Surgeon Feedback from a Simulated Surgical Lab Comparing Three Wire-Free Localization Systems for Breast Lesion Removal

Introduction

Breast-conserving surgery (BCS), also known as lumpectomy, has become the preferred surgical approach for early-stage breast cancer due to its ability to preserve breast tissue while achieving oncologic outcomes equivalent to mastectomy when combined with adjuvant radiation therapy.[1,2] The proportion of patients undergoing BCS has steadily increased over the past decades, driven by advancements in preoperative imaging, tumor localization, and surgical techniques.[3,4]

With the increasing detection of nonpalpable breast lesions due to improved imaging and screening practices, the need for reliable, precise lesion localization systems has become paramount in breast-conserving surgery (BCS). Traditional techniques, such as wire-guided localization (WGL) and radioactive seed localization (RSL), are being steadily replaced by newer wire-free technologies designed to overcome long-standing limitations in workflow, patient comfort, and intraoperative precision.[3,5] WGL involves percutaneous placement of a wire under imaging guidance, typically on the day of surgery, but poses challenges such as wire migration, patient discomfort, and scheduling constraints.[2,3,6] RSL, involves implanting an iodine-125 seed preoperatively, allows for greater scheduling flexibility and precise localization but introduces radiation exposure, regulatory complexities, and disposal challenges.[3,6]

To overcome these limitations of WGL and RSL, wire-free and radiation-free localization systems have been developed. These novel localization technologies offer the potential to improve intraoperative efficiency, patient experience, and scheduling flexibility.[3]

To evaluate these wire-free localization systems under controlled and reproducible conditions, sa simulated surgical lab study was executed comparing three leading technologies: the MOLLI® 2 System (Stryker), Scout® Radar Localization (Merit Medical), and Sentimag® with Magseed® (Endomag/Hologic). This study was designed to assess surgeon preferences, device usability and procedural efficiency of each device in a high-fidelity, soft-tissue surgical model using a raw chicken breast to mimic human tissue.

Study Design and Methodology

A simulated lab was executed by the Sponsor, Stryker Endoscopy, at the Center for Advanced Medical Learning and Simulation (CAMLS) in Tampa, Florida. Surgeons were asked to localize and excise a target marker embedded in a raw chicken breast using three wire-free localization systems.

- MOLLI® 2 System (Stryker): Magnetic localization with real-time distance feedback
- Scout® Radar Localization (Merit Medical): Electromagnetic reflector detected via radar guidance
- Sentimag® with Magseed® (Endomag/Hologic): Magnetic seed with handheld detection probe

Surgeons rotated through all three device stations, completing standardized surgical tasks in accordance with the study protocol for each device. The study protocol was reviewed and approved by the Institutional Animal Care and Use Committee prior to execution of the simulated lab. All participants voluntarily agreed to participate and signed a study-specific release form, consistent with study protocol requirements for non-interventional simulation studies.

The study aimed to collect both qualitative and quantitative feedback regarding the usability, localization performance, and surgeon preference. Each task was timed for marker localization and retrieval, and surgeons completed a structured questionnaire after all simulated tasks were completed. Surgeons were instructed to assume a lesion size of 12 mm for purposes of planning their excision margins. Raw chicken breast was selected as the tissue model due to its similarity to human soft tissue in terms of resistance and tactile feedback, enabling realistic simulation of excision technique.[7]

Primary evaluation metrics included:

- Localization time – time to identify the marker using the probe
- Retrieval time – time to excise the tissue containing the marker
- Usability and feedback rating – including audio/visual response, device interface, and surgeon confidence in device performance.

To reduce bias, surgeons were assigned to one of three groups which randomly assigned wire-free localization system order. All surgeons received standardized training before beginning

the evaluation to ensure consistency in device familiarity. Data were captured using paper-based case report forms (CRFs), which served as the source documents for subsequent electronic data entry and analysis.

Devices Evaluated

Each wire-free localization system has distinct technological characteristics, user interfaces, and feedback mechanisms.

MOLLI® 2 System (Stryker)

The MOLLI® 2 System is a magnetic, wire-free, and radiation-free soft tissue localization platform. It consists of a small ferromagnetic marker and a handheld probe that is designed to provide real-time distance-based feedback, enabling accurate lesion localization without wires or radiation exposure.[2,3,8] The system is designed to detect the implanted marker at distances of up to 45 mm, with accuracy maintained across a range of surgical working depths. The marker is MR-conditional and designed for long-term implantation, offering flexibility in surgical scheduling and workflow integration. The system includes the following components: MOLLI Introducer, MOLLI Marker, MOLLI OncoPen and MOLLI 2 Tablet.

Figure 1. MOLLI® 2 System Components

Scout® Radar Localization (Merit Medical)

The Scout® Radar Localization System is a wire-free, electromagnetic localization platform that employs radar technology to detect a reflector implanted into the lesion. A console emits radar signals that are received and processed by a handheld surgical probe, which provides real-time depth measurements and spatial orientation guidance. The system includes the following components: Reflector, Console & Probe

Sentimag® with Magseed® (Endomag/Hologic)

The Sentimag® system is a magnetic seed localization solution designed to replace wire-guided and radioactive seed localization. It uses a paramagnetic Magseed marker and a Sentimag® handheld detection probe.[6,9] Sentimag® supports marker detection up to 30 mm and is commonly used as a radiation-free alternative to RSL. The system includes the following components: Magseed® and Sentimag® Probe.

Results

A total of 13 surgeons participated in the simulated lab and provided feedback on device usability. The participants included 9 breast surgeons, 2 oncoplastic surgeons, 1 plastic surgeon, and 1 surgical oncologist. None of the participating surgeons were consultants of the Sponsor. Each surgeon performed marker localization and retrieval procedures on raw chicken. The time taken for each task was recorded using a stopwatch. Following completion of the procedures, surgeons independently completed a questionnaire evaluating the ease of use, proficiency of localization, and confidence in device performance using each system.

All 13 surgeons had prior experience with at least one of the wireless localization systems. The median duration of marker localization was 18 seconds while the median duration of marker retrieval was 114 seconds.

Evaluation of Markers Localization Ease of Use

The MOLLI® system demonstrated the highest ease of use for marker localization among the three evaluated systems (Figure-2), with 84.6% of surgeons rating it “Very Easy,” while only 7.7% rated it as “Easy” and another 7.7% as “Neutral.” Notably, no surgeons rated MOLLI as “Difficult” or “Very Difficult.”

Scout® Radar received more varied feedback. While 38.5% of surgeons found it “Very Easy” to use, 30.8% rated it “Easy”, and 15.4% “Neutral”. A small percentage, 7.7% each, rated it “Difficult” or “Very Difficult.”

Sentimag® yielded the least favorable responses. Only 23.1% of surgeons rated it “Very Easy,” while 30.8% rated it “Easy.” However, a notable portion of responses were neutral or difficult, with 15.4% each choosing “Neutral,” “Difficult,” and “Very Difficult,”

Overall, MOLLI was perceived as the most user-friendly system for marker localization, based on surgeon-reported experiences.

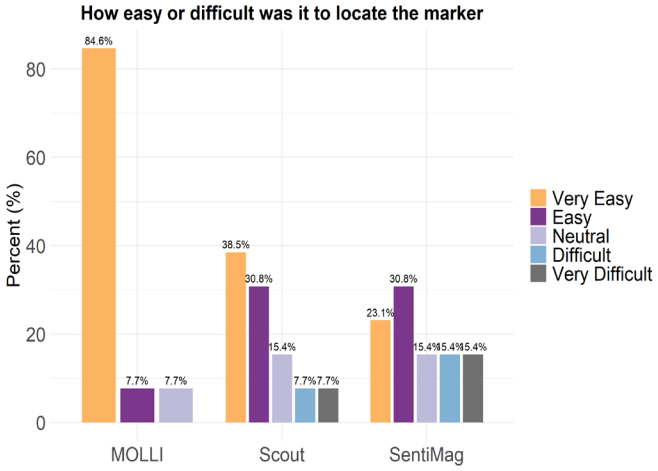

Figure 2. Ease of use for Marker Localization

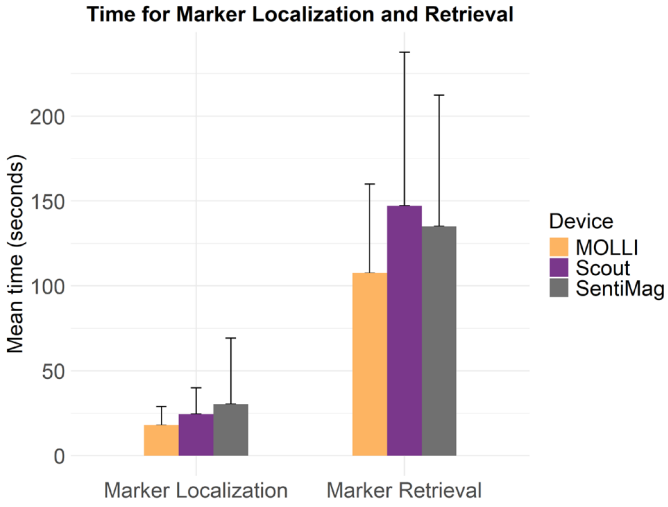

Figure 3. Time for Marker Localization and Retrieval

Evaluation of Marker Localization and Retrieval Time

The mean time taken for marker localization and retrieval was assessed across three devices: MOLLI®, Scout® Radar, and Sentimag®. (Figure- 3) MOLLI® demonstrated the shortest mean times for both tasks, with 17.9 seconds for localization and 107.5 seconds for retrieval. Scout® Radar required around 24.4 seconds for localization and 147.2 seconds for retrieval, while Sentimag® had the longest times, with approximately 30.3 seconds for localization and 135 seconds for retrieval.

All 13 participating surgeons (100%) were able to successfully localize and retrieve the marker using the MOLLI® system, demonstrating equivalent performance to Scout® Radar and superior performance to Sentimag®, which achieved a 92.3% success rate (12 of 13). Notably, MOLLI® demonstrated high technical reliability, with no reported issues such as equipment failure, signal interference, or marker deactivation in 92.3% of cases (12 of 13). In comparison, Scout® Radar had a lower rate of technical reliability rate of 84.6% (11 of 13), while Sentimag® demonstrated the lowest rate of technical reliability with only 38.5% (5 of 13) of procedures completed without incident.

Post-Surgical Task Surgeon Questionnaire

Following the completion of simulated surgical tasks as described above, surgeons completed a post-procedure questionnaire evaluating key usability and feedback areas for each system such as audio and visual feedback, ergonomics, ease of use, and overall user experience. Ergonomics was defined as the overall comfort and usability of the probe during handling, the positioning of the console to minimize physical strain, and the intuitiveness of system feedback to reduce cognitive load during the procedure.

Among the three devices, MOLLI® consistently received the highest ratings across all categories (Figure- 4). Specifically, 83.3% of surgeons rated MOLLI's visual feedback as their preferred, compared to only 8.3% for both Scout® Radar and Sentimag®. MOLLI® also received the highest ratings for overall user experience (66.7%), ease of use (66.7%), and ergonomics (66.7%), while Scout® Radar followed with 33.3% across these areas and Sentimag® was rated at 8.3%. In terms of audio feedback, MOLLI® was rated favorably by 58.3% of users, versus 33.3% for Scout® Radar and 8.3% for Sentimag®.

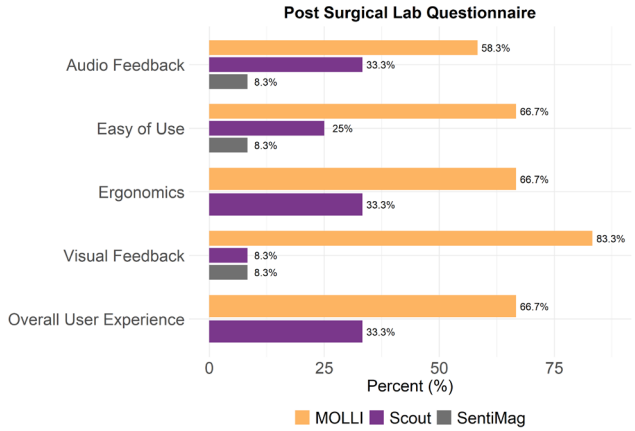

Figure 4. Post Surgical Surgeon Feedback

General Feedback

The surgeons were asked to share their subjective opinions regarding the main benefits and limitations of the system. The most commonly reported benefits of the MOLLI System centered around the compact size and ergonomic design of the OncoPen probe, which contributed to greater ease of use during procedures. Surgeons frequently valued the system's clear and intuitive visual feedback, describing it as "excellent" and particularly helpful for precise localization. They also highlighted the lightweight feel of the probe, commenting on how comfortable it was to handle. Additional positive feedback included the direct, focused localization (as opposed to circumferential detection), and the distinct, high-quality audio cues, with few surgeons referring to it as the "best sound" among systems evaluated.

Overall, surgeon satisfaction with the MOLLI system was very positive. A total of 92.3% of surgeons reported they are likely to consider implementing the MOLLI localization system into their clinical practice. The MOLLI System was perceived as user-friendly, efficient, and supportive of accurate surgical performance.

In contrast to the reported benefits, fewer surgeons noted drawbacks. A concern raised by a few surgeons involved interactions between the magnetic components of the system and metal surgical instruments, which in some instances led to unintentional probe adherence.

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