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INTRODUCTION

Background

- Constant use of needle drivers causes fatigue and discomfort especially for smaller hands (male designed)
- Common needle drivers are Mayo Hegar and Mathieu
- Mayo Hegar has several grips [1] Finger grip
 - Palming grip
- Finger grip causes stress at the carpometacarpal (CMC) joint
 - CMC arthritis is seen in 25% of women over the age of 50 [2]
 - Treatment includes splints, medication, surgery
- Needs: inclusivity for all hand sizes, ergonomic adjustments for comfort



Figure 1: Mayo Hegar (left) and Castroviejo (right) Needle Drivers

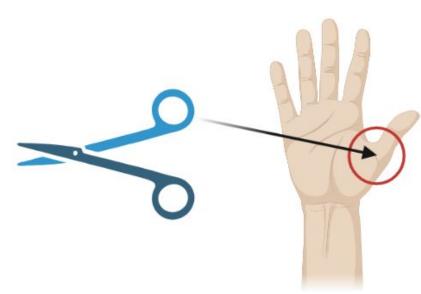


Figure 2: Pain at the CMC Joint Caused by Needle Drivers

DESIGN CRITERIA

Criteria	Requirements
Functionality	Pass the ASTM standard needle retention test
Ease of Use	Decrease time of repetitive suturing by 10% to measure reduction in fatigue compared to Mayo Hegar and Castroviejo
	Have the EMG signal of locking the needle driver be less than 95% MVIC
Cost	Cost less than the average needle driver (\$60 - \$80)
Universal	Can be manufactured in 2 sizes (5", 6.5")
Simplicity	Reduces training time by 10%

Human Factors Needle Driver Redesign

PROTOTYPE

Prototyping Iterations:

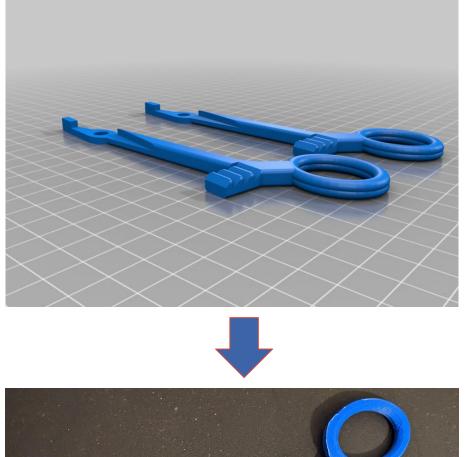
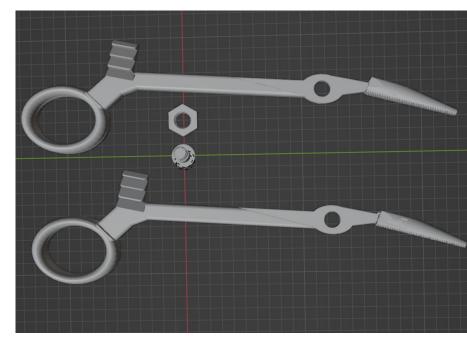




Figure 3: 3D Printed Mayo Hegar

Current Prototype:



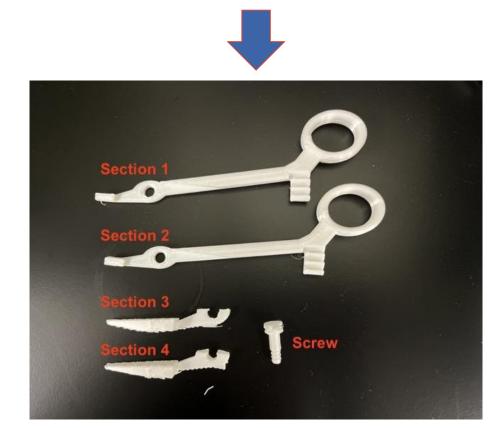


Figure 4: Prototype #1 -Modular Needle Driver with Large Rings



Figure 5: Prototype #2 -Connected Needle Driver with Large Rings





Figure 7: Current Prototype with Ergonomic Body and Offset Circular Locking Mechanism

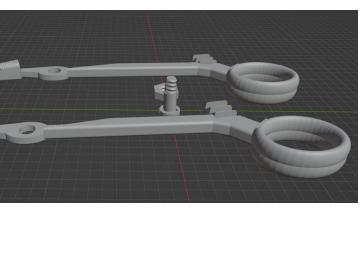
- concept
- comfort

- 3 different locking positions

TESTING

- Current testing is preliminary
- Test 1: Mathieu vs Mayo-Hegar Metal
- 30 consecutive cycles of locking and unlocking (60s)
- Measure EMG signal for forearm and CMC joint
- Test 2: Same as Test 1 but utilizing printed Mayo-Hegar and our design
- Test 3: Repetitive suturing with printed Mayo-Hegar and our design
- 20 consecutive square knots using silk suturing thread





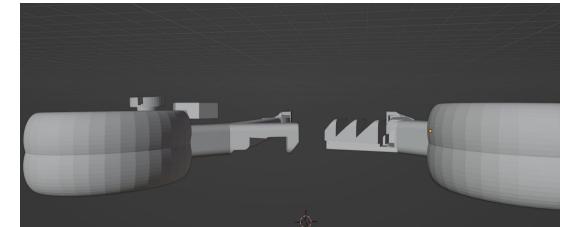




Figure 6: Prototype #3 -Connected Needle Driver with Large Rings and Circular Locking Mechanism

Design Elements • 3D Printed with PLA for rapid prototyping for proof of

• Large Rings to distribute force generated by CMC joint • Ergonomic body near rings for more grip options and

• Circular locking mechanism to allow left and right handed users to use the needle driver in the same manner • Grip tips connected to allow for stronger grip of the needle

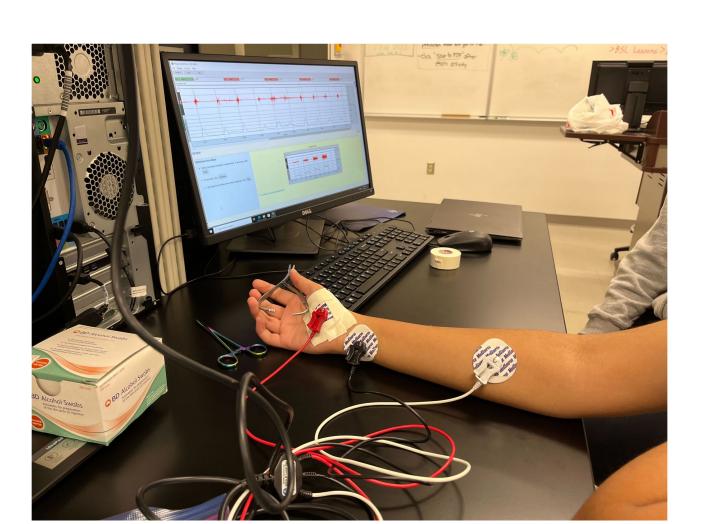
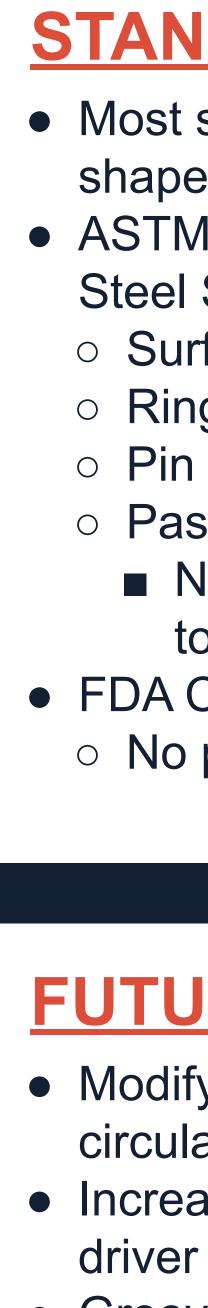


Figure 8: Preliminary EMG testing with Mathieu Needle Holder







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STANDARDS

- Most standards address materials, not shape of needle driver
- ASTM Standard Specification for Stainless Steel Suture Needle Holders [3]
 - Surface uniform, not sharp
 - Rings well rounded
- Pin or screw fixed, peened and flush
- Passes Needle Retention Test
 - No needle movement with pull and torsion
- FDA Class I device [4]
- No premarket notification procedures

FUTURE DIRECTIONS

- Modify locking mechanism to be a smooth circular motion
- Increase support for stability of the needle
- Grooves or grips on outside edges for
 - thumbs and additional support
- Print final needle driver prototype with SLA printer
- Create a stainless steel or other high
 - fidelity prototype
- Perform tests such as:
 - More accurate EMG
 - Timed training and suturing
 - ASTM Needle Retention Test [3]

ACKNOWLEDGEMENTS

REFERENCES

- [1] "Lab 1 . Part 4 Needle Holders VSAC WCVM University of Saskatchewan." https://wcvm.usask.ca/vsac205/Lab1/needle-holders.php#Basics (accessed Sep. 26, 2022)
- 2] O. Schuth, J. Powers, W. Merritt, and N. Blanchet, "Resolution of Thumb Pain following Adoption of Mathieu Needle Holder: An Ergonomic Analysis," Plastic and Reconstructive Surgery - Global Open, vol. 8, no. 4, p. e2768, Apr. 2020, doi: 0 1097/GOX 000000000002768
- [3] Standard Specification for Stainless Steel Suture Needle Holders-General Workmanship Requirements and Corresponding Test Methods, ASTM F1325-91, ASTM International, Washington, D.C., USA, Dec. 27, 2016. [4] Manual Surgical Instrument for General Use, 21 C.F.R. § 878.4800 (2021)

