Dual-Use Breast Biopsy Marker and Preoperative Localization Marker

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Background

- The most common cancer in the United States is breast cancer.
  - Estimated number of new cases in 2024 is 313,510
  - Estimated number of deaths in 2024 is 42,250
- 180,000 patients/year undergo breast-conserving surgery (BCS)
- Current protocol for BCS involves 3 separate invasive procedures:
  (1) Tissue biopsy with placement of a biopsy site marker
  (2) Placement of a second preoperative localization marker which is used to target the lesion in the operating room
  (3) Breast-conserving surgery procedure (*viz.* "lumpectomy")
- Some currently used localization methods prioritize economy and ease of use for the physicians over patient safety and comfort.
  - Wire localization is less accurate and very uncomfortable.
- **A dual site marker/localization device placed at the time of biopsy eliminates an entire procedure, benefiting all parties.**

Mission Statement

Our team seeks to innovate and deliver advanced solutions in the field of breast localization, addressing the pressing issues faced by patients and healthcare providers. Our mission is to develop a more cost-efficient solution for breast localization that also improves patient quality of life.

Final Product Specifications

Material & Biocompatibility - Silicone Encapsulation

- Chosen to limit migration and ensure biocompatibility, minimizing risk of allergic reaction and permitting long-term placement.
- Imaging Compatibility: Testing done with a 6 x 1.5 mm silicone blank inserted into a 5% w:v porcine gelatin to ensure tag has good mammographic and sonographic visibility.

RSSI-Based Distance Estimation:

- The RFID reader utilizes received signal strength indicator (RSSI) and path loss values to estimate tag distance, providing real-time feedback to surgeons for improved precision.

RFID Tag Specifications

- Frequency: Operates at 13.56 MHz, optimized for deep tissue penetration while minimizing external tissue interference.
- Size: Increased to ~2.8 cm to improve signal strength, enhance detection reliability, and ensure durability.

RFID Reader Performance

- Read Range: Accurate to within <3 mm at 6 cm, enabling precise and non-invasive localization at clinically relevant depths.

Final Technical Model and Prototype

Figure 1. Final Design of Mold for Silicone Blank.

Current conceptual design of silicone tag with dimensions of 6 x 1.5 mm.

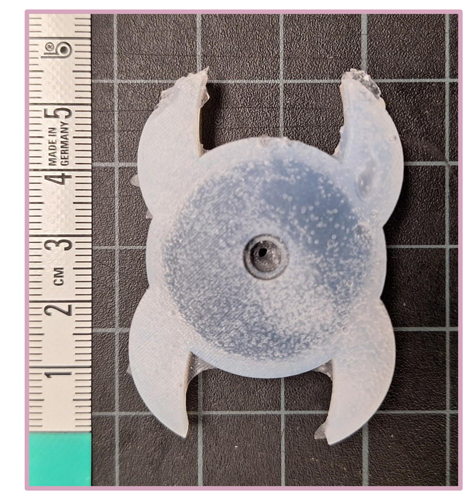

Figure 2. RFID Tag Encased in Silicone.

This is the tag used for testing RSSI values to derive read distance.

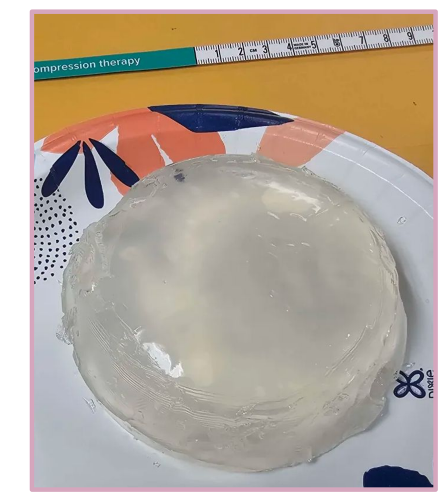

Figure 3. Ultrasound Phantom.

Used to simulate breast tissue for read distance and imaging verification.

RSSI Accuracy Verification Results

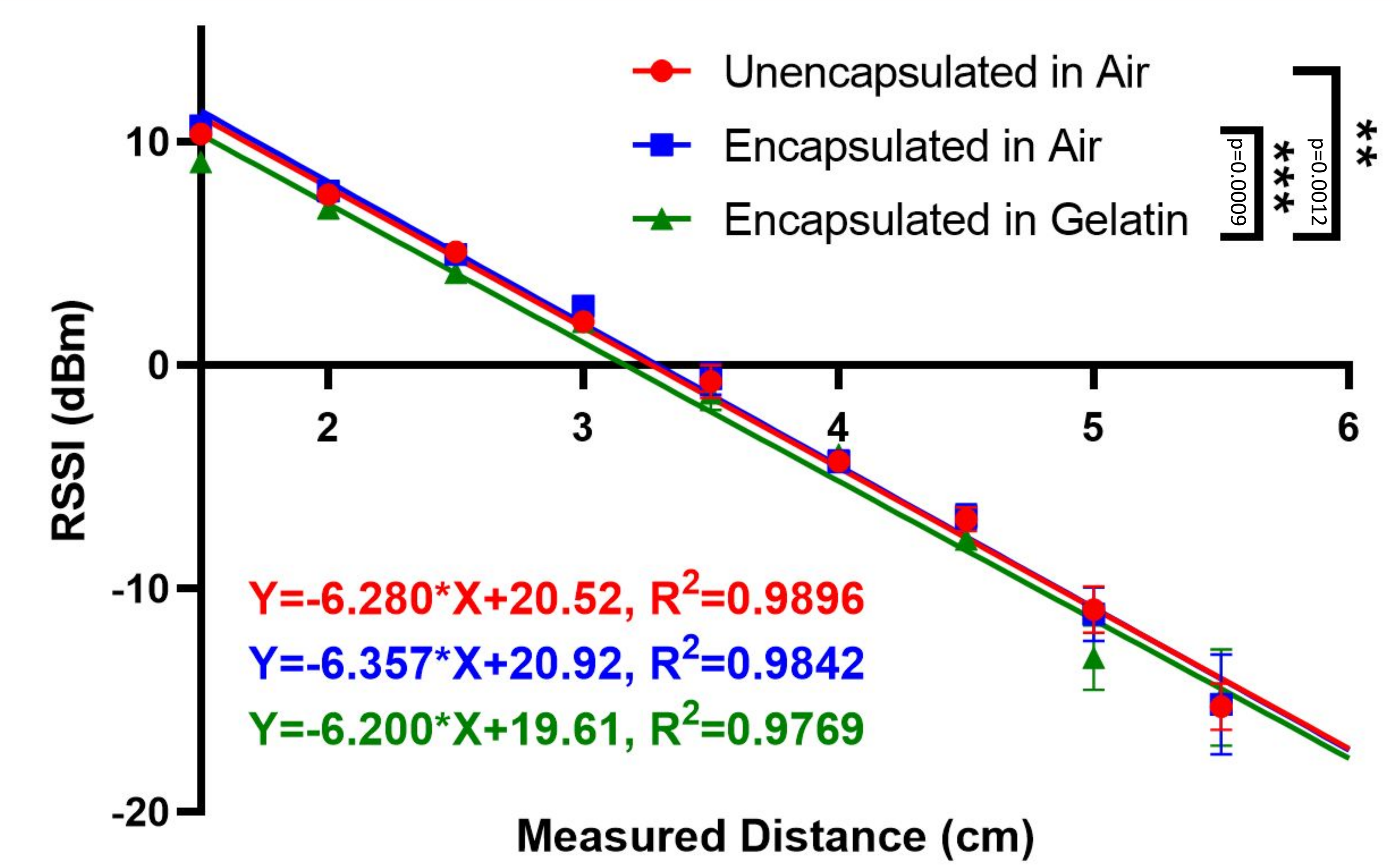

Figure 4. Silicone Encapsulated and Non-encapsulated RFID Tag Distance Verification in Air and Ultrasound Phantom.

Tag could be detected up to 7 cm from reader in both air tests with only 0.5 cm lost read distance in an ultrasound phantom. Models were optimized with linear regression and removal of noise at read ranges from 1.5 cm to 5.5 cm. Average relative spatial error in non-encapsulated RFID in air, encapsulated in air, and encapsulated in phantom validation was 3.00%, 3.14%, and 4.77%, respectively. In a phantom, this amounts to 2.38 mm average spatial error at a 5 cm depth.

Figure 5. Read Distance Testing in Air and in Ultrasound Phantom.

Non-encapsulated RFID in air *(left)*, silicone encapsulated RFID in air *(middle)*, and silicone encapsulated RFID tag in ultrasound phantom *(right)*.

Imaging Verification Results

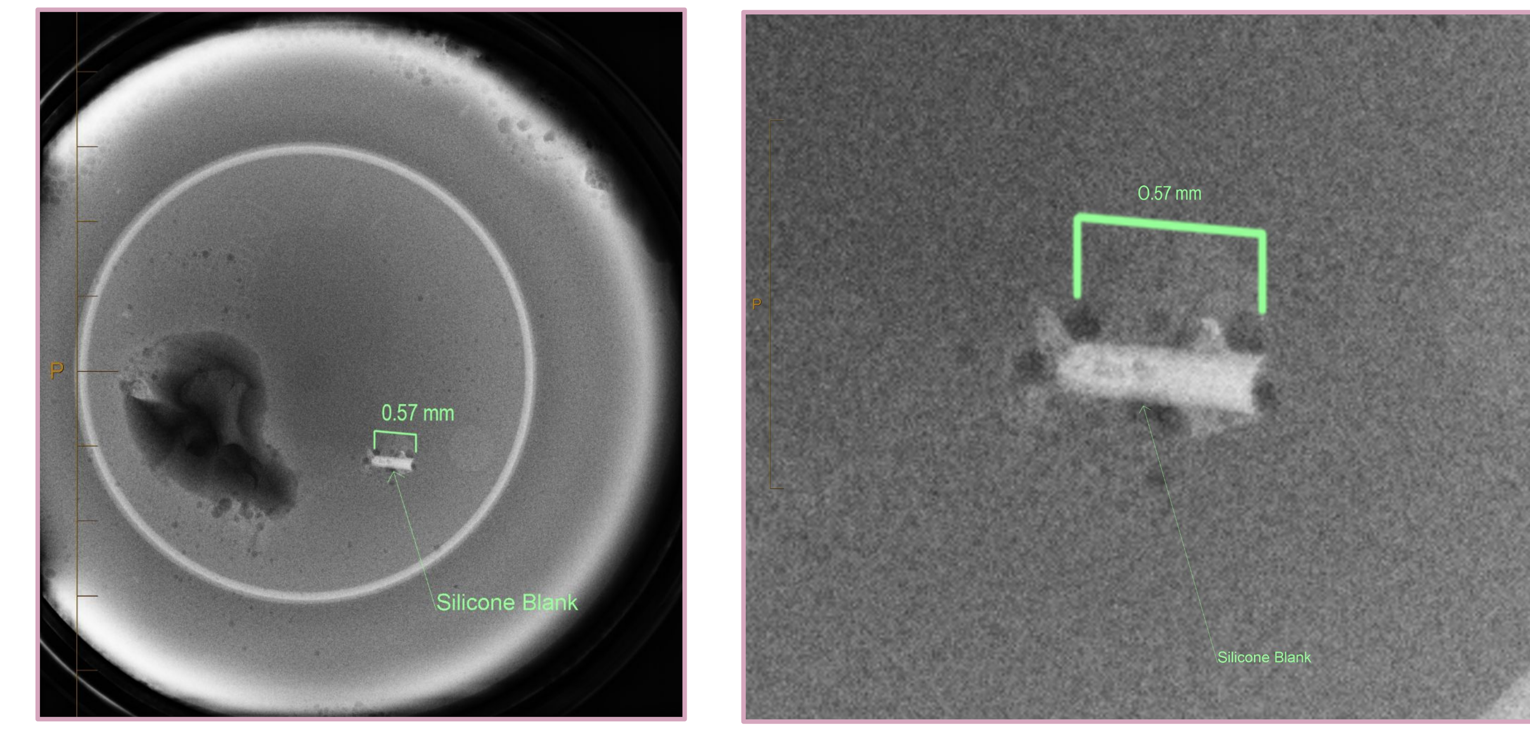

Figure 6. Mammogram of Silicone Blank in Gelatin Phantom Simulating Extremely Dense Breast Tissue.

Like traditional metallic biopsy clips, the silicone substrate achieves excellent visual contrast and high edge definition in all soft tissue densities, which is expected to facilitate reliable mammographic discrimination between different shapes. Image acquired at 31 kVp, 180 mAs on Hologic Selenia Dimensions platform.

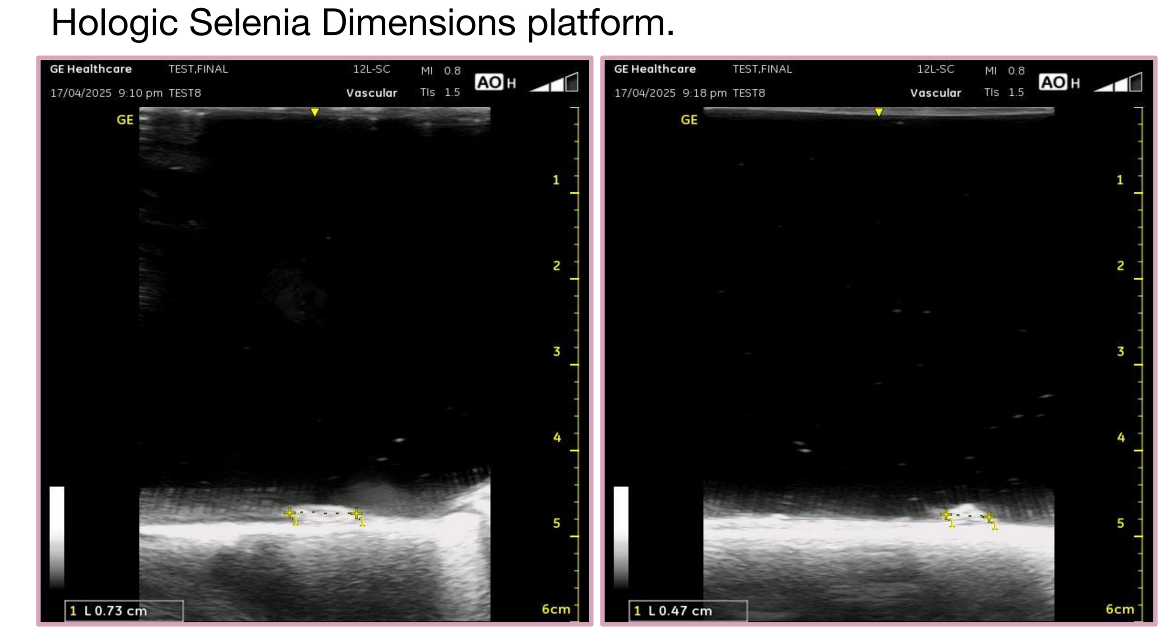

Figure 7. Sonogram of Silicone Blank in Gelatin Phantom at 5 cm Depth.

A silicone blank was assessed for sonographic visibility in a gelatin phantom simulating extremely dense breast tissue at 5 cm in longitudinal *(left)* and transverse *(right)* planes.

Design Status and Future Work

- Develop specialized version of RFID tag with target dimensions of <6 x <1.5 mm that can produce similar accuracy and read distances and is compatible with a 14G applicator for placement.
- Expecting Medical Device Class II designation due to indication for long-term implantation.
- Funding through grants and investment necessary to conduct further testing, demonstrate safety and efficacy for FDA approval.
- If our smaller version tag works, we expect to pass FDA approval since similar predicate devices have passed.
- Once passed we will focus on manufacturing, shipping logistics, and post-market surveillance.

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References