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

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Motivation

- Back and neck pain affect up to 80% of adults globally with an annual expense of $87.6 billion [1]
- Epidural Steroid Injections (ESIs) are a common treatment and require manual, repetitive needle adjustments
- A precise, low-cost device could improve ESI outcomes → reduce procedure time, radiation risk and operator fatigue
  - Potential for widespread adoption

Problem Statement

- Image-guided radiology procedures require precise and stable needle control
- Awkward angles increase operator strain and error risk
- Current methods lack ergonomic and stable support
- Goal is to develop a device that stabilizes and guides needles with precision, improving comfort, accuracy, and safety

Clinical Needs

- ESI
  - Pain treatment
  - Lumbar ESIs
  - Cervical ESIs
    - Higher risk of serious spinal adverse events [2]
    - Punctures may cause stroke or nerve damage [3]
- Competing Designs
  - Patented Needle Holder for Image-Guided Interventions [4]
  - Ultra-Pro II™ In-Plane Needle Guide (Civco Medical) [5]
  - Robotic Systems for Image-Guided Procedures [6], [7], [8]

Figure 1: Fluoroscopy-guided cervical epidural steroid injection. (A) Anterior-posterior view and (B) Oblique view. [11]

Design Criteria

- Lightweight, comfortable, intuitive - improved ergonomics
- Ability for precise angulation
- Disposable and sterilizable
- One handed, ambidextrous use
- Fit multiple needle and hub sizes

Figure 2: The device should be adaptable to different needle gauges. Examples shown above.

Final Design

- Index and thumb movement (strongest/most stable) [9]
- Naturally in compression (less exertion required) due to spring mechanism (stainless steel)
- Sliding mechanism controlled by finger grips
- 3D printed prongs (PLA)
- Non-slip, rubber attachment

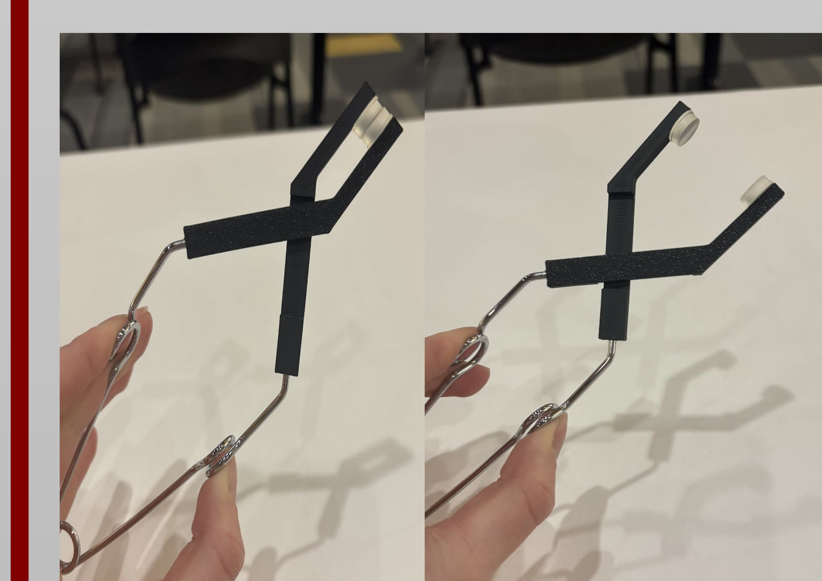

Figure 3: Operation of device.

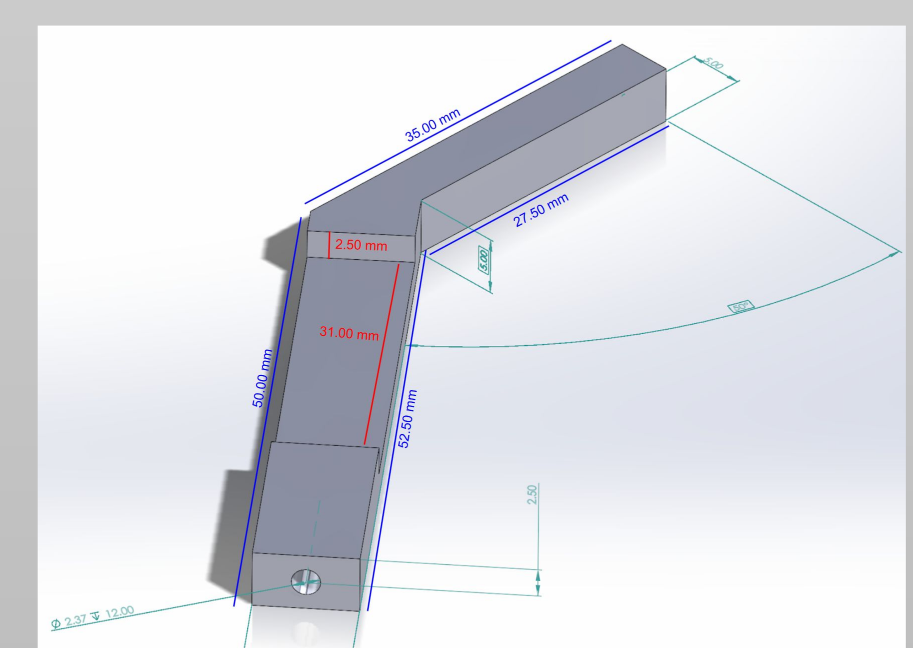

Figure 4: SolidWorks model for the prongs of the device.

Testing

<u>Circle Accuracy Test (64 trials total)</u>
Task: 16 individuals repeated a needle path-tracing
Metric: Max deviation from target path (in)

<u>User Feedback (Radiologists)</u>
Task: Test prototype and give professional feedback
Metric: 1–5 scale survey focusing on ergonomics and workflow integration

Figure 5: The device prongs are radiolucent under X-ray

Results

- Threshold: 0.0787in (space between two vertebrae)
- One-tailed t-test (p = 0.9899) [10]
- Failed to support the claim that the mean < threshold
- Mean max deviation (0.1056 in)
- Confidence range ([0.083, 0.128] in)

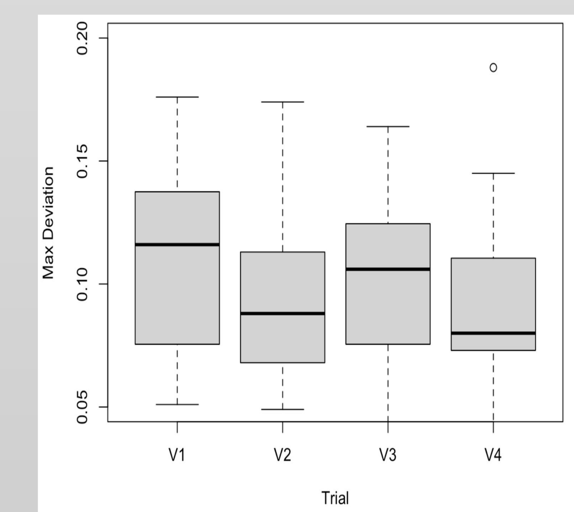

Figure 6: Bar plots of the maximum deviation.

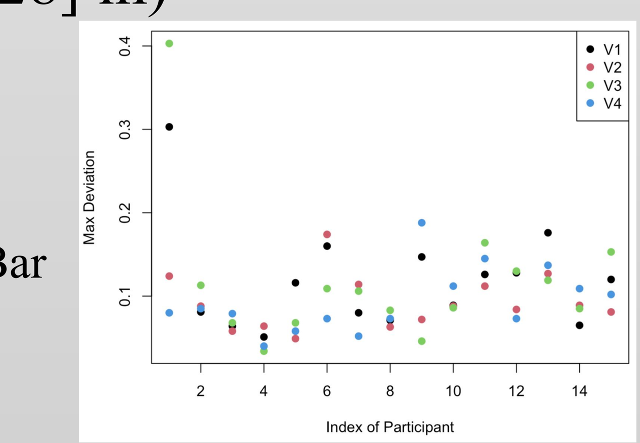

Figure 7: Scatter plots of the maximum deviation.

Discussion

- Fabrication of device is simplistic and easily manufactured
- 3D printed component is radiolucent and does not interfere with fluoroscopy imaging
- Device is easy to use and provides the necessary compression in order to grip and release the needle

Future Work

- Conduct additional ergonomic testing with a larger sample size
- Incorporate a "third hand" design to promote stability and reduce fatigue throughout procedure
- Introduce a "bevel" attachment for needle rotation

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