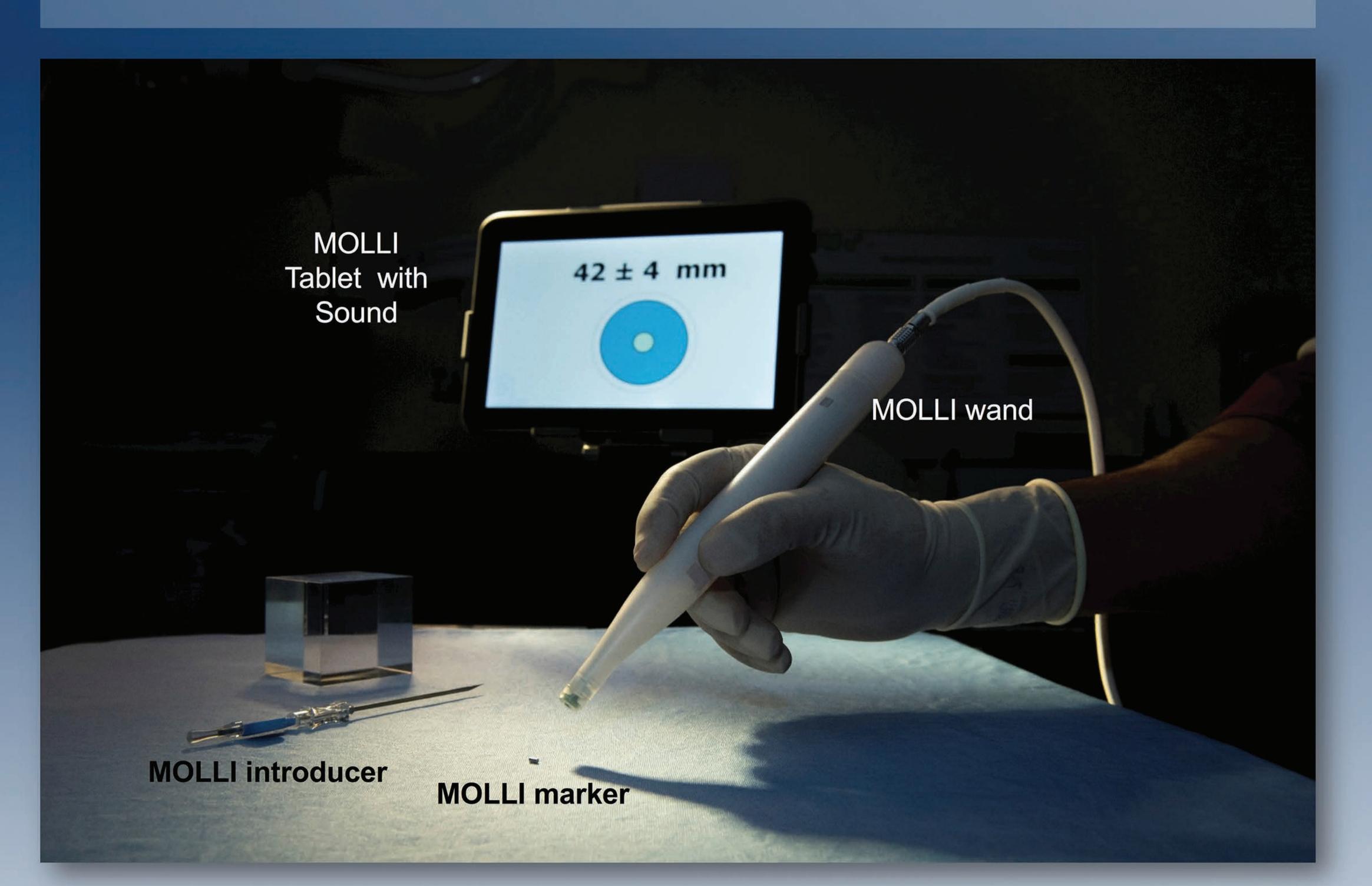


Figure 1: A photograph highlighting the components of the MOLLI system. The MOLLI introducer consists of a pre-loaded 8 & 12 cm needle, designed for single-handed implantation procedures. The MOLLI marker is a 3.2 mm long magnetic marker. The MOLLI wand detects the local magnetic field from the MOLLI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

### 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

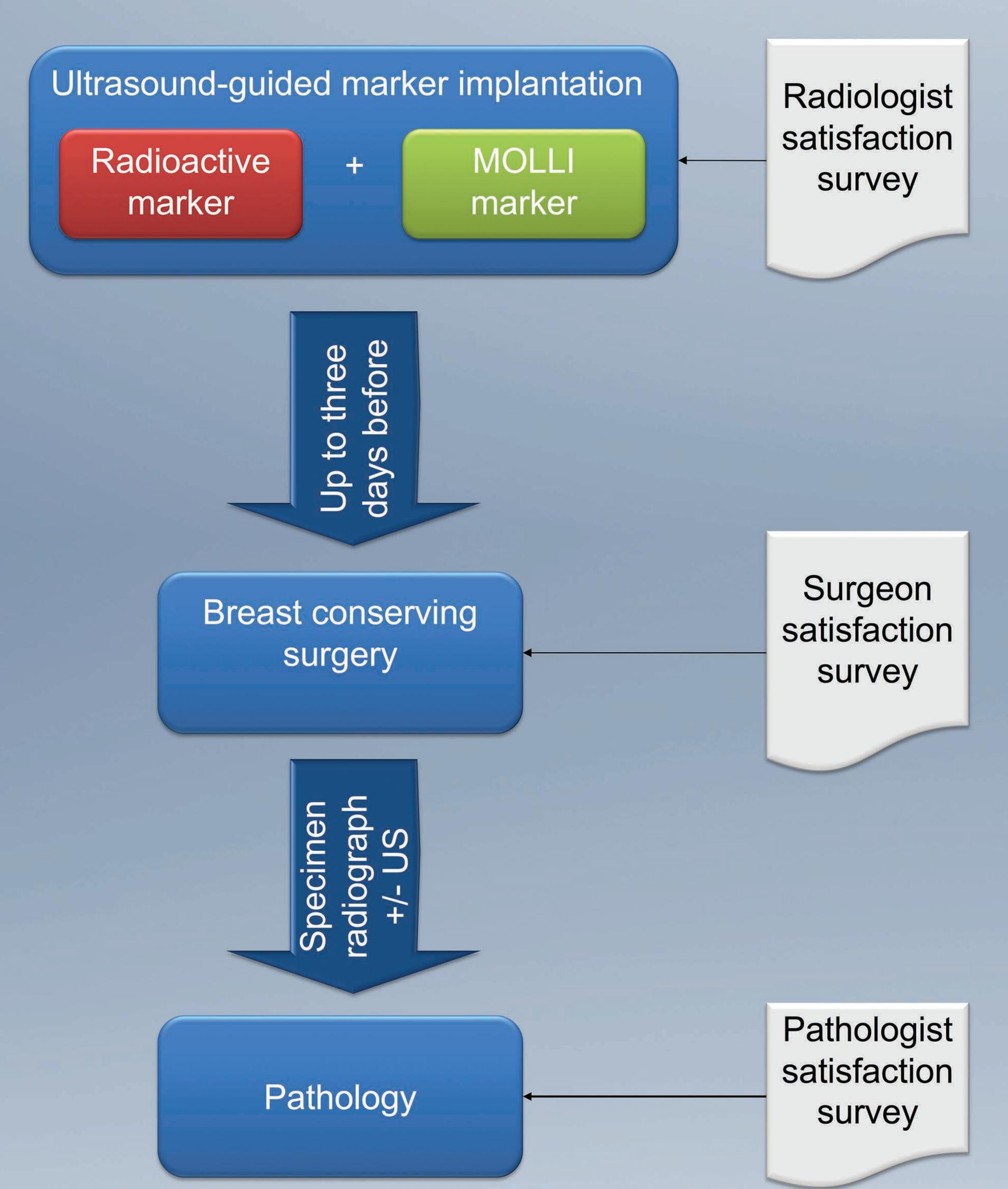


Figure 2: Flowchart representation of the clinical trial protocol

- 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, S.E. = Standard Frror

tandard Error	
N = 20	Mean± S.E.
Age (years)	60.3 ±13.0
Height (m)	$1.6 \pm 0.1$
Weight (kg)	$66.7 \pm 12.6$
Menopausal status	
Pre	6
Post	14
Tumor Type	
DCIS	3
IDC	12
Other	5
Receptor Status	
ER / PR +, HER2 -	10
ER - / PR +, HER2 -	1
ER / PR -, HER2 -	1
Not Applicable	8
Largest Tumor Size	
(mm on imaging)	$15.7 \pm 8.7$
BIRADS category	
5	10
	4.0

N = 20	Mean± S.E.
Tumor Stage	
p2a	4
p2a p1a	8
p0	5
Other	3
Tumor Grade	
3	5
2	8
1 1 1 1 1 1 1 1.	4
Not Evaluated	3
Multifocal Disease	
Yes	1
No	19
Lymph Node	
Metastases	
Yes	3
No	9
Not Evaluated	8
Marker Removal	20
<b>Positive Margins</b>	0

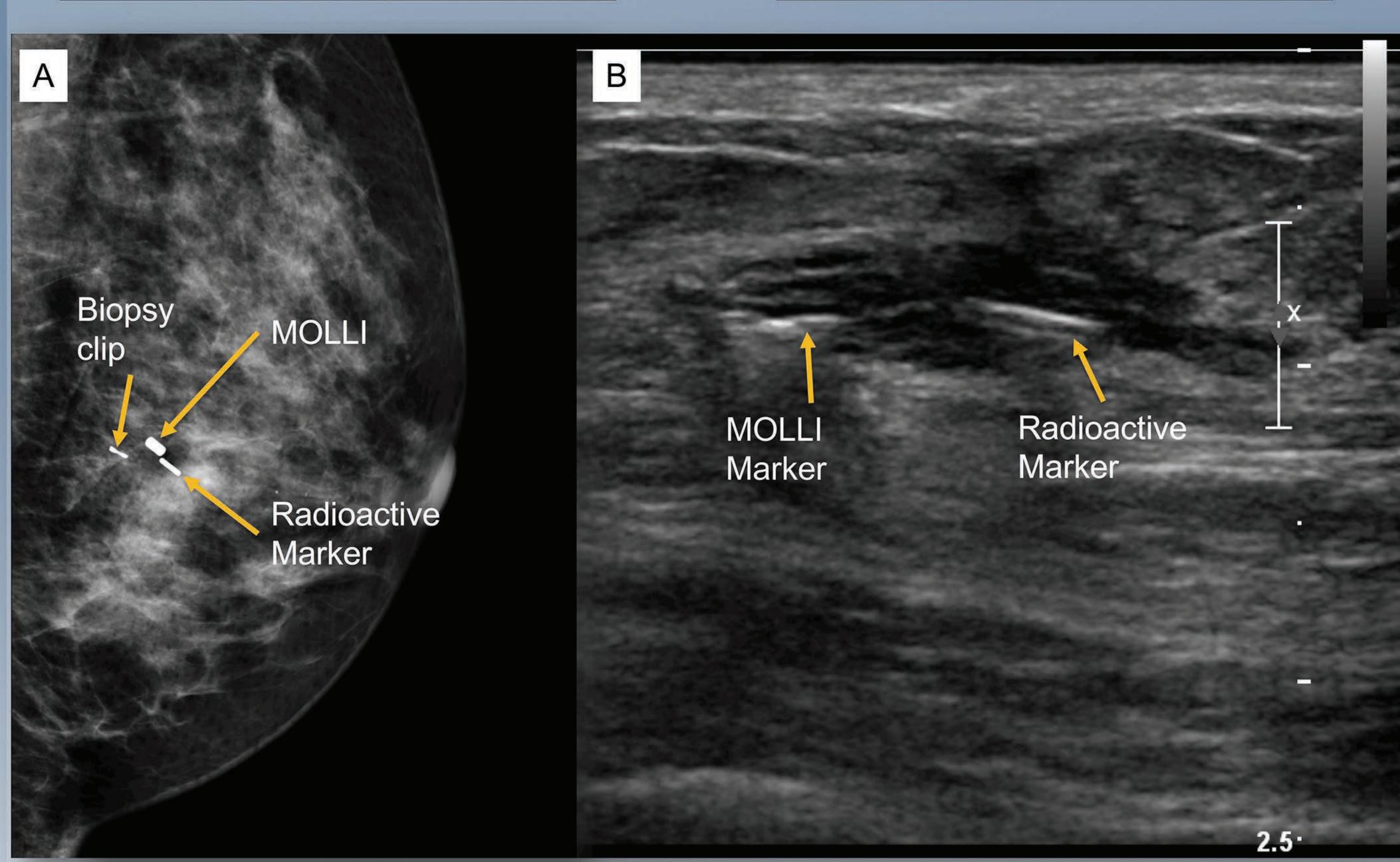


Figure 3: (A) Post implant mammogram of a typical patient enrolled in the trial. Image illustrates the radiographic appearance of the MOLLI marker with respect to an implanted biopsy clip and the radioactive seed. (B) Post implant ultrasound image of the MOLLI marker beside a radioactive marker.

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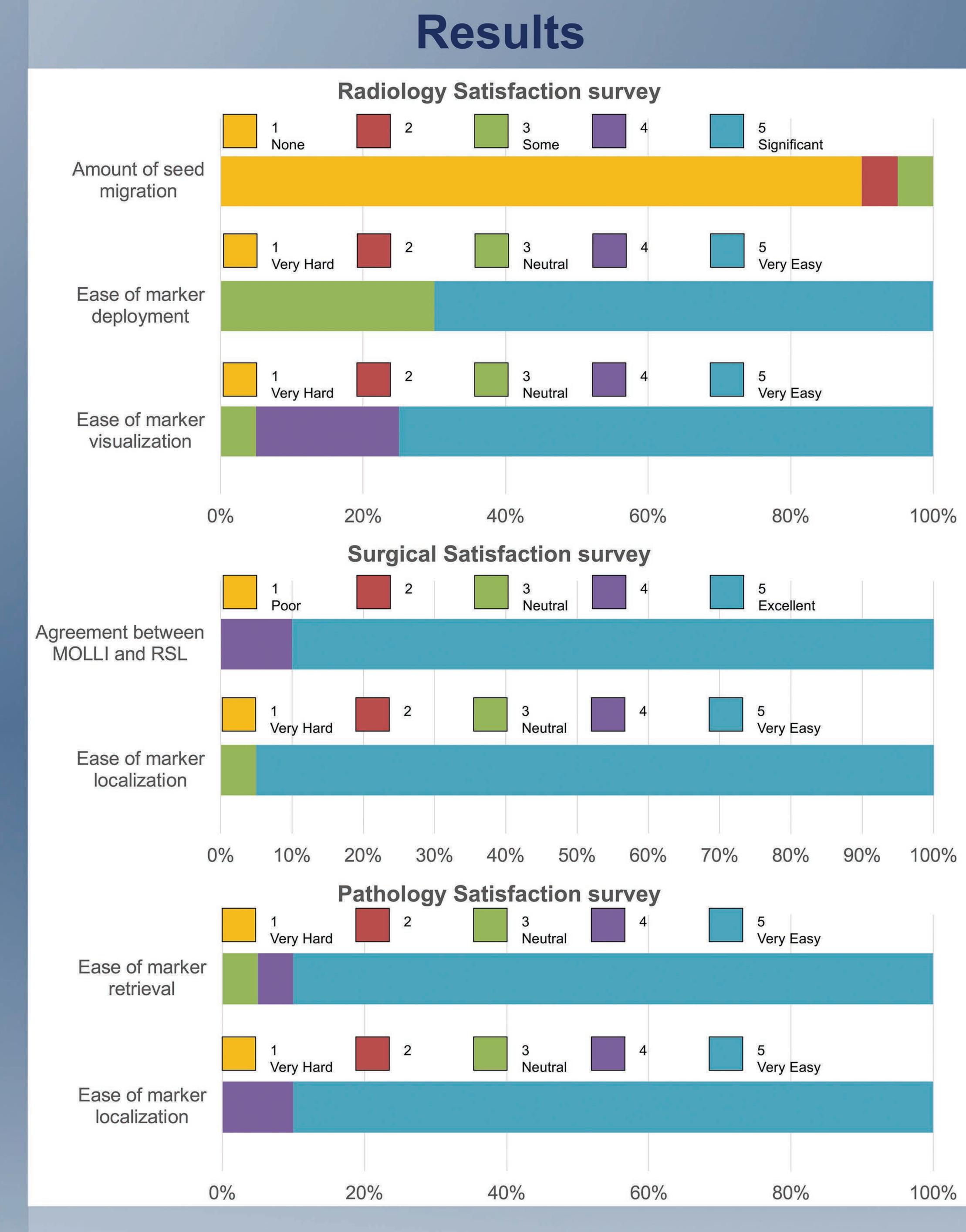


Figure 4: Results from the Likert scale satisfaction questionnaires.

## Clinical Implications / Future Directions

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







