Needle Navigator Preliminary Report

Project Title: Needle Navigator: support and control device for image-guided minimally invasive procedures

Course Name: BME 301

Date: 02/26/25

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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. Testing will include ergonomic evaluations, fluoroscopic imaging validation, and mechanical compression loading. 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.

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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. Despite this high prevalence, ESIs provide only short-term relief (2–6 weeks) with no strong evidence for pain reduction beyond 3 months [2]. For every 4 to 7 patients who receive an epidural steroid injection (ESI), only one experiences meaningful pain relief [2]. Additionally, 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. Additionally, fewer needle adjustments would lead to less radiation exposure, lower risk of nerve damage, and patient discomfort.

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.

Problem Statement

Cervical and lumbar injections under fluoroscopy require precise needle placement, but current methods rely on manual, repetitive adjustments, which increase radiation exposure, procedural time, patient discomfort, and clinician fatigue. 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. Since the patient remains awake, reducing procedural time is essential to minimize discomfort and stress. Needle angulation plays a crucial role in procedural success, the Conventional Transforaminal Approach Line (CTAL) uses an insertion angle of approximately 50°, while the New Transforaminal Approach Line (NTAL) employs an angle of around 70° [9]. To ensure compatibility with both techniques, the design must allow for a range of approximately 45° to 75°. This accommodates for different approaches and patient anatomies. 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

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.

Biology and Physiology

Epidural Steroid Injection (ESI) is a frequently used form of pain management [10]. 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 [10]. 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 [11].

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 sometimes is 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 place 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 [11].

For these procedures, minimally invasive needle insertions target small, specific areas around the spine, requiring extreme precision with minimal margin of error [12]. The seven vertebrae of the cervical spine (C1 to C7) protect the spinal cord and brainstem and support head movement [13]. 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 [14]. In order to mitigate such risks, the needle navigator must include a stabilization mechanism capable of reducing unintended movements and a controlling, precise needle insertion angulation.

Challenges in Minimally Invasive Radiology Procedures

Deflection on 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 [15]. Frictional forces during needle movement can also result in tissue deformation [16]. Research suggests that such deflection can be counteracted by controlled rotational adjustments and force-based feedback, a feature whose implementation feasibility must be evaluated [17].

In order to quantify these deviations, experimental data and mathematical models are used to analyze needle-tissue interactions. Insertion force, tip trajectory curvature, and lateral deflection are generally measured to assess steering precision. The stiffness force model accounts for the tissue's elastic response and is expressed as:

Equation 1: Stiffness Force Model

$$Fstiffness = \frac{(2\,E\,r\,tan(\alpha)\,h^2)}{\pi}$$

Where E is the Young's modulus, r is the radius, α is the insertion angle, and h represents tissue deformation depth. Additionally, frictional forces between the needle and tissue impact trajectory control, given by:

Equation 2: Friction Force Model

$$Ffriction = \mu \times Fn$$

where μ is the coefficient of friction and Fn is the normal force. As the needle advances, soft tissue rupture occurs, requiring a fracture force model defined as:

Equation 3: Fracture Force Model

$$Fn \propto \sqrt{\frac{Kc \times Ac}{R}}$$

where Kc is the fracture toughness, Ac is the contact area, and R is the needle radius. For trajectory control, steering models such as Webster's nonholonomic model help predict the needle's deviation. The needle tip position in 3D follows:

Equation 4: Webster's Nonholonomic Model

$$n(t) = (R(t)\,l\,e) + p(t)$$

where R is the rotation matrix, l is the needle length segment, and e is a unit vector. These models help refine insertion strategies and optimize robotic-assisted needle placement. Finite Element Models (FEM) simulate tissue response under varying insertion conditions, while energy-based and viscoelastic models calculate deformation and rupture thresholds [18]. In order to complement the models, force sensors and real-time tracking systems give empirical measurements to confirm theoretical models and assist in refining control algorithms for accuracy in percutaneous procedures.

Direct needle manipulation, inherent to X-ray and fluoroscopy-guided interventions, places the operator's hands in the radiation beam exposing them to additional risks associated with radiation [17]. The IR performs about 200 procedures a year, and without needle holders, the maximum allowable exposure limit (500mSv) is reached after only 100 procedures [19]. The radiation dose can be expressed as:

Equation 5: Radiation Dose Formula

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

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.

Efforts to minimize procedural time help reduce patient discomfort while increasing workflow efficiency. One-handed operation, ambidextrous usability, and an intuitive, adaptable, and ergonomic grip were all considered as part of the design of the needle navigator. The lightweight construction ensures ease of handling while the smooth sliding mechanism provides fine angulation control without excessive force. In addition, due to needle stability and the elimination of image checks that require repeated adjustments, the device improves procedural safety and minimizes the time of completion.

Design Specifications

The device is intended for minimally invasive radiology procedures and must include adjustable support, reduce bending of the needle, and enable single-handed and ambidextrous operation 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. 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. As far as prototyping, the budget of $300 will be used to fabricate 35 units, 5 being test units and 30 for validation. This device is classified as a Class II medical device by the FDA and should comply with the corresponding regulations and ISO standards. 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 I].

Preliminary Designs

Design 1: Between Finger Stabilizer

The Between Finger Stabilizer consists of two rings that are interconnected via a separate ring that is rotated 90° perpendicular to the two large rings. The large rings are for the index and middle finger to be inserted in order for the clinician to guide the needle with their fingers. The hole in between the two rings is where the needle will be inserted into, in which a locking mechanism will hold the needle in place throughout the course of the procedure. This design must be compatible with surgical-grade gloves and must not allow for any tears of gloves during the procedure. This device must also be compatible with the X Ray fluoroscopy guidance to keep needle trajectory visibility clear during the needle injection.

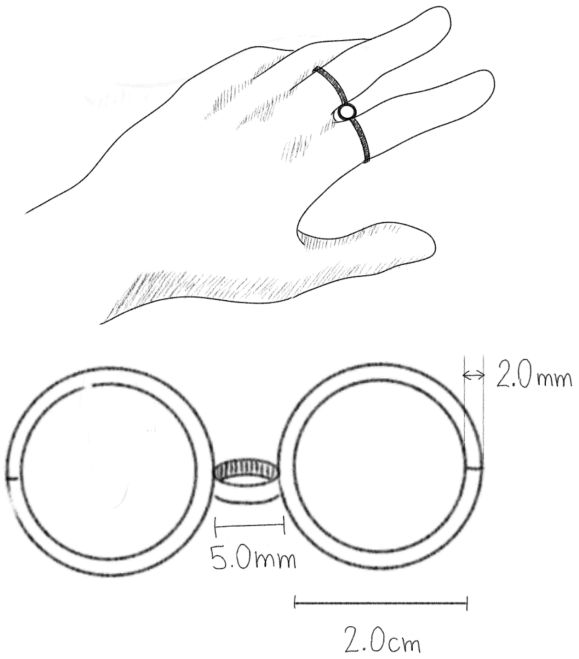


Figure 1: Drawing of Between Finger Stabilizer design.

Design 2: Phantom Tissue Guidance Pad

The Phantom Tissue Guidance Pad design aims to provide a backup check of the needle angle and alignment prior to injection into the patient. The clinician will insert the properly aligned needle into the phantom tissue pad which will be placed above the injection site of the patient. If the needle alignment is correct in the Phantom Tissue Guidance Pad, the clinician will insert the needle into the patient and perform the injection. The advantage of this design is that the material properties of the phantom tissue provide additional stability to the needle when compared to the thin layer of human tissue where doctors insert the needle to check for path alignment, minimizing the need for repeated adjustments.

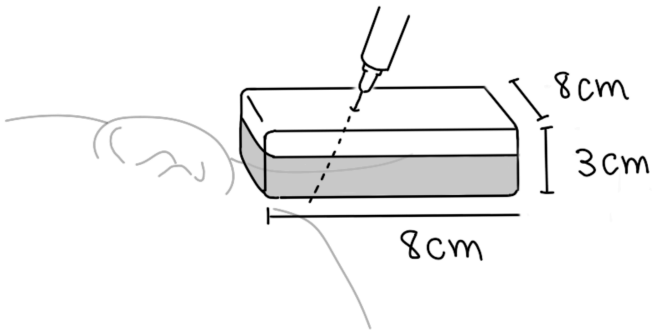


Figure 2: Drawing of the Phantom Tissue Guidance Pad device.

Design 3: Modified Scalp Vein Needle

The Modified Scalp Vein Needle is a modification of a scalp vein needle device that is commonly used in the market for the collection of blood. The main modification of the proposed Modified Scalp Vein Needle device is that the flaps on the needle will be rotated 90° perpendicular to the needle. The needle

will be inserted in between the flaps of the modified scalp vein needle and will be controlled via the middle and index fingers. This device will be customizable to accommodate a range of needle sizes for the different injection procedures.

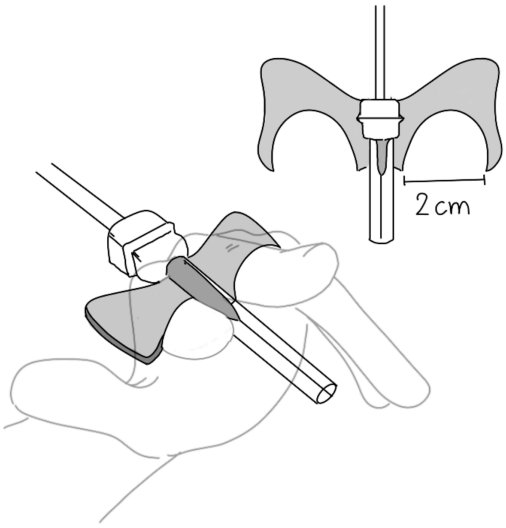
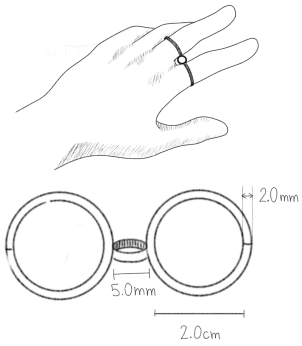
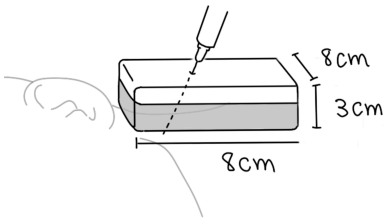
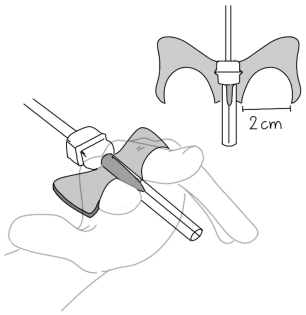


Figure 3: Drawing of the Modified Scalp Vein Needle device.

Preliminary Design Evaluation

Design	Between Finger Stabilizer		Phantom Tissue Guidance Pad		Modified Scalp Vein Needle	
Criteria (weight)						
Effectiveness (35)	4/5	28	3/5	21	4/5	28
Ergonomics (30)	4/5	24	3/5	18	2/5	12
Safety (20)	4/5	16	5/5	20	4/5	16
Ease of Use (10)	4/5	8	2/5	4	3/5	6
Cost (5)	4/5	4	2/5	2	5/5	5

Total (100)	**80**	**65**	**67**

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

Criteria for Needle Navigator Design Matrix:

Safety:

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 device has as its priority to ensure proper needle alignment to avoid incorrect medication delivery and nerve or vascular injury. The device must keep the needle stable and not shift over 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.

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. The client also stated that the given budget is flexible and a “starting point”.

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 have been determined with surveys done by the operator themself. The Between Finger Stabilizer ranked the highest (4/5) because of its passive design that doesn’t require force.

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. The Between Finger Stabilizer ranked the highest (4/5) due to its familiar grip and allows fine adjustments during the procedure.

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 the purpose of this project is to improve the traditional needle injection procedure. Currently, the needle injection procedure is inefficient as it requires physicians 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 criteria 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.

Final Design

The final design selected is the Between Finger Stabilizer device that will consist of two rings for the index and middle finger with the gap between them including a hole where the needle will be inserted. This hole will include a locking mechanism to secure the needle in place throughout the course of the procedure. This design is effective because it allows for the provider to easily insert their fingers into the two rings of the prototype and perform the needle injection procedure. The stabilizer will include a hole for the needle to be inserted through the device once and it will maintain proper alignment throughout the course of the procedure. This allows for there to be control over the device throughout the procedure which will minimize complication and increase effectiveness. While effective, this device is still susceptible to error which can lead to variations in the performance of the procedure. For this reason, this design was given a 4/5 rating. For its ease of use, this design is expected to offer intuitive control since it stabilizes the needle between two fingers, similar to holding a pen. By mimicking a familiar gripping technique, it allows for easy adjustments during the procedure with minimal repositioning, reducing disruptions. However, its compatibility with surgical gloves must be carefully evaluated, as the stabilizer could create friction that may lead to tearing and contamination. The size and material of the stabilizer does not interfere with CT imaging, as visibility is crucial for accurate needle placement. For this reason, this design was given a 4/5 rating. Considering ergonomics, this design received the highest ranking (4/5) due to its ability to function with minimal to no applied force. Unlike traditional designs that use gripping or holding, this device doesn’t require hand strain by securely resting between the pointer and middle fingers. This ergonomic approach enhances user comfort, reduces fatigue, and ensures ease of use, making it particularly beneficial for operators that are multitasking. This is the best presented fit for the client because it addresses their ergonomic needs while being advantageous towards multitasking between a CT computer and the patient/needle. Additionally, to remain within the constraints of the budget, based on calculations done in the PDS, the cost of a single prototype is approximately $8.50 using polycarbonate filament (for 3D printing purposes). Its relatively low cost contributes to its ranking of 4/5.

Fabrication

The client, Dr. Ross, requested plastic for the Needle Holder device. The chosen material for the Needle Holder device is polycarbonate. It is widely used for its superior mechanical properties, medical compatibility, and radiolucency, which prevents imaging artifacts in fluoroscopy-guided procedures [20]. Polycarbonate is also used in medical applications due to its high impact resistance (Izod impact strength of 850–900 J/m) and temperature resilience, maintaining stability under sterilization conditions up to 135°C, which is crucial for ensuring device safety and reusability in clinical settings [21]. Furthermore, considering its high ultimate tensile strength (approximately 70 MPa), it can be assumed that the device can withstand forces exceeding the average grip strength of 55 kg without deformation [22].

Polycarbonate was selected over other polymers such as polyethylene and polyvinyl chloride (PVC) due to its superior durability and flexibility to be 3D printed. Additionally, it is the only available 3D-printable plastic in the Makerspace. Unlike PVC, which raises environmental concerns due to toxic byproducts released during disposal, polycarbonate is more sustainable and compliant with medical-grade standards [23]. Furthermore, polycarbonate's compatibility with 3D printing allows for the precise fabrication of complex geometries required for ergonomic design, while its cost-effectiveness at $0.05 per gram enables the production of 35 iterations within the allocated $300 budget (See: Preliminary Design Evaluation) [24].

The primary method of fabrication is 3D printing. First, a CAD model will be prepared for 3D printing with adjustments made to layer height and infill density for optimal strength and durability. The prototype will then be 3D printed using a polycarbonate-compatible fused deposition modeling (FDM) printer available at the Makerspace, which ensures dimensional accuracy within ±0.1 mm, minimizing discrepancies between design and final product [25]. After printing, the prototype will be inspected for structural integrity and dimensional accuracy. Subsequently, post-processing will involve removing supports and excess material, followed by surface smoothing techniques such as sanding and polishing to ensure a smooth finish for ease of handling and as to not tear the glove worn by the operator.

Testing and Results

Validation for our design involves multiple tests to ensure the device meets Product Design Specification (PDS) criteria, identifies sources of error, and provides insights into performance. An ergonomic survey of radiologists assesses comfort, usability, and fatigue, while weight testing ensures the device remains under 170g for ease of handling. Smooth sliding mechanisms and fine angle adjustments will be evaluated through qualitative questions given to the client and his team of radiologists. Ambidextrous operation will be checked through trials with both left- and right-handed individuals. Functionality is assessed using simulated procedures with medical phantoms, making sure 22-gauge and 25-gauge needles are compatible throughout the procedure. Fluoroscopic imaging tests will confirm non-visibility of the device under imaging and accuracy of needle placement. Additionally, visual/flat surface tests will detect unintended needle deviations or bending. Finally, durability will be assessed through compressive load testing to establish the structural limits relative to grip strength measurements. A comprehensive analysis of the UW Health radiology team will be conducted using the equations in Figure 4, converting megapascals (MPa) from compression testing into pound-force per square inch (lbf/in^2, psi) to compare the test results with the predicted maximum grip strength.

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.

Figure 4: Grip Strength Regression Equations from "Grip Strength in Healthy Caucasian Adults" [26]

Additionally, material degradation is analyzed after operating conditions (approximately one hour in 15 °C–30 °C, 40%–70% humidity, and sterilization) to ensure long-term reliability [27]. Each test is designed to minimize sources of error, such as user variability, material inconsistencies, and environmental fluctuations, ultimately providing a comprehensive evaluation of the device's performance and limitations.

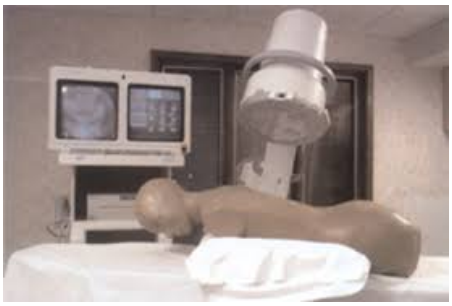


Figure 5: RSD Needle Placement Phantom from Supertech to visualize what a phantom looks like [28].

Discussion

In order to make the Needle Navigator device as inclusive as possible, the Between Finger Stabilizer design must be customizable for a range of finger sizes. In order for the clinician to perform the injection procedure safely and efficiently, the device must fit the size of the fingers of the clinician. Typically, women physicians have smaller hand sizes with a median glove size of 6.0 versus 7.5 for male physicians [29]. The Between Finger Stabilizer design must account for the varying hand sizes from provider to provider. Additionally, this device must be customizable for physicians who have a dominant left hand. To ensure safety of the device, an immediate disengagement system will allow the needle to be safely removed in case of device failure, ensuring manual control can be resumed without harming the patient. In this event, radiologists will follow a manual intervention plan ensuring the needle remains stable, procedural adjustments take no longer than 10 seconds, and patient risk is minimized.

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 Between Finger Stabilizer, which will allow the clinician to guide the needle insertion with their index and middle fingers throughout the procedure. This device will include a locking mechanism for the needle to remain in place. 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. This device will be made of polycarbonate filament which will be 3D printed at the UW Makerspace. 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 as seen in Figure 6. 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.

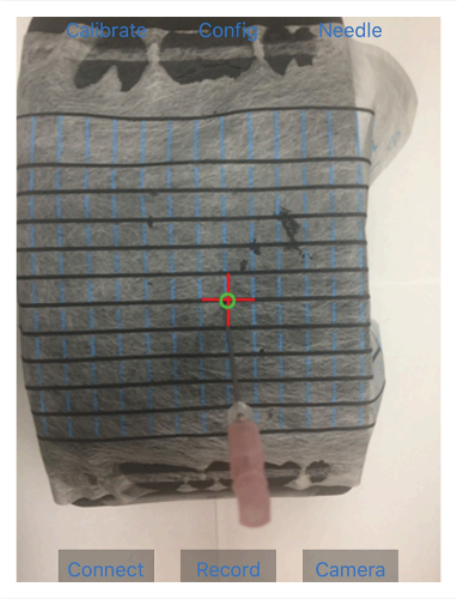


Figure 6: Photographs show smartphone in Bull's Eye View mode [29].

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Appendix

Appendix I: Product Design Specification

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 precise control over the needle's position while allowing for fine adjustments to its angle in real time. Needle trajectory alignment

must be rapid and precise but not allow for movement or bending. The device should be compatible with needles of multiple sizes, ranging from 22 gauge to 25 gauge, and efficiently work 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}. 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. Additionally, this device is meant for one-time use and must be packaged in sterile packaging prior to use, and will be discarded after use.

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. In addition, it should maintain a stable hold while allowing for fine angle adjustment 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 the forces exerted by the operator's hand without loss of precision or significant deformation.

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 [2]. 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 [3]. 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 [4]. 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 [5]. 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 [6, 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 [7]. 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 [8]. 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.

i. Weight

The device must have weight constrictions to accommodate for 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 minimizes fatigue, while heavier needle holders handle heavy-duty procedures or tasks [9]. 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 Mayo-Hegar needle holder which weighs approximately 170g [10]. To maintain consistency with existing equipment used by radiologists, the proposed device should have a similar weight to 170g.

j. Materials

The client specified to use plastics in our design. Plastic is generally durable, cost effective, and lightweight [11]. 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) [12]. Plastics' low density accounts for their radiolucent appearance through x-rays [13]. 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 [14]. On the other hand, PVC has been noted to be environmentally unfavorable due to its degradation and disposal methods [15].

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 [16].

Polycarbonate has an ultimate tensile strength of 70 megapascals (MPa) [17]. This will be adequate to resist deformation under an average grip strength of 55 kilograms (kg) [18]. 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” [19]

Certain materials, namely metals, should be avoided in the CT field because of metal artifacts and beam hardening [20]. Metal is radiopaque since they have a material composition that absorbs and scatters radiation [21] If metal becomes required for the Needle Holder device design, then there are techniques such as iterative reconstruction and metal deletion methods [20]. Metal should be avoided so that yielding distortions/artifacts do not appear on imaging scans [22].

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 [23].

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 [24].

b. Target Production Cost

The client's proposed budget is $300 to make a prototype and conduct testing.

The material of choice, Polycarbonate {See Section j: Materials}, is five cents per gram. If a maximum of 170 grams is used, the cost per prototype iteration would be $8.50. This allows for approximately 35 prototype iterations within the given budget. This overall cost is significantly lower than the Ultra-Pro II competing design from Civco Medical which retails for $1600.

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 [25]. 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 [26]. After 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 [27].

    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 [28]. 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 [29]. 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.

Appendix II: Projected Materials and Budget

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Category 1 - Material										
Plastic	Polycarbonate Filament	-	-	-	-	TBD	35 x 170 gram device	0.05 cent/gram	$300.00	-
								APPROX TOTAL:	**$300.00**	