Rapid Needle Alignment for Effective Localization of Breast Tumors

Client: Dr. Frederick Kelcz

Advisors: Dr. Lonie Salkowski and Dr. Beth Meyerand

Gopika Senthilkumar

Kevin Fantl

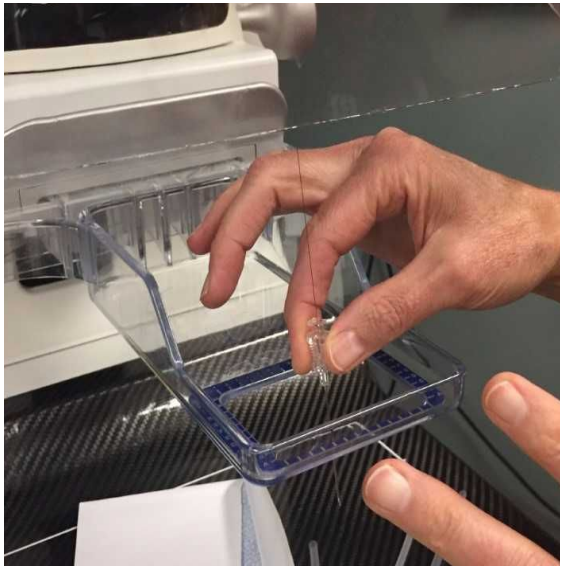
Colin Schrof

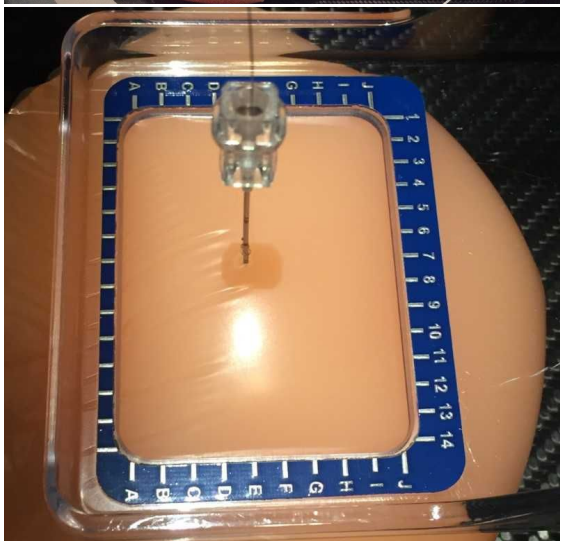
Alex Henry

Kari Borowski

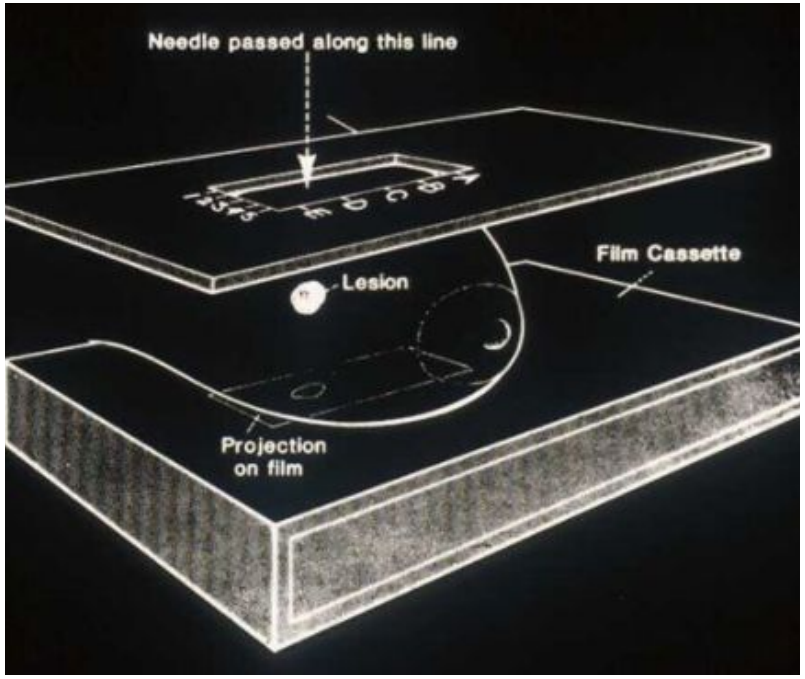
UNIVERSITY OF WISCONSIN-MADISON

Background - Current Method





Problem Statement



- Standardize localization technique

http://slideplayer.com/slide/8046649/

Important Design Constraints

- Clinically effective
- Accurate - Perpendicular approach
- Easy and quick to use
- Safe for patients
- Safe for physicians
- Removable/ Radiotranslucent

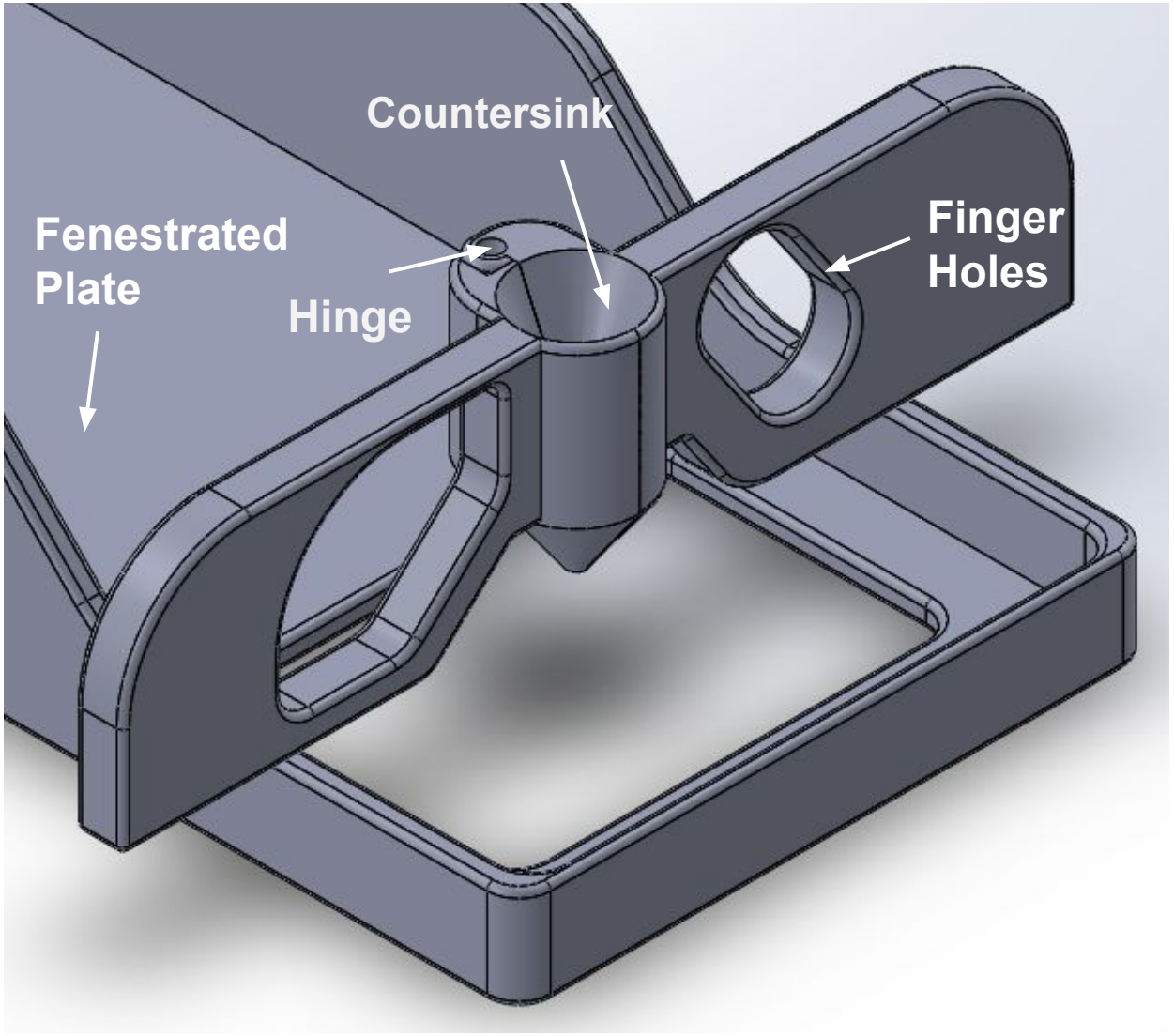
Justification

- Standardization - Quality Control and Save Cost
- Easier to learn procedure
- More comfortable experience for patients
  - Time
  - Reduced radiation
  - Not freehand
- Efficiency
- Technology may be applied in other situations

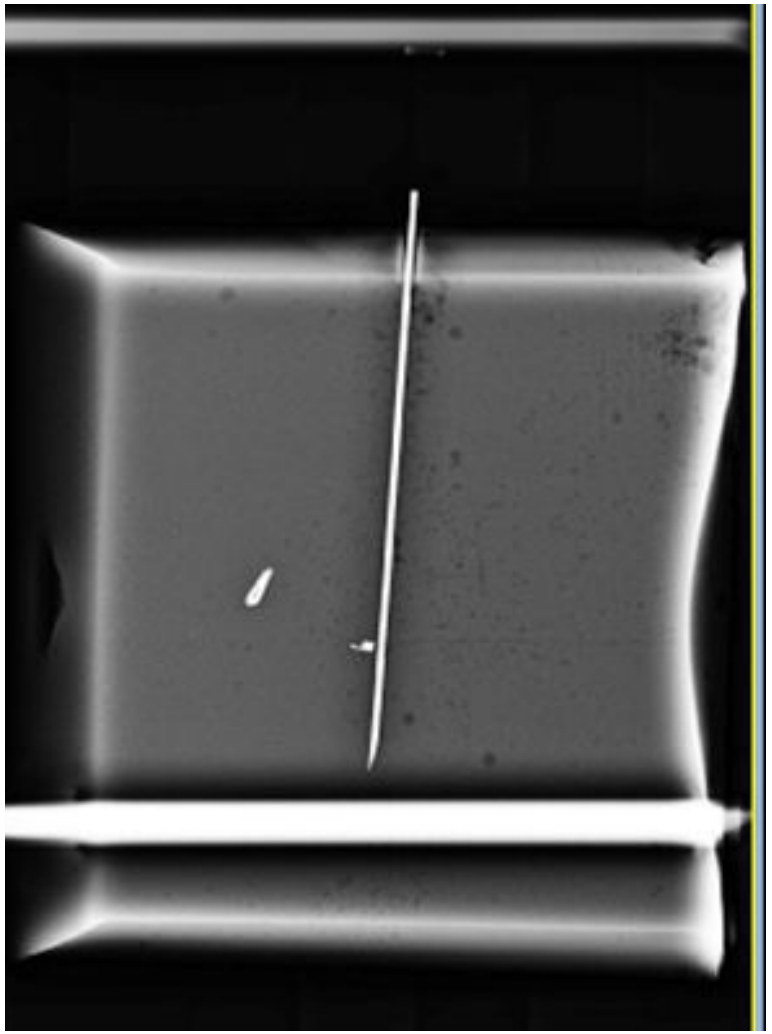
Last Semester

- Finalized design of guide
- Designed and validated new Breast Model
- Perfected and practiced study method
- Started IRB approved clinical testing - three subjects
- Started drafting the publication

Final Design of Guide



New Breast Model Validation



Study Design: Overview

Step 1:

Standard localization procedure on model

Step 2:

Training with needle guide design (30 mins)

Step 3:

Localization using needle on model

Step 4:

Post-procedure survey

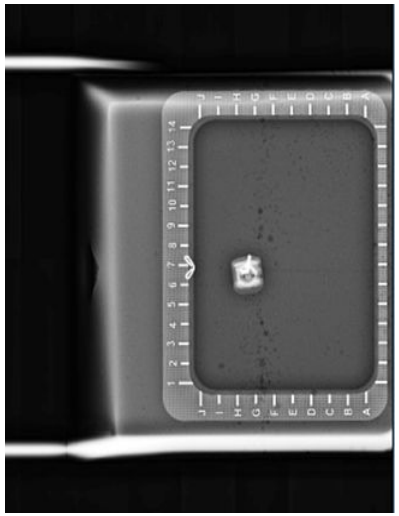
Study Design: Participants

- Breast Imaging Fellows
- Physicians
- Residents on Clinical Service
- Any staff authorized to perform localizations

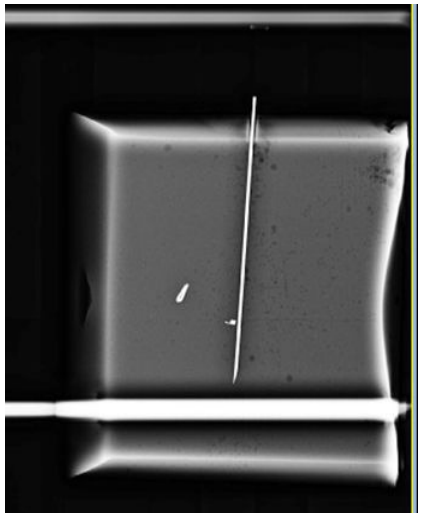
Testing Goals

1. Validate that our device can accurately guide the needle to its intended location
2. More efficient and standardized than the traditional technique
3. User friendly design. Does it feel comfortable to use?
4. Better for new learners? Other Correlations?

Final Design Testing Results

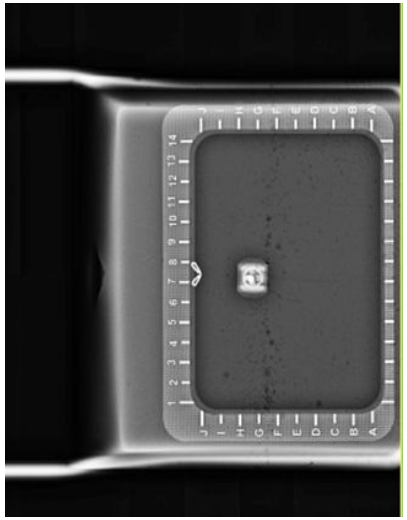


Top-image

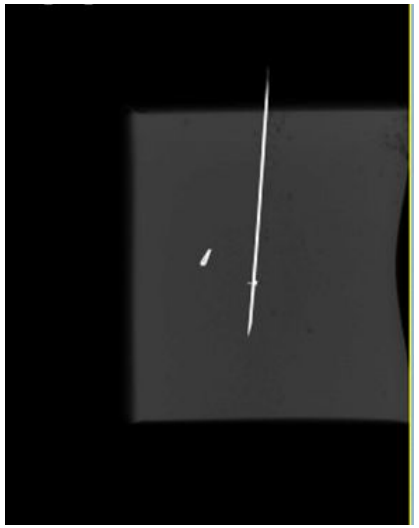


Orthogonal-view

Free-Hand Localization



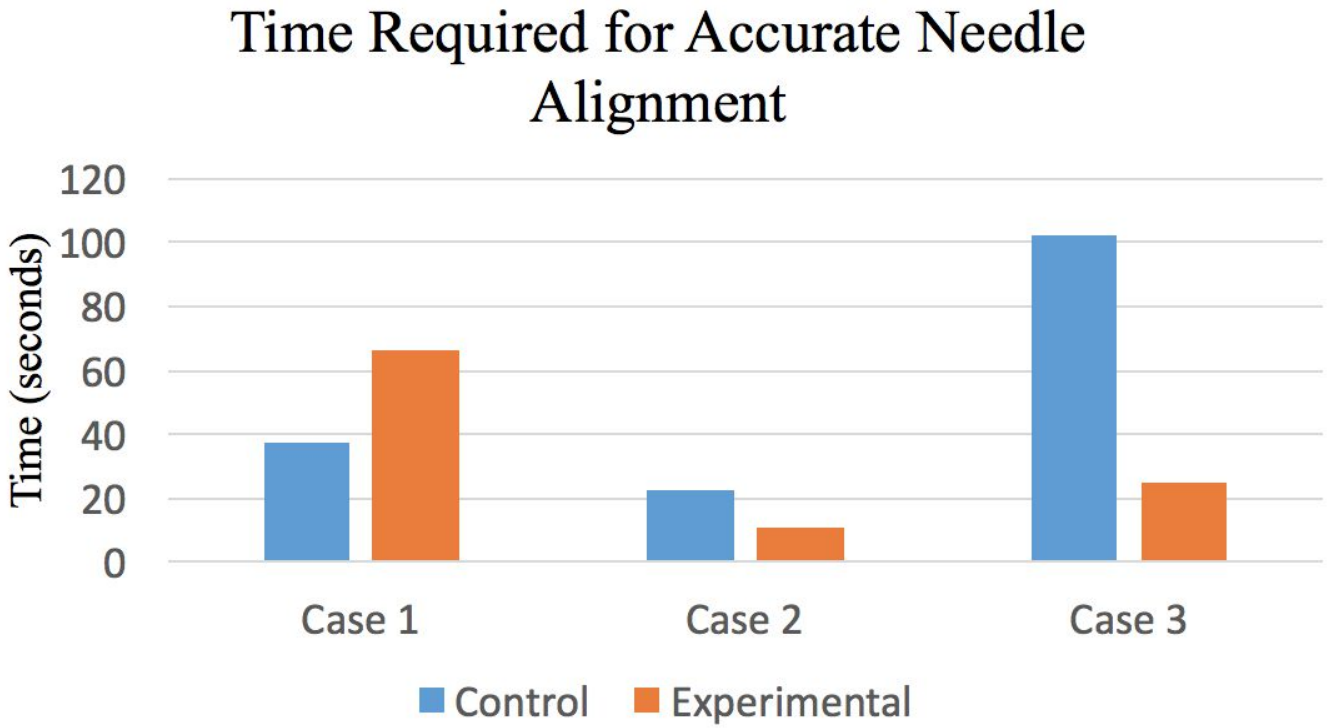
Top-image



Orthogonal-view

Localization with Guide

Clinical Testing Results

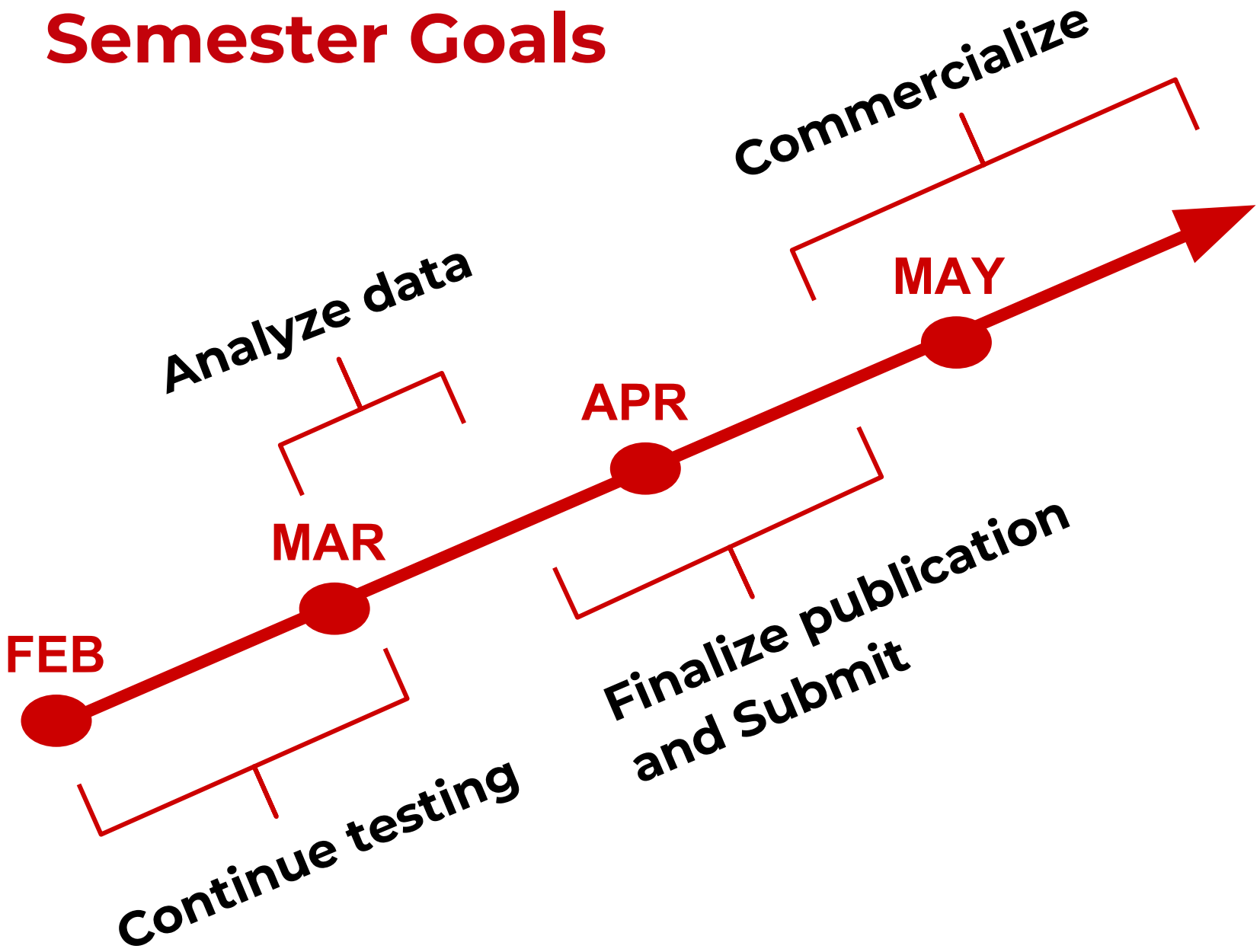


- Reduced localization time for ⅔ subjects
- Maintained accuracy *n=3

Draft of Publication

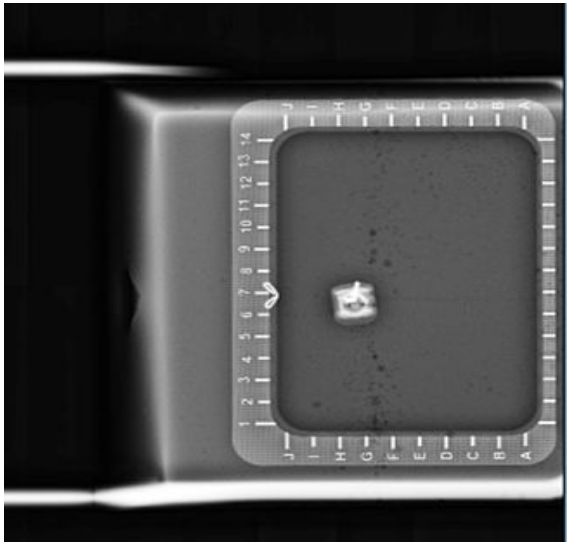
- **Goal :** Introduce a validated, Novel Needle Guide for standardizing and improving the efficiency of Preoperative Wire-Guided Localizations of Breast Lesions
  - Maybe:
    - Easier for new learners
    - correlation with current skill level
- Potential Journal: IEEE Journal of Translational Engineering in Health and Medicine
  - Maybe higher impact - based on results

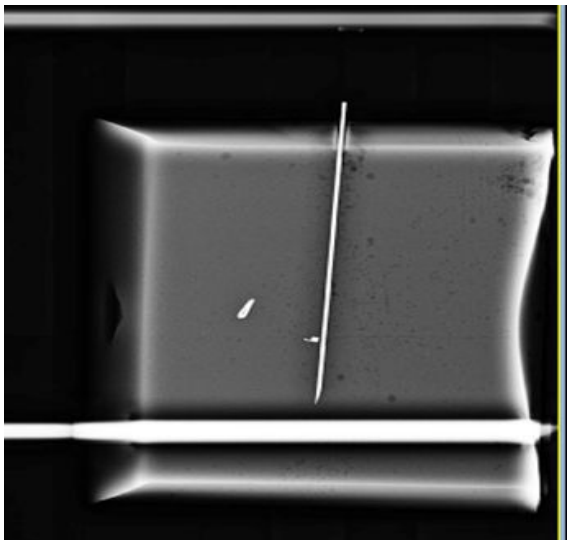
Semester Goals



Data Analysis Plan

1. Difference in time from initial needle puncture to final removal of needle
2. Perpendicular puncture
3. Distance between clip and needle
4. Number of corrections during procedure
5. Other correlations from Survey
6. Statistical Analysis





Expected Results

1. Procedure with device is faster while maintaining/ improving accuracy
2. Gets perpendicular puncture every time
3. Device is comfortable to use

*Other client requirements already met

Commercialization Details

1. Provisional Patent
2. Find faster, cheaper, more sterile manufacturing method.
3. Each guide packaged in sterile bags - one per patient use.
4. Include pictographic user guide - maybe send representatives to train users
5. Include safety information - for patients and physicians.
6. Approach Hologic with our device.

Budget Info

- Fall Semester Budget: $200.00
- Spring Semester Budget: <$100.00

Description	Part #	Source	Quantity	Cost (Per Unit)
Humimic Phantom gel	852844007819	Humimic Medical	1	$46.05
4x4x4 tin mold for phantom gel	111-4682432-464	Amazon.com	1	$29.99
Humimic Phantom gel	2955	Humimic Medical	1	$35.11
Flesh tone, opague pigment dye	111-5042561-625	Amazon.com	1	$11.50
Printed Design presentation poster	N/A	UW-Madison	1	$48.00

Acknowledgements

Dr. Lonie Salkowski

Dr. Beth Meyerand

Dr. Frederick Kelcz

BME Design Faculty

UW Makerspace Faculty