NEEDLE ALIGNMENT FOR BREAST CANCER LOCALIZATION

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Abstract

1 in 8 women in the United States are diagnosed with Breast Cancer each year. The most common method for combating this disease is a lumpectomy or local tumor removal [1]. 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

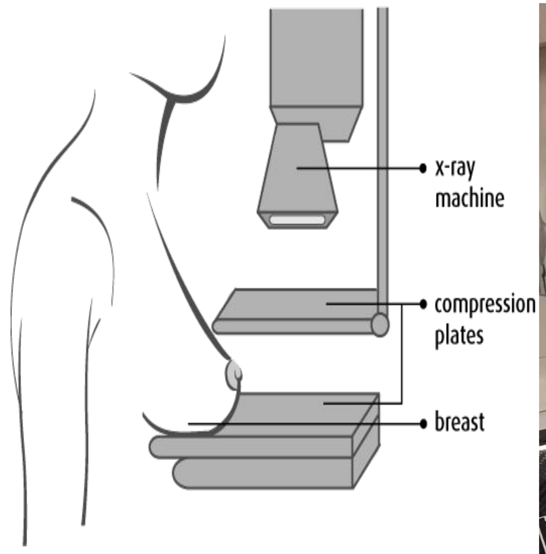

Figure 1. Hologic Mammography machine showing the set-up for imaging [1].

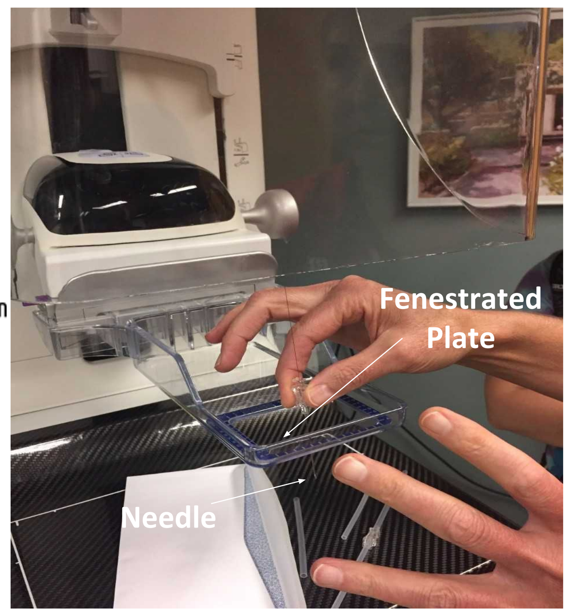

Figure 2. Needle insertion through fenestrated plate. The X-ray beam and light are directly above.

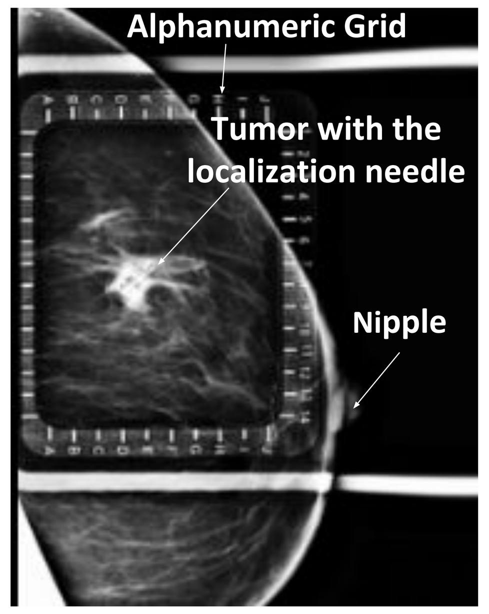

Figure 3. Mammogram image of needle-wire localization placed through the tumor.

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

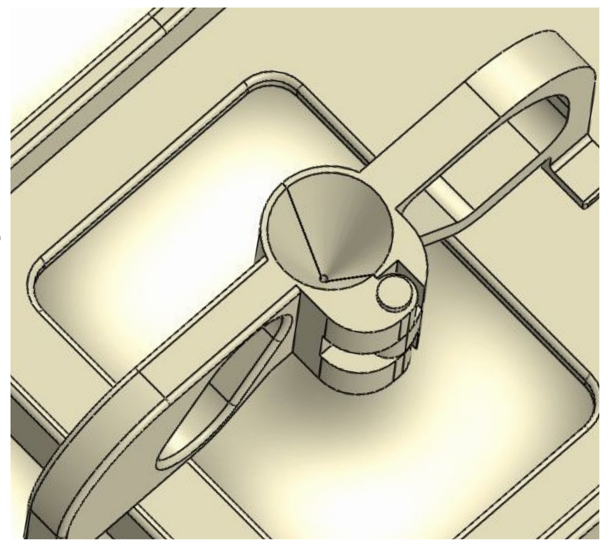

Figure 4. Top-diagonal view of needle guide model.

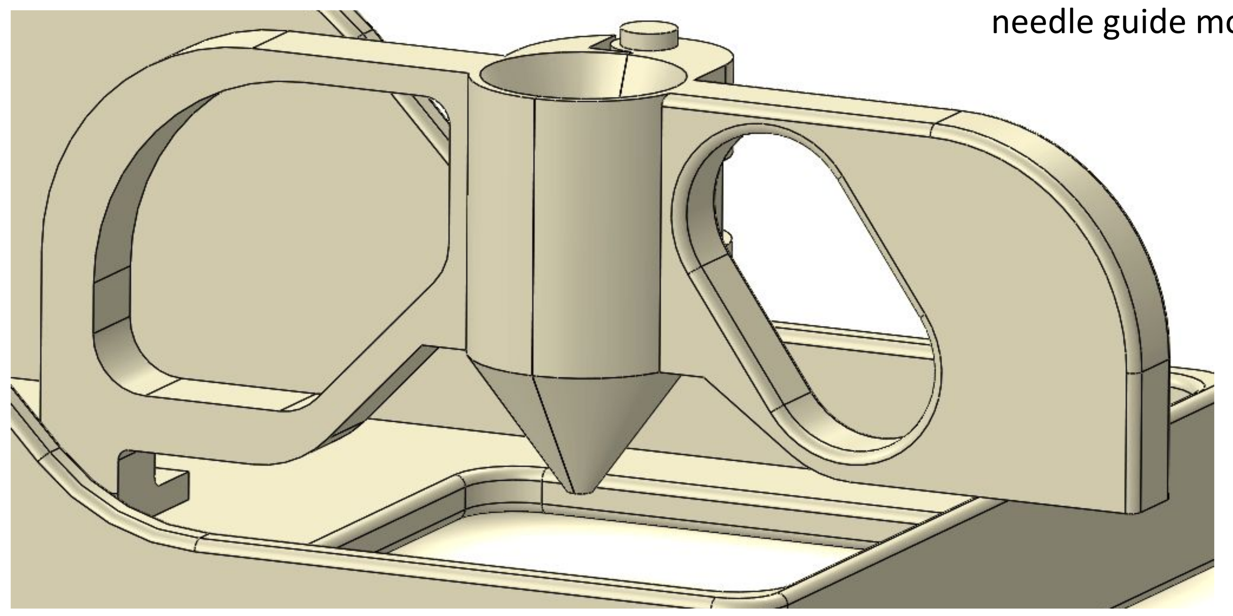

Figure 5. Side-view of needle guide model.

Testing

Preliminary Testing:

1. Hamburger Bun test to understand current procedure on Hologic machine
2. Testing of each iteration using Chicken Breast and 3D Fenestrated plate model.
3. Preliminary testing of device with hologic machine before clinical study

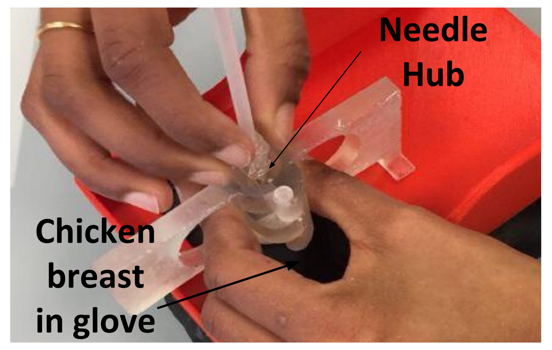

Figure 6. Preliminary testing with chicken breast and 3D printed fenestrated plate

IRB Approved Study:

Metrics:

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

Participants: Any clinician approved to perform localization

Study Design:

1. Standard localization procedure
2. Training with needle guide design (30 mins)
3. Localization using guide
4. Post-procedure survey

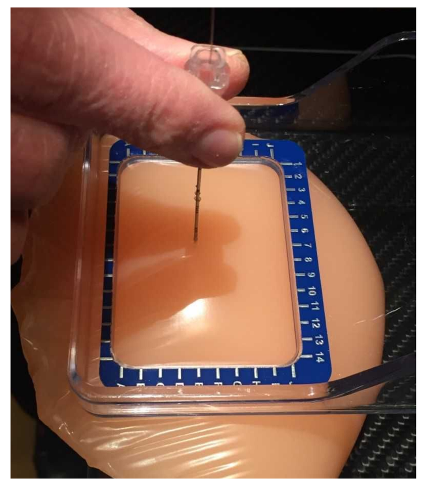

Figure 7. Standard localization with corrections.

Figure 8. Shadow created by light.

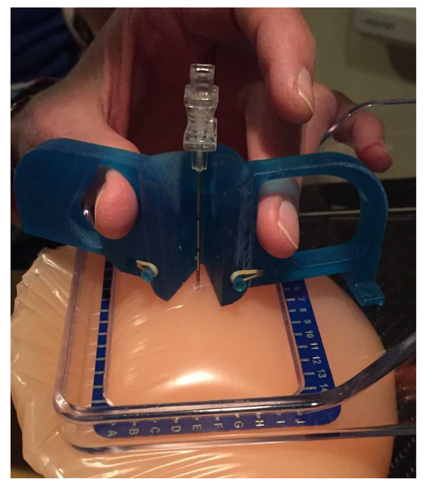

Figure 9. Localization with needle guide.

Figure 10. Lateral compression for final image.

Results & Discussion

Preliminary Chicken Breast Testing and Design Iterations:

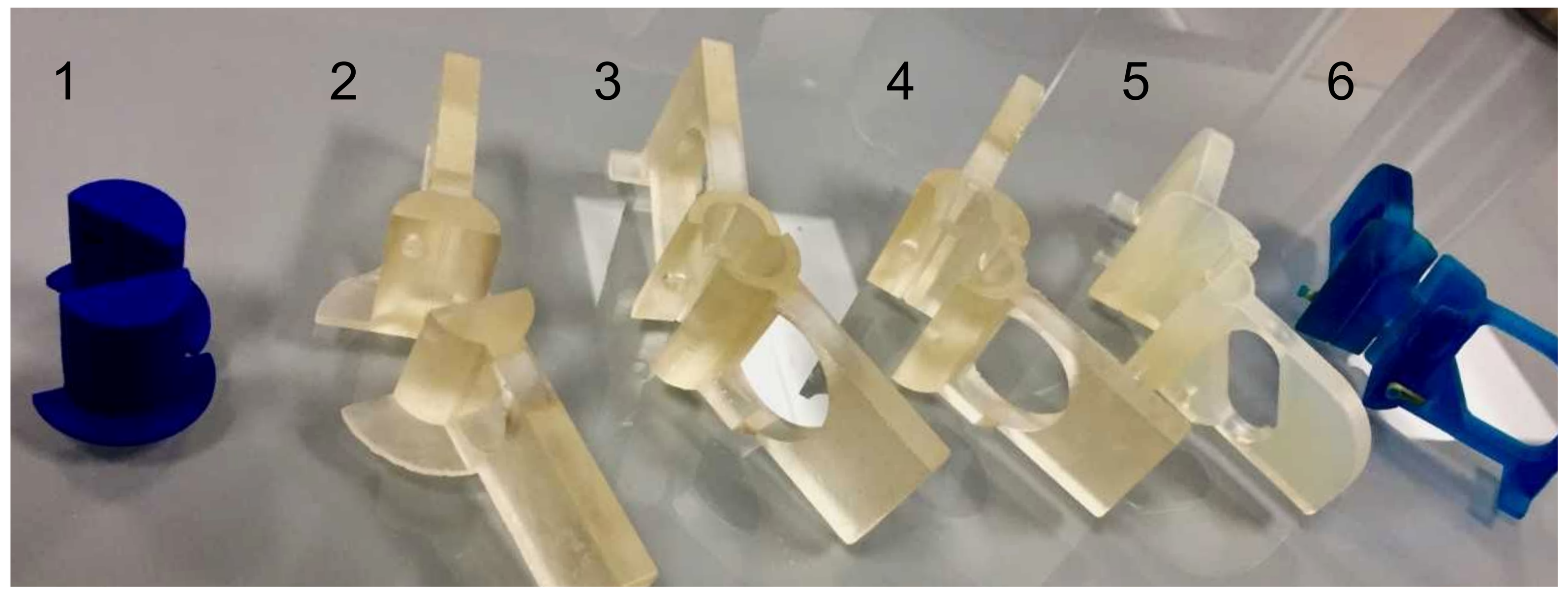

Figure 11. Iterations of the needle guide following preliminary testing on chicken breast model.

1. Required two hands and did not ensure perpendicularity.
2. Needle had to be free-hand inserted too far after guide removal, pressure in Z-axis caused design to snap inward.
3. Countersink assisted needle farther, but Z-axis pressure still caused design to snap inward.
4. Hinge prevented snapping, but flat bottom of counter sink caused needle to scrape plastic while trying to find the hole. Additionally, material was brittle, and the guide broke when dropped.
5. Most problems above were fixed, but the durable resin had too much friction by the hinges.
6. Met functional requirements and rubber band made the opening more ergonomic, but subject had trouble localizing the mark on the model, and the direction of device interfered with patient location.

Hologic Pre-Clinical Study Testing:

1. Model localized biopsy clip accurately.
2. Difficulty with locating mark on the model.
3. Clinician positioning interfered with patient location.

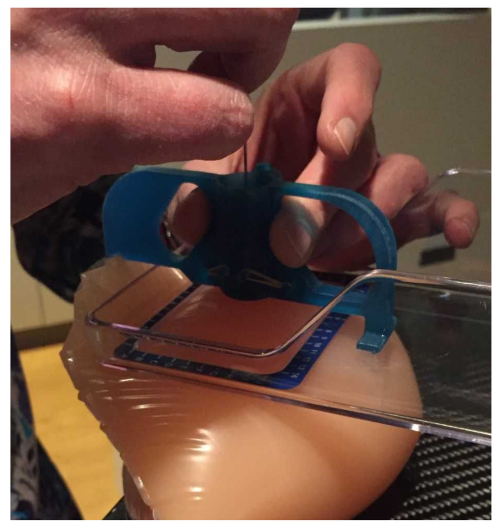

Figure 12. Clinician has to interfere with patient.

Figure 13. The guide localizes biopsy clip accurately.

Future Work

- Test newest iteration with the hologic machine.
- Draft and submit design paper for publication.
- Conduct study and analyze results using new design.

Acknowledgements & References

- Client: Dr. Frederick Kelcz
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- UW-Madison Department of Biomedical Engineering

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