Needle Navigator:

Support and control device for image-guided minimally invasive procedures

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Client

Dr. Andrew Ross

Advisor

Dr. Megan McClean

Team

Ana Toscano (Leader)

Gabriela Cecon (BPAG)

Kshirin Anand (Communicator)

Sofia Yeates-Delahoz (BSAC/BWIG)

Overview

- Field Visit: Dr. Andrew Ross
- Problem Statement
- Introduction
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Field Visit: Dr. Andrew Ross – Client Description & Observations

- Radiologist at the University of Wisconsin School of Medicine and Public Health
- Expertise in radiology and medical imaging

Cervical Injection Observation Notes:

- **Key Takeaways:**

1. *Sedative given, but patient remains awake*
2. *Performed in an operating room with an X-ray machine*
3. *Needle positioning adjusted multiple times*
4. *Recommended 45° tube rotation for optimal visualization*
5. *Low-back injection: Patient lies on their stomach*
6. *Neck injection: Patient lies on their side*

Figure 1: Proper needle placement for a cervical injection under fluoroscopy at UW Health Hospital, Radiology Wing (February 12, 2025).

Problem Statement

Need for Precision and Efficiency in Minimally Invasive Radiology Procedures

- Requires stable and controlled needle movement under imaging guidance
- Ensures precise control and optimal angulation to reach targets without unnecessary movements
- Reduces radiation risk by minimizing hand exposure to X-ray

Project Objective

- Develop a device that maintains optimal needle alignment, adjustable support and intuitive control
- Ensure the design is ergonomic and easy to use, allowing for quick adjustments with minimal effort
- Seamlessly integrates into clinical workflows for practical and efficient use

Background

- Challenges with Image-Guided Procedures
  - Constant need for needle adjustment
    - Hand radiation exposure [1]
    - Physical strain due to awkward positions
  - Epidural Steroid Injection (ESI)
    - Lumbar Epidural Injections
      - Pain: lower back → legs, hips, and feet
    - Cervical Epidural Steroid Injections
      - Pain: neck → shoulders, arms, and hands
      - Higher risk of serious spinal adverse events [2]
    - Punctures may cause stroke or nerve damage [3]

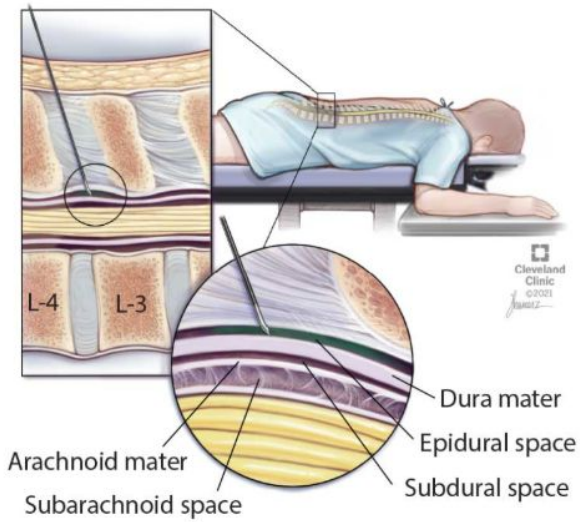

Figure 2: Fluoroscopic Guided Lumbar Epidural Steroid Injection, Cleveland Clinic, 2021.[12]

Competing Designs

- Patented Needle Holder for Image-Guided Interventions [13]
  - Clip for needle holding
  - Guide for angle control relative to the patient
  - Resealable connection for lateral disengagement of the needle
- Ultra-Pro II™ In-Plane Needle Guide (Civco Medical) [4]
  - Reusable bracket + disposable snap needle guide
  - Used with ultrasound, not applicable to this project
- Robotic Systems for Image-Guided Procedures [5], [6], [7]
  - Many still in research phase
  - Expensive

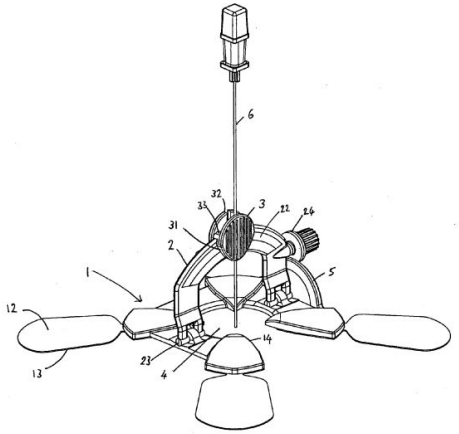

Figure 3: Patented Needle Holder for Image-Guided Interventions [13]

Figure 4: Ultra-Pro II™ In-Plane Needle Guide (Civco Medical) [4]

Product Design Specifications

- One-handed sliding mechanism
- Ambidextrous operation
- Secure & stabilize needles (2–6 in.)
- Compatible with 22- & 25-gauge needles
- Lightweight (~170g) & ergonomic grip
- Sterile, disposable, medical-grade material (ideally plastic)
- Works with fluoroscopy & X-ray imaging
- Locking mechanism to prevent shifts
- Target cost: $8.50/unit, $300 prototype budget
- Prototypes: 35 (5 test units, 30 for validation)

Figure 5: 22 and 25 gauge needles. [8]

Design 1: Between Finger Stabilizer

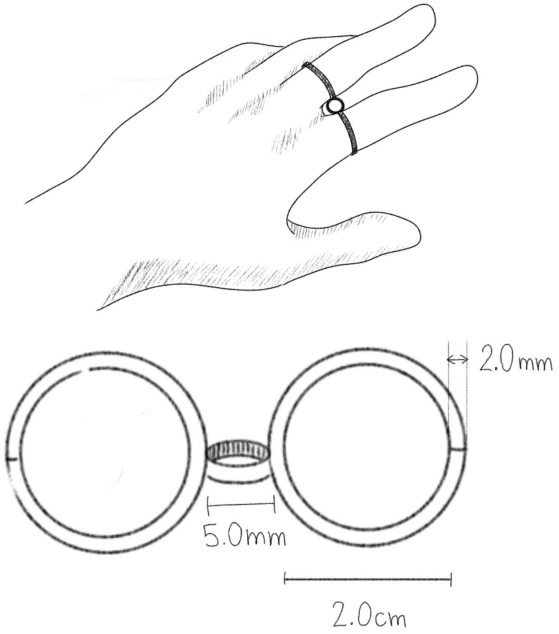

Figure 6: Drawing of Between Finger Stabilizer proposed design.

- Two rings that are connected by a circular opening
- Circular opening will be where the needle is inserted
- Made of 3D-printed Polycarbonate filament
- Easy adjustments with minimal repositioning
- Index and middle finger guide the device
- Requires minimal strain for adjustment
- Increased user comfort
- Must be compatible with surgical gloves
- Estimated cost is ~$8.50 per unit

Design 2: Phantom Tissue Guidance Pad

- Phantom Tissue is made of a material that is similar to human tissue
- Ensures precision before needle injection
- Does not accommodate the standard hemostat clamp
    - May cause discomfort throughout procedure
- No real-time adjustment during procedure
- Estimated cost ranges from $5 - $10

Figure 7: Image of a phantom tissue pad.

Design 3: Modified Scalp Vein Needle

- Modification of a generic scalp vein needle
- May cause hand fatigue over time
- Increased strain can lead to errors
- Structure is rotated 90° to to be applicable for cervical spine injections
- Estimated cost is $6 per needle

Figure 8: Image of a scalp vein needle that is currently used in the market.

Design Matrix

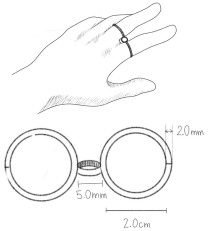

Figure 9: Drawing of the Between Finger Stabilizer proposed final design.

Figure 10: Image of a phantom tissue pad.

Figure 11: Image of a scalp vein needle that is currently used in the market.

Design	Between Finger Stabilizer		Phantom Tissue Guidance Pad		Modified Scalp Vein Needle	
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 needle navigator device.

Final Design - Between Finger Stabilizer

- Device will not require excessive hand strain increasing user comfort and reducing fatigue
- Allows for easy adjustments with minimal repositioning
- Size and material do not interfere with imaging guidance
- Needle slit will allow for proper alignment throughout course of procedure
- Low-cost device: ~$8.50 per unit

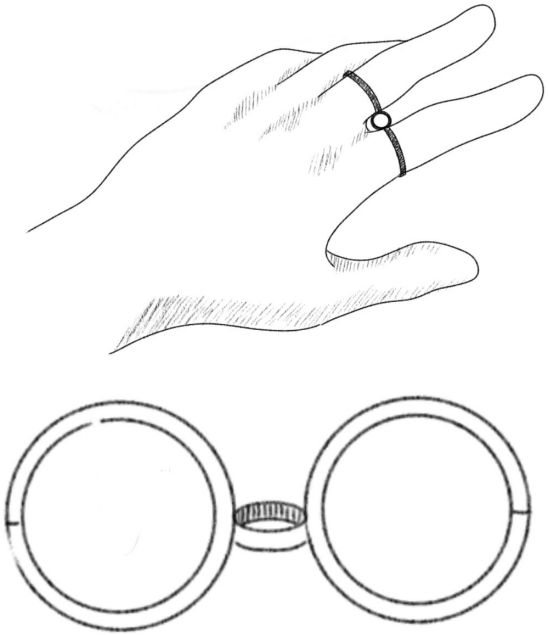

Figure 12: Drawing of the Between Finger Stabilizer proposed final design.

Testing and Results

- Ergonomics - Survey of Radiologists
  - Comfort and weight (<170g)
  - Smooth sliding mechanism and fine angle adjustments
  - Ambidextrous operation
- Functionality
  - Compatibility with 22-gauge and 25-gauge needles
  - Functionality under fluoroscopic imaging using phantom
  - Visual/Flat surface test for unintended needle deviations/ bending
- Durability - Compressive testing
  - Determine comparative limits of grip strength
  - Material degradation under operating conditions (15°C–30°C, 40%–70% humidity, sterilization)[12]

Figure 13: RSD Needle Placement Phantom from Supertech [9]

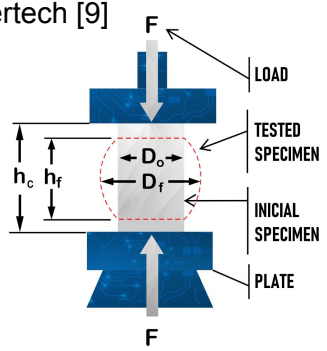

Figure 14: Compressive testing diagram [10]

Future Work

- **Material Limitations:**
  - Polycarbonate may degrade over time if not stored properly[14]
  - 3D printing may introduce inconsistencies in complex geometries
- **Design Improvements:**
  - Incorporate feedback from client and radiologists
    - Explore alternative designed for safety against excess radiation exposure
    - Optimize ergonomic design for broader hand sizes and grip strengths
  - Technology Integration
    - Enhance needle angle validation with smartphone app accuracy, particularly in Bull's-Eye View mode, to improve needle placement precision[11]

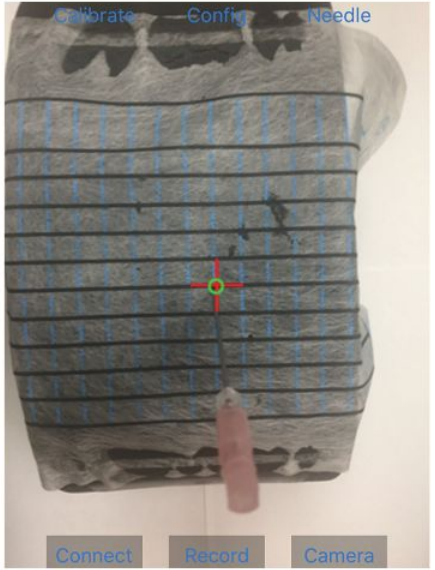

Figure 15: Photographs show smartphone in Bull's Eye View mode. [11]

References and Acknowledgements

Acknowledgements: Dr. Megan Mcclean, Dr. Andrew Ross, Dr. Monica Cooley, Dr. Ken Lee, Taylor Brendemuehl

[1] 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, 2018, doi: 10.1002/acm2.12234.
[2] “Risk of serious spinal adverse events associated with epidural corticosteroid injections in the Medicare population - PubMed.” Accessed: Feb. 20, 2025. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/33277405/
[3] “Surgical Neurology International.” Accessed: Feb. 06, 2025. [Online]. Available: https://surgicalneurologyint.com/surgicalint-articles/neurological-complications-of-lumbar-and-cervical-dural-punctures-with-a-focus-on-epidural-injections/
[4] “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/
[5] 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.
[6] 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.
[7] 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.
[8] “50 Pack of Blunt Tip Lure Lock Dispensing Fill, Industrial/Arts and Crafts Needles, 22 Gauge - Blue, 1" / 2.54cm - Walmart.com.” Accessed: Feb. 20, 2025. [Online]. Available: https://www.walmart.com/ip/50-Pack-of-Blunt-Tip-Lure-Lock-Dispensing-Fill-Industrial-Arts-and-Crafts-Needles-22-Gauge-Blue-1-2-54cm/411579816
[9] “RSD Needle Placement Phantom.” Accessed: Feb. 18, 2025. [Online]. Available: https://www.supertechx-ray.com/Anthropomorphic/PainManagement/KIP.php
[10] Mardoqueu, “Compression Testing: Methods, Applications, and Benefits,” Biopdi. Accessed: Feb. 20, 2025. [Online]. Available: https://biopdi.com/compression-testing/
[11] S. Xu, V. Krishnasamy, E. Levy, M. Li, Z. T. H. Tse, and B. J. Wood, “Smartphone-Guided Needle Angle Selection During CT-Guided Procedures,” AJR Am J Roentgenol, vol. 210, no. 1, pp. 207–213, Jan. 2018, doi: 10.2214/AJR.17.18498.
[12] S. Xu, V. Krishnasamy, E. Levy, M. Li, Z. T. H. Tse, and B. J. Wood, “Smartphone-Guided Needle Angle Selection During CT-Guided Procedures,” AJR Am J Roentgenol, vol. 210, no. 1, pp. 207–213, Jan. 2018, doi: 10.2214/AJR.17.18498.
[12] “Operating Room Conditions: Something Surgeons Shouldn’t Sweat.” Accessed: Feb. 20, 2025. [Online]. Available: https://www.polygongroup.com/en-US/blog/operating-room-conditions-something-surgeons-shouldnt-sweat/
[13] 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
[14] A. Pye, “Polycarbonate – an overview,” Prospector Knowledge Center. Accessed: Feb. 20, 2025. [Online]. Available: https://www.ulprospector.com/knowledge/11442/pe-polycarbonate-an-overview/