

Abstract and Motivation

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 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, making the procedure very inefficient and uncomfortable for patients. According to Merrill et al., the average time spent on this procedure per patient is 157.7 ± 71.7 minutes, however, the operative time for lumpectomies is only 55.5 ± 16.6 minutes. Thus, this procedure limits the number of lumpectomies performed per day, and reducing procedure time will greatly improve efficiency and save cost for Breast Centers while improving patient comfort. The goal of our product is to standardize this procedure, reduce procedure time, and enhance quality of care.

Needle-Guide Design

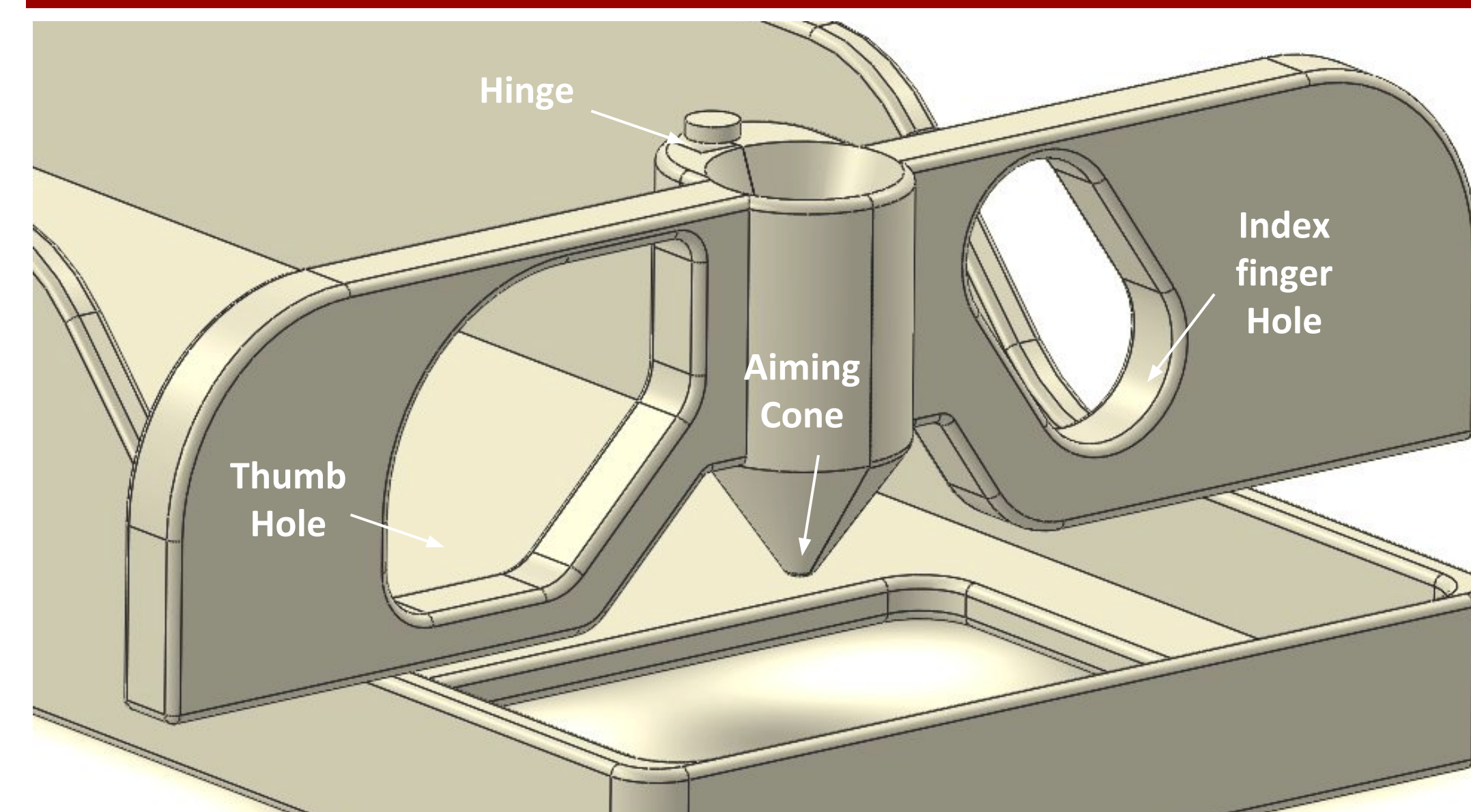


Figure 4. Side-view of needle guide model.

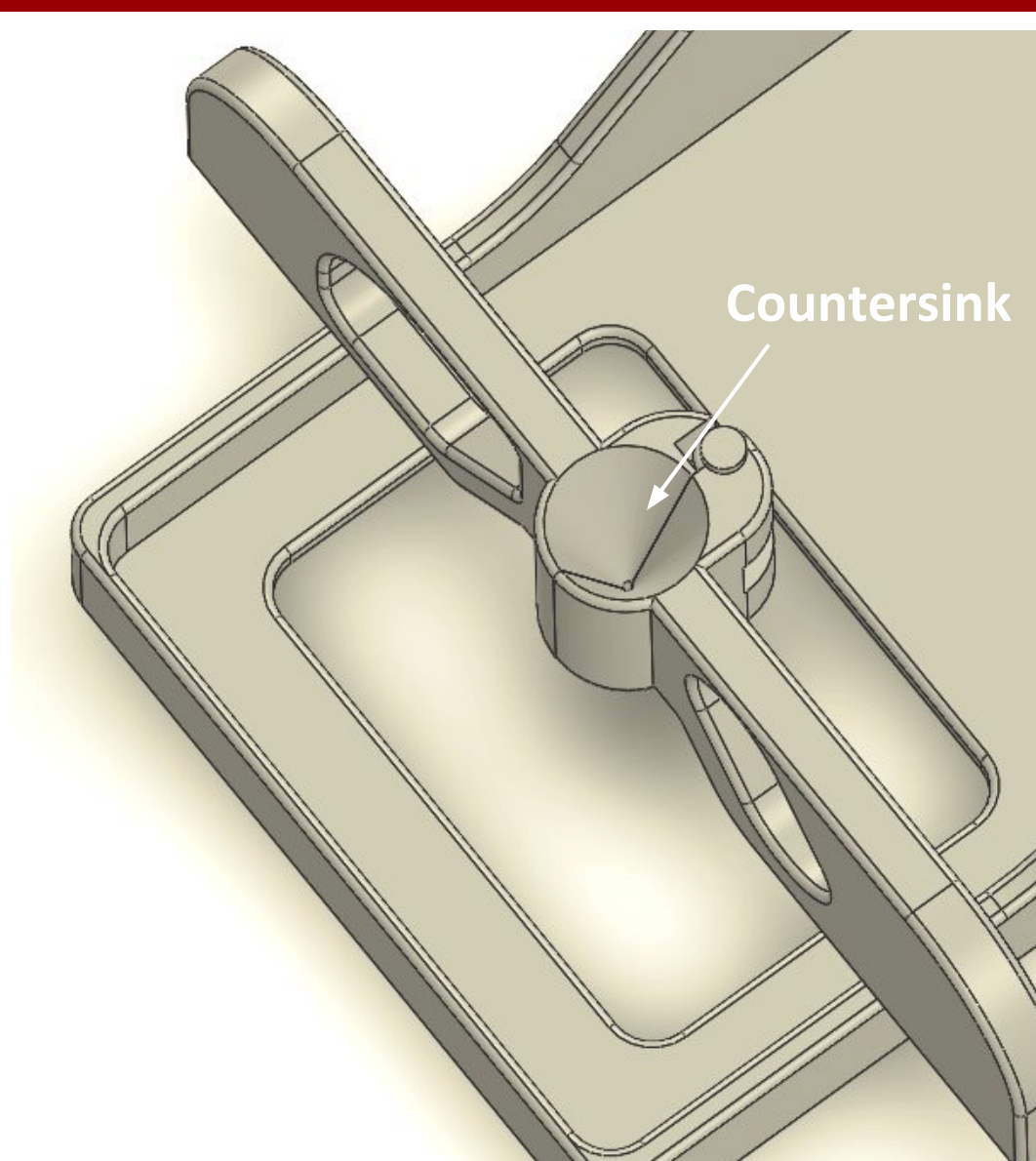


Figure 5. Top-diagonal view.

Ring Design:

- Hinges: stability under Z-axis pressure
- Cone: assist with mark localization
- Countersink: accommodates the needle

Manufacturing Method: SLA 3D Printer

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 Grey Pro Resin

Testing Methods

Survey and Consent - 5 min

Standard Localization - 10-20mins

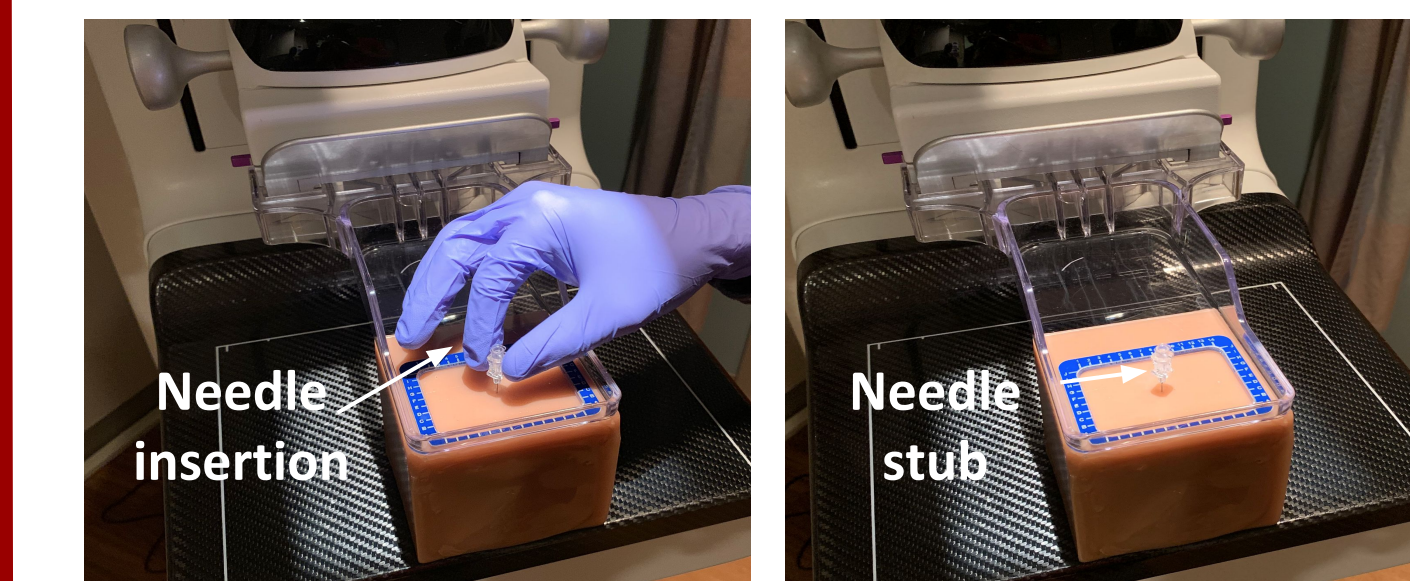


Figure 6a and 6b. Free Hand Localization

Training with Guide - 15mins

Localization with Guide - 10-20mins



Figure 7a and 7b. Localization using the guide

Post Study Survey/ Feedback - 5mins

IRB Approved Metrics:

1. Time from initial needle puncture to final removal
2. Total Procedure Time
3. Accuracy
4. Number of images needed (corrections)

Participants:

Any clinician approved to perform localizations - Recruited 9 total

Background

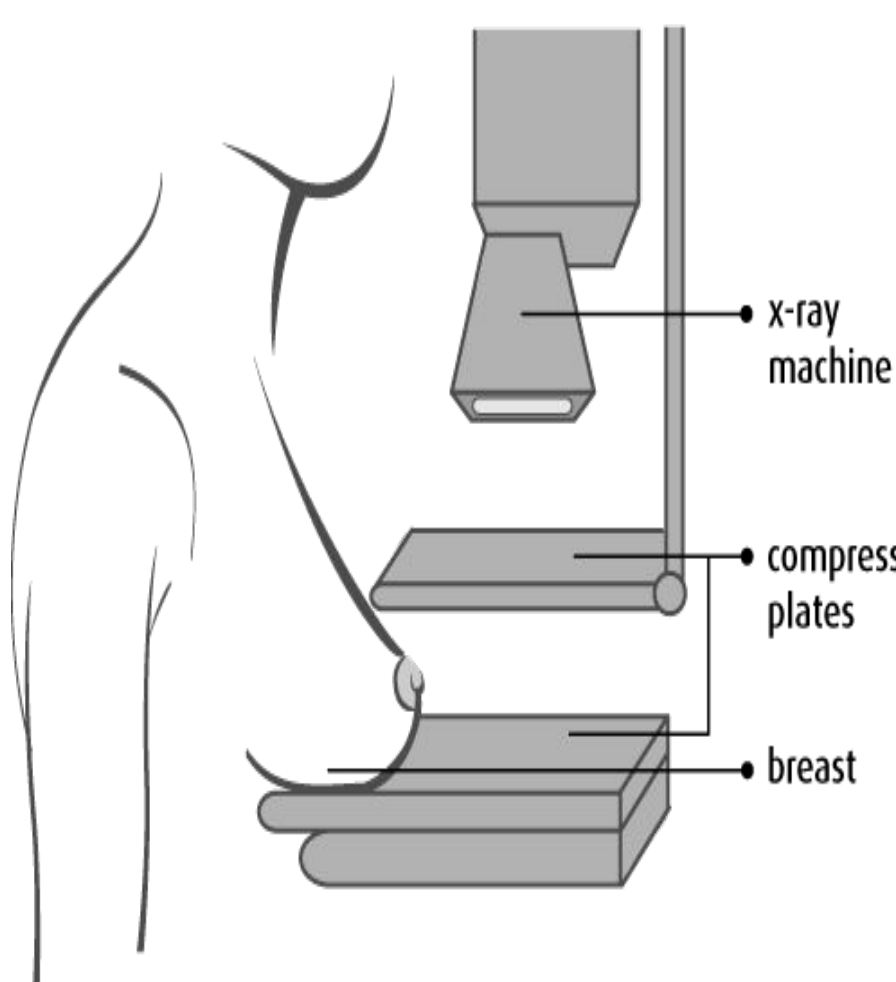


Figure 1. Hologic Mammography machine showing the set-up for imaging [3].

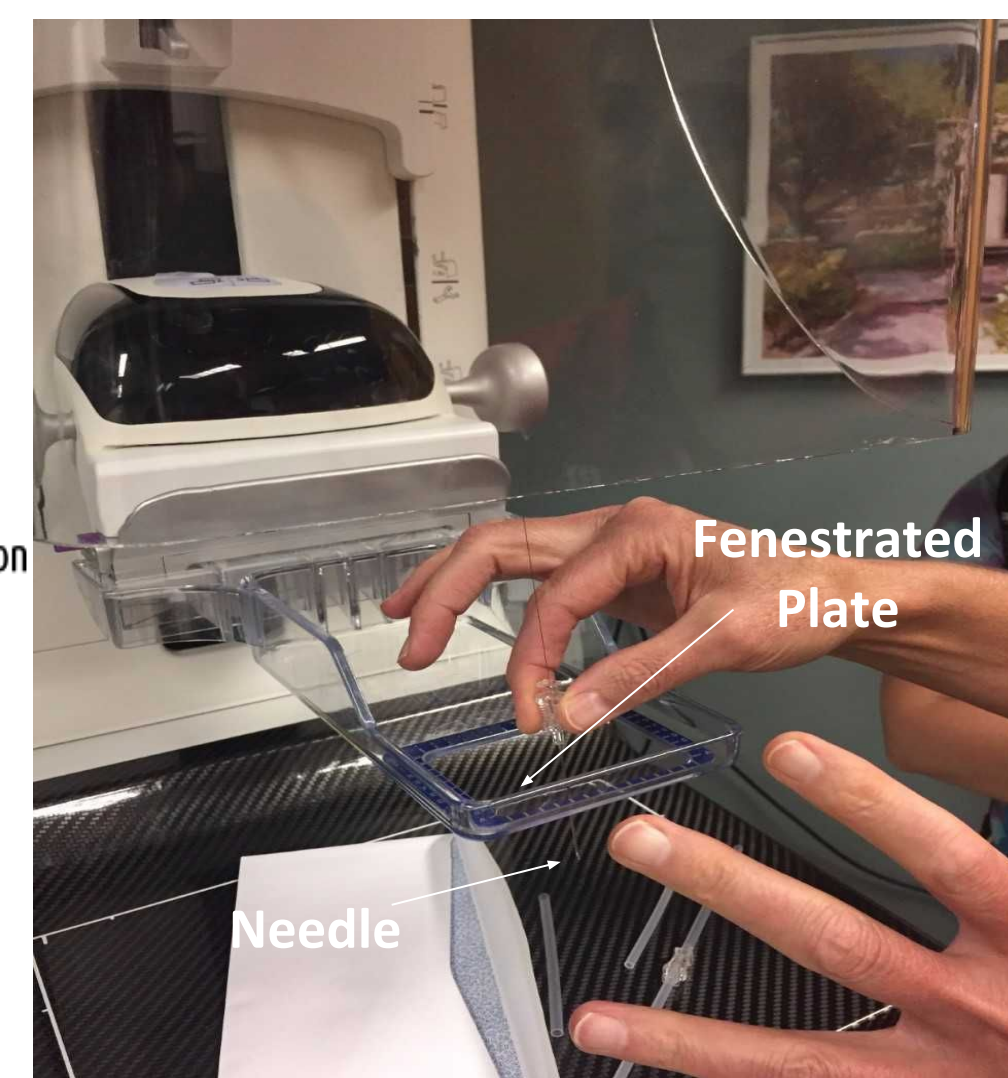


Figure 2. Needle insertion through fenestrated plate. The X-ray beam and light are directly above.

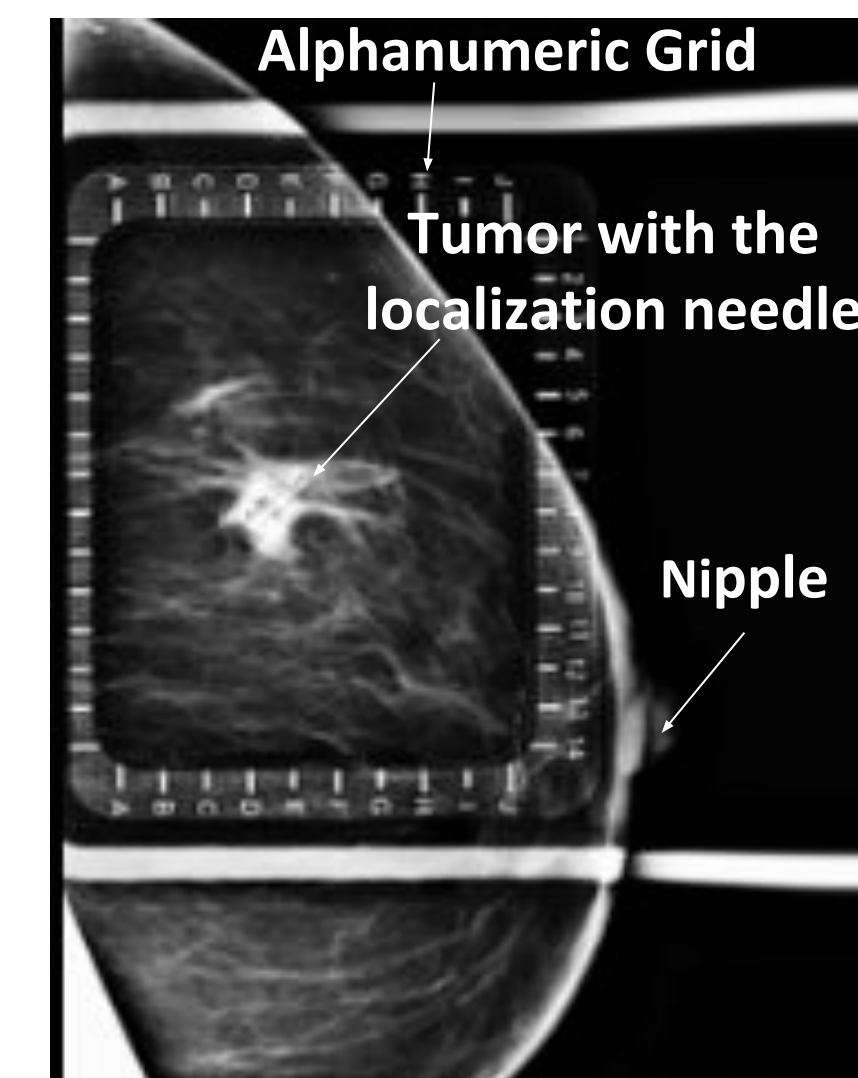


Figure 3. Mammogram image of needle-wire localization placed through the tumor.

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.

Results

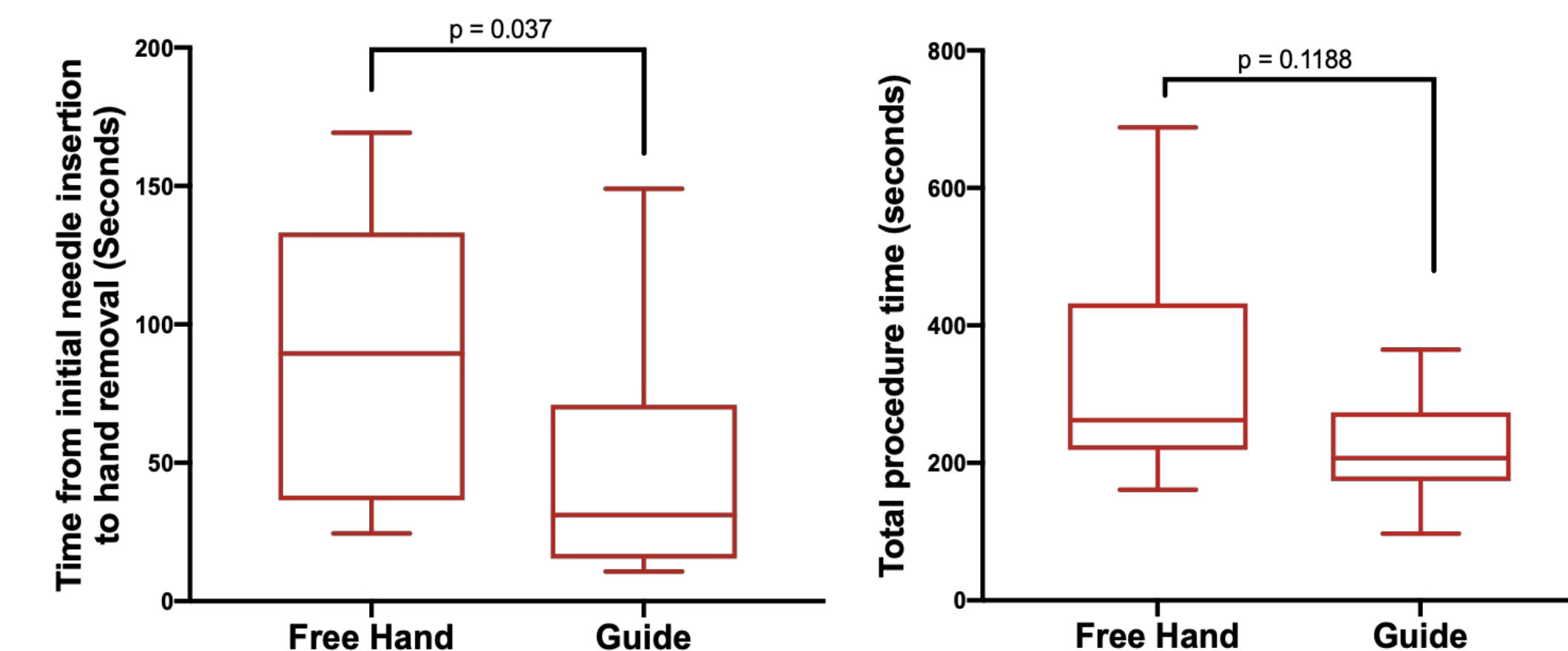


Figure 8. Two metrics for procedure time were measured. The needle guide significantly decreases procedure time.

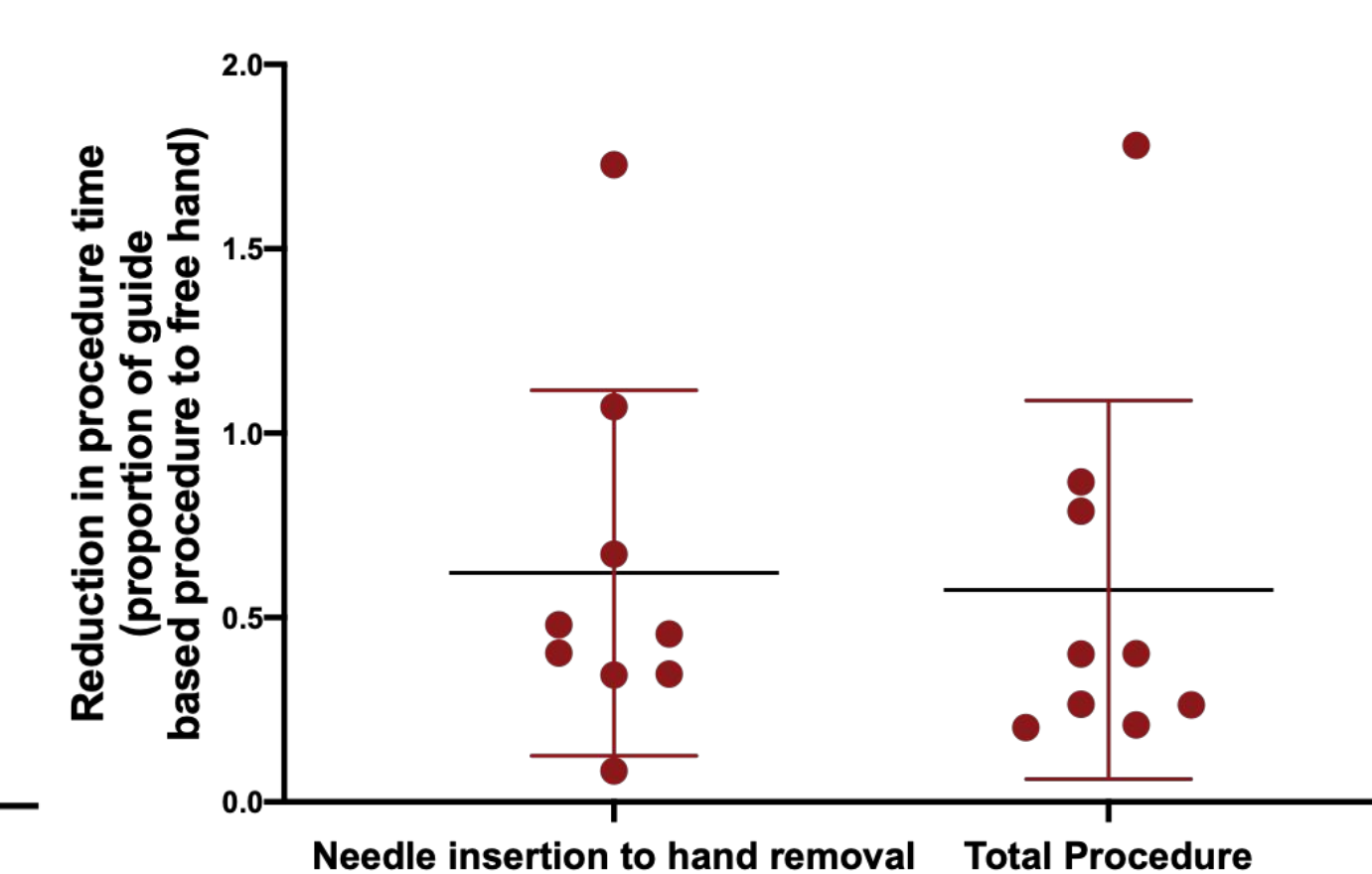


Figure 9. Over 50% reduction in procedure time was seen in 6/9 subjects.

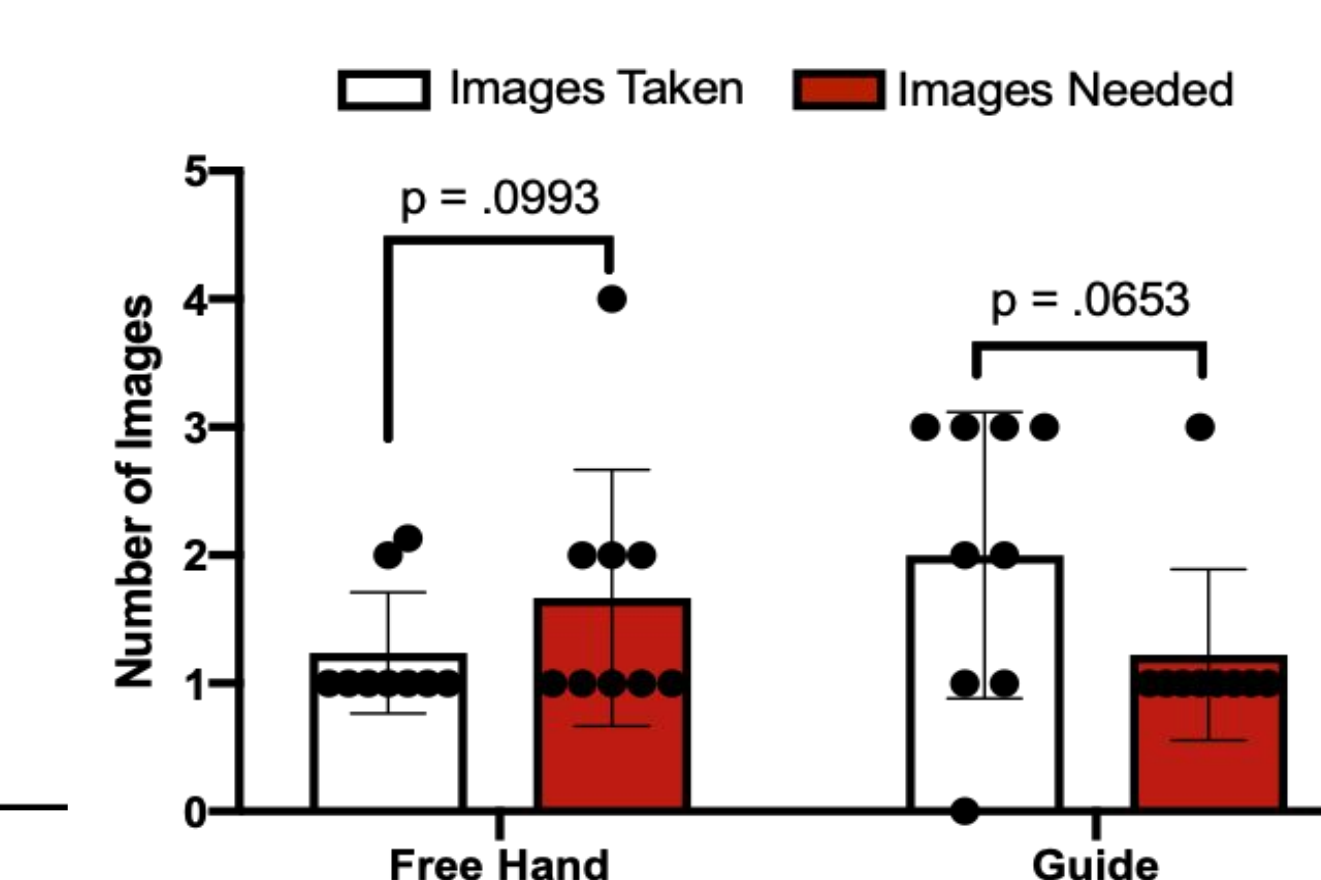


Figure 10. 8/9 subjects only needed 1 image (no corrections) with the guide.

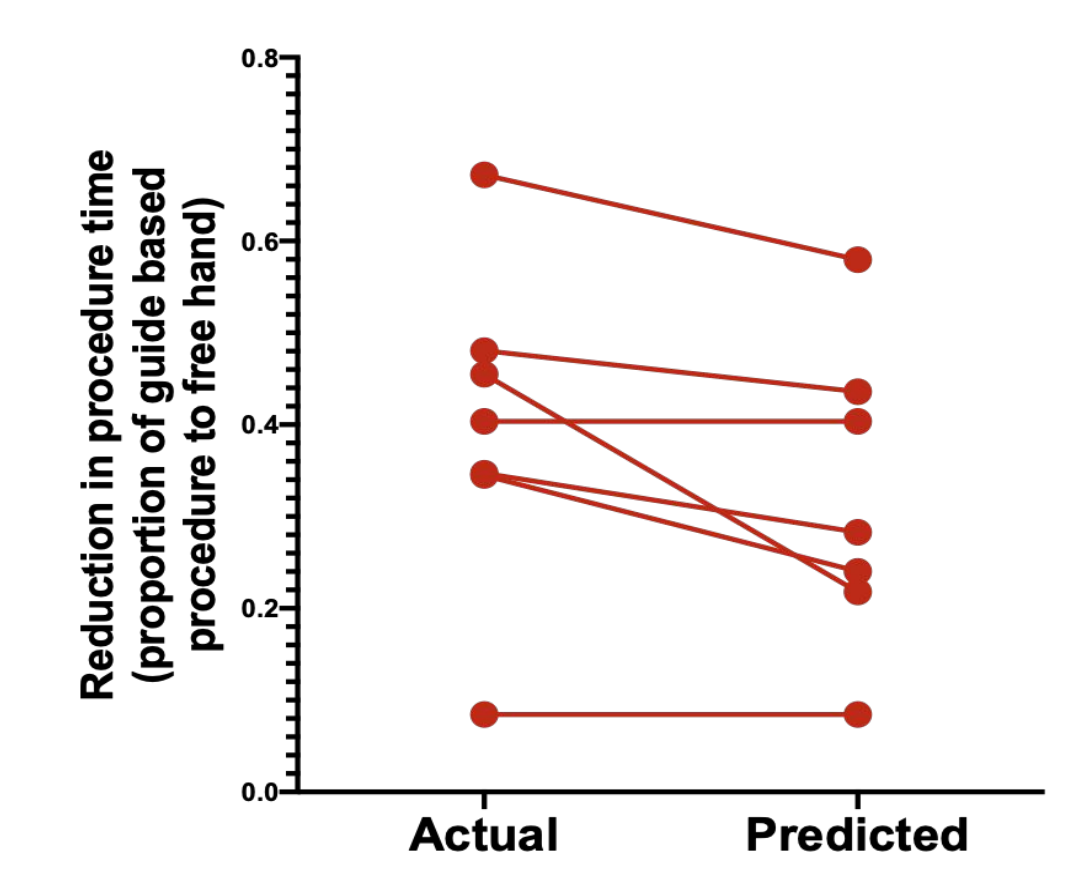


Figure 11. 5/9 subjects took longer time than needed.

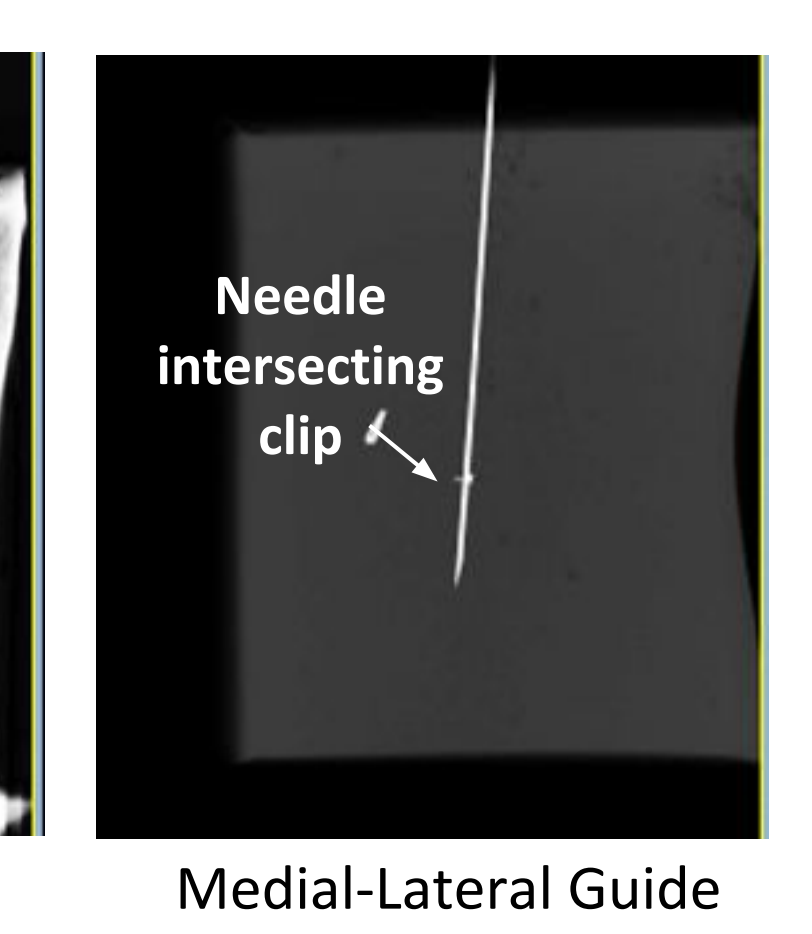
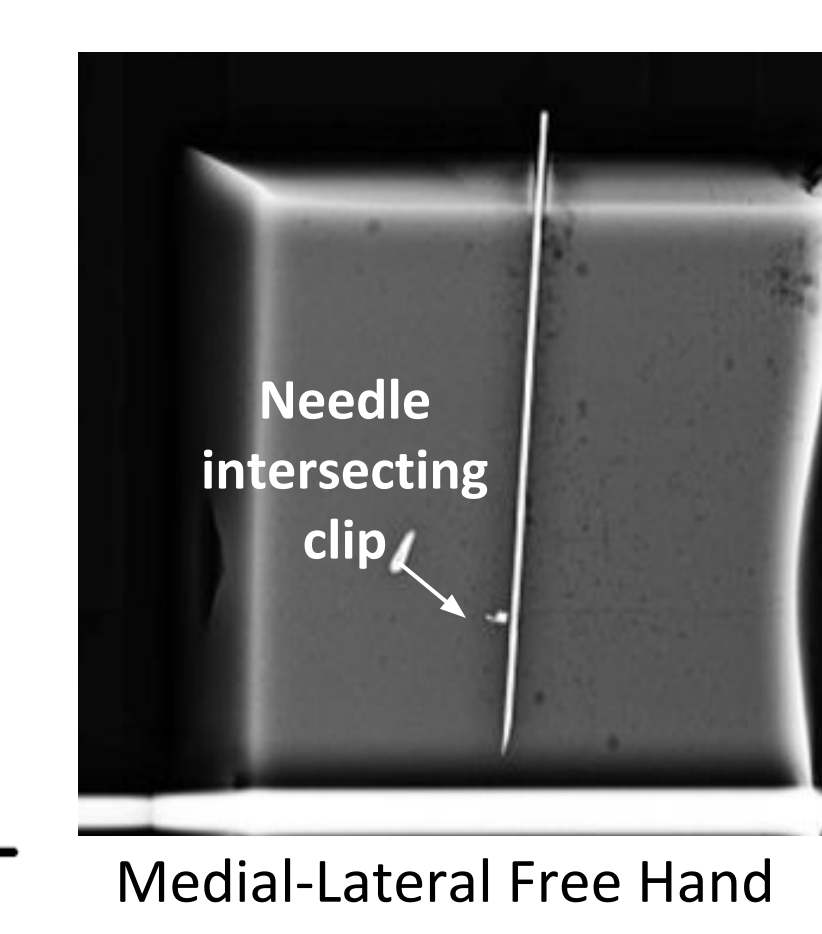
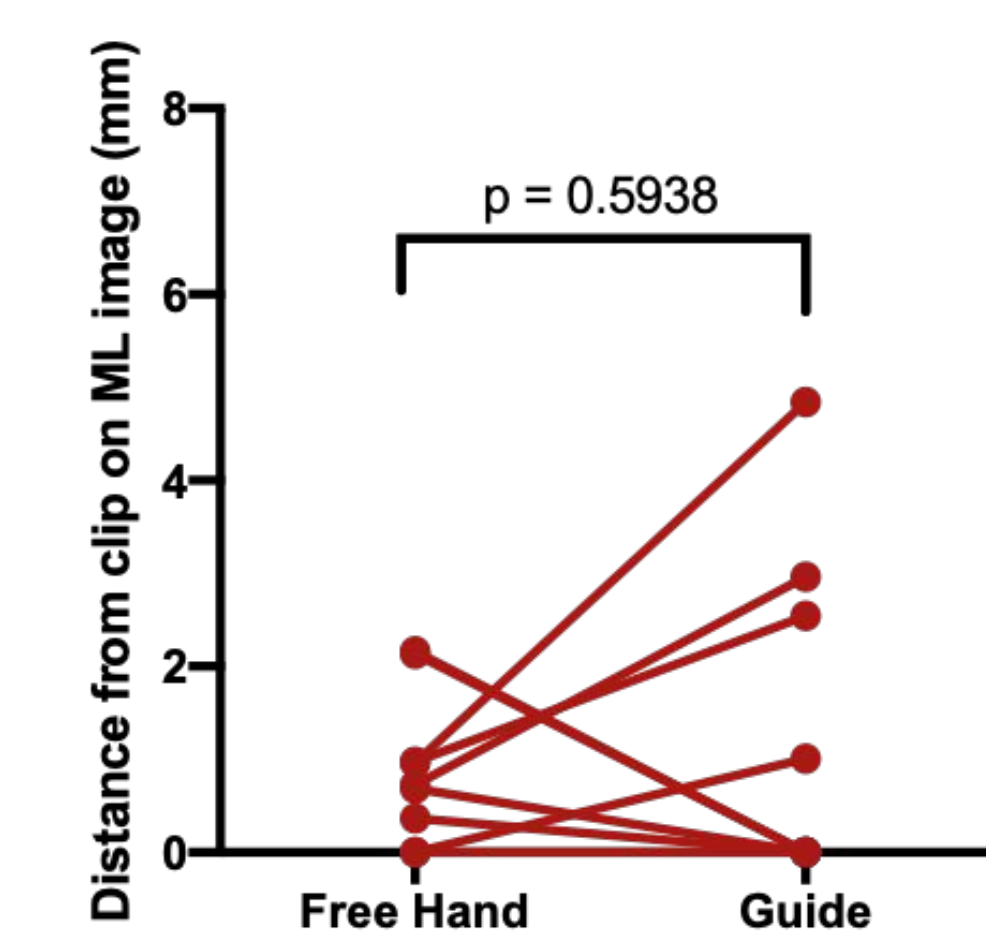
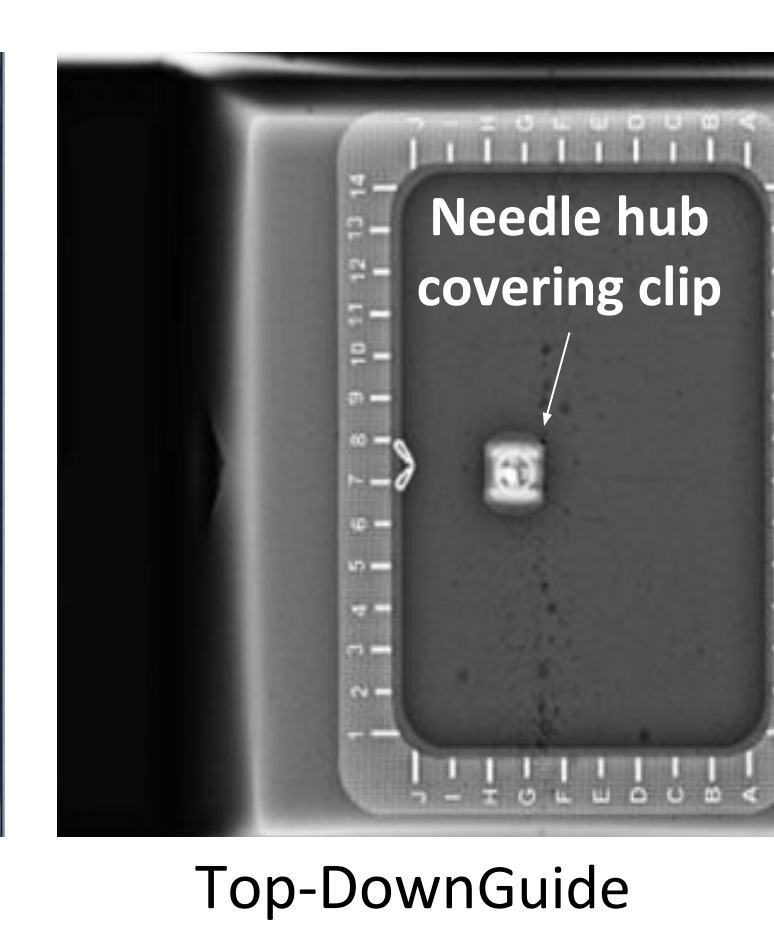
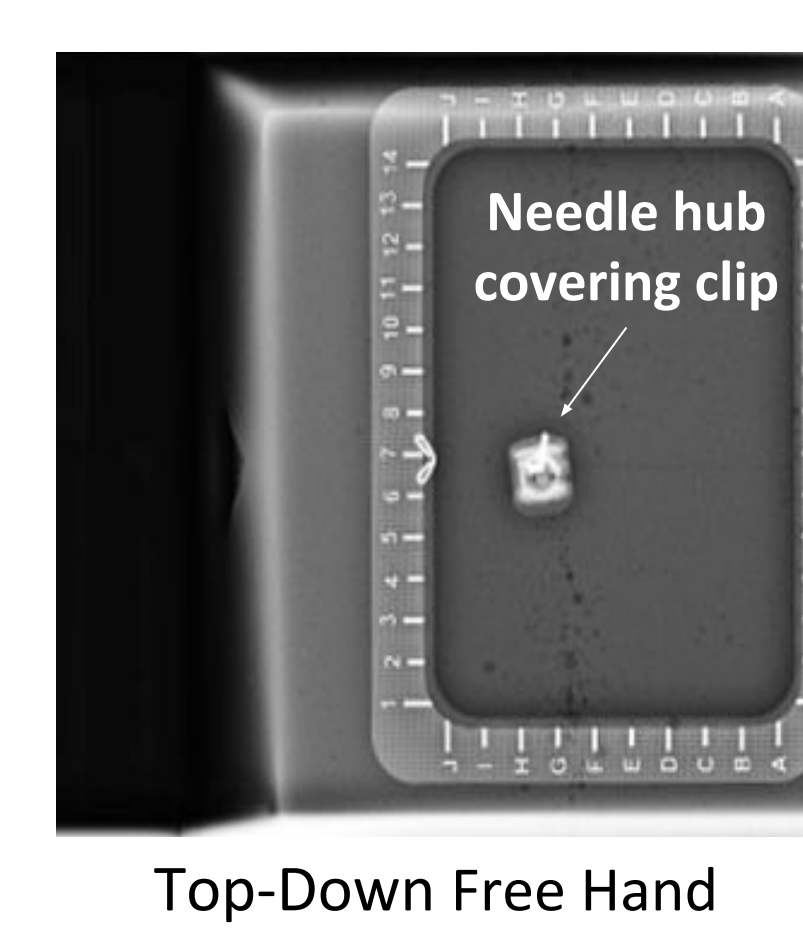
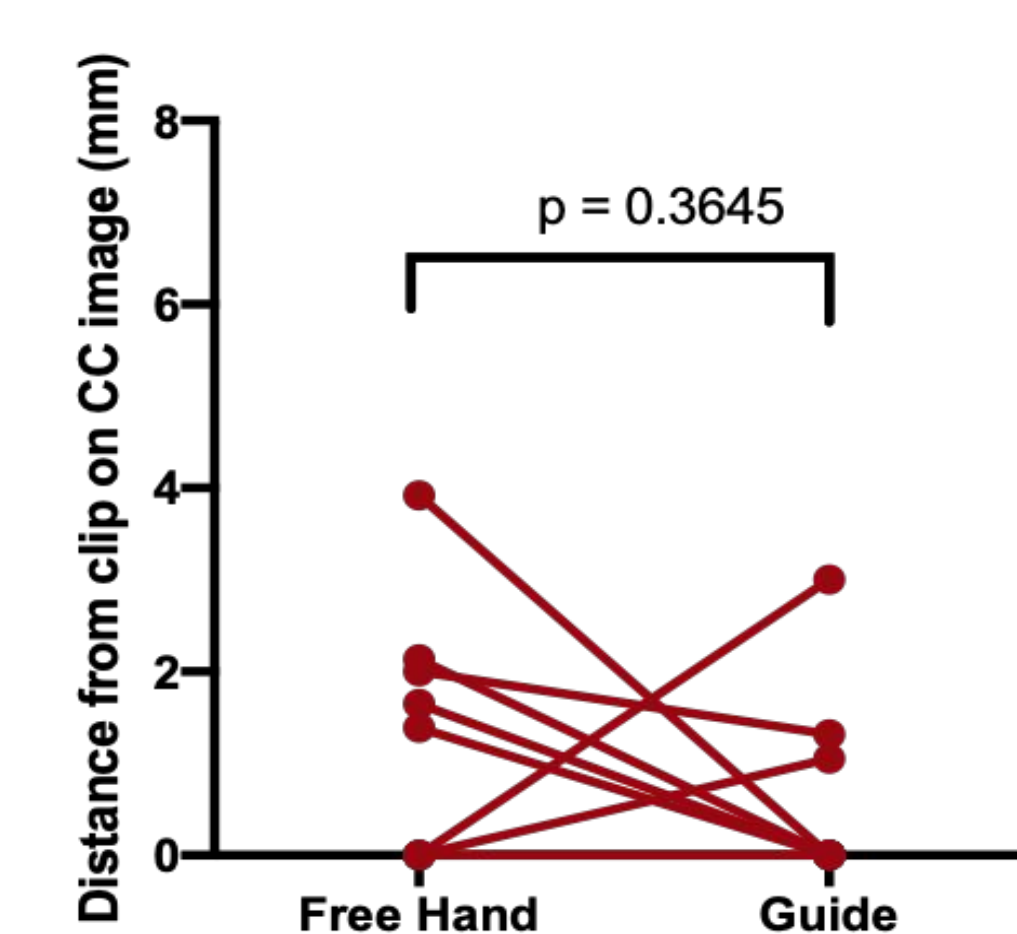


Figure 12. Accuracy was maintained with the needle guide as assessed in the Top-down and medial-lateral images. Sample images from subject 3 are shown above.

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

Updated Design

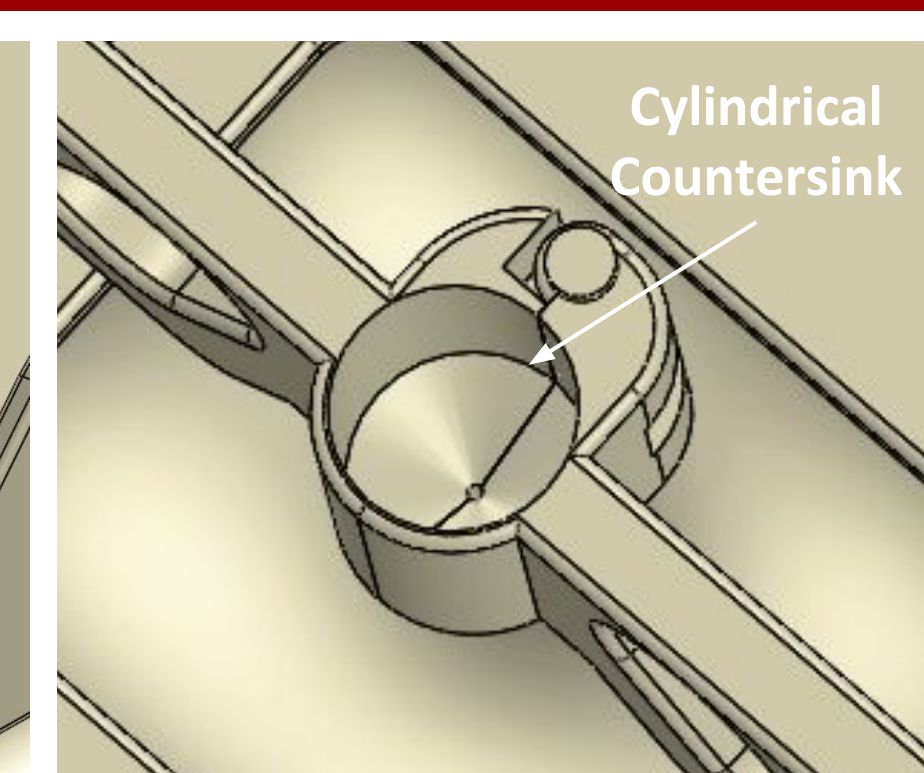
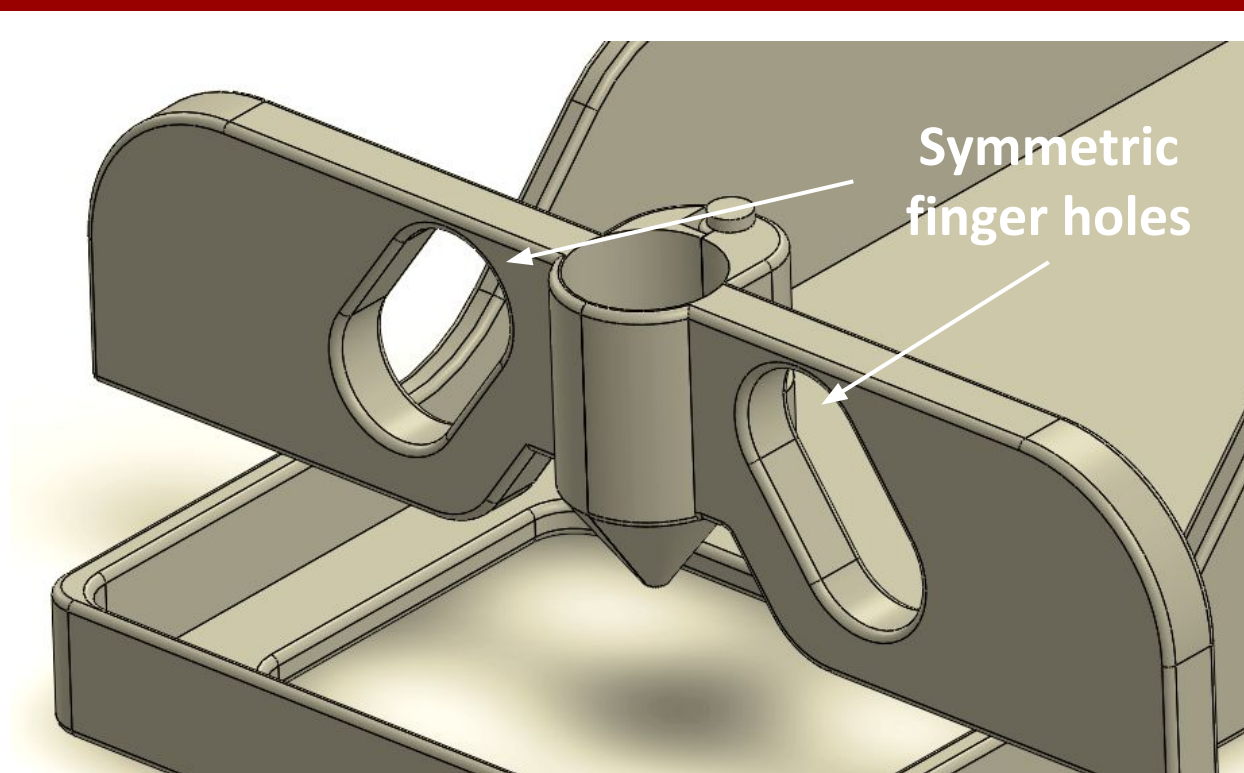


Figure 13. Side-view and top-diagonal view of updated needle guide.

- Updated based on participant feedback
- Symmetric finger holes
- Cylindrical insertion chamber
- Modified countersink
- Extended aiming cone

Acknowledgements & References

- Client: Dr. Frederick Kelcz
- Advisors: Dr. Beth Meyerand, Dr. Lonie Salkowski
- UW-Madison Department of Biomedical Engineering

[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/newscoms/2014_26/181416/140212-mammogram-100_0_d48f27862046309f3cddc1d83d37d8f9.nbcnews-ux-2880-1000.jpg [Accessed 3 Oct. 2017].