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

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Abstract

The objective of this article is to introduce a novel needle guide that helps streamline the pre-lumpectomy, breast lesion localization procedure. Lumpectomy, surgical removal of the tumor mass, followed by radiation therapy (RT) is the standard treatment for patients with early-stage or small tumor breast cancer [1]. Lumpectomies are prefaced by an X-ray mammography-based wire-guided localization (WGL) in which the lesion is localized using a fine wire and hook to assist the surgeon in identifying non-palpable lesions [4,5]. WGL is mostly manual, depending heavily on the radiologist's skill level; localizations require approximately 60 minutes with repeated corrections and imaging, exposing patients to sources of radiation and thus risks for secondary malignancies [4]. Our team has designed a needle guide that can eliminate the need for excess X-ray imaging once the location of the tumor is marked, thereby reducing patient radiation exposure while optimizing the time of procedure. The guide is a single-hand, 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. Preliminary testing on phantom breast models by radiologists confirmed the ergonomic and assistive characteristics of the needle guide. IRB approval for a clinical study has been received for 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.

I. Introduction

1 in 8 women in the United States are diagnosed with breast cancer in their lifetime [6]. Though the predominant demographic for this disease is women, about 2000 men in the United States are diagnosed per year as well [6]. Once diagnosed, patients fight an emotionally and physically draining battle through the treatment process. The standard of care for patients with early-stage or small tumor 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]. The National Comprehensive Cancer Network (NCCN) also recommends radiation therapy following the lumpectomy, increasing patient risk for developing secondary malignancies by 15-20% [1,2,3,4]. Lumpectomies are prefaced by an X-ray mammography-based wire-guided localization (WGL) procedure in which the lesion is localized using a needle containing a fine wire and hook, so the surgeons can identify the location of non-palpable lesions[4,5]. The current method for performing WGL, as further detailed below, is highly manual, requiring multiple corrections and x-ray images during the procedure for accurate localization of the lesion; this further exposes patients to radiation and increases their risk for secondary malignancies, and increases their discomfort, pain, and anxiety [5]. In this paper, we introduce a novel needle guide that streamlines WGL and increases accuracy of initial puncture, thereby reducing the need for numerous x-ray images, patient exposure to radiation, and procedure time.

1.1 Wire Guided Localization Procedure

X-ray integrated mammography machines are widely used in a preoperative procedure for localizing non-palpable breast lesions. While numerous other methods for localization such as the Radioguided Occult Lesion Localisation and Radiolabeled Seen Localisation are being studied, WGL remains the gold-standard preoperative localization procedure in clinics [5,7]. During WGL, the titanium clip left at the area of lesion during the initial biopsy is identified by taking a mammographic image with the breast under compression (Figure 1.A). The breast is compressed with a fenestrated plate that has an alphanumeric-labeled window, which the radiologist can use to identify the location of the titanium clip in the XY plane (Figure 1.B). Once the location is marked, a needle housing a fine wire with a hook is inserted with assistance both from the light source shining down from the top 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 the clip 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 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. The machine 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 adjustment process is repeated until the needle is in the correct position in relation to the breast. 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. The surgeon uses the mammography images with the hook 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, and takes approximately 60 minutes during which the patients are under local anesthesia [4,5].

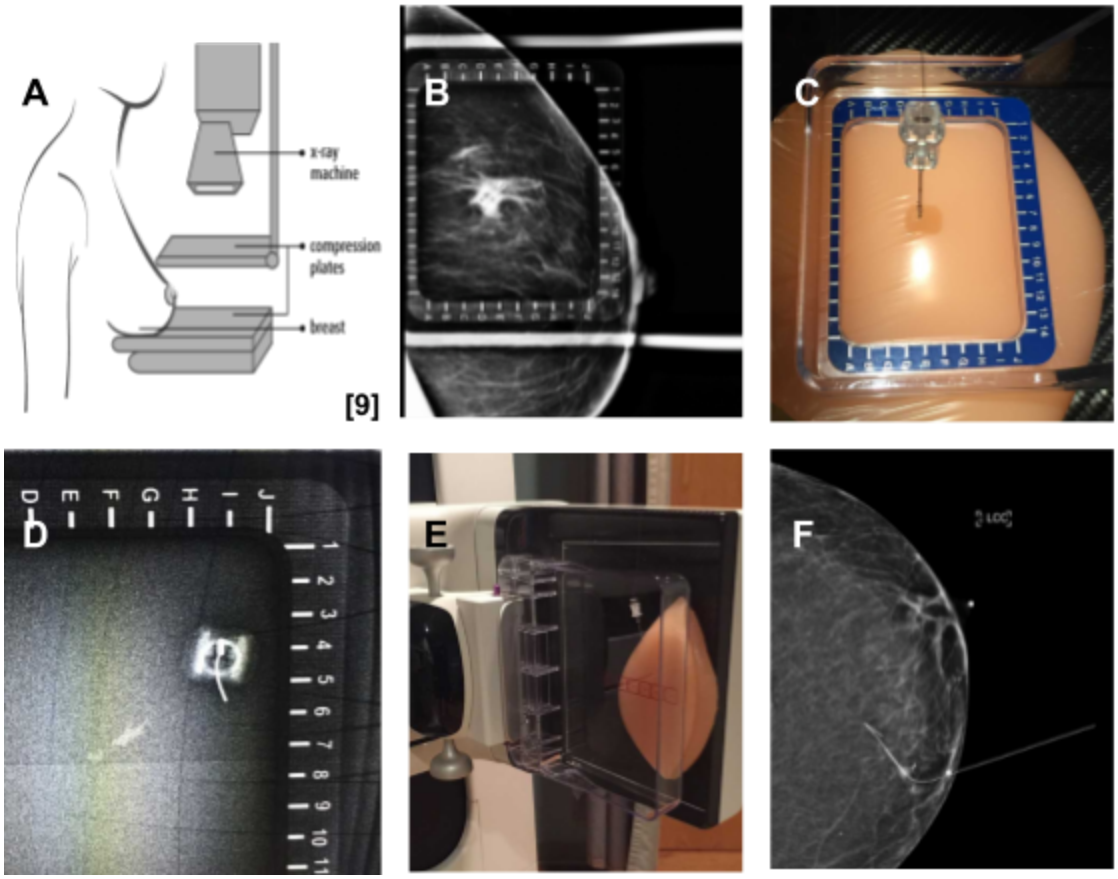

Figure 1: The images above show a few of the important steps of WGL. **A:** A diagram of the patient orientation and breast compression with the mammography machine. **B:** X-ray image tumor location and alphanumeric grid. **C:** The hub of the needle creating a shadow. **D:** Top image with needle and hub. **E:** Mediolateral compression of a phantom breast. **F:** Final image with wire-placement after needle removal.

1.2. Drawbacks of Current WGL

The current method for performing WGL is highly manual, requiring numerous corrections and images; the quality of procedure also depends on the skill level and experience of the radiologist. This exposes patients to additional sources of radiation and therefore risks for secondary malignancies, and it also changes the quality of care they receive depending on the expertise of the radiologist. Additionally, patients present high incidence of vasovagal reactions, complain of discomfort from the long duration of the procedure, and show high anxiety from having a major procedure performed right before surgery. 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 and lowering radiation exposure.

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 in clinics 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 WGL 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, and eliminate the need for top images (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 X-ray 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 testing.

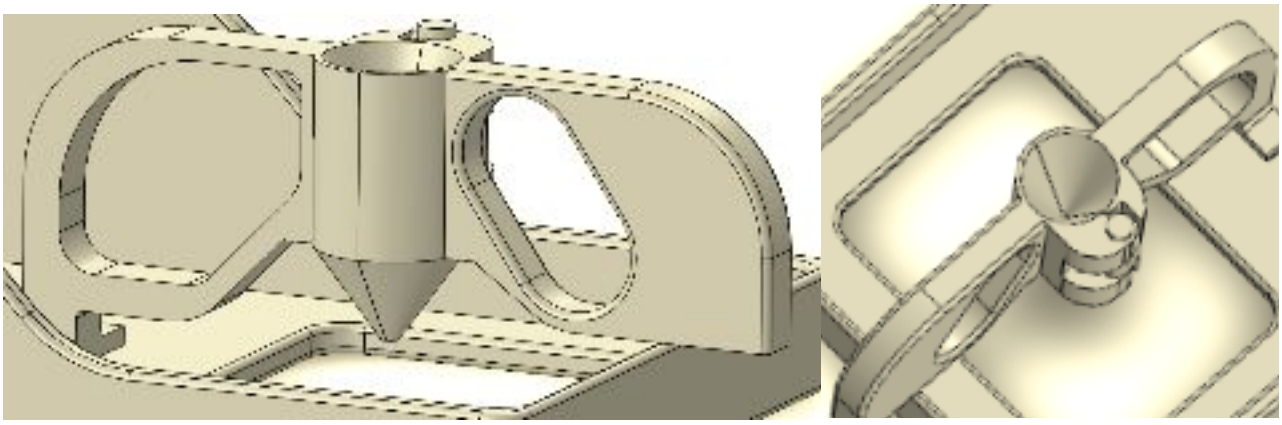

Figure 2. 3D SolidWorks models of the needle guide placed on the fenestrated plate in its functional insertion position. The radiologist will insert the needle into the countersink region at the top of the guide until the desired depth has been achieved.

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; it mimics the movement of using ones fingers to compress the breast tissue before needle insertion. 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 3D printed with Grey Pro SLA resin for easy hinge rotation while ensuring strength is shown in figure 3. For mass production, injection molding will be used, and the needle guide will be sterilized using Ethylene Oxide and/or Hydrogen Peroxide [21].

Figure 3. Grey Pro SLA resin 3D printed and assembled prototype of needle-guide.

IV. Preliminary Prototype Testing

Preliminary testing with the current working prototype confirmed that it effectively meets the functional requirements discussed in Section II. This needle guide was wielded by two practiced physician to perform the localization procedure using a 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 WGL procedure using the overhead light's shadow to guide the needle into the breast model and then utilized our device for WGL. The physicians placed the guide on the fenestrated plate with one hand, aligning the conical component of the device with the external mark on the tissue. A bubble-tap was used to prove 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 then 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, 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, and the precision of insertion was not affected. The physician was told to avoid taking top pictures as shown in Figure 1.D and directly take the image seen in Figure 1.F. Since the device verified perpendicularity, the physician did not need to take X-ray images to ensure this, as is standard in the current procedure. The final figures taken after the freehand technique and the needle-guide showed similar accuracy, but the use of our guide required less time and images. 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, eliminates the need for the set of X-ray images that ensured needle perpendicularity as seen in figure 1.D, lowers the time of procedure, and has a low barrier to introduction in the clinics. [IMAGES STILL NEED TO BE TAKEN FOR THIS SECTION. WILL SCHEDULE TIME WITH DR. SALKOWSKI].

V. Conclusions and Future Work

The primary goal of the needle guide is to streamline the WGL process in breast cancer treatment and reduce the amount of patient radiation-exposure 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 carry out this validation through an institutional review board (IRB) approved study in which trained clinicians as well as inexperienced clinicians in-training will perform the procedure with and without the device. Qualitative and quantitative data from this research will verify the clinical effectiveness of our instrument, as well as show the efficacy of implementing our device from the training process to avoid differences in standard of care based on the expertise of the clinician.

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VII. References

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

[2]L. Burt, J. Ying, M. Poppe, G. Suneja and D. Gaffney, "Risk of secondary malignancies after radiation therapy for breast cancer: Comprehensive results.", *The Breast*, no. 35, 2018.

[3]E. Obedian, D. Fischer and B. Haffty, "Second malignancies after treatment of early-stage breast cancer: lumpectomy and radiation therapy versus mastectomy.", Journal of Clinical Oncology, 2000.

[4]"Pre-Surgical Needle-Wire Localization - UCLA Radiology, Los Angeles, Westwood, Manhattan Beach, Santa Monica, CA", *Radiology.ucla.edu*, 2018.

[5] S. Dua, M. Keshtgar and R. Gray, "Strategies for localisation of impalpable breast lesions", *The Breast*, vol. 20, no. 3, 2018.

[6] R. L. Siegel, K. D. Miller, and A. Jemal, “Cancer Statistics, 2017,” *Wiley Online Library.*

[7] R. Gray, C. Salud, K. Nguyen, E. Duaway, J. Friedland, C. Berman, E. Peltz, G. Whiteland and C. Cox, "Randomized Prospective Evaluation of a Novel Technique for Biopsy or Lumpectomy of Nonpalpable Breast Lesions: Radioactive Seed Versus Wire Localization", *Annals of Surgical Oncology*, vol. 8, no. 9, 2001.

[8] J. Berna-Serna, J. Nieves, M. Madrigal and J. Berna-Mestre, "A new system for localization of nonpalpable breast lesions with adhesive marker plate", *The Breast*, vol. 13, no. 2, 2004.

[9]“Mammography - Canadian Cancer Society,” *www.cancer.ca*.

[10] M.J. Homer, “Localization of nonpalpable breast lesions: technical aspects and analysis of 80 cases,” *AJR Am J Roentgenol,* no. 140, pp. 807-811, 1983.

[11] M.J. Homer, “Nonpalpable breast lesion localization using a curved-end retractable wire,” *Radiology*, no.157, pp. 259-260, 1985.

[12] M.J. Homer Preoperative needle localization of lesions in the lower half of the breast: needle entry from below." *AJR Am J Roentgenol*, no.149, pp. 43-45, 1987.

[13] D.B. Kopans, S. DeLuca, "A modified needle-hookwire technique to simplify preoperative localization of occult breast lesions." *Radiology*, no. 134, p. 781, 1980.

[14] D.B. Kopans, K. Lindfors, K.A. McCarthy, J.E. Meyer, "Spring hookwire breast lesion localizer: use with rigid-compression mammographic systems." *Radiology,* 157 (1985), pp. 537-538

[15] N.J. Parekh, J.N. Wolfe, "Localization device for occult breast lesions: use in 75 patients." AJR Am J Roentgenol, 148 (1987), pp. 699-701

[16] J.D. Berná, V. García-Medina, J. Pérez, C.C. Kuni, "A new apparatus for the localization of nonpalpable mammary lesions." *Eur J Radiol, 12*, 1991.

[17] H.H. Chen, J.R. Bernstein, M.L. Paige, A.R. Crampton, "Needle nonpalpable breast lesions with a portable dual-grid compression system. Work in progress." *Radiology*, no. 170, pp. 687-690, 1989.

[18] J. Bolmgren, B. Jacobson, B. Nordenström, "Stereotaxic instrument for needle biopsy of the mamma." *AJR Am J Roentgenol*, no. 129, pp. 121-125, 1977.

[19] L. Brattain, C. Floryan, O. Hauser, M. Nguyen, R. Yong, S. Kesner, S. Corn and C. Walsh, "Simple and effective ultrasound needle guidance system", *IEEE*, 2018.

[20] N. Bluvol, A. Kornecki, A. Shaikh, D. Fernandez, D. Taves and A. Fenster, "Freehand Versus Guided Breast Biopsy: Comparison of Accuracy, Needle Motion, and Biopsy Time in a Tissue Model", *Vascular and Interventional Radiology*, 2018.

[21] "Sterilization Methods and Their Impact on Medical Devices Containing Electronics", 2011. [Online]. Available: https://www.maximintegrated.com/en/app-notes/index.mvp/id/5068. [Accessed: 02- Mar- 2018].

[22] "Selenia Dimensions mammography system," *Hologic.com*, 2017.

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