Novel Needle Guide for Preoperative Wire-Guided Localization of Breast Lesions

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Abstract

Lumpectomy, surgical removal of the lesion is the standard treatment for patients with early-stage or small breast cancers [1]. Most lumpectomies are preceded by a tumor localization procedure that can be performed using various methods. One method is by using mammography for Image guided localization (IGL). IGL involves localizing the lesion using a fine wire with a hook to assist the surgeon in identifying non-palpable lesions [4,5]. IGLs are a manual technique, depending heavily on the radiologist's skill level. The procedure takes approximately 15 to 45 minutes to place the wire(s) depending on the complexity of the case. Often this can result in multiple corrections of the needle placement prior to wire deployment to ensure that the wire(s) properly localizes the lesion for surgical removal [4]. Our team has designed a needle guide that can streamline the process and reduce variability between physicians. The guide is a single-handed, ring-based model that can be removed from the imaging area with ease to prevent interference with the X-ray. The hinges and cylindrical composition of the guide stabilizes the needle and ensures perpendicular puncture, its conical bottom opening allows the clinician to easily locate the initial marking on the patient, and the countersink allows for maximum assisted-puncture. It is also one-time use for maintaining sterility and is made of Grey-Pro SLA resin for mechanical strength and stability. Pilot testing on a phantom breast model was performed by a radiologist to confirm the ergonomic and assistive characteristics of the needle guide. Further understanding of its benefits over the standard procedure, as well as to test whether the guide improves procedures performed by new and/or inexperienced clinicians, will be studied in the future. The objective of this article is to introduce a novel needle guide that helps streamline the pre-lumpectomy, image-guided breast lesion localization procedure.

I. Introduction

Breast cancer is the leading cause of cancer death in women [6]. The standard of care for patients with early-stage or small breast cancer is a conservative surgical approach to remove only the cancerous tissue and some surrounding healthy tissue while preserving the breasts (i.e. lumpectomy) [1]. Tumors that are best seen on mammography undergo a mammographic-image based wire localization procedure in which the lesion is localized using a needle containing a fine wire with a hook, so the surgeons can identify the location of non-palpable lesions during the lumpectomy procedure [4,5]. The current method for performing the procedure, is a manual technique that often requires multiple corrections and x-ray images; this contributes to patient discomfort, pain, and anxiety [5]. In this paper, we introduce a novel needle guide that streamlines image-guided localizations (IGL) and increases accuracy of initial puncture, thereby reducing the need for numerous x-ray images, corrections, and procedure time.

1.1 Mammography Guided Wire Localization Procedure

Preoperative procedures for localizing non-palpable breast lesions are often performed with mammographic guidance. While numerous other methods for localization such as the Radioguided Occult Lesion Localization and Radiolabeled Seen Localization are being studied, image-guided wire localizations (IGL) remains the gold-standard preoperative localization procedure [5,7]. During IGL, the lesion is first identified by taking a mammographic image with the breast under compression (Figure 1.A). If a biopsy was performed, a titanium clip is left at the region of interest and this clip can also be used a marker for localization.

The breast is compressed with a fenestrated plate that displays an alphanumeric-label at the margins of the window which the radiologist can use to identify the location of the lesion (or titanium clip) in the XY plane (Figure 1.B). After marking this location, it is anesthetized with the injection of a local anesthesia such as lidocaine. Next a needle housing a fine wire with a hook is inserted with assistance both from the light source shining down from the top (craniocaudal projection) of the mammography machine and the shadow created by the needle hub. The hub creates a square shadow on the breast with which the physician can center the needle to insert it perpendicularly (Figure 1.C). Once the needle is inserted, another X-ray is taken to determine if the needle intersects lesion, or area of interest, within the square of the needle hub (Figure 1.D). The accuracy tolerance of this insertion is typically considered to be up to 1 cm from the lesion (or titanium clip) [8]. If the intersection does not meet the margin, the needle must be backed out and realigned with another X-ray taken after each adjustment. After proper location this imaging plane, the imaging head is then rotated orthogonally and the patient's breast is put into lateral-medial compression for another X-ray to evaluate the depth of the needle (Figure 1. E). The depth of the needle is adjusted by pulling the needle out of the breast to optimally localize the lesion. Once the

radiologist is satisfied with the localization, the needle is removed, and the wire is left inside the breast, after which the patient is transported to the operating room.

This procedure can also be performed starting in the lateral projection and later imaging in the craniocaudal project. Overall this procedure needs two orthogonal imaging planes to ensure the accuracy of wire placement in 3D space. The surgeon uses the mammography images with the hook-wire inside as seen in figure 1.F, as well as the exposed wire, to plan the incision and remove the lesion. The procedure is performed by radiologists the day of the planned lumpectomy, takes approximately 30 to 45 minutes [4,5].

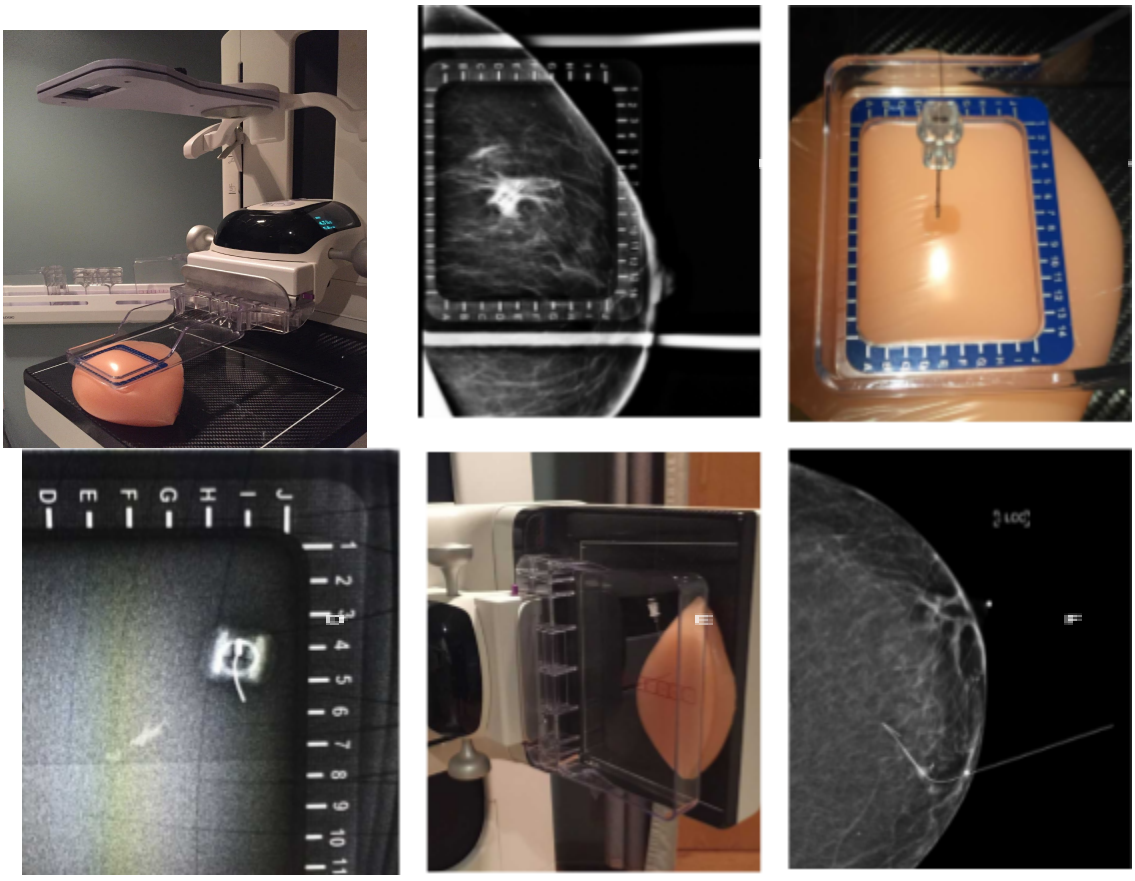

Figure 1: The images above show a few of the important steps of IGL. **A:** Image of a breast phantom in compression with the mammography machine. **B:** X-ray image tumor location and alphanumeric grid. **C:** The hub of the needle creating a shadow on the breast phantom. **D:** Top image with needle, wire and hub. **E:** Lateral compression of a phantom breast with localization needle and wire. **F:** Final image with wire-placement after needle removal.

1.2. Drawbacks of Current IGL

The current method for performing IGL is highly manual, often requiring numerous corrections and images; the quality of procedure also depends on the skill level and experience of the radiologist. This introduces variability in the quality of care patients receive depending on the expertise of the radiologist. Additionally, patients have an increased risk of vasovagal reactions (due to fasting and associated anxiety), complain of discomfort from the long duration of the procedure, and show high anxiety from having a major procedure performed right before surgery [5]. The time required for the current procedure also introduces scheduling problems and limits the number of patients that can effectively be treated [5]. Therefore, it is essential that the procedure is streamlined and made more efficient while improving accuracy of lesion localization.

1.3 Competing Devices

In 2003, a grid system with holes for needle insertion was recommended by researchers from the University General Hospital, Murcia, Spain [8]. However, the system is not shown to be widely used clinically since it does not guide the needle insertion to ensure accurate localization (i.e. procedure is still mostly free-handed), still relies on radiologist skill level, adds time for adding the plate into the procedure, and introduces high barrier of introduction since it requires the clinicians to change their current training and methods significantly. Numerous studies have also suggested methods for improving the wire and hook, compression mechanism of the breast, as well as insertion directions or tactics, however the procedure is still extensive and continues to have the drawbacks described in section 1.2 [10-18].

1.4 Efficacy of Needle Guides in improving other related-procedures

Needle guides have been introduced in the ultrasound-guided biopsy procedure, and clinical studies have shown their usefulness in improving accuracy, standardizing care, lowering time of procedure, and reducing errors in both experienced and inexperienced operators [19,20]. We are confident that our needle guide will provide similar benefits in improving the IGL procedure.

II. Functional Requirements

The needle guide must assist with the localization process by allowing for exact orthogonal needle alignment by the physician to ensure accuracy of procedure (Figure 1.D). This product must be compatible with the current mammography machine and procedures that are used, and have a low barrier to introduction in the clinics. In addition, the device must be safe for the physician and the patient. Along with safety, the product must be easily sterilized after manufacturing, and have a low enough cost for one-per-patient use. It must also be ergonomic, easy to use, withstand drops and pressure from use.

1. Operational Potential:	How effectively does the design improve the localization process?
2. Radiolucency:	Will the design interfere with X-ray images?
3.Versatility/Handling:	How easily/well can the physician use and operate the device?
4. User and Patient Safety:	Is the design safe for both the physician and the patient?
5. Ease of Integration:	How easily can the design be integrated into the current localization procedure?
6. Sterility:	Can the design be easily sterilized?
7. Stability:	How stable is the design during its use?
8. Durability:	Can this design be reused many times without breaking?

Table 1. Primary criteria for the design of the rapid needle alignment device in order of relative importance/significance.

III. Needle Guide Design Description

The assistive needle localization guide we propose for use with the mammography machine is shown in Figure 2. It consists of two pieces, connected by a pin inserted into a pin hinge. In use, it is designed to be single-use to ensure sterility and minimize durability concerns. This design was finalized after 6 iterations of 3D printed guides followed by physician client validation.

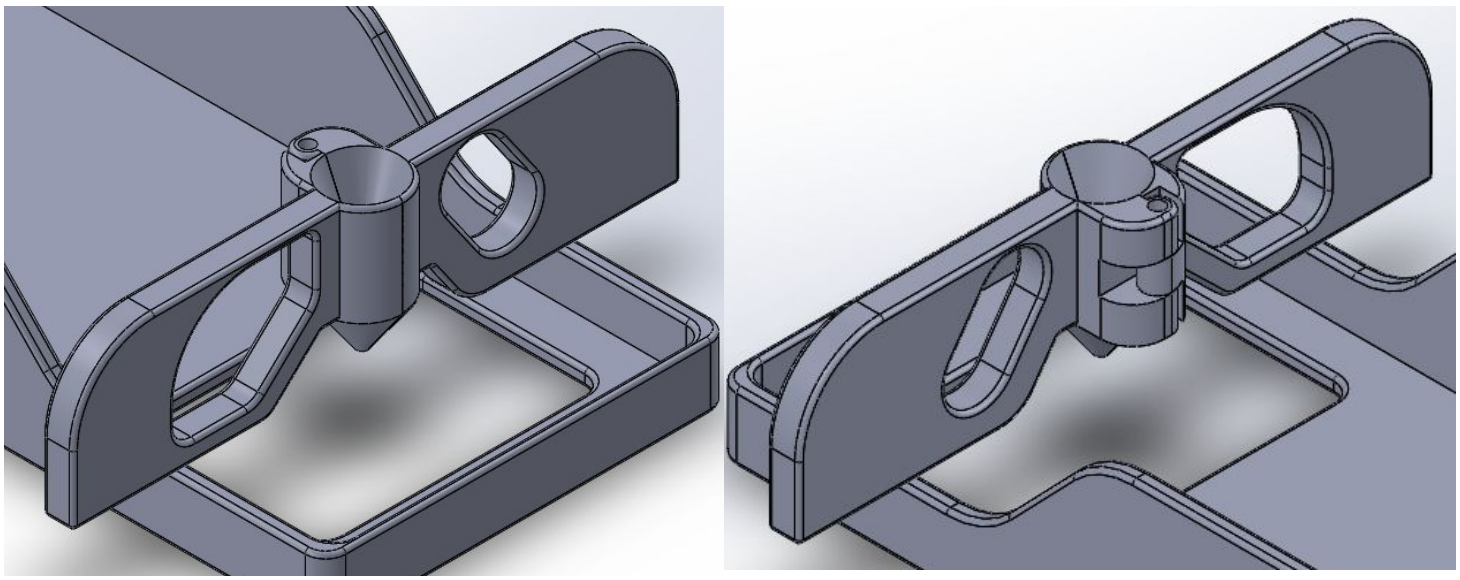

Figure 2. 3D SolidWorks models of the front and back of the needle guide placed on the fenestrated plate in its functional insertion position (on a scale model of the fenestrated plate). The radiologist will insert the needle into the countersink region at the top of the guide until the desired depth has been achieved.

3.1 Mechanical Specifications

Our final design of the needle guide incorporates a handheld design to achieve perpendicular puncture during localization. This is enacted by the use of two flanges which use reference points on the fenestrated compression plate to rest on. The needle is inserted through a tubular chamber in the center of the guide, between the flanges. This chamber is prefaced with a large countersink to provide both an easy aiming experience for the physician and a maximal insertion depth without reducing mechanical stability. At the bottom of this chamber, there is a cone which comes down to the point where the needle exits the chamber. This allows for easy and ergonomic aiming of the mark on the patient. On either side of the insertion chamber, two large holes exist for the user to place their fingers into. This, alongside the hinge, will allow for single-handed use, which allows for easy integration into the current procedure. The pin hinge was incorporated to prevent out-of-plane rotation, providing additional stability. Finally, the edges of the guide are rounded to provide a smooth finish for comfortable use. The prototype was 3D printed with Grey Pro SLA resin for easy hinge rotation while ensuring strength. For mass production, injection molding will be used, and the needle guide will be sterilized using Ethylene Oxide and/or Hydrogen Peroxide [21]. This device has been designed to be completely mechanical and disposable to provide ease of integration in the clinics and provide physicians with the option to not use it for highly unique or intricate patients.

IV. Methods

4.1 Preliminary Testing

Preliminary testing using the breast model and our final needle guide was wielded by a practiced physician who performed the localization procedure on silicone breast model rather than a human subject. The testing was performed on the Selenia Dimensions mammography machine: Hologic, Marlborough, MA [22]. During testing, the physicians first performed the free-handed IGL procedure using the overhead light's shadow to guide the needle into the breast model and then utilized our device for IGL. The physician's feedback regarding the comfortability of the device, ease of use, etc. was taken into consideration while drafting the clinical study. Additionally, a bubble tap was used to ensure the device maintained perpendicularity on the plate, and researchers observed the physician's technique multiple times to ensure that the hinge worked well, the device was easy to remove, the countersink allowed for maximum insertion, and the removal of the device did not interfere with the accuracy or perpendicularity of insertion. Additionally, mammography images from the current method and after the use of our device was taken to assess the preliminary accuracy of our device. Finally, the efficacy of the silicone breast model for testing and objective metric measurement was analyzed.

4.2 Clinical Testing

To determine the effectiveness of our designed localization needle guide compared to the traditional freehand method, we received IRB approval for clinically testing the device. The testing set-up is identical to the set-up used in the current methodology of a needle localization procedure, except a phantom breast model will be used in the place of a patient. The newly developed breast model will be in a hospital or clinic room with a radiologist, a mammography machine, and any other support staff necessary for the localization procedure. Breast models will be randomly assigned to each phase (control vs. experimental). Each physician participating will complete both phases of the study. The study subjects will be any hospital staff trained to perform the needle localization procedure. They will first take a pre-study survey reporting their current experience with the procedure and amount of training received. Next, the subjects perform the standard localization procedure while the researchers record the following metrics: time from initial needle puncture to final removal and number of corrections and images during procedure. Next, the subjects are trained to use the needle guide using a standard training protocol. They are all given 15 minutes maximum for training. Then, they perform the procedure with our needle-guide while the researchers measure the same metrics. After all the subjects finish with testing, we will analyze the accuracy of needle puncture in the final medio-lateral images; the researcher performing the analysis will be blinded to the images.

V. Preliminary Testing Results

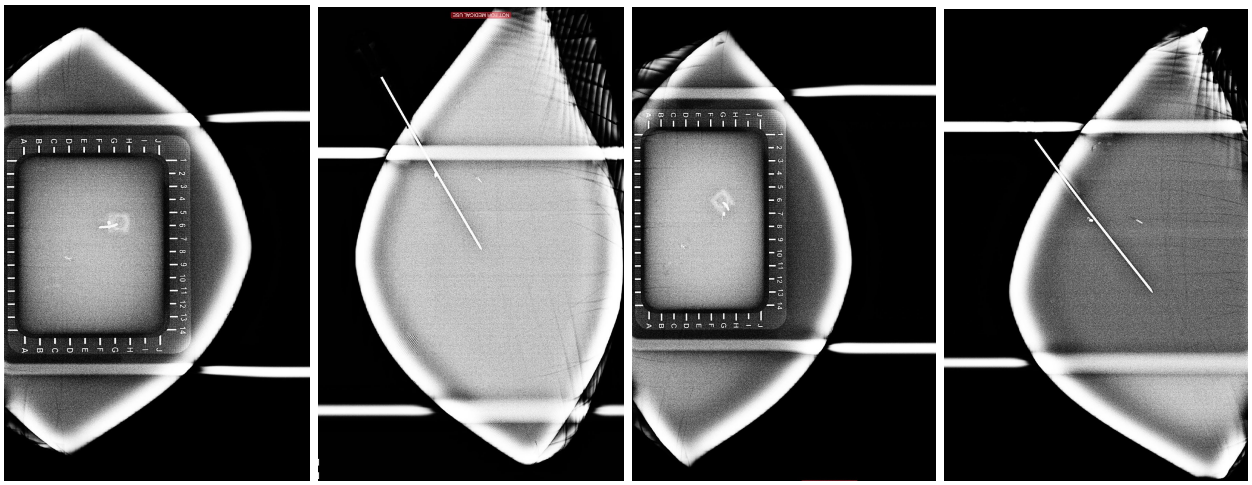

Figure 3: Mammographic images from testing using silicone breast phantom model. **A:** Top-image from free-hand localization. **B:** Image from mediolateral compression after free-hand localization. **C:** Top-image from guide-assisted localization. **D:** Image from mediolateral compression after guide-assisted localization.

The physician was very well trained and performed the free-handed localization procedure with ease. However, after the physician performed the procedure with the needle guide device, it was found that the number of corrections and x-ray images used as well as procedure time was higher during the free-handed procedure. Since this testing was purely for fine-tuning our device and clinical testing procedure, those numbers/ times are not reported. During the needle-guided procedure, a bubble-tap proved that the needle guide's horizontal surface was aligned parallel with the plate, thereby proving that the cylindrical component of the guide was perpendicular the plate. The physician inserted the needle through the middle of the countersink into the model until the hub was impeded from further penetration. After insertion, the physician easily removed the device from the fenestrated plate without affecting the needle, thereby verifying the functionality of the hinge mechanism as well as the ease of integration into the current procedure. The physician did not have any discomfort free-handing the last part of the needle after device removal. The final figures taken after the freehand technique and the needle-guide showed similar accuracy (Figure 3). Effectively, this testing verified that the needle guide stably holds the needle in an orthogonal position relative to the fenestrated plate, is usable with one hand, is stable in guiding the needle, lowers the number of corrections and the time required for the procedure, and has a low barrier to introduction in the clinics. Additionally we discovered problems with our current breast model and decided to develop a new model as described below in part VI for the actual clinical testing. The silicone breast model used for preliminary testing had a tendency to accordion-out when taken out of compression for imaging the medio-lateral orientation. Thus, there was variability in how the breast was re-compressed for the second image. In a real patient, this is not a problem since the breast cannot freely rotate; therefore, we decided that our model will need to be a cube that is less compressible, so we can ensure that the model orientation is standardized between testing subjects.

VI. Development of Breast Model

Trials with tissue explants, soft silicone models, and a number of gels were done to idealize a phantom breast model for IRB studies. The breast model material best suitable for the localization device testing was determined to be an elastomeric copolymer gel produced by Humimic Medical™. The properties of the gel allowed for numerous advantages including moldability, anatomically similar density and reusability. In order to allow for simple X-ray imaging (i.e. mediolateral and craniocaudal images), the breast model was made in a cubical shape. The fabrication steps shown in Figure 4 illustrate the melting and molding process utilized to produce the final model. First, the clear raw gel is melted down at approximately 230 degrees fahrenheit until liquified. Once the gel is in its liquid state, concentrated flesh tone pigment dye is added at approximately 2% by weight. This allows for the phantom to be opaque for the purposes of the study. Lastly, the homogeneous gel is removed from the heat source and immediately poured into a 4 inch x 4 inch x 4 inch aluminum mold. After being left to harden and cool for 18-24 hours, the elastomeric gel is usable for the study and can be remolded for extended use.

Figure 4: Images depicting breast model fabrication steps. **A:** (Left) Liquified gel at 230 degrees Celsius. **B:** (Center) Pouring flesh-toned gel into aluminum. **C:** (Right) Semi-solid phantom gel during hardening process.

VII. Clinical Testing Results

Thus far, three study subjects have tested the guide in the clinical setting. The procedure for this study can be found in Section 4.2. The images in Figure 5 show the craniocaudal (CC) and mediolateral (ML) X-ray images taken during both the control and experimental phase of the study from just one participant. Seen in each X-ray image are two titanium clips placed into the breast model at the outset of this testing session. The clip that the clinician localized is the smaller mark seen closer to the needle in Figure 5B.

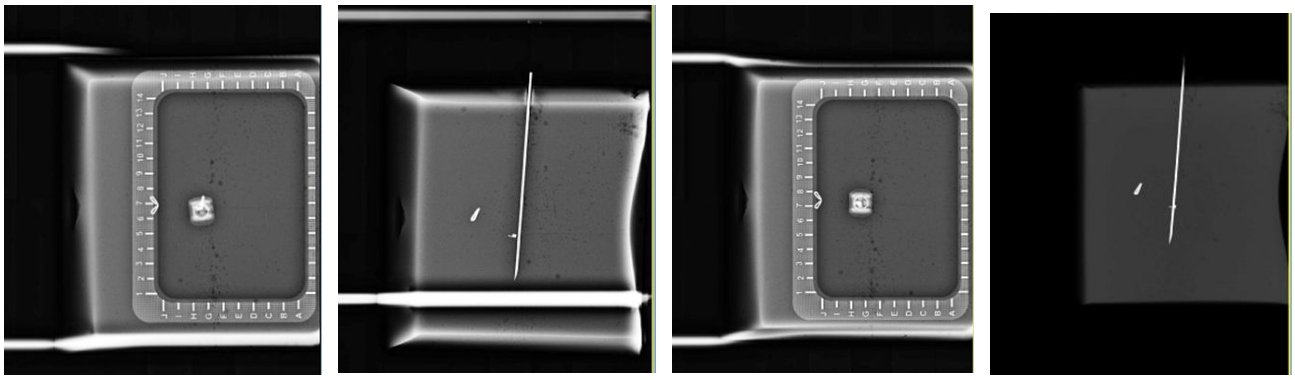

Figure 5: Mammographic images from testing using elastic co-polymer breast phantom model. **A:** Top-image from free-hand localization. **B:** Image from mediolateral compression after free-hand localization. **C:** Top-image from guide-assisted localization. **D:** Image from mediolateral compression after guide-assisted localization.

Since there have only been three trials in the study so far, a full statistical analysis cannot be run at this point. There are a few general trends that we have seen, though, throughout our data collection. One such observation is that the guide appears to reveal a time reduction in needle alignment while using the needle guide, which can be seen in Figure 6. While reducing time, our device also maintained the accuracy of the procedure. According to practicing physicians in the clinic, the needle need only be inserted within about 5 mm of the titanium clip it localizes in order to be considered a successful localization. The images in Figure 5 show that use of the device maintained the accuracy of the procedure, getting the needle as close, if not closer, to the clip as the standard localization did.

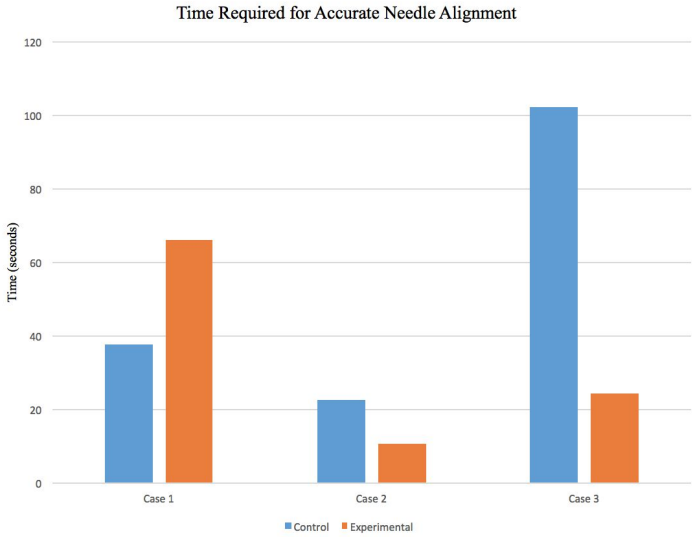

Figure 6: Graph showing the time required for accurate needle alignment for each of the three participants during both the standard procedure (control) and the procedure using the guide (experimental) parts of the study. This is the time the physicians spent inserting the needle into the breast tissue and then adjusting it to get a proper puncture. Note: The Case 3 participant took a few X-ray images before she felt comfortable with her needle insertion in the experimental phase of the study. As such, the time plotted in the graph displays the time for her final needle alignment.

After reviewing the qualitative data gathered thus far from the pre- and post-study surveys, it was observed that some physicians preferred using device during the procedure while some did not. Affinity for the guide correlated with age, with the younger physicians favoring the device and the older physicians preferring the traditional technique. Medical learning techniques, training time with the device, and study design may have an effect on device affinity as well. The breast phantom used in the study also may have an effect on the results as well. Noteworthy suggestions from the study subjects included softening the phantom to more accurately represent breast tissue. While this may

not directly cause issues with the accuracy or efficiency of our device, it may cause an uncomfortable or unfamiliar experience while completing our study.

VIII. Conclusions and Future Work

The primary goal of the needle guide is to streamline the IGL process in breast cancer treatment and reduce the variability in procedure between physicians by providing exactly orthogonal needle alignment during puncture by the physician. Our hand-held ring design achieves this goal by incorporating two flanges that sit on the localization plate perpendicularly, forcing orthogonal alignment of the needle. Our guide is 3D printed, features a hinge for stability, and utilizes a conical shape to guide the needle down to a specific point with accuracy in the range of a fraction of a millimeter. Secondary goals that were achieved in development include seamless integration into the current mammography machine, equipment, and procedures that are currently used, safety for the physician and the patient, ease of use, durability over repetitive use, and sterility. Though our device meets all of the aforementioned design specifications, the design can only truly be validated through clinical testing. We will continue carrying out this validation through an institutional review board (IRB) approved study in which trained clinicians as well as inexperienced clinicians in-training perform the procedure with and without the device. More qualitative and quantitative data from this research will be collected, and a full blind statistical analysis will be run. These results hope to verify the clinical effectiveness of our instrument, as well as show the efficacy of implementing our device from the training process to avoid variability in standard of care based on the expertise of the clinician.

IX. Acknowledgements

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