DECEMBER 2, 2024

WHITE PAPER: MOLLI 2

PRECISION SURGERY MADE SIMPLER

SIMON MCNEELY
TWR2009

Executive Summary

The purpose of this paper is to highlight how the MOLLI2 System can improve the process of breast cancer surgery for both patients and physicians. The MOLLI2 system is less invasive and more efficient than other options on the market, and adopting it into common healthcare practice will improve the standards of comfort and safety during the surgical process.

An estimated 30,000 women will be diagnosed with breast cancer in 2024 alone [1]. One third of these cases are nonpalpable, or unable to be felt upon physical examination. Removing the abnormal tissue is difficult in these cases and requires the use of a marker so the surgeon can find the tissue and remove it with minimal error. While alternative forms of breast cancer localization are being introduced to hospitals, Wire Guided Localization continues to be the most common form of localization today [2].

Wire Guided Localization involves the insertion of wires into the breast tissue, where the length of the protruding wires is used to determine the location of the anomalous tissue [2]. This process can be distressing for patients, as the wires may stay in for the entire day of the surgery. Wire Guided Localization has been criticized for the risks involved such as wire migration and patient discomfort [2].

The MOLLI 2 System creates a solution for the drawbacks of Wire Guided Localization by replacing the wires with an implantable magnetic marker the size of a sesame seed. This marker can be placed into the breast tissue up to a month before surgery, allowing for a more flexible schedule for the patient and surgical team [3]. Oncologists can use the MOLLI Re:Markable, a needle fixed with a magnet, to remove the seed in case of misplacement [4]. During surgery, the oncologist will receive directional feedback from the MOLLI2 tablet and use the MOLLI Oncopen to detect the location of the marker [4]. The MOLLI2 Tablet is mounted on an IV pole and the Oncopen is wireless, allowing for a broad range of movement for the oncologist during surgery [3].

Introducing Magnetic Seed Localization with the MOLLI2 System will streamline the process of breast cancer surgery by making it more comfortable for patients, more intuitive for physicians, and creating flexibility in scheduling for both parties.

Contents

Glossary

Breast Cancer Localization is a medical procedure done by a radiologist used to mark anomalous tissue in preparation for breast conserving surgery.

Breast Conserving Surgery is a medical procedure done by a surgical oncologist where only the cancerous tissue and the tissue directly adjacent to it is removed from the breast to conserve as much tissue as possible. This procedure is more typically done on those whose cancer was detected in the early stages.

Excision is the act of removing tissue by cutting out during a surgical operation.

Magnetic seed localization is a form of breast cancer localization in which the radiologist implants a metal seed which emits a magnetic field into the breast at the location of the anomalous tissue. The location of the tissue is detected during the surgery using a handheld magnetic probe.

Nonpalpable Breast Cancer is a classification of breast cancer referring to those which cannot be found during clinical examination of the breast and requires a localization technique for the surgeon to identify the location of the tumour.

Non-aggressive Breast Cancer is a type of breast cancer referring to those which have developed into cancer within the ducts of the breast but have not spread to the lymph nodes or nearby non-breast tissue.

Oncology is a branch of medicine dedicated to the study, treatment, diagnosis, and prevention of cancer. For example, a surgical oncologist focuses on treating cancer through surgery.

Obturator is device which blocks the opening of an instrument (such as a needle) that is being introduced into the body

Radiology is a branch of medicine which uses medical imaging to diagnose diseases and other maladies. For example, a radiologist interprets medical images and communicates these findings to other medical professionals.

Radioactive seed localization is a form of breast cancer localization in which the radiologist implants a seed containing a small amount of radioactive material into the breast at the location of the anomalous tissue. The location of the tissue is detected during the surgery using a radiation detector.

Wire guided localization is a form of breast cancer localization in which the radiologist marks the anomalous tissue using a series of wires. The location of the tissue is detected during surgery using the length of the protruding wires as depth indicators.

1. Introduction

The purpose of this white paper is to demonstrate the value of the MOLLI 2 Surgical System to the evolving fields of radiology and oncology by introducing a safe and intuitive wire-free breast cancer localization system.

Breast cancer can be detected sooner with the development in imaging techniques and screening programs, resulting in more nonpalpable cases than ever [1]. This increase in demand has coincided with the development of more modern techniques of breast cancer localization. Many of these new techniques involve transitioning from wire-guided localization to wire-free options. However, these new techniques come with their own drawbacks as well. For example, one critique of radioactive seed localization points to the complexity of regulations and training required to handle radioactive material [2].

This paper will discuss the currently available options for breast cancer localization, what they do well, and what may be improved upon. Then, it will introduce the MOLLI 2 System and explain how it advances the field of oncology with the Oncopen and the directional feedback from the MOLLI2 Tablet. The conclusion will provide further educational information for physicians and patients interested in learning more about the MOLLI 2 System.

2. Evolution of Breast Cancer Localization

It is most common for patients with non-aggressive breast cancers to undergo breast conservative surgery, where only the necessary tissue is removed and no more [5]. This can be difficult, especially for reducing excision scarring to produce the optimal cosmetic output chosen by the patient. The current options for breast cancer localization provide a variety of obstacles to overcome.

2.1 Wire Guided Localization

Since the 1970s, the most common technique for localization has been through wire-guided localization [4]. The process is done on the same day as surgery and involves the radiologist inserting wires into the breast using a needle [4]. When complete, the end of the wire is exposed, and the surgeon uses the length of the wire to localize the anomalous tissue [4]. There are various risks involved, including patient anxiety, wire dislodgement, and wire migration [2].

Wireless options for breast cancer localizations revolutionized the market, reducing or even eliminating many of the issues that came with wire guided localization. For example, the re-operation rate of wired vs non-wired localization options varied significantly (see figure) [2]. Two popular options for wireless localization include radioactive seed localization and magnetic seed localization.

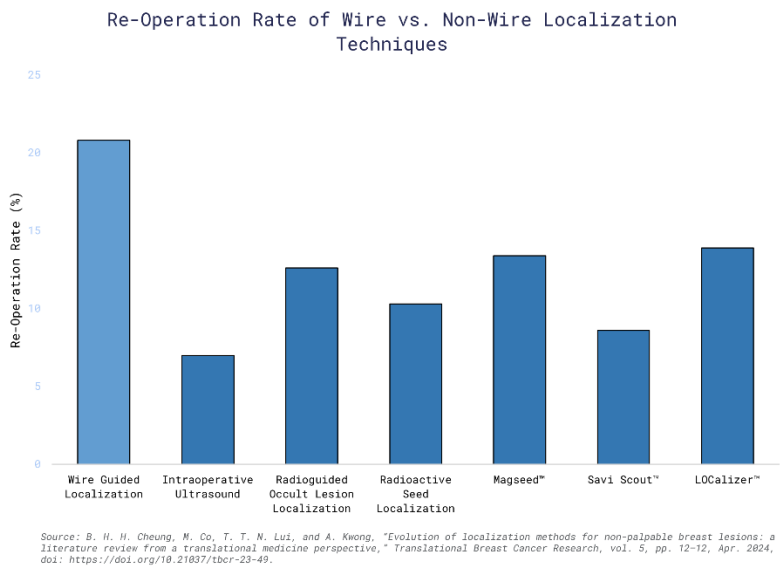

Figure 1: Re-operation rate of a variety of localization techniques.

2.2 Radioactive Seed Localization

One popular form of wireless localization is radioactive seed localization. Radioactive seed localization increased the efficiency of the radiology department at the Ottawa Hospital, with up to nine more procedures performed each day [5]. However, the need for close collaboration between nuclear medicine and surgical departments introduces an obstacle for the implementation of this technique [2]. In addition, the radioactive seed must be implanted five days before surgery [2]. While a five-day window for scheduling improves on same-day wire guided localization, the sensitive nature of radioactive material comes with severe risk. If there is a need to reschedule the surgery for a later date, damage to the seed could release radioactive material [2].

2.3 Magnetic Seed Localization

Other companies have introduced magnetic seed localization onto the market, such as Endomagnetics and their product Magseed. Magnetic Seed Localization improves upon radioactive seed localization by eliminating the complications of using radioactive materials. Magnetic seeds can be implanted up to a month before surgery with little to no long-term risk for the patient [2]. However, the magnetic fields of the seeds cause interference when placed within 20mm of each other. [2]. Nearby operating room equipment is also known to cause signal interference with the Magseed system, therefore requiring non-ferromagnetic surgical instruments for most accurate use [2].

While each of these new technologies improves upon the last, there are complications in each that are left unaccounted for. Ideally, a system for breast cancer localization would:

- Have a simple, easy to understand design
- Eliminate the need for any additional special instruments or procedures
- Allow for flexible scheduling between the appointment with radiology and surgery
- Limit the chances for complications as best as possible

The MOLLI 2 System provides all these features.

3. The MOLLI 2 System

The following section will introduce the MOLLI 2 system, explore the product's history, provide an overview of its hardware, and explain its functionality.

3.1 Definition of the MOLLI 2 System

The Magnetic Occult Lesion Localization Instrument 2 (MOLLI 2), produced by MOLLI Surgical Inc., is a wire-free, radiation-free breast cancer localization system consisting of four pieces of technology: The MOLLI 2 Tablet, the MOLLI Oncopen, the MOLLI Introducer, and the MOLLI Re:Markable. In 2023, MOLLI Surgical revolutionized the magnetic seed localization process by introducing directional feedback to their seed detection tool, the MOLLI 2 tablet [4]. Additionally, MOLLI Surgical introduced the Re:Markable, a tool that allows the radiologist to replace a misplaced marker, something that would have previously been left alone or, if possible, removed during surgery [4].

3.2 Improvements in the Field of Breast Tumour Localization

Magnetic seed localization was introduced in the mid 2010s and adopted by MOLLI Surgical in 2018 [2]. Now, the process of marking the anomalous tissue can be done up to a month before surgery, allowing for more flexibility between doctors and patients [2]. Further, with minimal scarring and lower risk of displacement, issues of patient anxiety significantly reduce when opting for magnetic seed localization [2].

The MOLLI 2 System improves upon the limitations of its competitors by expanding upon the possibilities of previously used localization techniques. Other forms of seed detection could only produce reliable results at depths around 30-40mm [3] whereas the MOLLI seed can be detected in tissue at distances up to 53mm with little to no signal degradation [3]. Further, the MOLLI Oncopen and marker do not experience significant signal interference, whether it be between another marker or with the metal equipment in the operating room.

3.3 Physical Description of the MOLLI 2 System

This section will describe the parts of the MOLLI 2 System (See Figure 2), it consists of five parts: (1) The MOLLI 2 Tablet, (2) the Oncopen, (3) the marker, (4) the Introducer, and (5) the Re:markable.

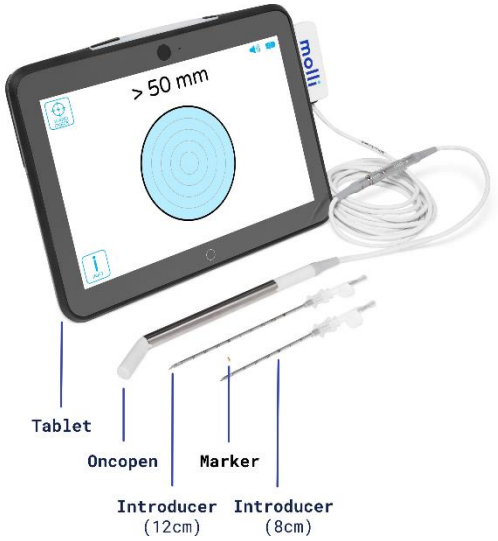

Figure 2: The MOLLI 2 System

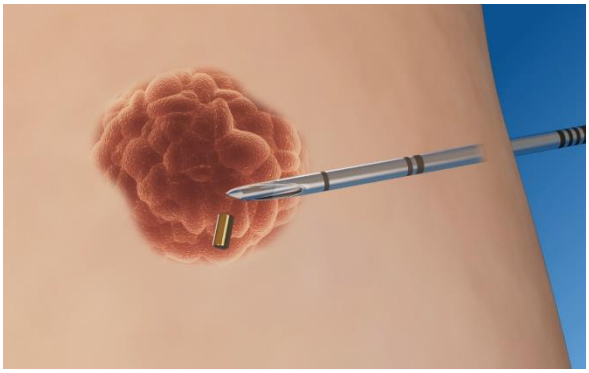

Figure 3: The Re:markable retrieving a misplaced marker

Marker: The MOLLI marker is implanted into the breast tissue to mark the location of the anomalous tissue. The marker is a neodymium magnet and is 1.6mm x 3.2mm in size, or about the size of a sesame seed [3].

Introducer: The Introducer is a needle which comes pre-loaded with the MOLLI marker and is used by the radiologist to implant the marker into the breast tissue. The 14-gauge (1.6mm interior diameter) Introducer needle has two sizes, 8cm or 12cm in length. The Introducer has 1cm depth indicators to ensure accurate placement of the seed. The Introducer needle is vented to prevent a vacuum effect from occurring upon retraction of the needle [3].

Re:markable: The Re:markable is the newest tool added to the MOLLI system. It is near identical to that of the Introducer, but instead of being pre-loaded with a marker, the Re:markable is fitted with a magnetic obturator which attracts the marker and removes it from the tissue (see Figure 3) [4].

Tablet: The MOLLI 2 tablet is used to provide directional feedback so the surgeon can locate the marker during surgery. To avoid clutter and to provide a good field of view for the surgeon, the tablet is fixed to an IV pole during surgery [4].

Oncopen: The Oncopen is a 9mm wide magnetic probe used to detect the magnetic seed. Its angled tip allows for a good field of view so the surgeon can make more precise incisions [6].

3.4 How the MOLLI 2 System Works

The process of using the MOLLI System involves two steps: (1) The implantation of the marker by the radiologist and (2) the detection of the marker by the oncologist to locate the anomalous tissue.

3.4.1 Implantation of the Marker

Before surgery, a radiologist is responsible for locating the patient's anomalous tissue. To mark the location of the anomalous tissue, the radiologist uses the MOLLI Introducer to implant the MOLLI marker into the breast tissue. In the rare occasion of seed displacement, the surgeon can use the MOLLI Re:Markable to easily remove the displaced marker and replace it with another.

Figure 2: Oncopen detecting the marker with directional feedback showing on the screen of the MOLLI 2 tablet

3.4.2 Detection of the Marker

On the day of surgery, the oncologist will use the Oncopen and MOLLI 2 tablet (see Figure 3) to locate the magnetic seed marker and the anomalous tissue. The tip of the Oncopen detects the location and distance of the marker, then sends directional feedback over to the tablet. This feedback will show on the screen and send auditory output, allowing for the surgeon to accurately pinpoint the location of the marker.

4. Benefits of Using the MOLLI 2 System

MOLLI Surgical introduces efficiency, safety, and comfort into breast cancer localization treatment through the variety of cutting-edge features within the MOLLI 2 System (Table 1).

Feature	Benefit
The MOLLI 2 tablet is mountable to an IV pole and has real-time distance, visual, auditory, and 3D directional feedback.	Allows **good line of sight** and gives detailed information via the simple UI to **minimize cognitive load**, giving the surgeon greater precision [4].
The Oncopen has an ergonomic design, with a 9mm profile and a 30° angled tip [6].	Provides a pen-like feel and an **unobstructed visual field** for greater surgical precision [6].
Re:markable allows the removal of the magnetic localization marker [4].	Minimizes **discomfort for patients** and **removes need for invasive surgery** in the case of marker displacement [4].
The MOLLI 2 System is robust, relatively strong against signal interference.	Markers can be placed up to **10mm apart** without interference and their **signals are unaffected by standard metal instruments** and electrocautery [3].
The marker can be implemented up to 30 days before surgery [4].	Allows greater **flexibility for scheduling** between doctors and patients.

5. Conclusion

MOLLI Surgical's mission is to save and improve lives with cutting-edge technology. In 2024, MOLLI Surgical received INOVAIT's Mount Logan award for reaching new heights as a Canadian company and treating patients across 170 hospitals throughout North America. The company is revolutionizing the medical field through its advancements in surgical technology, producing better outcomes for patients and physicians alike.

Physicians can find further information, including clinical studies and imaging, on the MOLLI Surgical website at: http://mollisurgical.com/healthcare-professionals/

Patients can find the H.O.P.E. (Help-Optimism-Positivity-Empowerment) collection on the MOLLI Surgical website for further information and resources at: http://mollisurgical.com/hope/.

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Visuals

http://mollisurgical.com/molli-surgical-press-kit-2024/