Needle Navigator Final Report

Project Title: Needle Navigator: Support and Control Device for Image-Guided Minimally Invasive Procedures

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Abstract

Epidural steroid injections (ESIs) are a common treatment for chronic pain; however, they provide only short-term relief and have a low success rate, leading to repeat procedures that increase cost, radiation exposure, and patient discomfort. Current fluoroscopy-guided needle placement relies on manual adjustments, which introduce variability, prolong procedural time, and increase radiation risk to the patient and operator. Existing technologies, such as robotic systems and ultrasound-guided devices, improve precision but are costly or incompatible with fluoroscopic procedures. This project proposes a cost-effective, 3D-printed polycarbonate needle stabilization device designed for fluoroscopic-guided ESIs. The device features a lightweight, ergonomic design that enables ambidextrous, single-handed operation, precise angular control, and compatibility with 22- and 25-gauge needles. It minimizes unintended needle movements, reduces procedural time, and enhances operator safety by limiting radiation exposure. The testing protocol includes ergonomic evaluations, fluoroscopic imaging validation, and trajectory accuracy testing. By improving procedural accuracy and reducing the need for multiple adjustments, this device has the potential to enhance patient outcomes, decrease clinician fatigue, and lower healthcare costs associated with repeat ESIs. Future development will focus on refining the final design, incorporating alternative materials for increased durability, and integrating smartphone-based angle validation for enhanced precision.

Table of Contents

Abstract **2**
Table of Contents **3**
Introduction 4
Global Impact 4
Competing Designs 4
Problem Statement 5
Background 5
Biology and Physiology 5
Challenges in Minimally Invasive Radiology Procedures 6
Client Information 6
Design Specifications 6
Preliminary Designs 7
Preliminary Design Evaluation 9
Design Matrix 9
Design Matrix Criteria 9
Proposed Final Design 10
Fabrication 10
Materials: 10
Methods 11
Final Prototype 11
Testing and Results 12
Testing 12
Results 12
Discussion 13
Conclusions 14
References 14
Appendix 16
Appendix I: Testing Protocol: 16
Appendix II: Material Expenses: 17
Appendix III: Fabrication Plan: 17
Appendix IV: CAD Images: 18
Appendix V: Survey Questionnaire 18
Appendix VI: Survey Raw Data: 18
Appendix VII: Product Design Specifications: 19

Introduction

Global Impact

Lower back and neck pain are among the leading global health burdens, affecting 50%–80% of adults (from 18 to 65+) in their lifetime [1]. In 2013 alone, these conditions ranked as the third-largest healthcare expense in the U.S., with an annual cost of $87.6 billion, trailing only diabetes and ischemic heart disease [1]. A significant portion of this cost is attributed to epidural steroid injections (ESIs), a widely used but imperfect treatment for radiculopathy. Lumbar radiculopathy affects 486 per 100,000 people annually, and cervical radiculopathy impacts 83 per 100,000 [2], contributing to significant workplace productivity loss and reduced quality of life.

Radiculopathy is a condition caused by compression, inflammation, or injury to a spinal nerve root, leading to symptoms such as pain, numbness, or weakness radiating into the limbs. It can severely impact mobility and daily activities depending on the nerve affected. Despite this high prevalence, ESIs provide only short-term relief (two to six weeks) with no strong evidence for pain reduction beyond three months [2]. For every four to seven patients who receive an epidural steroid injection (ESI), only one experiences meaningful pain relief [2]. ESIs may not reduce the need for surgery, raising concerns about their cost-effectiveness [3]. Compounding these limitations, complications occur in 2.4% to 16.8% of cases, with severe risks including stroke, paralysis, nerve damage, and bacterial meningitis [1]. A more precise device could reduce the number of failed injections and minimize unnecessary repeat procedures. Reducing the need for multiple ESIs could create the opportunity to save millions annually in unnecessary injections and follow-up care. Therefore, a cost-effective and widely adoptable device could help standardize ESI success rates across various healthcare settings.

Competing Designs

Existing devices for image-guided interventions offer different advantages and limitations. The Patented Needle Holder for Image-Guided Intervention provides precise angle control and secure needle placement through its clip and guide arrangement [4]. Additionally, its resealable connection allows for easy needle disengagement. However, this device may not accommodate a wide range of needle gauges or varying insertion techniques since it is designed with a specific clip and guide mechanism. The Ultra-Pro II™ In-Plane Ultrasound Needle Guide by Civco Medical features a two-part system with a reusable bracket and a disposable snap needle guide, offering ease of use and cost efficiency in clinical settings [5]. The design allows for secure and consistent needle guidance, reducing variability in insertion. However, the device is specifically designed for ultrasound applications, making it incompatible with fluoroscopy-based procedures. Robotic systems like the 7-axis robotic platform, CRANE, and Zerobot® enhance precision and safety in image-guided procedures. The 7-axis platform improves needle accuracy in CT scanners [6], while CRANE enables dexterous tele-surgical manipulation within imaging bores [7]. Zerobot® allows remote-controlled needle insertion, minimizing radiation exposure for clinicians [8]. While these systems significantly improve accuracy, safety, and efficiency, their high costs and limited accessibility hinder widespread clinical adoption. The limitations observed in existing designs will shape the development of the prototype, guiding the project toward a more adaptable, cost-effective, and accessible solution for needle stabilization.

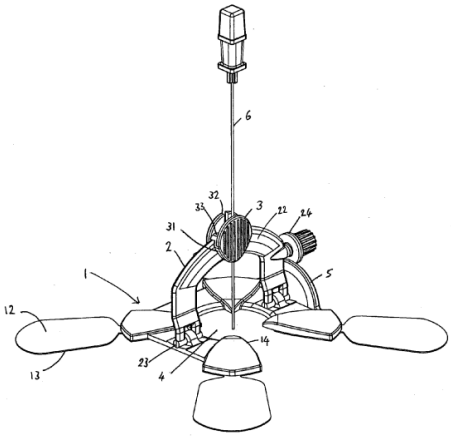


Figure 1: Patented Needle Holder for Image-Guided Interventions [4].

Figure 2: Ultra-Pro II™ In-Plane Needle Guide (Civco Medical) [5].

Problem Statement

Fluoroscopy provides only a two-dimensional view, limiting the ability to accurately assess needle depth and trajectory on the first attempt. Consequently, multiple fine adjustments are often required, further prolonging the procedure and exposing both the patient and clinician to additional radiation. A solution is needed to stabilize needle positioning, reduce the number of adjustments, and enhance procedural efficiency to improve accuracy while minimizing patient discomfort, clinician fatigue, and radiation exposure.

Background

Biology and Physiology

Epidural Steroid Injection (ESI) is a frequently used form of pain management [9]. Lumbar ESIs are used to reduce inflammation and alleviate pain radiating from the lower back to the hips, legs, and feet, resulting from conditions like herniated discs or spinal stenosis [9]. On the other hand, cervical ESIs treat inflammation and pain radiating from the neck to the shoulders, arms, and hands, especially for cervical radiculopathy, degenerative discs, and herniated discs [10].

Cervical ESI, the type of injection most commonly performed by the client, is typically given in a hospital or outpatient clinic, and the procedure takes about 15 to 30 minutes. The patient is required to lie down and stay still for the procedure to be precise. The targeted injection site is cleaned to prevent infections, and local anesthetic is sometimes administered to numb the area. The provider uses imaging guidance to slightly insert a thin epidural needle into the target and adjust its position until the correct placement is confirmed. The needle is then fully inserted into the affected nerve in a

transforaminal ESI through the foramina, the openings through which nerve roots exit the spine. A contrast dye can be injected into the patient to confirm proper needle placement on the imaging screen. The needle is guided into the right epidural space where the provider injects a corticosteroid medication and/or a local anesthetic to decrease inflammation and relieve pain. The provider then withdraws the needle as carefully as possible and places a dressing in place. Patients are observed for a few minutes to an hour after the procedure before they are discharged [10].

For these procedures, minimally invasive needle insertions target small, specific areas around the spine, requiring extreme precision with minimal margin of error [11]. The seven vertebrae of the cervical spine (C1 to C7) protect the spinal cord and brainstem and support head movement [12]. The epidural space, which surrounds the spinal cord, contains fat, blood vessels, connective tissue, and spinal nerves. Due to the critical structures in those regions and the abundance of blood vessels leading to the brain, improper needle placement or vessel puncture has a high risk of neurological complications such as stroke and spinal cord injury [13]. In order to mitigate such risks, the needle navigator must include a stabilization mechanism capable of reducing unintended movements and a controlled, precise needle insertion angulation.

Challenges in Minimally Invasive Radiology Procedures

Deflection of needles and tissue deformation are common problems in percutaneous procedures. Needle tip geometry and mechanical properties of the soft tissue may result in deviations from the intended path. For example, beveled tip needles tend to curve toward the bevel direction and make accurate trajectory control difficult [14]. Frictional forces during needle movement can also result in tissue deformation [15]. Research suggests that such deflection can be counteracted by controlled rotational adjustments and force-based feedback, a feature whose implementation feasibility must be evaluated [16].

Direct hand manipulation not only reduces precision due to instability but also places the operator's hands in the radiation beam, exposing them to additional risks associated with radiation [16]. The IR performs about 200 procedures a year, and without needle holders, the maximum allowable exposure limit (500 mSv) is reached after only 100 procedures [17]. The radiation dose can be expressed as:

$$D = \frac{A \times T}{m}$$

Equation 5: Radiation Dose Formula

where A represents the activity or exposure rate of the X-ray source (mSv/hr), T is the time of exposure (hr), and m is the mass (kg) of the tissue exposed. Equation 5 demonstrates how a decrease in exposure duration would lower total annual hand radiation exposure, keeping it below the regulatory limit and maximizing operator safety.

Client Information

Dr. Andrew Ross is a radiologist at the University of Wisconsin School of Medicine and Public Health. He has expertise in minimally invasive radiology and extensive experience with cervical spine injections. For this project, the client requested a solution that improves stability and adjustable control of needles in minimally invasive procedures.

Design Specifications

Efforts to minimize procedural time help reduce patient discomfort while increasing workflow efficiency. The device, intended for minimally invasive radiology procedures, incorporates features such as adjustable support to reduce needle bending, as well as one-handed, ambidextrous usability with precise angular control. It must secure and stabilize needles ranging from 2-6 in and be compatible with 22 and 25-gauge needles. Key client requirements include replacing the existing clamps, improving ergonomics, and being lightweight and easy to use. To enhance safety for both the patient and the doctor, the device must employ a locking mechanism to prevent accidental needle shifts. It must also be

fabricated using medical-grade, non-toxic materials. Due to its cost-effectiveness, 3D-printed polycarbonate filament was chosen for its radiolucency and durability. The design has a target weight of 170g that must comfortably fit within the operator's hand span to minimize physical strain [18]. It must be compatible with X-ray and fluoroscopic imaging, but it should not interfere with the imaging path. The device is intended for single-procedure use, therefore, it must contain sterile packaging and be easily disposable. Shelf life is approximately 1 year under defined storage conditions [19]. The device is classified as a Class II medical device by the FDA and should comply with the corresponding regulations and ISO standards [20]. Ultimately, the goal is to emphasize ergonomic operation, safety, stability, and procedural efficiency while addressing patient and doctor safety concerns, improving the method of minimally invasive radiology procedures, especially in anatomically delicate regions such as the cervical spine [see Appendix VII].

Preliminary Designs

The preliminary brainstorming process included the following three designs.

Design 1: Between-Finger Stabilizer

This device features two large rings for the index and middle fingers, connected by a smaller ring rotated 90°, creating a central hole for needle insertion. A locking mechanism secures the needle during the procedure. It must be compatible with surgical-grade gloves (no tearing) and allow clear needle visibility under X-ray fluoroscopy.

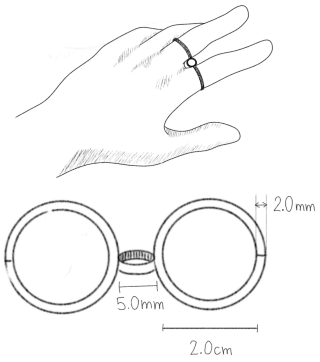


Figure 3: Between-Finger Stabilizer Drawing

Design 2: Phantom Tissue Guidance Pad

This pad provides a pre-injection check of needle angle and alignment. Positioned above the injection site, the clinician inserts the needle through the phantom tissue to confirm alignment before proceeding. The phantom material offers better stability than human tissue, reducing the need for repositioning.

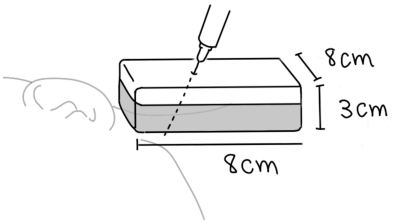


Figure 4: Phantom Tissue Guidance Pad Drawing

Design 3: Modified Scalp Vein Needle

A standard scalp vein needle is adapted by rotating its flaps 90° perpendicular to the needle. The clinician controls the needle between the flaps using the index and middle fingers. The design will support various needle sizes for different procedures.

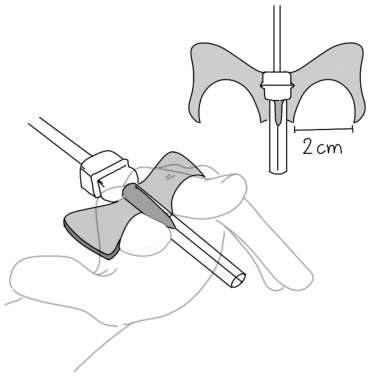


Figure 5: Modified Scalp Vein Needle Drawing

Following the presentation of the initial three designs to the client, the feedback received led to the development of a new design.

Design 4: Prong Extender

This design leverages the natural strength and stability of index and thumb movement to control needle placement. The device features a stainless steel spring mechanism, allowing the clinician to compress and release the stabilizer with minimal exertion. A sliding mechanism with ergonomic finger grips provides smooth, precise control, while a non-slip rubber attachment ensures steady handling of various needle sizes during procedures. The needle is supported by radiolucent 3D-printed PLA prongs so as not to obstruct movement or visibility under fluoroscopy. This design prioritizes comfort, stability, and fine motor control for accurate needle injections.

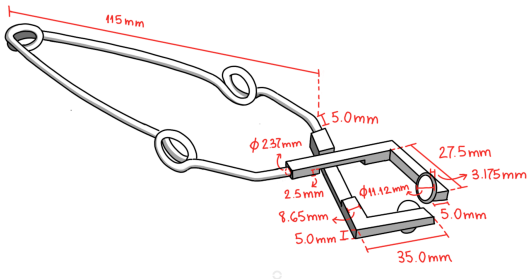


Figure 6: Prong Extender Drawing

Preliminary Design Evaluation

Design Matrix

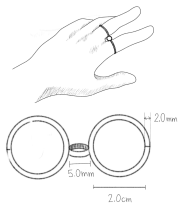
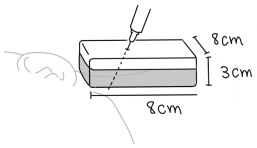
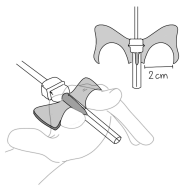
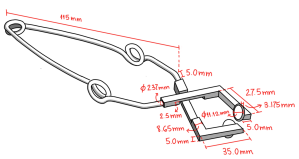
Design	Between Finger Stabilizer		Phantom Tissue Guidance Pad		Modified Scalp Vein Needle		Prong Extender	
Criteria (weight)								
Effectiveness (35)	3/5	21	2/5	14	3/5	28	4/5	28
Ergonomics (30)	1/5	6	3/5	18	2/5	12	5/5	30
Safety (20)	1/5	4	3/5	12	4/5	16	4/5	16
Ease of Use (10)	2/5	4	3/5	6	3/5	6	5/5	10
Cost (5)	2/5	2	4/5	4	5/5	5	4/5	4
Total (100)	**37**		**54**		**67**		**88**	

Table 1: Design Matrix of Competing Designs for the Needle Navigator device.

Design Matrix Criteria

Effectiveness: The criteria for “Effectiveness” will be assessed by evaluating the results from testing the prototype for its accuracy. Effectiveness is weighed the most out of all the criteria, as the purpose of this project is to improve the traditional needle injection procedure. Currently, the needle injection procedure is inefficient as it requires radiologists to repeatedly stop and ensure accurate needle angle and placement at various stages of the injection. This design aims to allow medical providers to accurately and easily align the needle with the desired trajectory and perform the injection procedure easily while maintaining accuracy. This criterion serves to consider how effective this device is and if it significantly improves the needle injection procedure as compared to the traditional method. As a result, effectiveness was weighted with a high score of 35/100.

Ergonomics: Ergonomics is assigned a weight of 30/100 due to its significant impact on the operator’s hand health and overall performance. Poorly designed surgical tools can lead to various musculoskeletal disorders and long-term conditions, including carpal tunnel syndrome, epicondylitis (tennis elbow), neck tension syndrome, shoulder tendonitis, and rotator cuff injuries. These conditions can cause discomfort, reduce dexterity, and impair fine motor skills, ultimately affecting the surgeon’s ability to perform procedures with precision and efficiency. Prioritizing ergonomics in the design of surgical tools helps minimize strain, improve control, and enhance overall surgical outcomes. Ergonomics has been determined with surveys done by the operator themself.

Patient Safety: Some of the major concerns regarding patient safety center around incorrect placement of the needle, injury to the tissue, the risk of infection, and related unintended device failure complications. The priority of this device is to ensure proper needle alignment to avoid incorrect medication delivery and nerve/vascular injury. The device must keep the needle stable and not shift during imaging and insertion. Another risk stems from excessive pressure on the skin and underlying tissue, which could lead to bruising and/or discomfort. Additionally, the materials used should be sterile and non-toxic to avoid allergic reactions, infections, or other foreign body responses. As it is disposable, the device should include sterility packaging with proper labeling. In addition, the design must not impair imaging guidance, since interference could lead to errors in needle placement and increase procedural risk.

User Safety: Hazards to the radiologist and medical staff include needle stick injury, physical strain, radiation exposure, contamination, and procedural inefficiencies. The device must have an effective safety mechanism for manipulation in use and disposal in order to avoid accidental needle sticks, which present a serious risk of blood-borne infection. Another issue is ergonomic distress due to deflective and awkward hand positions as well as potentially excessive force. The device should contain an adjustable and comfortable grip so that normal hand placement and manipulation can be performed without risks to the operator. There must also be proper sterile packaging and labeling containing use and disposal protocols to minimize risks. Additionally, the design should minimize the need for manual adjustments and consequent hand radiation exposure.

Ease of Use: Ease of use in this context refers to how simple and intuitive each needle stabilization design is to handle during the procedure. The design should improve the doctor's ability to perform the procedure with minimal physical and cognitive strain, allowing for efficient and precise needle placement without interruptions or difficulty in positioning.

Cost: The project budget is set at $300, as outlined in the PDS. Cost is assigned a weight of 5/100 since the device is handheld and requires fewer materials. The primary expense is material costs, which remain manageable due to the compact design.

Proposed Final Design

In accordance with the Design Matrix above, the Prong Extender is the proposed design for the Needle Navigator device, achieving the highest overall score of 88/100.

- The device scored 4/5 in *effectiveness*, tied for the highest among all designs, indicating strong performance in accurate needle alignment and a significant improvement compared to traditional needle manipulation methods.
- The *ergonomic* design of the Prong Extender scored a 5/5 score, leading all other options. This highlights its user-oriented ergonomic design, reducing strain on the operator's hand and minimizing the risk of musculoskeletal disorders. This is due to the finger grip and natural compression mechanism.
- This design also ties for the highest *safety* score of 4/5. Its stable needle alignment, secure positioning during imaging, and use of safe materials contribute to minimizing patient/ user injury and procedural complications.
- The Prong Extender also scored a 5/5 for *ease of use,* meaning that it is the simplest design for the radiologists to adjust to, as well as having minimal setup.
- Finally, the proposed final design scored a 4/5 for *cost* of production. This indicates that it is low cost and well within budget, without compromising functionality.

Fabrication

Materials:

The proposed final design contains 2 materials: stainless steel, polylactic acid (PLA), and rubber. A stainless steel spring is ideal for this device because it offers excellent strength and durability, maintaining its shape even after repeated use [21]. The spring also provides a consistent and reliable force, allowing for smooth, natural finger movements with minimal

exertion. It is highly resistant to corrosion, which is crucial in medical environments where exposure to moisture and sterilization is common. PLA was chosen first for its convenience in rapid prototyping. However, in addition, it is also biocompatible for short-term contact, making it safe for limited use around patients [22]. Rubber is a suitable material for the tip of the device because it provides a non-slip surface that helps maintain a stable grip during procedures. It also offers a slight cushioning effect, reducing the risk of damaging delicate needles, which improves overall control and accuracy. An expense sheet including all materials is listed in Appendix II.

Methods

The fabrication of the prong extender consisted of 3 steps: preparing the 3D print, modifying the test tube clamp, and assembling the components. To prepare the 3D print, the SolidWorks file was exported as a .stl format and uploaded into Bambu Studio. See Appendix IV for detailed CAD images. Print settings were configured, including material selection, printer type, infill density, layer height, part orientation, and necessary support structures. After reviewing the estimated cost, payment was completed for the 3D-printed part. While the print was being prepared, the test tube clamp was modified by securing it in a vise at full extension and trimming both ends at the base of the rectangular section using heavy-duty wire cutters. After removing it from the vise, the cut edges were smoothed with sandpaper. A rotating force was used to fix the ends of the modified test tube clamp into the holes of the 3D-printed parts to assemble the components, ensuring a secure interlock. Finally, rubber material was attached to the ends of the 3D-printed parts using the pre-existing adhesive. A fabrication plan is listed in Appendix III.

Final Prototype

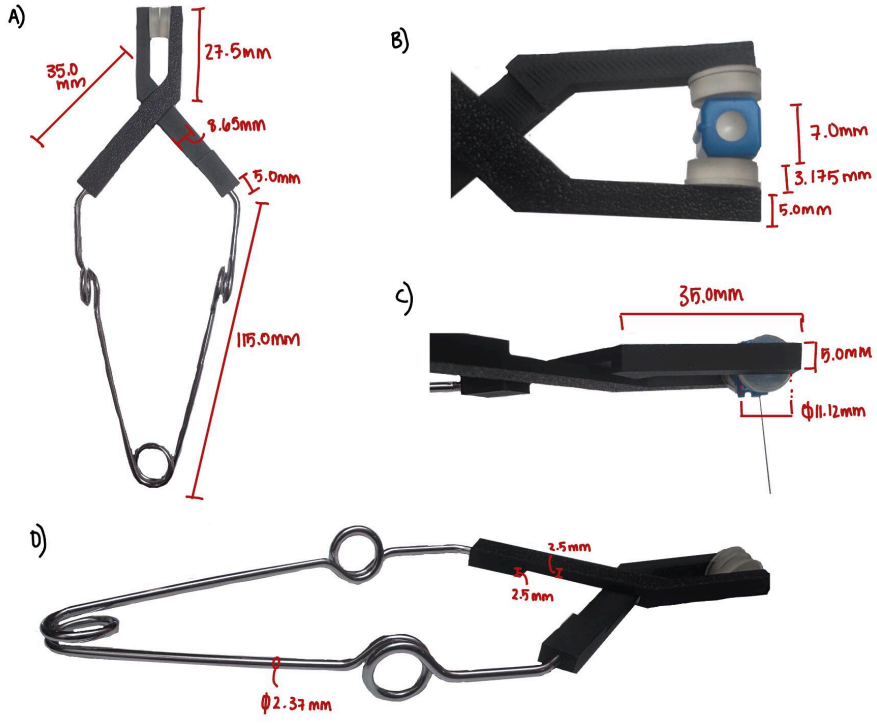


Figure 7: Final Prototype with dimensions in:
A) Top view, resting state B) Top view, working state C) Side view, working state D) Isometric view, resting state

Testing and Results

Testing

Two tests were performed to evaluate the performance of the Needle Navigator and to determine how well the design met the Product Design Specifications (PDS) criteria (see Appendix VII). The first test consisted of surveying radiologists to gather feedback after handling and using the device (see Appendix V). The survey consisted of multiple questions on a 1–5 scale evaluating various aspects of user experience. Participants were asked to rate their hand and wrist fatigue after using the new tool versus a typical procedure, evaluate the grip comfort and weight balance of the device, estimate the reduction in procedure time over standard tools, and overall rating of the device. Finally, participants were also given an open-ended question to share additional suggestions or comments.

The second test aimed at quantitatively evaluating the accuracy and repeatability of the needle navigator. Participants were asked to hold a pen using the device and trace printed circular paths on a fixed sheet, which simulates the fine control of an actual needle guidance procedure. To minimize any external sources of variability, such as lighting or surface stability, each participant underwent four trial bouts under controlled conditions. The maximum deviation from the intended path on each trial was measured in inches using ImageJ software (see Appendix I). The average maximum deviation was expected to be less than the design threshold of 0.11811 inches, which was the value provided by the client for the margin of error of the needle placement in the procedure.

Results

Due to time constraints, limited data were obtained from the radiologist survey, which limits the ability to draw meaningful conclusions about user perceptions of the device. However, the preliminary response was positive, stating that the device was comfortable to use and stable in handling, and the overall experience improved compared to standard practice. Even though these initial impressions were encouraging, in order to validate the ergonomic and user experience performance of the device on a population basis, further responses would be needed.

The tracking accuracy test provided a quantitative evaluation of the device's guidance performance. Maximum deviation measurements were collected across 15 participants in 4 trials, resulting in 60 data points (Figure 8). The sample mean maximum deviation resulted from the experimental data set was 0.1056 inches, and the standard deviation was 0.0429 inches. A one-tailed t-test was performed comparing the experimental mean to the threshold of 0.11811 inches to determine whether the device met the design criterion for accuracy. The resulting t-statistic was -1.129, with a p-value of 0.139. Given that this p-value is higher than the standard significance level of 0.05, we cannot conclude with a high level of confidence that the mean maximum deviation is lower than the threshold. This statistical analysis demonstrates that the experimental mean was not significantly different from the target, which could be attributed to sample variability (as seen in Figure 9). These results overall indicate that the device has the potential to enhance needle guidance accuracy, but more comprehensive testing with a larger and more specialized sample size would be needed to establish the performance of the device.

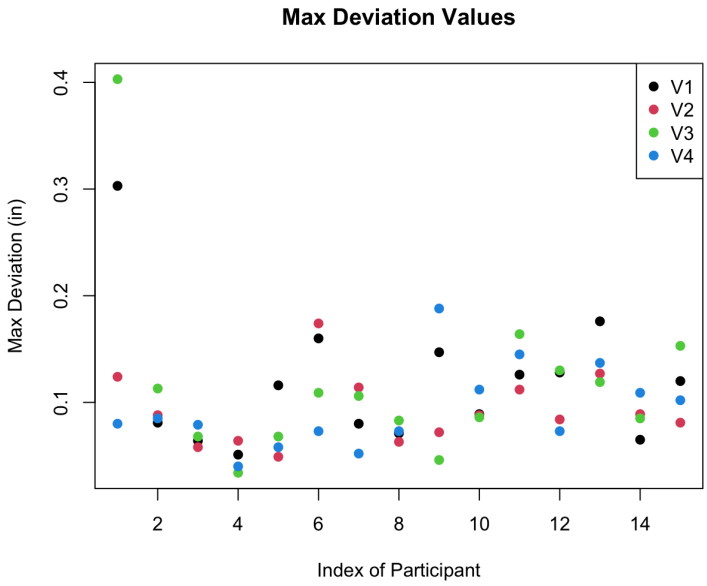


Figure 8: Scatter plot of maximum deviation measurements for each of the 4 trials (n=15).

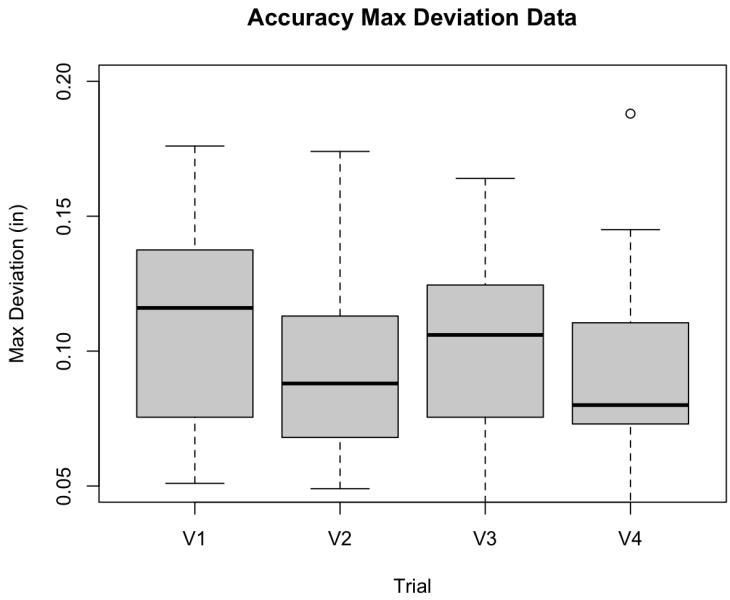


Figure 9: Boxplot of maximum deviation measurements for each of the 4 trials (n=15).

Discussion

In order for the clinician to perform the needle injection procedure safely and efficiently, the device must be stable and allow the radiologist to maintain a firm grip on the device. Typically, women physicians have smaller hand sizes with a median glove size of 6.0 versus 7.5 for male physicians [23]. The Prong Extender design must account for the varying hand sizes from provider to provider. Since the Prong Extender device is an adaptation of a standard test tube clamp, it is universally used for people with various hand sizes. However, in the future, it would be beneficial to seek ways in order to make the device more inclusive by adjusting the size of the grips of the clamp. Additionally, further testing is necessary to ensure that all materials used are radiation-attenuating and do not interfere with imaging technologies like fluoroscopy.

Verifying the compatibility of the device materials with imaging modalities is a crucial step toward improving the safety and clinical viability of the design.

As part of the iterative development process, a major modification was made to the 3D-printed prongs following initial user testing. Initially, the prongs were made to be in separate planes, which resulted in improper needle alignment. The original design placed the prongs in separate planes, resulting in misalignment and improper needle guidance. To resolve this, the prongs were modified to include a cleaved portion that would allow for both prongs to remain in the same plane. Despite this improvement, testing showed that the mean maximum needle deflection still exceeded the set threshold of 0.11811 inches. A likely contributor to this result was the use of untrained participants and substitute tools (pens instead of surgical needles), which may not accurately represent clinical conditions. Moving forward, testing with trained radiologists will be essential to obtaining more accurate performance data and refining the design for real-world application.

Conclusions

The Needle Navigator serves the purpose of creating a device that will stabilize needle positioning during cervical and lumbar needle injections to improve the accuracy of the procedure while providing additional support to the clinician to reduce fatigue. This device also aims to minimize radiation exposure and patient discomfort. The proposed final design is the Prong Extender device, which is a device that is naturally in compression due to the stainless steel spring mechanism. The spring mechanism included in the device allows the radiologist to maintain their hand at rest when the needle is locked in place, thus requiring less exertion as compared to the traditional needle insertion procedure. This device provides a length that allows the radiologist to guide the needle insertion from a distance that is outside of the radiation field. The Needle Navigator device will also be used in tandem with the X-ray fluoroscopy guidance, allowing clear visibility of the trajectory of the needle during the procedure. The 3D printed prongs are made of Polylactic Acid filament and were 3D printed at the UW Makerspace. This device was tested under X-ray fluoroscopy imaging, and the 3D printed prongs were radiolucent, allowing for a clear view of the needle throughout the procedure. Future iterations will explore alternative materials to improve durability and consistency while maintaining affordability. Enhancing the device with technology integration, such as a smartphone-based angle validation system, could further improve precision and usability. By refining these aspects, the device has the potential to become a widely adopted solution for minimizing procedural variability, reducing patient and clinician risks, and optimizing the success rate of ESIs.

References

[1] Armon, Carmel, et al. “Epidural Steroids for Cervical and Lumbar Radicular Pain and Spinal Stenosis Systematic Review Summary.” Neurology, vol. 104, no. 5, 12 Feb. 2025, https://doi.org/10.1212/wnl.0000000000213361.

[2] Armon, C., et al. “Assessment: Use of Epidural Steroid Injections to Treat Radicular Lumbosacral Pain: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.” Neurology, vol. 68, no. 10, 5 Mar. 2007, pp. 723–729, https://doi.org/10.1212/01.wnl.0000256734.34238.e7.

[3] Carreon, Leah Y., et al. “Cost-Effectiveness of Lumbar Epidural Steroid Injections.” SPINE, vol. 43, no. 1, Jan. 2018, pp. 35–40, https://doi.org/10.1097/brs.0000000000000989. Accessed 23 Mar. 2020.

[4] Morley, R. E., Richter, E. J., & L‘ Engel, G. (2007, May 1). METHOD AND APPARATUS FOR AUTHENTICATING A MAGNETIC FINGERPRINT SIGNAL USING AN ADAPTIVE ANALOG TO DIGITAL CONVERTER. https:///patents.google.com. file:///Users/kshirinanand/Downloads/US7210627.pdf

[5] “Ultra-Pro IITM In-Plane Ultrasound Needle Guides-Multi-Angle | CIVCO.” Accessed: Feb. 06, 2025. [Online]. Available: https://www.civco.com/products/ultrasound-needle-guides/ultra-pro-2-ultrasound-needle-guides-multi-angle/

[6] D. A. Schreiber, D. B. Shak, A. M. Norbash, and M. C. Yip, “An Open-Source 7-Axis, Robotic Platform to Enable Dexterous Procedures within CT Scanners,” in 2019 IEEE/RSJ International Conference on Intelligent Robots and Systems (IROS), Nov. 2019, pp. 386–393. doi: 10.1109/IROS40897.2019.8968552

[7] D. Schreiber et al., “CRANE: a 10 Degree-of-Freedom, Tele-surgical System for Dexterous Manipulation within Imaging Bores,” in 2022 International Conference on Robotics and Automation (ICRA), May 2022, pp. 5487–5494. doi: 10.1109/ICRA46639.2022.9811732.

[8] T. Hiraki, T. Kamegawa, T. Matsuno, T. Komaki, J. Sakurai, and S. Kanazawa, “Zerobot®: A Remote-controlled Robot for Needle Insertion in CT-guided Interventional Radiology Developed at Okayama University,” Acta Med Okayama, vol. 72, no. 6, pp. 539–546, Dec. 2018, doi: 10.18926/AMO/56370.

[9] Cleveland Clinic, “Lumbar Epidural Steroid Injections: What It Is, Benefits, Risks & Side Effects,” Cleveland Clinic, Nov. 19, 2021. https://my.clevelandclinic.org/health/treatments/22091-lumbar-epidural-steroid-injection

[10] “Cervical Epidural Steroid Injections: What It Is, Benefits, Risks & Side Effects,” Cleveland Clinic. https://my.clevelandclinic.org/health/treatments/22293-cervical-epidural-steroid-injection

[11] T. J. Amrhein, S. N. Parivash, L. Gray, and P. G. Kranz, “Incidence of Inadvertent Dural Puncture During CT Fluoroscopy–Guided Interlaminar Epidural Corticosteroid Injections in the Cervical Spine: An Analysis of 974 Cases,” American Journal of Roentgenology, vol. 209, no. 3, pp. 656–661, Jun. 2017, doi: https://doi.org/10.2214/ajr.16.17738.

[12] E. Eworuke et al., “Risk of serious spinal adverse events associated with epidural corticosteroid injections in the Medicare population,” Reg Anesth Pain Med, vol. 46, no. 3, pp. 203–209, Mar. 2021, doi: 10.1136/rapm-2020-101778.

[13] “Neurological complications of lumbar and cervical dural punctures with a focus on epidural injections - Surgical Neurology International,” Surgical Neurology International, 2015. https://surgicalneurologyint.com/surgicalint-articles/neurological-complications-of-lumbar-and-cervical-dural-punctures-with-a-focus-on-epidural-injections/).

[14] N. Abolhassani, R. V. Patel, and F. Ayazi, “Minimization of needle deflection in robot-assisted percutaneous therapy,” The International Journal of Medical Robotics and Computer Assisted Surgery, vol. 3, no. 2, pp. 140–148, 2007, doi: https://doi.org/10.1002/rcs.136.

[15] P. Li, Z. Yang, and S. Jiang, “Needle-tissue interactive mechanism and steering control in image-guided robot-assisted minimally invasive surgery: a review,” Medical & Biological Engineering & Computing, vol. 56, no. 6, pp. 931–949, Apr. 2018, doi: https://doi.org/10.1007/s11517-018-1825-0.

[16] B. M. Stoeckelhuber et al., “Radiation Dose to the Radiologist’s Hand During Continuous CT Fluoroscopy-Guided Interventions,” CardioVascular and Interventional Radiology, vol. 28, no. 5, pp. 589–594, Jun. 2005, doi: https://doi.org/10.1007/s00270-005-0104-2.

[17] S. Sarmento et al., “The use of needle holders in CTF guided biopsies as a dose reduction tool,” Journal of Applied Clinical Medical Physics, vol. 19, no. 1, pp. 250–258, Nov. 2017, doi: https://doi.org/10.1002/acm2.12234

[18] “Mayo-Hegar Needle Holder| Length-cm| 14cm,” Gynex Corporation. Accessed: Feb. 05, 2025. [Online]. Available: https://www.gynexcorporation.com/product/mayo-hegar-needle-holder-2/

[19] “3D printer filament Product Description.” Accessed: Feb. 26, 2025. [Online]. Available: https://www.3d-printerstore.ch/media/content/Clariant/Polycarbonate.pdf

[20] “Classify Your Medical Device | FDA.” Accessed: Feb. 06, 2025. [Online]. Available: https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

[21] “Stainless Steel Properties, Grades and Applications.” Accessed: Apr. 30, 2025. [Online]. Available: https://alroys.com/stainless-steel-grades-and-applications/

[22] S. Y. Shilov, Y. A. Rozhkova, L. N. Markova, M. A. Tashkinov, I. V. Vindokurov, and V. V. Silberschmidt, “Biocompatibility of 3D-Printed PLA, PEEK and PETG: Adhesion of Bone Marrow and Peritoneal Lavage Cells,” Polymers (Basel), vol. 14, no. 19, p. 3958, Sep. 2022, doi: 10.3390/polym14193958.

[23] H. M. Weinreich, M. Babu, R. Kamil, Q. Williams, and I. A. Buhimschi, “Gender-differences of proceduralists in perception of hand-held surgical instrument fit – A cross-sectional survey,” The American Journal of Surgery, vol. 224, no. 6, pp. 1482–1487, Dec. 2022, doi: 10.1016/j.amjsurg.2022.05.011.

Appendix

Appendix I: Testing Protocol:

Objective: To determine the accuracy and repeatability of the Needle Navigator in guiding needle positioning by evaluating the maximum deviation from a defined trajectory.

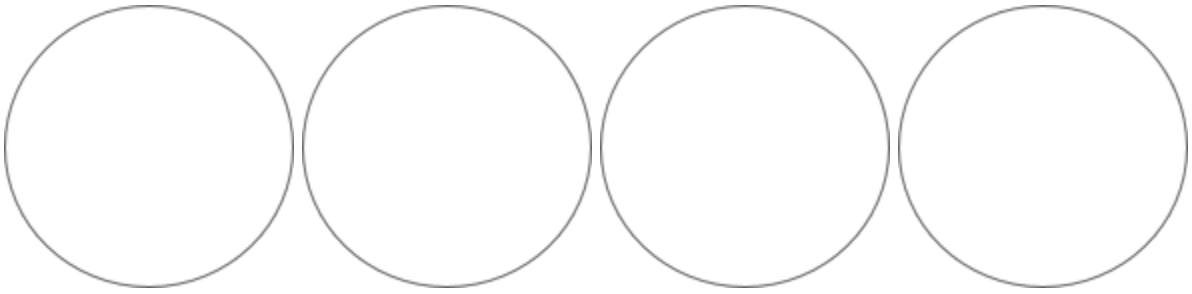
Materials:

- Needle navigator prototype
- Standard pen
- Paper with printed circles
- Flat drawing surface
- ImageJ software statistical analysis

Overall Setup:

- Hold a pencil with the device and align it above the printed test sheet.
- Task: Each participant will attempt to trace directly over the printed circular paths using the device, attempting to match the line as closely as possible.
- Metric Recorded: For each trial, record maximum deviation from the line (inches).
- Each participant will complete 4 trials.

Example From Testing Sheet:



Appendix II: Material Expenses:

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1										
Needle Holder Jaws	3D-printed PLA needle holder jaws	UW-Madison Makerspace	N/A	N/A	N/A	03/19/2025	2	$0.28	$0.57	N/A
Test Tube Clamp	Labs Stoddard Test Tube Clamp, Stainless Steel with Finger Grips, 6" Length	SUCOHANS	SUCOHANS-TBC-Unique-Identifier	N/A	N/A	03/19/2025	10	$1.43	$14.28	https://a.co/d/iC2k5td
Needle Holder Jaws #2	3D-printed PLA needle holder jaws	UW-Madison Makerspace	N/A	N/A	N/A	04/01/2025	6	$0.12	$0.73	N/A
Epoxy Adhesive Glue	Hubble Bubble Extra Fast Setting Epoxy	Hardman	4001	N/A	N/A	04/07/2025	1	$1.25	$1.25	N/A
Adhesive Bumpers	Adhesive Rubber Bumpers	ONUEMP	43239-160262	N/A	N/A	04/05/2025	304	$0.03	$9.99	https://a.co/d/43RNYro
								TOTAL:	**$26.82**	

Appendix III: Fabrication Plan:

Prepare the 3D Print

1. Export the SolidWorks file as a .stl format.
2. Upload the file to Bambu Studio to configure print settings, including material selection, printer type, infill density, layer height, part orientation, and support structures.
3. Review the estimated cost and proceed with payment for the 3D-printed part.

Modify the Test Tube Clamp

4. Secure the test tube clamp in a vise at full extension.
5. Use heavy-duty wire cutters to trim both ends of the clamp at the base of the rectangular end.
6. Remove the clamp from the vise and grit the cut edges using sandpaper.

Assemble the Components

7. Use a rotating forcing to fix the ends of the test tube clamp into the hole of the 3D-printed parts, ensuring proper interlocking.
8. Attach rubber material to the ends of the 3D-printed parts using pre-existing adhesive.

Appendix IV: CAD Images:

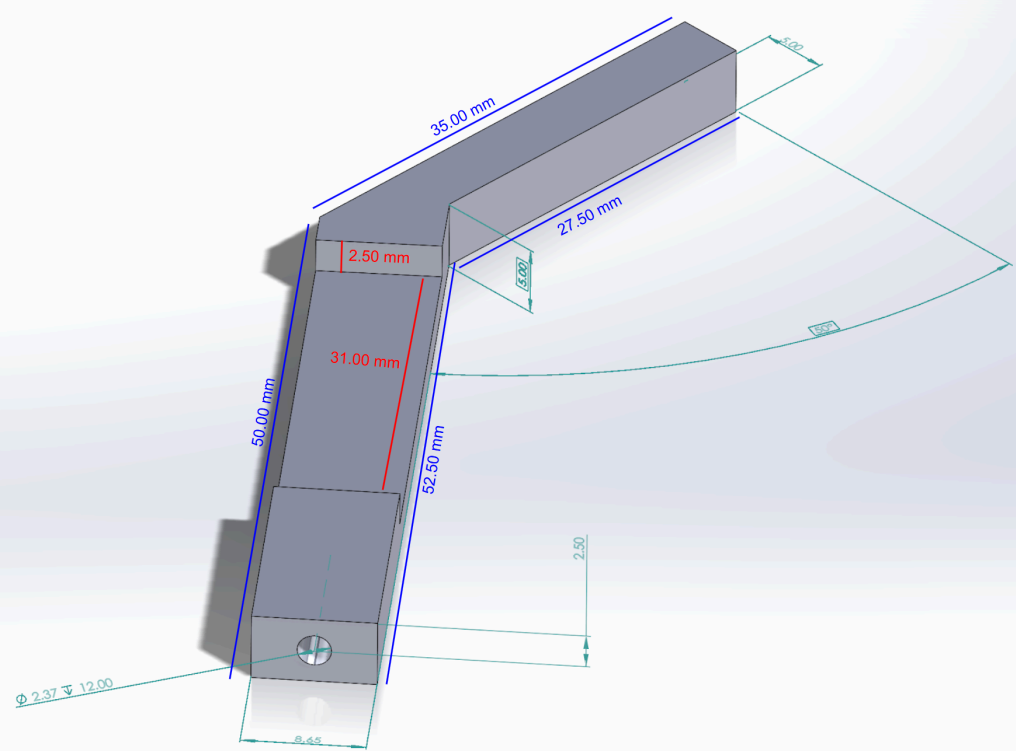


Figure 10: SolidWorks Image of a Singular Prong

Appendix V: Survey Questionnaire

Questions:

1. After a typical procedure, rate your hand/wrist fatigue level on a scale of 1-5.
2. After performing the procedure with the new tool, rate your hand/wrist fatigue level on a scale of 1-5.
3. Rate the grip comfort of the new cervical injection tool on a scale of 1-5.
4. Rate the weight balance of the tool on a scale of 1-5.
5. Estimate the reduction in procedure time compared to standard tools (0%, 1-25%, 26-50%, 51-75%, or >75%).
6. In general, how would you rate the device? (on a scale of 1-5)
7. (Open Ended) Do you have any suggestions/ concerns/ comments? If the procedure was timed, enter here.

Appendix VI: Survey Raw Data:

Timestamp	After a typical procedure, rate your hand/wrist fatigue level on a scale of 1-5.	After performing the procedure with the new tool, rate your hand/wrist fatigue level on a scale of 1-5.	Rate the grip comfort of the new cervical injection tool.	Rate the weight balance of the tool on a scale of 1-5.	Estimate the reduction in procedure time compared to standard tools.	In general, how would you rate the device?	Do you have any suggestions/ concerns/ comments? If the procedure was timed, enter here.
4/18/2025 14:03:33	3	5	5	4	1-25%	5	The new device feels much more comfortable in my hands than a standard pair of forceps. I appreciate how smoothly it hinges and that the silicone offers good grip on the object you're holding.

Appendix VII: Product Design Specifications:

Function

The device is designed to enhance the stability and precision of the needle during minimally invasive radiology procedures. These procedures require precise control and optimal angulation to reach the target without unnecessary movements. In constrained or awkward positions, maintaining control becomes challenging, increasing the risk of procedural errors. The device aims to provide adjustable support, reduce needle bending, and facilitate smooth angulation adjustments, improving both accuracy and usability. Intended for radiologists and healthcare professionals, it integrates seamlessly into workflows, offering ergonomic and practical benefits in clinical settings.

Client requirements

Purpose & Functionality

- Designed to replace the current clamp used in minimally invasive radiology procedures, such as image-guided needle insertions.
- Improves ergonomics for easier handling compared to the existing technique.
- Functions as an assistive tool, providing stability and control without directly aiming the needle.

Key Features

- Incorporates a sliding mechanism that enables the users to slide and adjust the needle with one hand for improved maneuverability.
- Enables precise angulation for enhanced procedural accuracy.

- Designed to accommodate 22-gauge and 25-gauge needles.
- A lightweight, comfortable, and intuitive-to-use design to minimize hand fatigue and integrate seamlessly into procedures.
- Disposable and sterile to ensure patient safety.

Design requirements

1. Physical and Operational Characteristics
    a. Performance requirements

Following client requirements, the device must securely support, stabilize, and precisely manipulate needles in the range of 2 to 6 inches in length while focusing on improving control for cervical spine injections specifically. It should facilitate single-handed operation and allow for fine control of the needle's position, including real-time adjustments to its angle. Needle trajectory alignment must be rapid and accurate without allowing uncontrolled movement or bending. The device should be single-use, compatible with needles ranging from 22 gauge to 25 gauge, and function efficiently with X-ray and fluoroscopic imaging.

    b. Safety

The device must be designed to reduce medical complications related to cervical spine injections, where the abundance of blood vessels near the brain increases the risk of a stroke if one of them is punctured [1]. After alignment is completed, the device must have a locking mechanism to prevent any unintended shifts. The support structure should enable the operator to anchor their hand to the procedure table to allow for more stability and precision. Additionally, the device should be made of medical-grade, non-toxic, and disposable material that complies with the regulatory standards of sterile surgical tools (see section J: Materials). The material must have a Young’s modulus between 2 GPa and 4 GPa to ensure an optimal balance of rigidity and flexibility [2]. It should be rigid enough to avoid needle bending but flexible enough to perform controlled and precise adjustments during the procedure. The needle should be firmly held without crushing or limiting movement.

    c. Accuracy and Reliability

The device must prevent unintended needle deviations that may lead to inaccurate procedures by ensuring that, once aligned, the needle stays on its intended path without requiring any external manual corrections. The maximum allowable deviation from the intended trajectory is 0.002 meters, corresponding to the intervertebral space used for steroid injections during the procedure. In addition, it should maintain a stable hold while allowing for fine-angle adjustment of up to ±5 degrees to fit various anatomical structures. It should work under fluoroscopic imaging and, therefore, keep the needle positioning clear and without any view blockages. It should provide a smooth and predictable sliding mechanism, and motion should be quick but controlled when and where it is required. Also, it should withstand forces up to 2.5 N exerted by the operator's hand without loss of precision or significant deformation [3].

    d. Life in Service

This is a disposable medical device that is expected to be limited to a single procedure, which usually ranges from 15 to 45 minutes [4]. Since the device will be used in minimally invasive radiology procedures that require precise needle control, it should be designed for reliable operation over the course of one procedure and discarded according to OSHA's initial measures for discarding regulated medical-waste items [5]. Maintaining safety and effectiveness is critical to equipment use and structure integrity, and sterility should be maintained for the duration of use.

    e. Shelf Life

The needle navigator system must remain sterile and effective upon storage under proper conditions. As stated by manufacturers of similar disposable medical devices, such as Teqler's Mayo-Hegar, these medical devices typically have a shelf life of 3 years [6]. Our client has requested that the device be made of plastic, and due to availability and

fabrication constraints, polycarbonate would be the only feasible option for this project. The shelf life of 3D-printed polycarbonate is approximately 1 year when stored properly in a cool, dry place [7]. In order to determine the exact shelf life of this particular device, a further analysis of the material stability, retention, degradation, and packaging integrity must be performed.

f. Operating Environment

The device will be used in clinical and hospital settings, specifically in radiology and interventional procedure rooms. The temperature range for operation is expected to be 15°C to 30°C, with the ability to withstand short-term storage at temperatures between 0°C and 50°C in accordance with ISO 11608-1:2022 [8, p. 1]. Additionally, the device must function in 40% to 70% relative humidity without experiencing material degradation or performance issues. As it will be used in controlled hospital environments, the material must withstand normal atmospheric pressure.

The device must be pre-sterilized and packaged for single use, preventing cross-contamination. Materials must be resistant to disinfectants, bodily fluids, and saline solutions to avoid degradation and maintain durability throughout their intended use. The device must also be mechanically resilient and capable of withstanding minor handling impacts, such as drops from a standard table height (~1.14m) and vibrations during transport [9]. Additionally, it should operate silently to avoid any disturbances in medical settings.

g. Ergonomics

The device must be designed for one-handed operation and be ambidextrous, ensuring comfortable use for both left- and right-handed radiologists. It should allow unobstructed access to the needle without requiring unnatural wrist movements or excessive reach. The ergonomic grip design must accommodate various hand sizes, incorporating anti-slip materials or textured surfaces to prevent unintended movement. To enhance stability, the design should minimize wrist strain and maintain a neutral wrist position during use. The overall weight should be light (<170g) to ensure comfort without compromising stability.

h. Size

The device must be compact and lightweight, fitting within the operator's hand span (~75-100mm width, ~150mm length) to ensure ease of handling and precision [10]. The device must be small enough for easy transport and sterile packaging, with dimensions that do not obstruct the operator's field of view or interfere with imaging equipment. As a single-use, disposable device, it requires no maintenance and must be easily discarded in standard medical waste containers (~150mm x 200mm opening) without excessive bulk [11].

i. Weight

The device must have weight constraints to accommodate one-handed, ambidextrous operation. The weight of the device will impact the control and comfort of the operator. Lighter needle holders provide precision for intricate procedures and minimize fatigue, while heavier needle holders handle heavy-duty procedures or tasks [12]. The device will be designed for a cervical injection procedure. This procedure is categorized as an intricate procedure by the client because it requires accurate needle placement, therefore, the device should be reasonably light. The current needle holder the client is using is a Mayo-Hegar needle holder, which weighs approximately 170g [13]. To maintain consistency with existing equipment familiar to radiologists, the proposed device should weigh within a range of approximately 136g to 204g.

j. Materials

The client specified that we use plastics in our design. Plastic is generally durable, cost-effective, and lightweight [14]. Plastics work well within the operating environment (see Section f: Operating Environment), since they have a relatively low density (compared to other commonly used medical materials), ranging from 0.9 to 1.4 grams per cubic centimeter (g/cm^3) [15]. Plastics' low density accounts for their radiolucent appearance through X-rays [16]. Three types of

plastic are commonly used for medical/surgical equipment: polycarbonate, polyethylene, and polyvinyl chloride. Polycarbonate has high-impact and temperature-resistant properties. Polyethylene is especially durable and resistant to steam sterilization. Polyvinyl chloride (PVC) is used for its high tensile strength [17]. On the other hand, PVC has been noted to be environmentally unfavorable due to its degradation and disposal methods [18].

The device will be 3D-printed due to its complex geometry (to accommodate hand shape) and high specifications (since the needle holder will need to perfectly hold a needle). Polycarbonate is the only available plastic offered by the Makerspace that is suitable for medical purposes and a Class 2 medical device (See Section 3a: Standards and Specifications). Polycarbonate is five cents per gram (¢/g), a low cost based on the following calculations in Section 2b: Target Production Cost [19].

Polycarbonate has an ultimate tensile strength of 70 megapascals (MPa) [20]. This will be adequate to resist deformation under an average grip strength of 55 kilograms (kg) [21]. There is also a regression equation that can be used to calculate the grip strength using BMI, age, sex, and height.

Side	Adjusted R^2	Regression Equation
R	0.762	$y = 21.57 - 16.14 \times \text{Female} - 3.13 \times 10^{-5} \times \text{Age}^3 + 3.15 \times 10^{-6} \times \text{Height}^3 + 0.74 \times \text{BMI} - 2.32 \times 10^{-4} \times \text{BMI}^3$
L	0.752	$y = 13.90 - 16.36 \times \text{Female} + 1.26 \times \text{Age} - 2.32 \times 10^{-2} \times \text{Age}^2 + 1.01 \times 10^{-4} \times \text{Age}^3 + 2.35 \times 10^{-6} \times \text{Height}^3 + 0.16 \times \text{BMI}$

y, predicted grip strength; R^2, amount of variance accounted for by the model; Age (years); Height (cm); Female = 0 for male patient; Female = 1 for female patient.

Table 1: Grip Strength Regression Equations from “Grip Strength in Healthy Caucasian Adults”[22]

Certain materials, namely metals, should be avoided in the CT field because of metal artifacts and beam hardening [23]. Metal is radiopaque since they have a material composition that absorbs and scatters radiation [24]. If metal becomes required for the Needle Holder device design, then there are techniques such as iterative reconstruction and metal deletion methods [23]. Metal should be avoided so that yielding distortions/artifacts do not appear on imaging scans [25].

k. Aesthetics, Appearance, and Finish

The device surface finish must not shine (which may block the medical provider’s field of vision), and the color of the device is arbitrary. The device should also be smooth to touch so the operator can seamlessly maneuver in hand [26].

2. Production Characteristics
    a. Quantity

At the client’s request, one finished/ adequately tested unit is the semester goal, however, the final design must be replicated easily for a higher volume production. The client requested that this device be disposable per a single procedure. Section 2b: Target Production Cost outlines an approximate total number of iterations, specifically 35 copies, of the device design that can be manufactured. A rough estimate for the number of prototype iterations is 5, with 30 copies allocated for testing. Pilot testing can be done with a sample size of 30, which is considered the minimum to calculate statistical significance [27].

b. Target Production Cost

The client's proposed budget is $300 to make a prototype and conduct testing. Robotic systems like the 7-axis platform and Zerobot® enhance precision but cost between $50,000 and $100,000, making them less accessible for many

clinics. In contrast, the proposed device, utilizing 3D-printed prongs made of PLA, is designed for single-use production at a cost of under $2 per unit.

3. Miscellaneous
    a. Standards and Specifications

According to the FDA, this needle navigation device would be classified as a Class 2 medical device, which thereby increases its regulatory control by the FDA [28]. If in the future this device is to be sold commercially on the market, a Premarket Notification 510(k) form must be submitted to the FDA for approval prior to market release according to 21 CFR Part 807, Part E [29]. After the 510k is approved by the FDA, the device will be subject to Medical Device Reporting, Quality System Regulation, Labeling Requirements, and Good Manufacturing Practices by the manufacturer. This device must also be compliant with ISO 11608, which outlines the regulations for the use of needle-based injection systems [30].

    b. Customer

The client has requested that the device contain a feature that incorporates some form of sliding mechanism, which allows for the needle to comfortably slide into the needle navigator during use to allow for accuracy. The client also requests that this device be compatible with X-Ray guidance to ensure minimal changes to current needle insertion procedures as well as accurate needle placement. The device should be designed for use with only one hand and should also be designed so that the user is able to hold the shaft of the needle during use. Additionally, the needle navigator device must be compatible with different diameter needles, including a 22 and 25-gauge surgical needle. The device must also be disposable after each use. The client also wants the device to be user-friendly and efficient to ensure the procedure duration remains as originally intended.

    c. Patient-related concerns

This needle navigation device itself will be disposable, however, the needle that is being used must be sterilized before use with the device. The device must ensure proper handling of the needle, avoiding contamination during insertion or removal of the needle. This device must also be stable to use, as any movement can lead to needle misplacement, which can cause potential harm to the patient. Needle angle and needle placement accuracy is imperative to reduce the risk of complications in the patient during the procedure. This is especially important for device use in cervical spine applications, as there are a lot of blood vessels close to the brain, and if the vessels are punctured, the patient can suffer from a stroke.

    d. Competition

There is currently a patent for a needle holder for image-guided intervention procedures that would provide competition with this device. This device includes a clip for holding the needle and a guide arrangement for supporting the needle and directing the needle at a desired angle relative to the patient's body [31]. This patented device also includes a resealable connection such that the needle can be disengaged from the guide arrangement by moving the clip laterally. Another product that is currently on the market is the Ultra-Pro II™ In-Plane Ultrasound Needle Guides-Multi-Angle, which can provide competition to the device. The Ultra-Pro device by Civco Medical utilizes a two-part system containing a custom reusable bracket and a disposable snap needle guide [32]. The Ultra-Pro device provides competition to the design; however, the intended use of the Ultra-Pro device is to be used with an ultrasound machine, which is not applicable to this project.