

Abstract

Breast cancer is the leading cause of cancer death in women [1]. The most common method for combating this disease is a lumpectomy or local tumor removal [2]. This surgery is prefaced by an x-ray imaging procedure in which the tumor is localized using a needle and a wire. The procedure is mostly manual, depending heavily on the radiologists' skill levels to get the necessary orthogonal puncture. Most radiologists require repeated corrections and imaging to secure the needle in the correct location, exposing patients to radiation and sources of secondary malignancies. Our proposed design aims to improve the accuracy, efficiency, and safety of this procedure by ensuring smooth, guided, perpendicular puncture on the first try.

Motivation

- Enhance efficiency and accuracy of localization procedure
- Lower patient radiation exposure
- Standardize localization procedure

Background

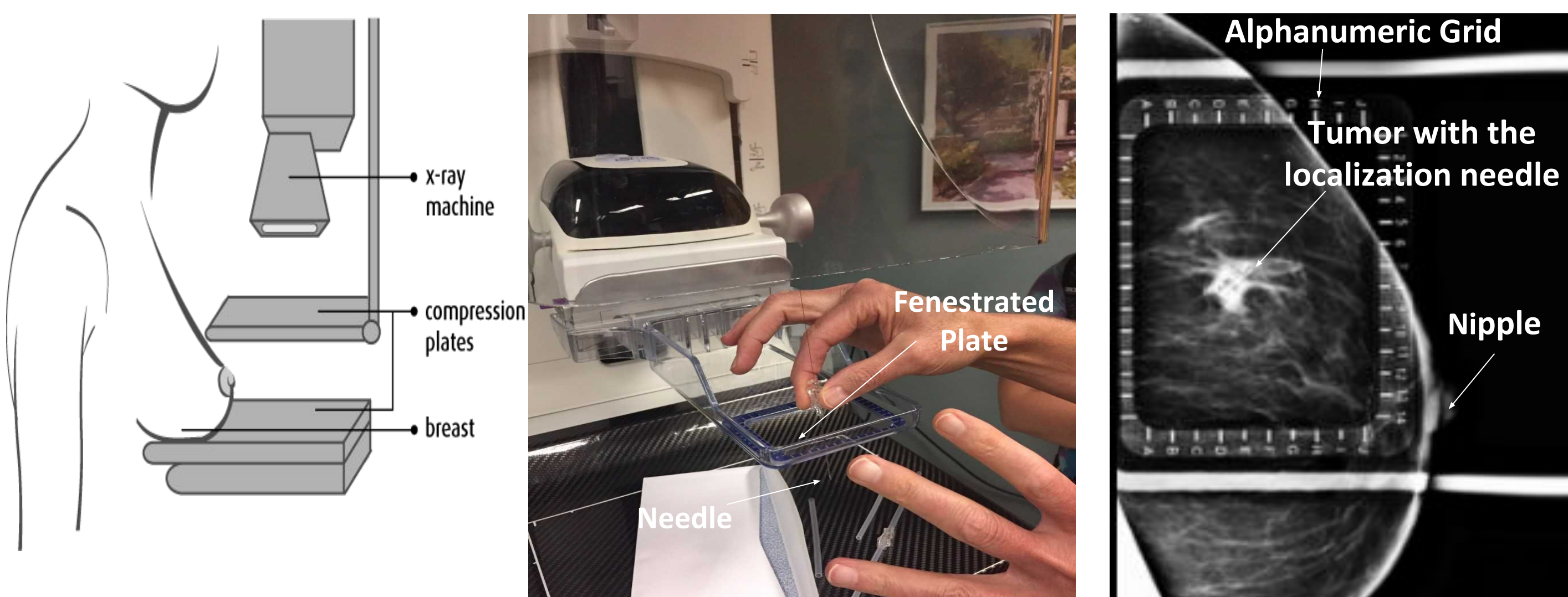


Figure 1. Hologic Mammography machine showing the set-up for imaging [3].

Figure 2. Needle insertion through fenestrated plate. The X-ray beam and light are directly above.

Figure 3. Mammogram image of needle-wire localization placed through the tumor.

Current Method for Tumor Localization: (1) An initial image is taken with alpha-numeric plate to localize the lesion within the breast, (2) a light is projected in the same direction of the x-ray beam, (3) the shadow of the needle hub assists the needle insertion, (4) the breast is imaged, after needle placement, in the orthogonal plane to ensure perpendicularity and to correct for errors in depth as needed, and finally (5) once satisfied, the needle is removed, leaving the wire in the breast to guide the surgical excision.

Design Specifications

- Perpendicular puncture
- Safe for patients and physicians (i.e. sterile)
- Radio translucent or removable
- Ease of integration in clinics
- Inexpensive
- Decrease number of images necessary in procedure

Final Design

Ring Design: 3D printed

- Hinges for stability under Z-axis pressure
- Cone for assisting with mark localization
- Countersink for accommodating the needle

Perpendicularity: Utilizes lips of the plate to allow for ergonomic positioning and movement of the device while also ensuring accuracy.

Cost per assembly: \$7.80 Tough Resin

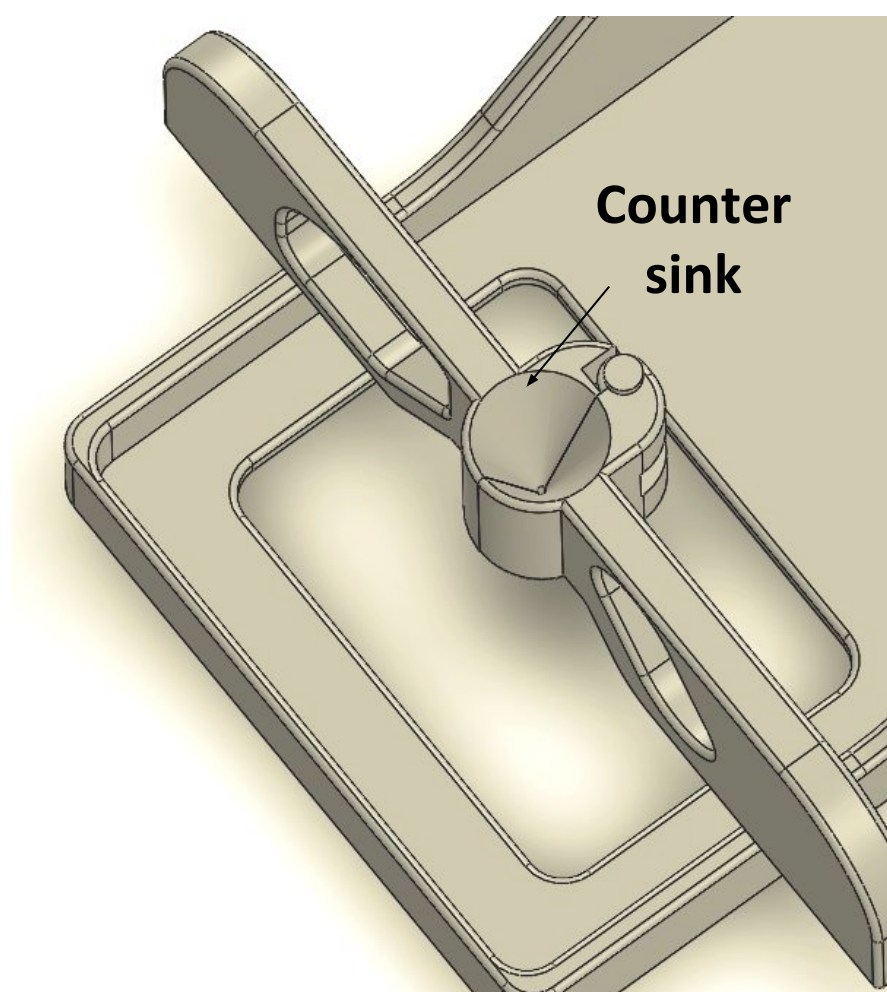


Figure 4. Top-diagonal view of needle guide model.

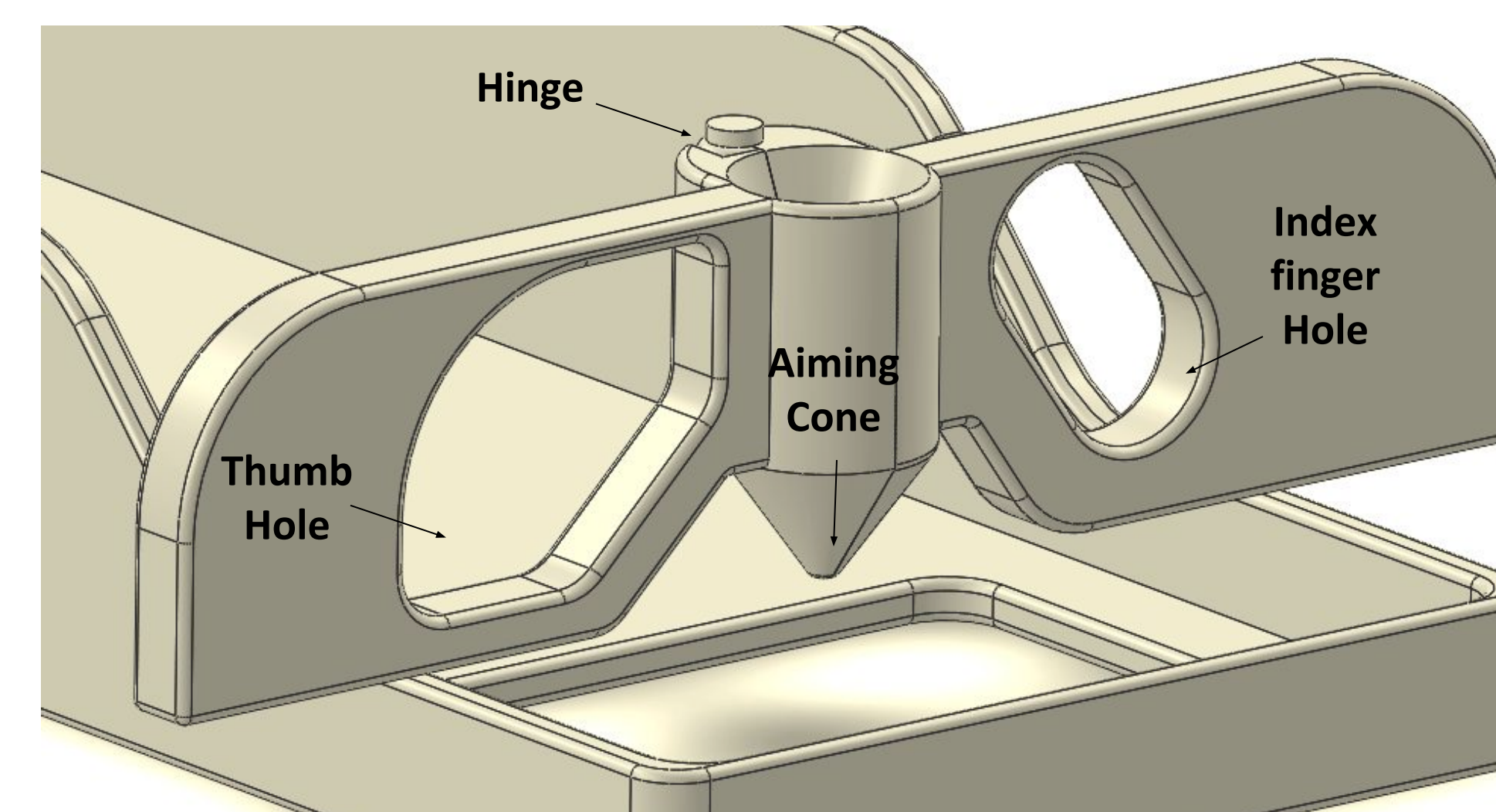


Figure 5. Side-view of needle guide model.

Development of Breast Model

Properties:

- Humimic Gel #4 (™)
- Elastomeric Co-Polymer Resin
- Allows for soft tissue impersonation with radio translucency

Fabrication Methods:

1. Gel liquified at approximately 230°F and pigment added (~1-2% by weight)
2. Gel poured in aluminum mold after roughly 120 min under heat
3. Resin left to harden for 24 hours prior to use



Figure 6. Humimic polymer gel in its unaltered form



Figure 7. Liquified gel after approximately 120 minutes under heat



Figure 8. Liquified is slowly poured into 4x4x4 aluminum mold

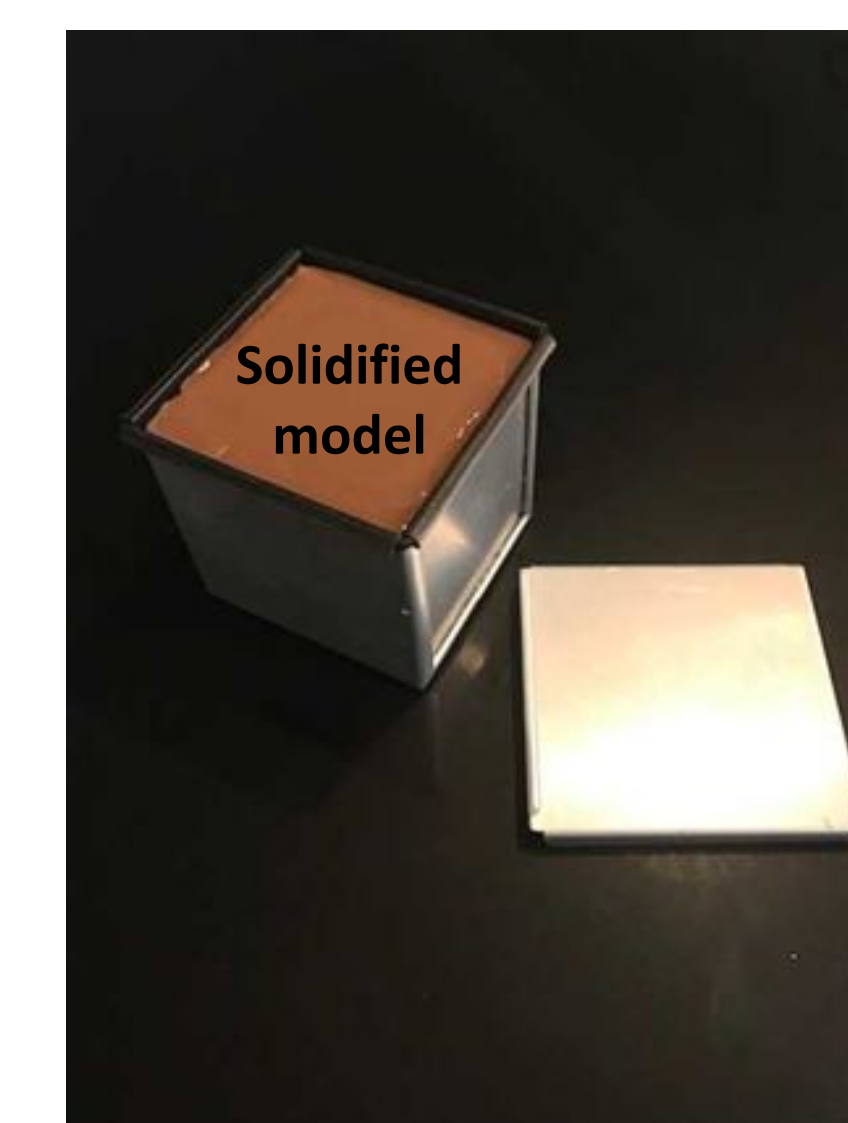


Figure 9. Gel left in mold to cool before testing

Study Description

IRB Approved Study:

Metrics:

1. Time from initial needle puncture to final removal
2. Angle from normal in final images
3. Number of corrections and images during procedure

Participants: Any clinician approved to perform localizations

Study Design:

1. Pre-procedure survey
2. Standard localization
3. Training with needle guide
4. Localization using guide
5. Post-procedure survey

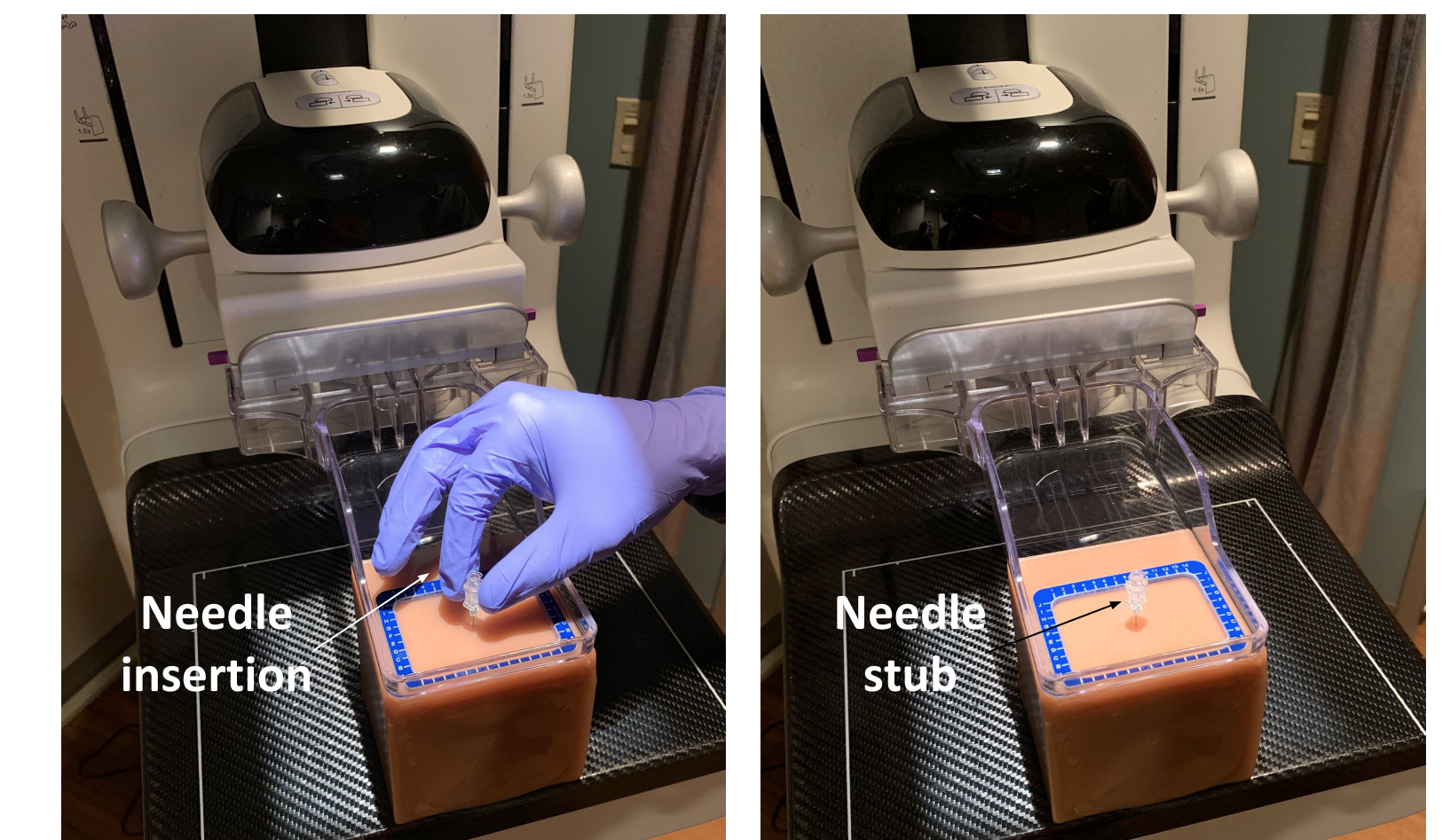


Figure 10a and 10b. Free Hand Localization

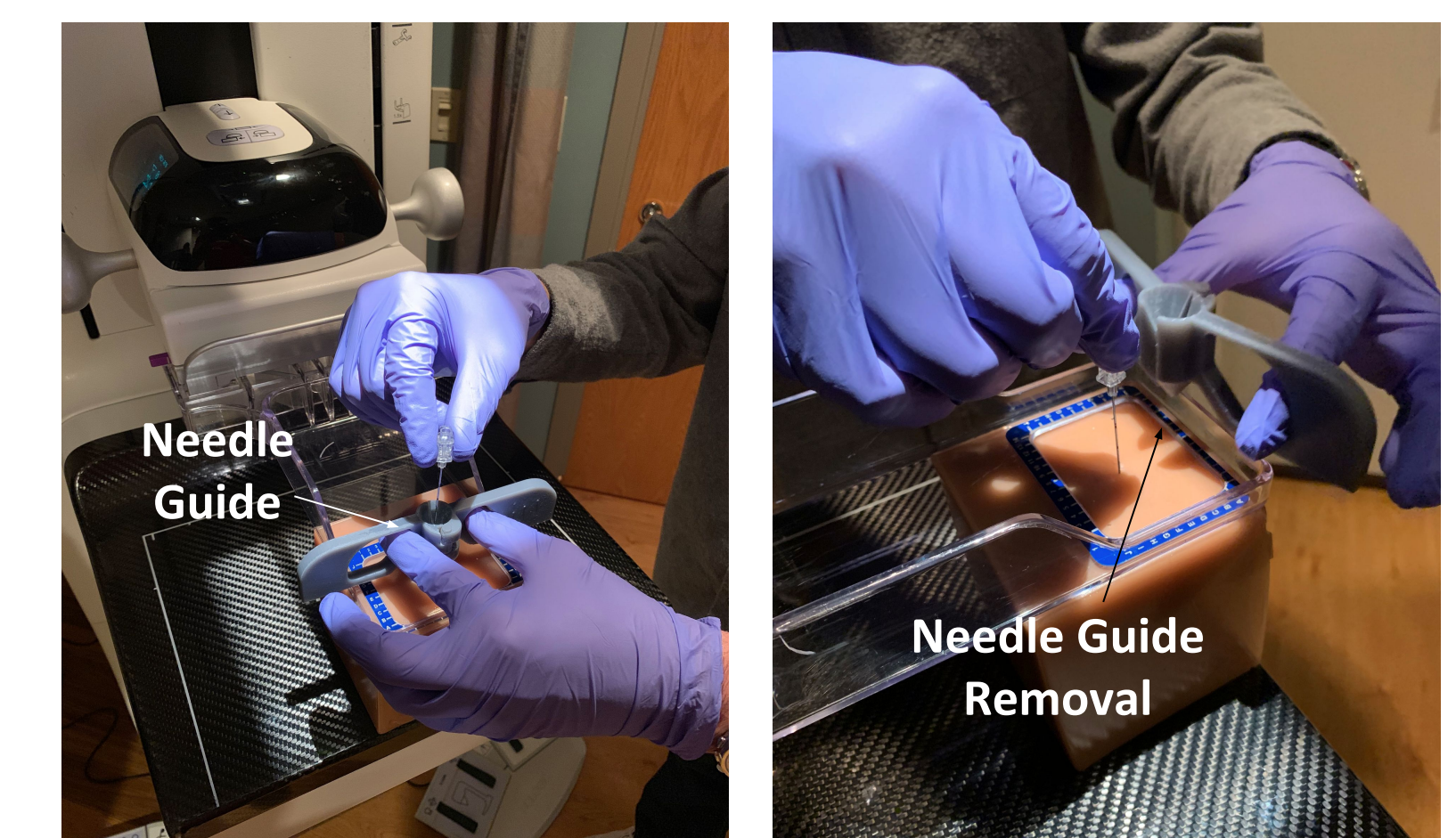


Figure 11a and 11b. Localization using the guide

Preliminary Results and Discussion

- Performed 3 testing sessions with faculty thus far
- On average, it appears that device cut down localization time and maintained accuracy.

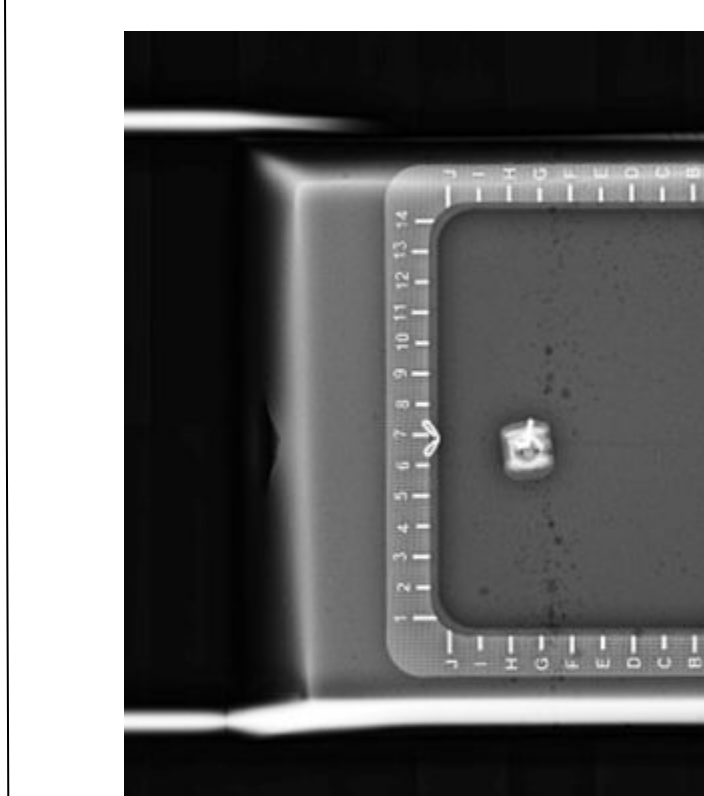


Figure 12. Top-down control

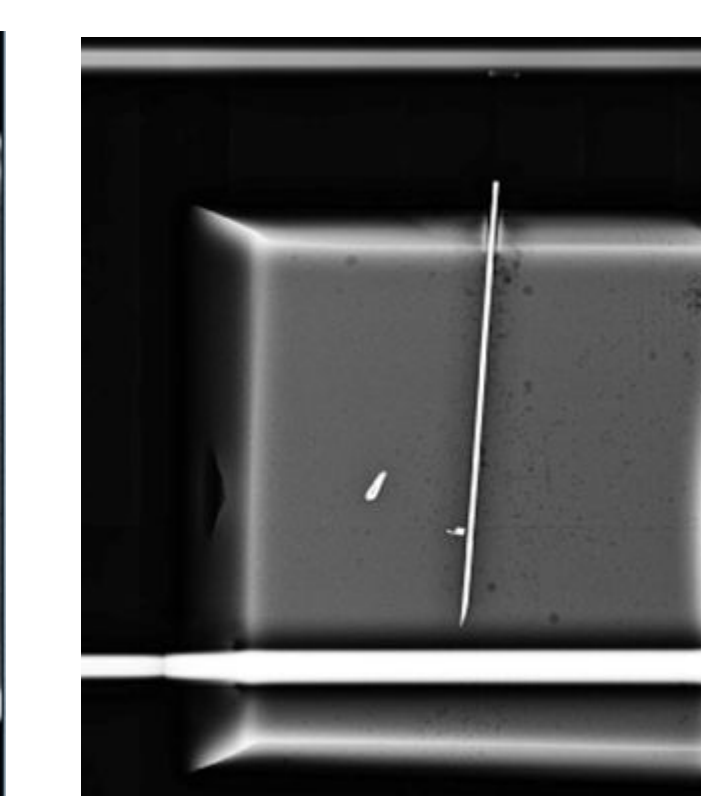


Figure 13. Medial-lateral control

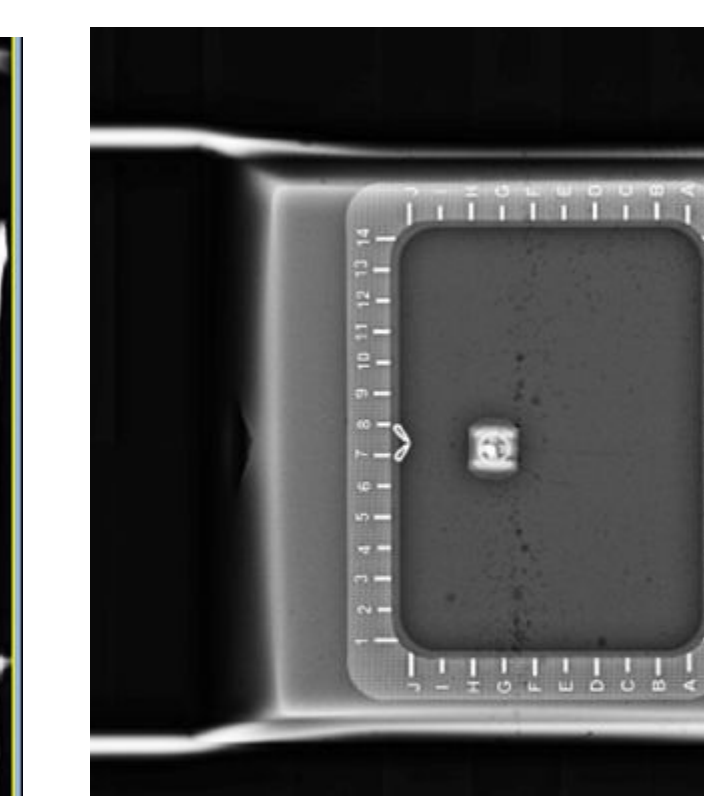


Figure 14. Top-down with guide

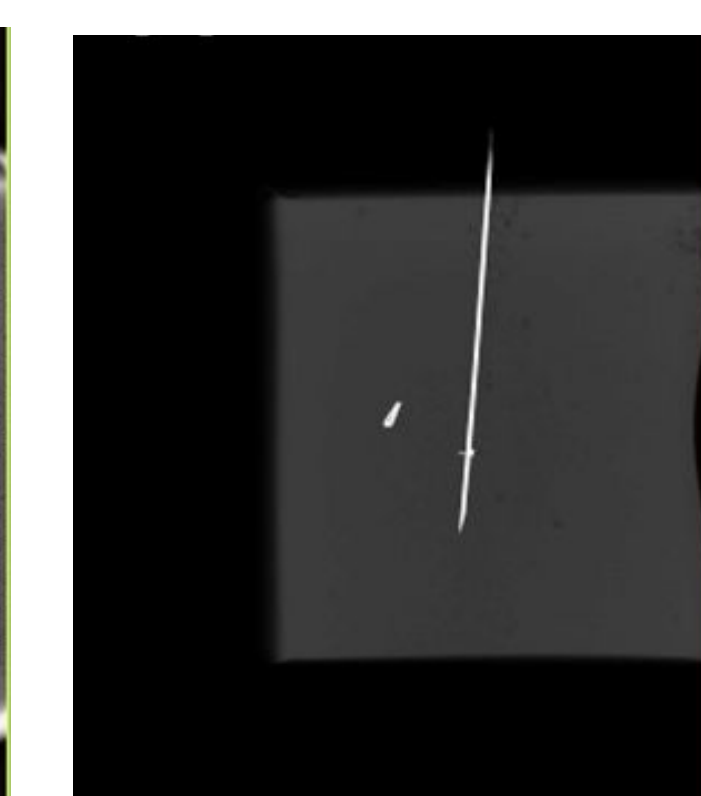


Figure 15. Medial-lateral with guide

Future Work

- Continue study and analyze data results
 - Acquire new participants
 - Refine study design
- Draft and submit design paper for publication

Acknowledgements & References

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[1]R. L. Siegel, K. D. Miller, and A. Jemal, "Cancer Statistics, 2017," Wiley Online Library.

[2]"Breast Cancer - Treatment Options", Cancer.Net, 2017.

[3]http://media1.s-nbcnews.com/j/newscms/2014_26/181416/140212-mammogram-1000_d48f27862046309f3cddc1d83d37d8f9.nbcnews-ux-2880-1000.jpg [Accessed 3 Oct. 2017].