# Creating a Benchtop Setup to Test Pacemaker Pseudo-Leads on Septum Tissue


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- Research conducted in the Dosdall Lab at the Nora Eccles Harrison Cardiovascular Research and Training Institute at the University of Utah

# Introduction

# Right Ventricular vs Conduction System Pacing

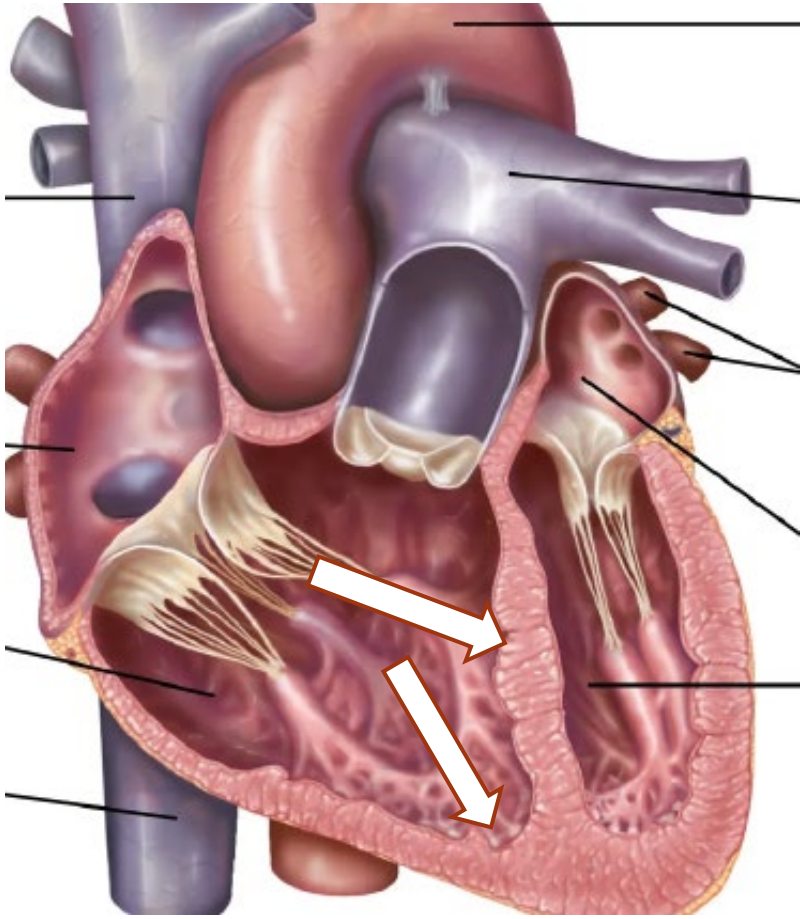


Figure 1 : Human Heart. Adapted from [2]

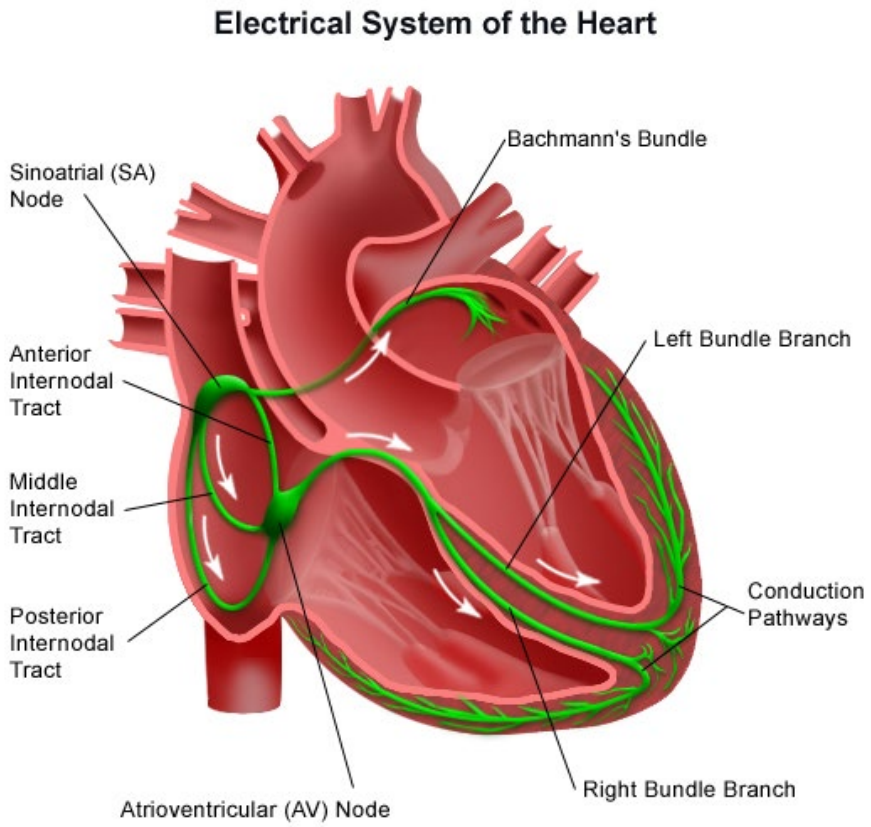


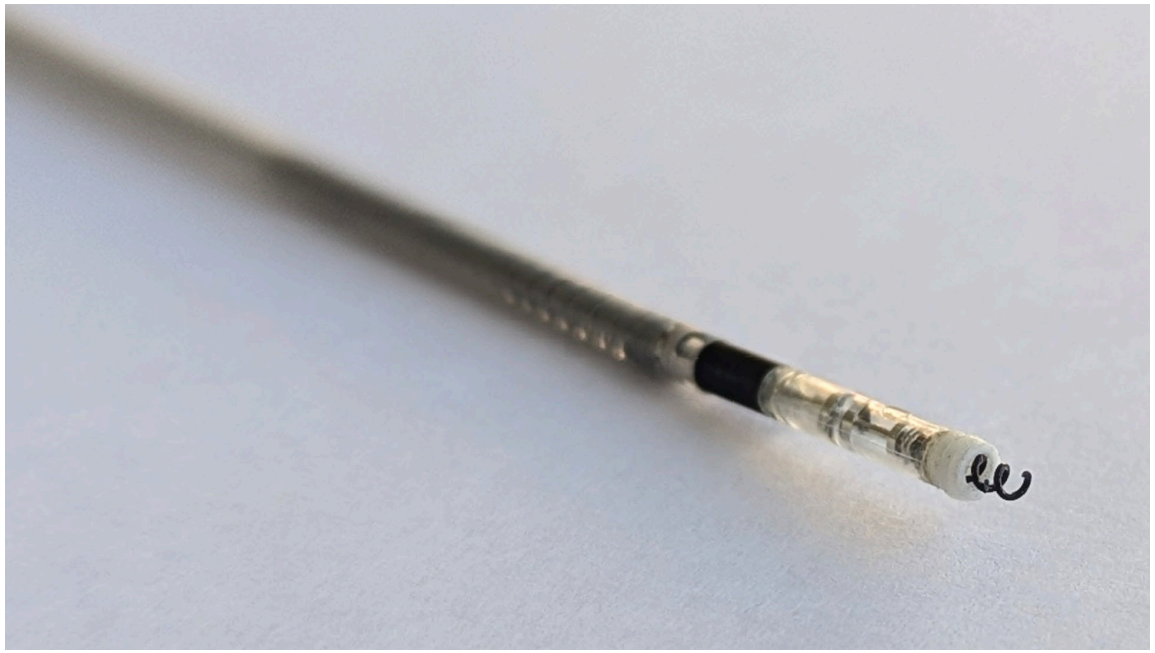

Figure 2 : Electrical System of Heart. Adapted from [3]


[1] Encyclopedia Britannica. “Human Heart”. https://www.britannica.com/science/heart#/media/1/258344/121131 (Accessed November 23, 2024).

[2] Stanford Medicine Children’s Health. “Electrical System of the Heart”. https://www.stanfordchildrens.org/en/topic/default?id=anatomy-and-function-of-the-electrical-system-90-P01762 (Accessed November 27, 2024).

# Background

- 6 million Americans have heart failure
- Increasing evidence and support for conduction system pacing (CSP) for Cardiac resynchronization therapy and anti-bradycardia pacing [3]
- Medtronic Model 3830 most used for CSP
- 44% effective on first attempt [4]

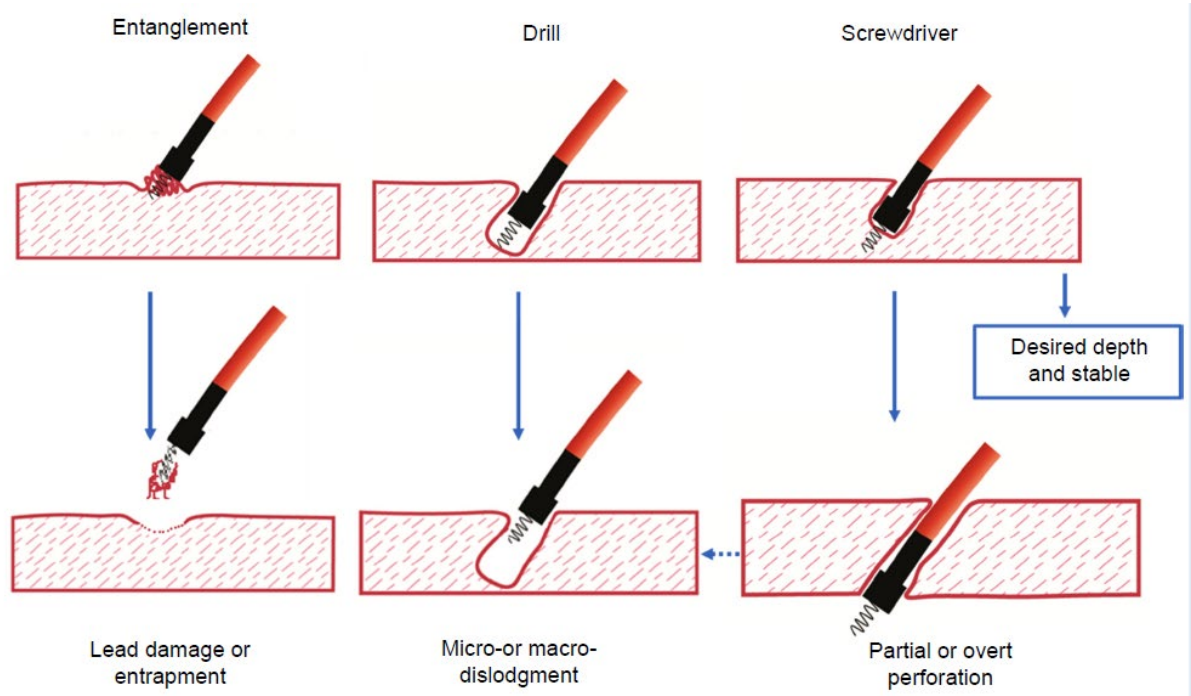


Medtronic 3830 lead. Source: Primary

[3] B. Kircanski et al., "Conduction system pacing in everyday clinical practice: EHRA physician survey," EP Europace, vol. 25, no. 2, pp. 682–687, Feb. 2023, doi: 10.1093/europace/euac201.
[4] J. Zou et al., "Clinical use conditions of lead deployment and simulated lead fracture rate in left bundlebranch area pacing," J Cardiovasc Electrophysiol, vol. 34, no. 3, pp. 718–725, Mar. 2023, doi:10.1111/jce.15843.

# Lead Behaviors

- 3 typical lead behaviors
  - Entanglement
  - Drill
  - Screwdriver




Lead Behaviors. Source: [5]

[5] H. Burri et al., "EHRA clinical consensus statement on conduction system pacing implantation: endorsed by the Asia Pacific Heart Rhythm Society (APHRS), Canadian Heart Rhythm Society (CHRS), and Latin American Heart Rhythm Society (LAHRS)," EP Europace, vol. 25, no. 4, pp. 1208–1236, Apr. 2023, doi: 10.1093/europace/euad043.

# Impacts

Increased length of procedure

Added risk to patient

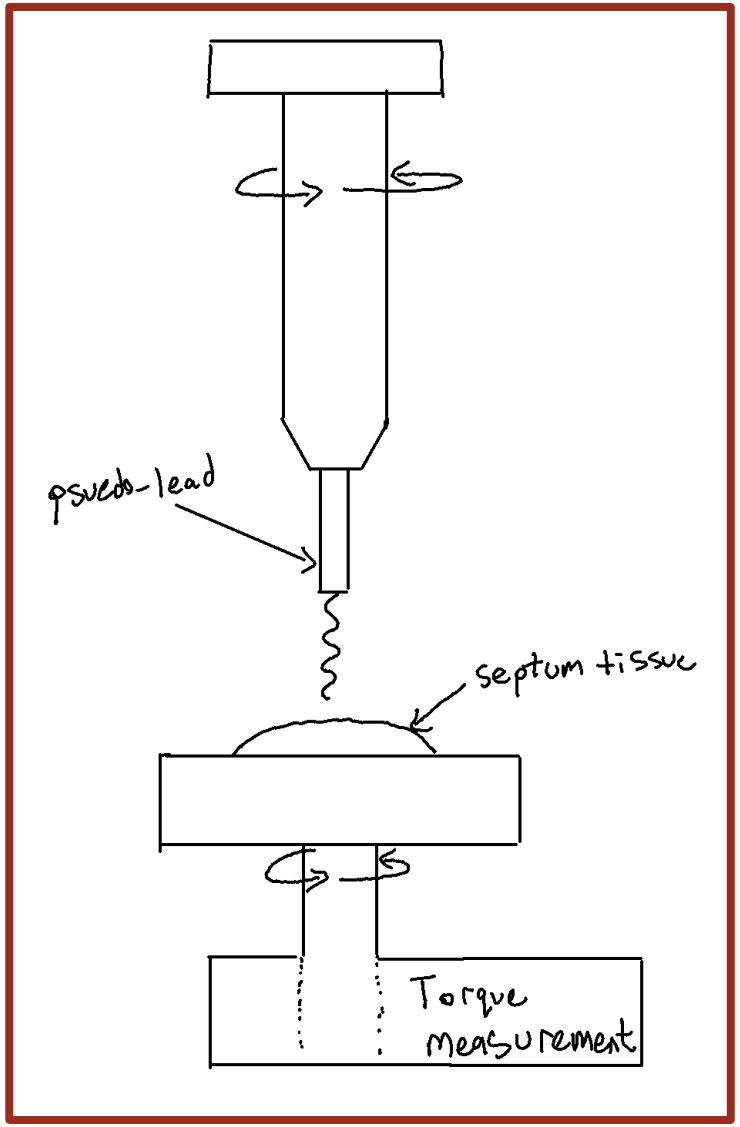
Decreased long term success rates

# Objective

- Investigate lead tips with different physical dimensions and how they impact the success of CSP lead implantation
- Create a benchtop setup that accurately simulates clinical workflow for CSP lead implantation into septal tissue

# Requirements for setup

- Concentric rotation of the leads
- High sensitivity torque measurement
- Repeatable measurements
- Clinically similar axial force (~ 20-30 g)
- Tissue secured

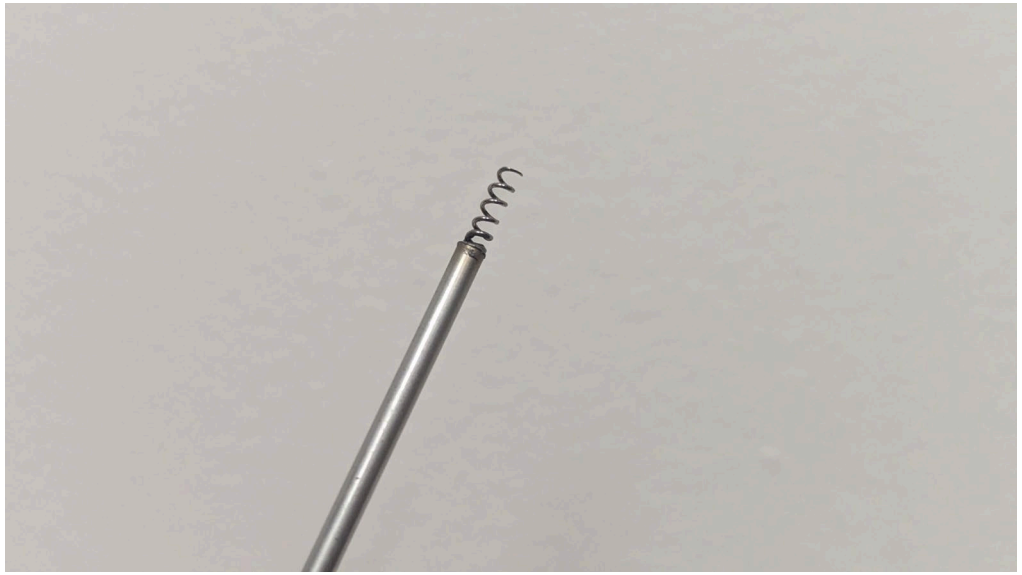


# Methods

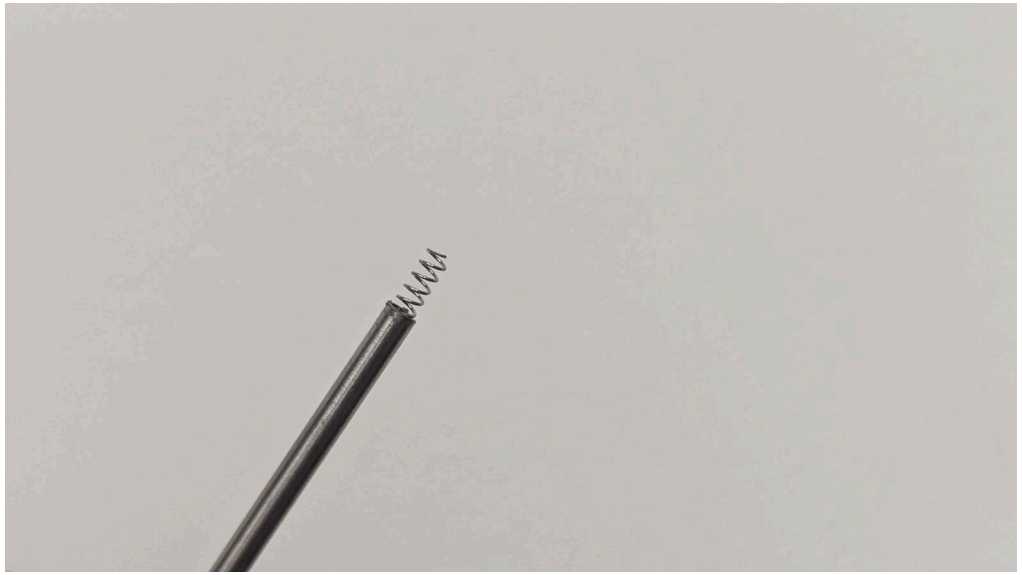
# Creating Pseudo-leads

- Instead of modifying 3830 leads, we created pseudo-leads
- Coils were inserted into hypodermic tubes and fixed with epoxy
- Lead tips were sharpened
- Each pseudo-lead was inspected under a microscope to ensure sharpness, accurate dimensions, and uniformity

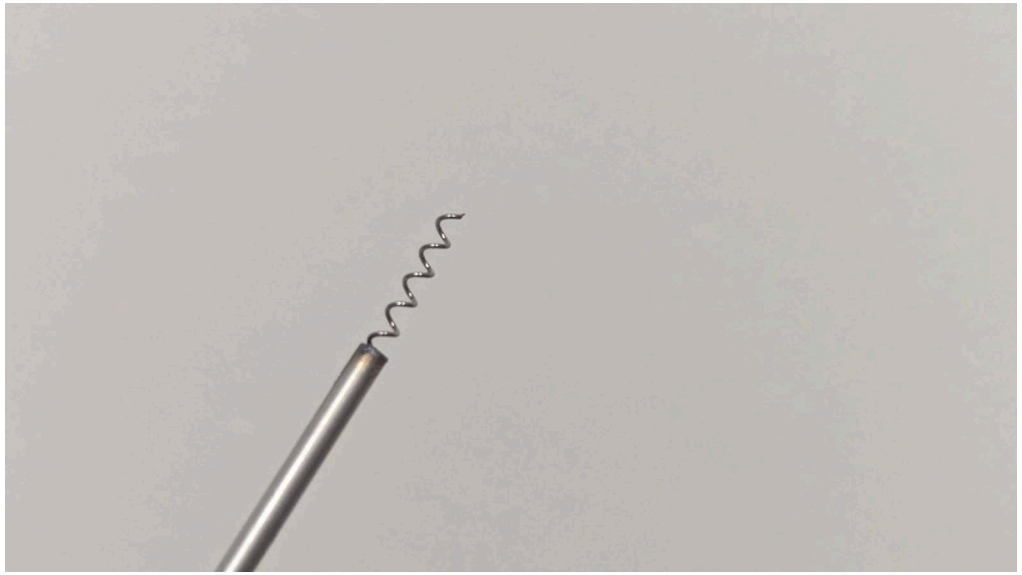
Medtronic 3830 lead. Source: Primary



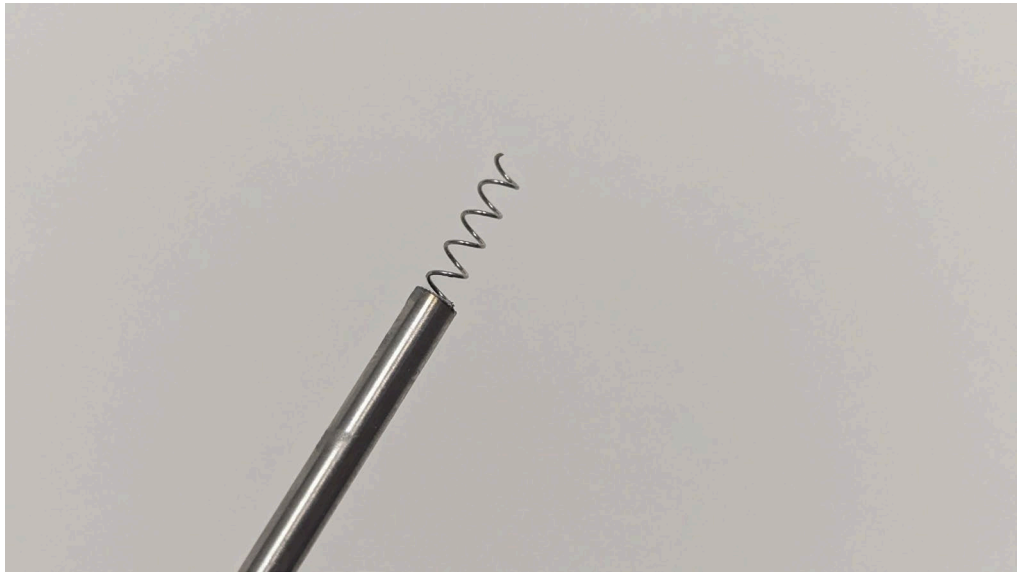
1 mm Outer Diameter, 1 mm Pitch



2 mm Outer Diameter, 1 mm Pitch



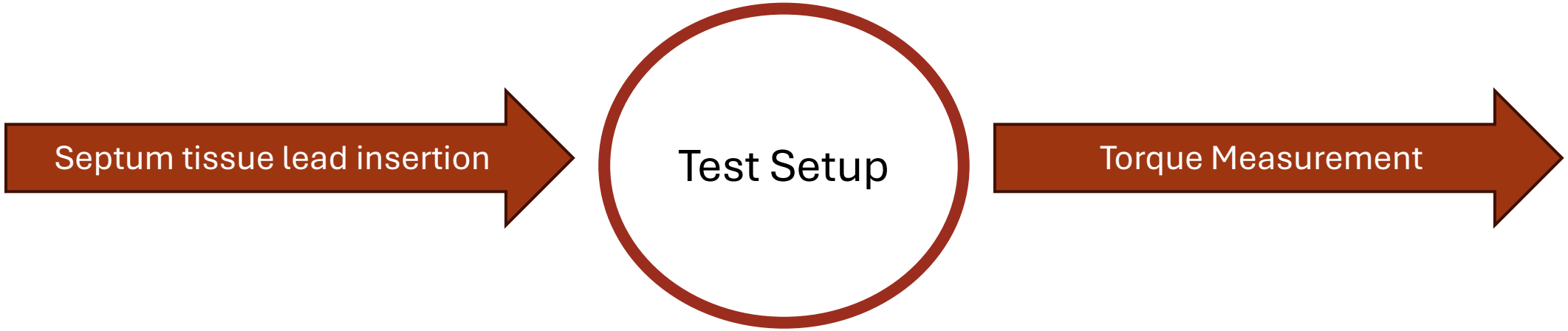
1 mm Outer Diameter, 2 mm Pitch



2 mm Outer Diameter, 2 mm Pitch

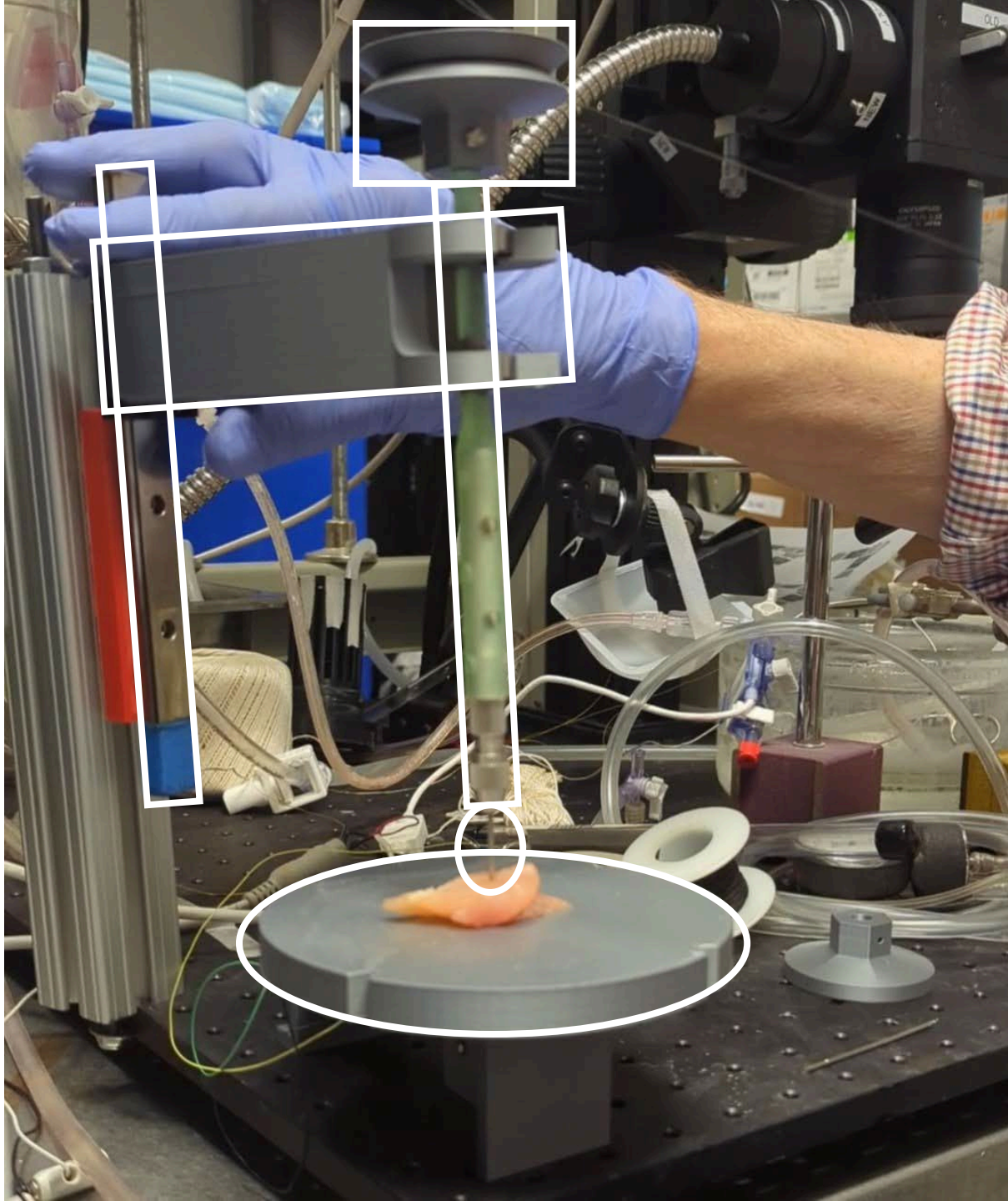
# Testing Setup

- A setup was created which quantitatively measured the success of lead tips during insertion into septum tissue



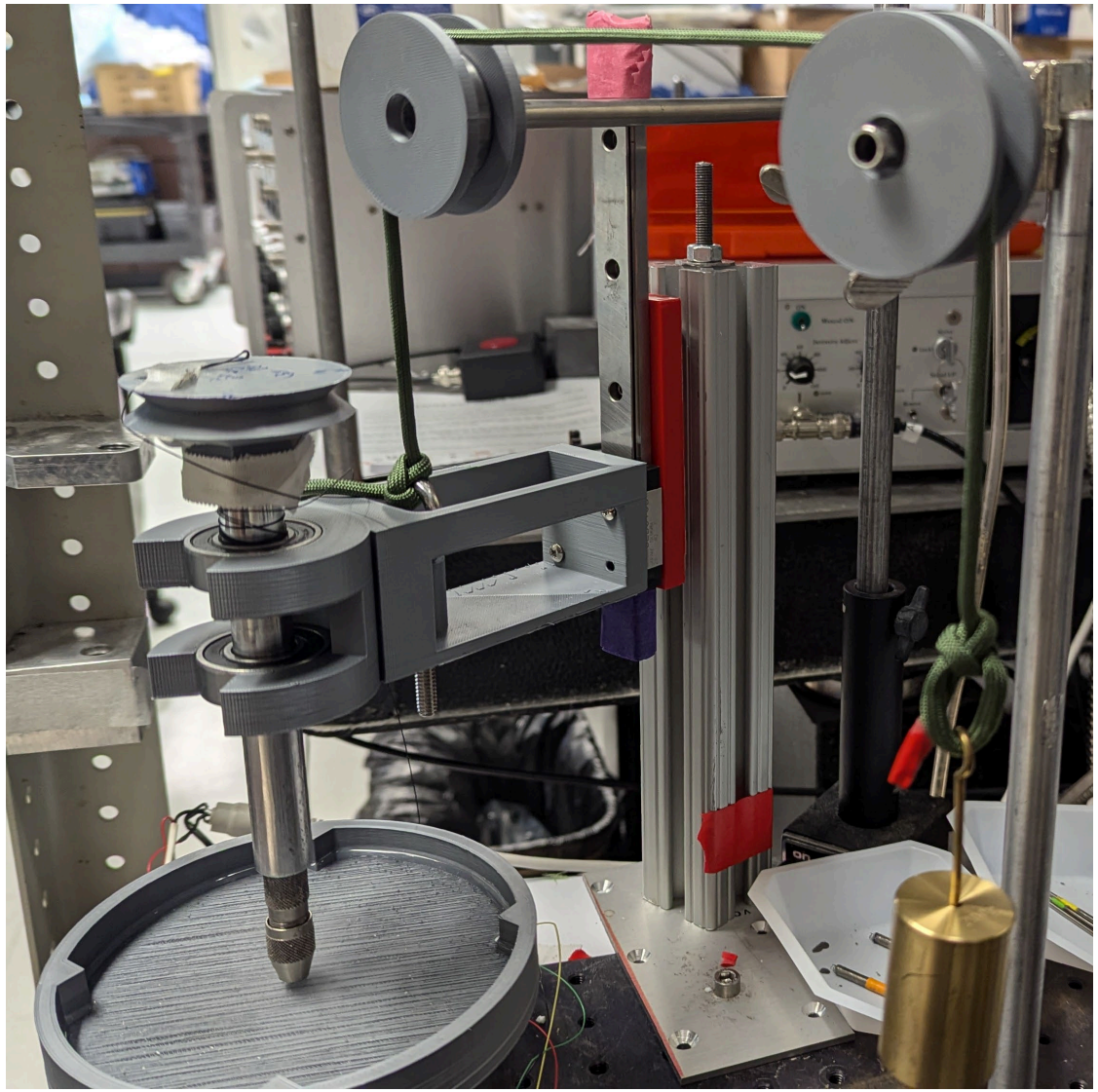
# Iteration one

- Linear slider
- Linear slider connector
- Lead holder
- Rotator
- Pseudo - lead
- Torque Measurement Tray



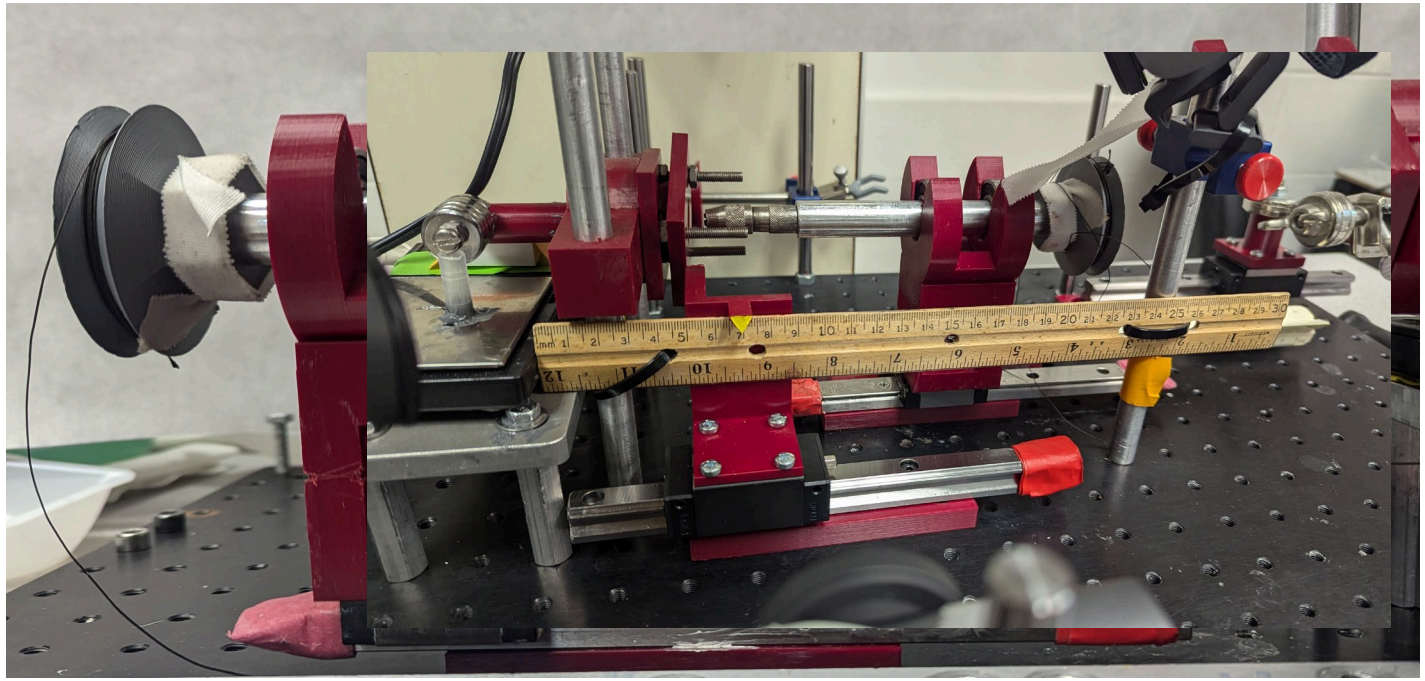
# Iteration two

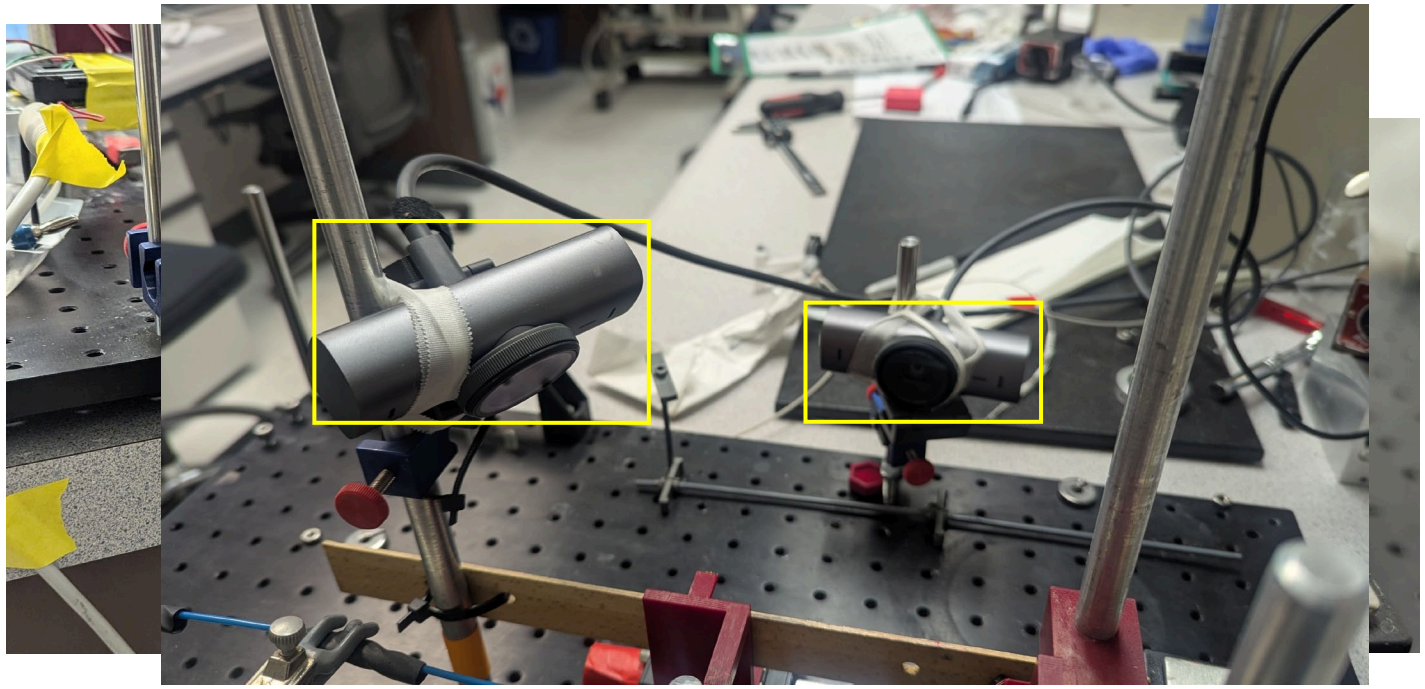
- Pulley added to reduce axial force
- Silicone added to tray to help secure tissue
- Modified torque sensor to be more rigid
- Lead holding stage replaced with all machined metal parts



# Final Setup

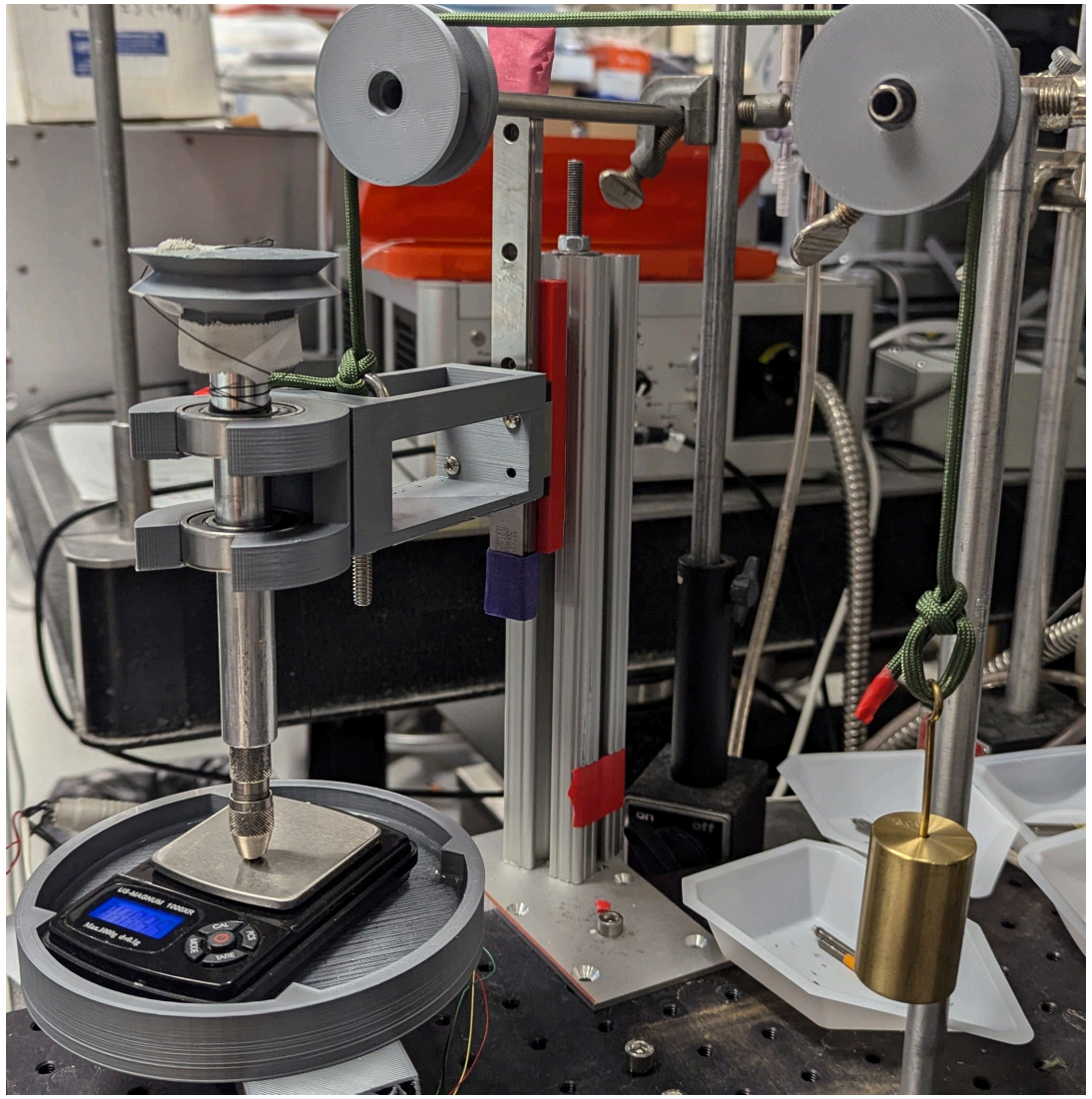
- Moved setup to horizontal axis
- Added clamp to tighten and secure the tissue
- Further Increased sensitivity of torque measurement
- Added cameras
- Added measure for insertion depth
- Added measure of septum thickness





# Accurate Axial force

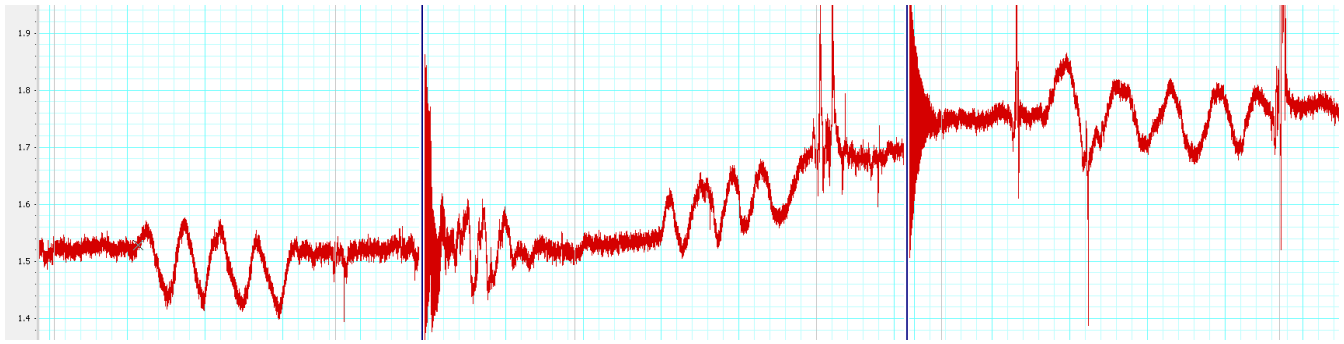
- To determine accuracy of axial force, some other system needed
- Scale added into setup to measure the force that the pulley was exerting on the tissue

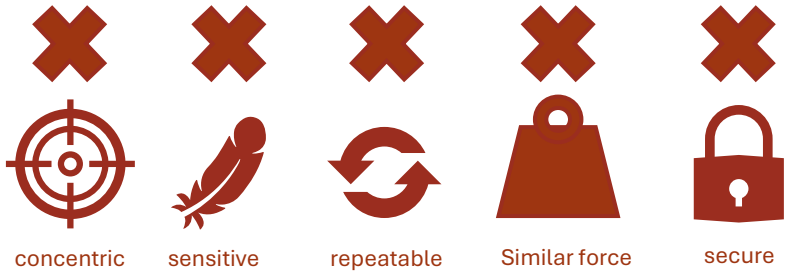


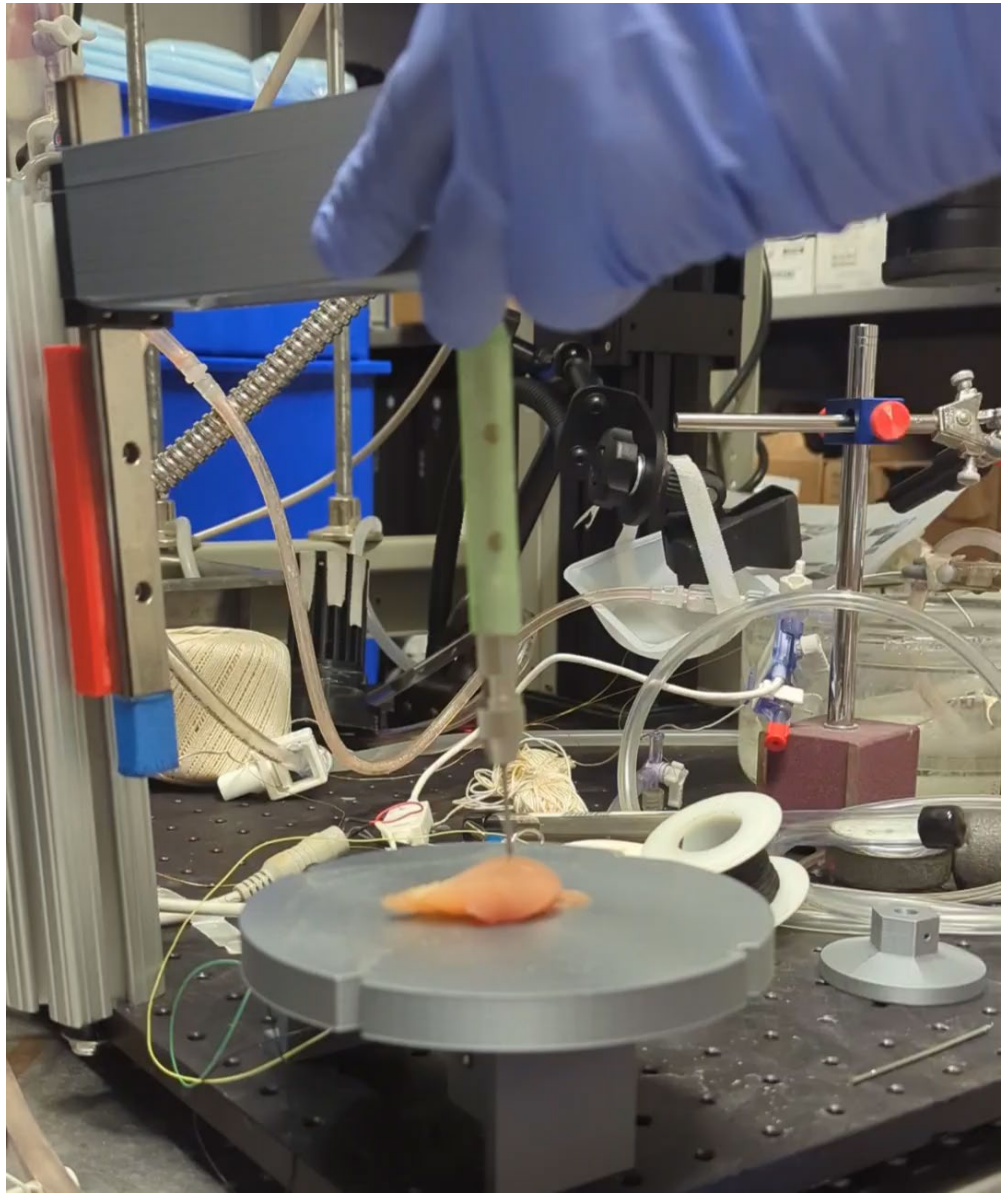
# Pseudo-lead Testing Procedure

- Divide septum into 3 pieces (seen right)
- Load thread on rotator
- Clamp pseudo-lead
- Clamp sample, measure sample thickness
- Attach coil
- Add axial load
- Measure start location of linear slider
- Rotate vice until string unspooled (½ rotation/second)
- Measure end location of linear slider
- Remove axial load
- Uncoil
- Repeat testing on next septal sample

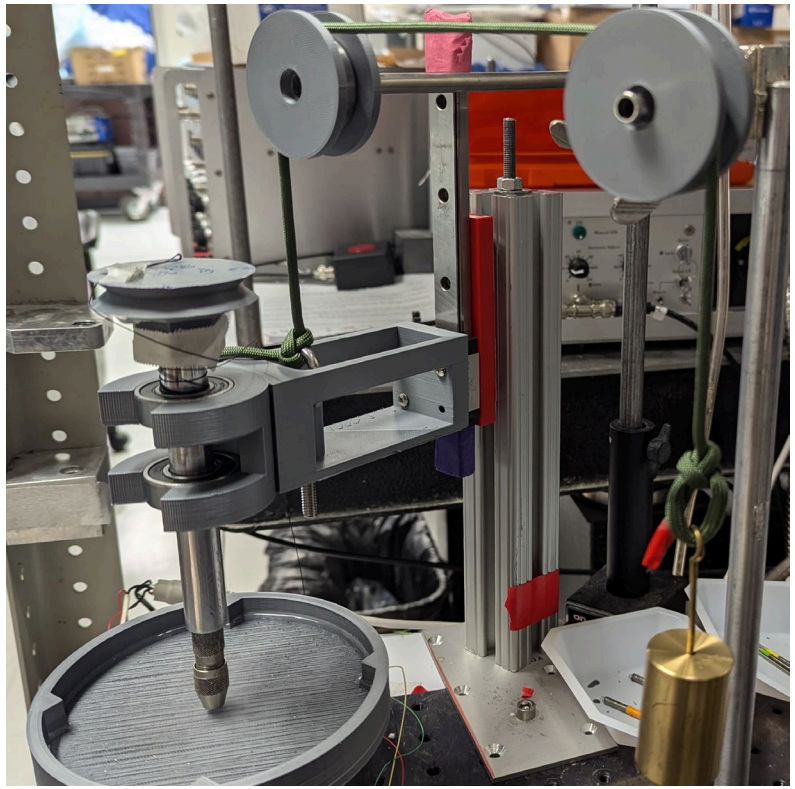
# Iteration one

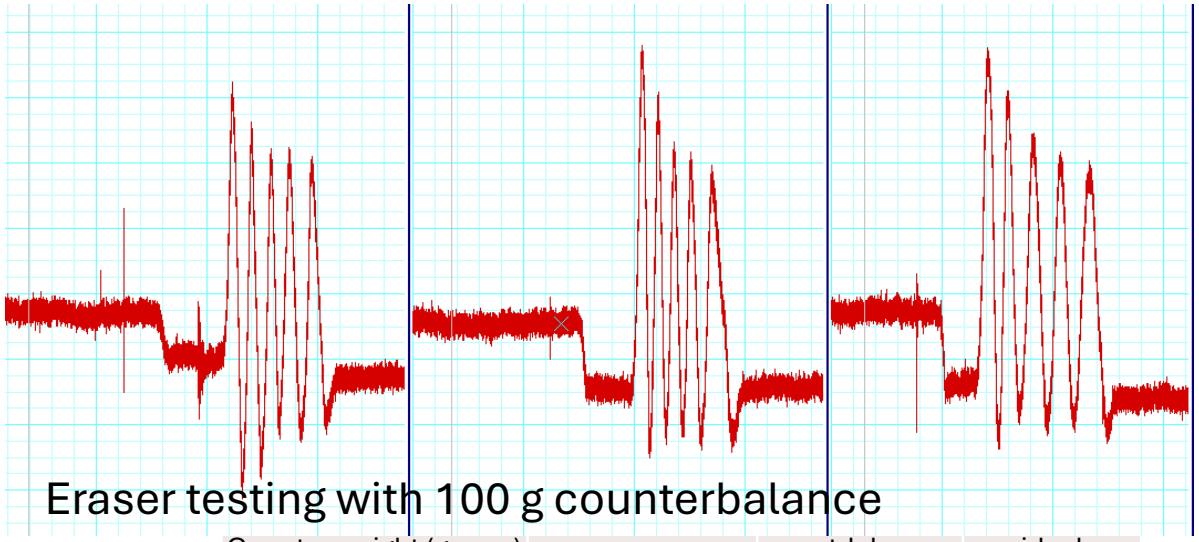


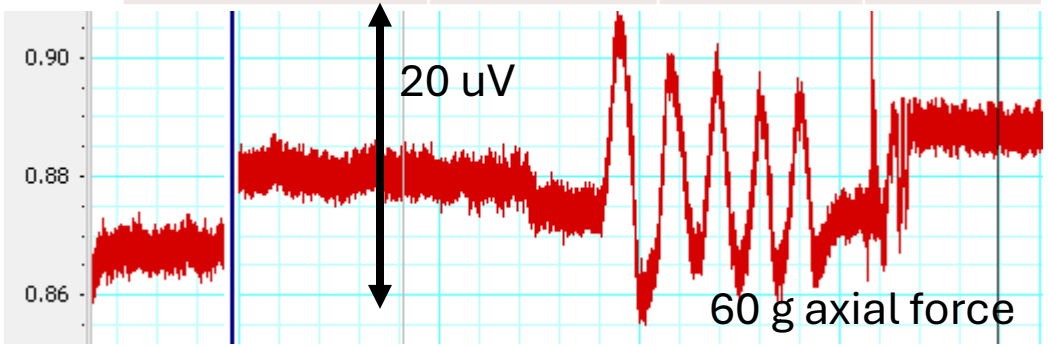



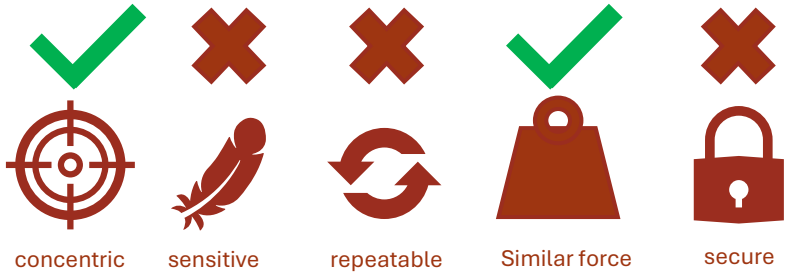
# Iteration two



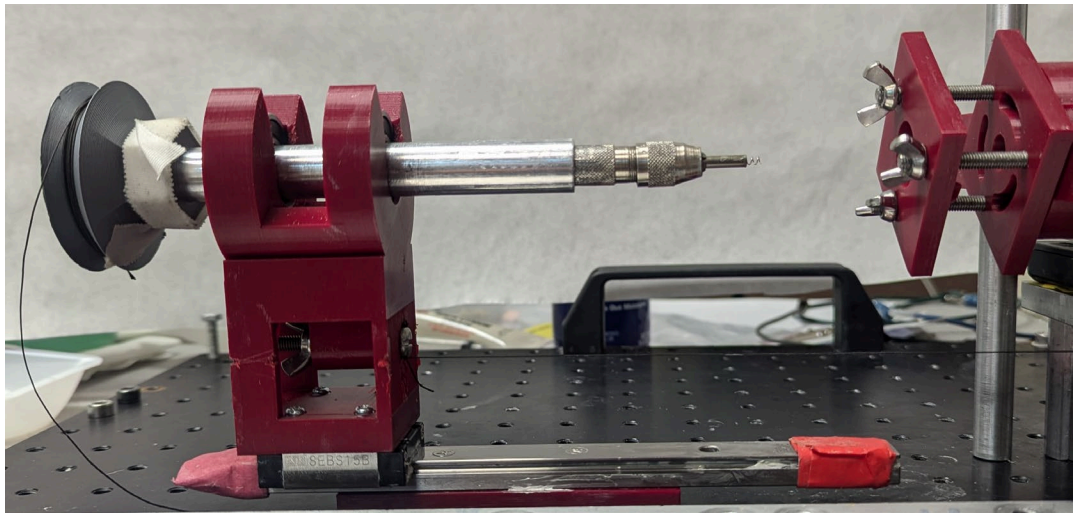


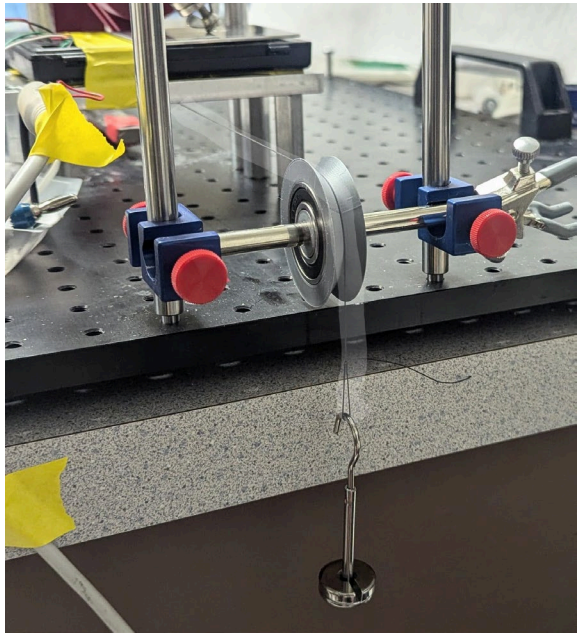

| Counter weight (grams) | mean | std dev | ideal |
|---|---|---|---|
| 0.00 | 312.80 | | 310.00 |
| 150.00 | 159.63 | 0.56 | 160.00 |
| 170.00 | 138.57 | 0.09 | 140.00 |
| 190.00 | 118.27 | 0.21 | 120.00 |
| 210.00 | 99.53 | 1.25 | 100.00 |
| 230.00 | 78.60 | 0.59 | 80.00 |
| 250.00 | 56.77 | 0.87 | 60.00 |
| 270.00 | 45.23 | 5.19 | 40.00 |
| 290.00 | 24.00 | 5.58 | 20.00 |



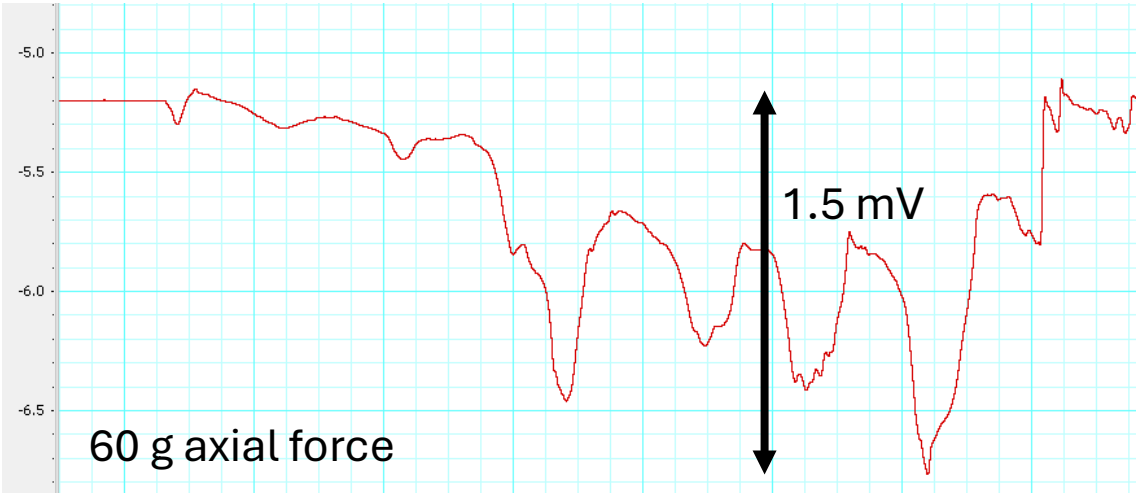



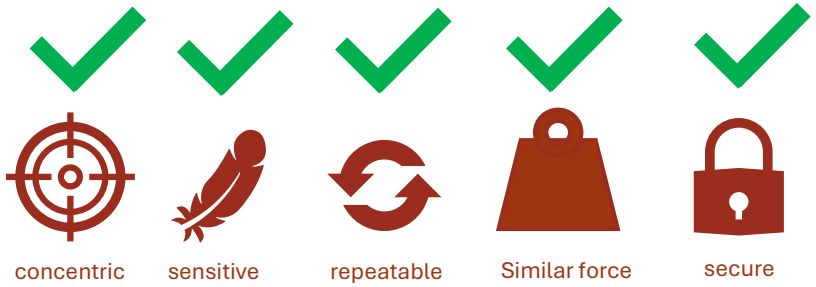
# Final Setup





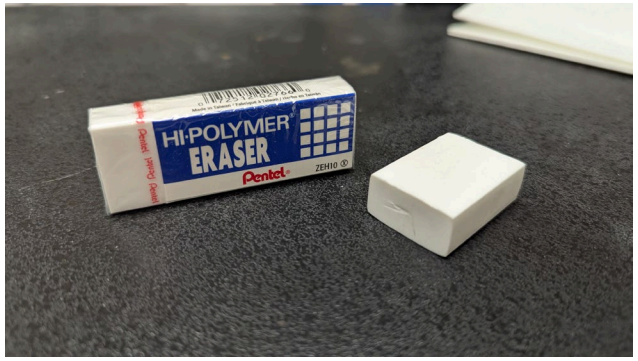
| Weight added | expected (mV) | Measured voltage (mV) (n=5) | Standard deviation (mV) |
|---|---|---|---|
| 30 | 0.49 | 0.496 | 0.033 |



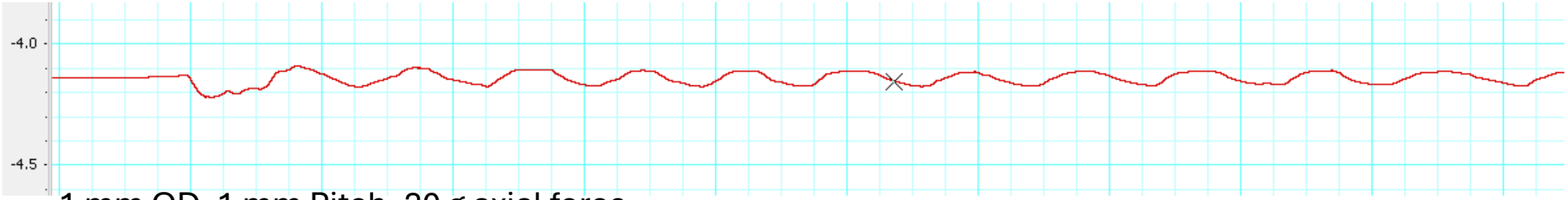
# Eraser testing

- Eraser is a homogeneous, somewhat soft material
- This data is preliminary and tells us if the test setup can be used to measure differences in coils

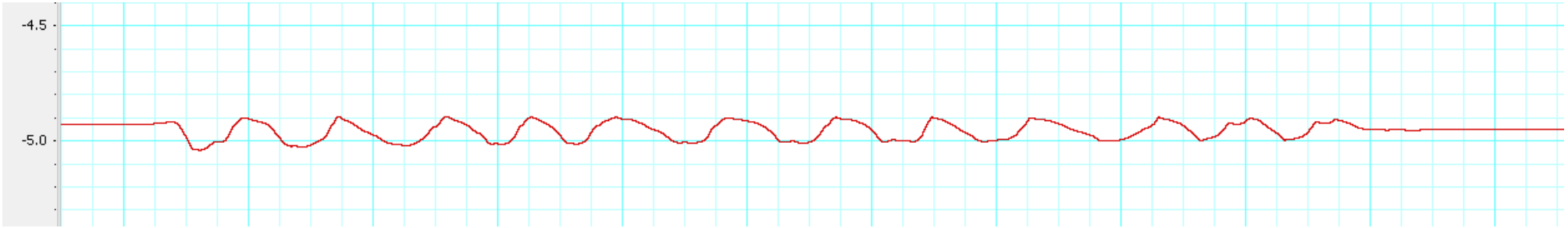



| | | 20 g | | | 40 g | | | 60 g | | |
|---|---|---|---|---|---|---|---|---|---|---|
| OD | Pitch | Burrow depth | std dev | Success rate | coil burrow | std dev | % times | coil burrow | std dev | % times |
| 1 | 1 | 3.345 | 1.11 | 4/5 | 4.32 | 0.50 | 4/4 | 4.175 | 1.69 | 4/4 |
| 1 | 2 | 6 | - | 1/4 | 6.025 | 0.41 | 4/4 | 4.91 | 1.50 | 4/4 |
| 2 | 1 | 0 | - | 0/4 | 3.75 | - | 1/4 | 4.555 | 2.38 | 2/4 |
| 2 | 2 | 6.65 | - | 1/4 | 6 | - | 1/4 | 3.235 | 0.84 | 2/3 |

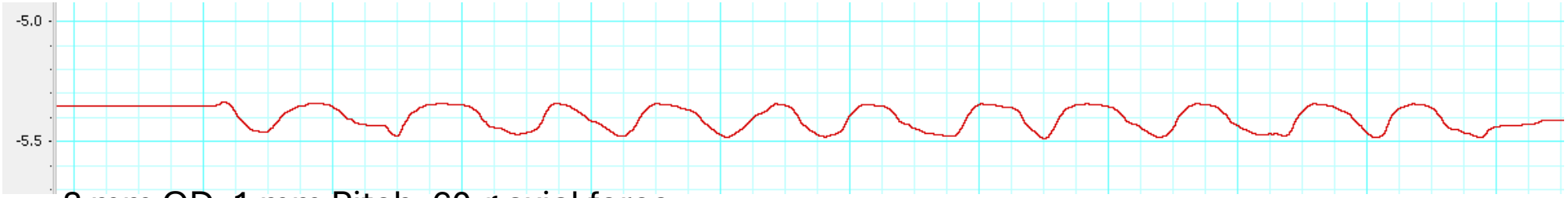
# Unsuccessful



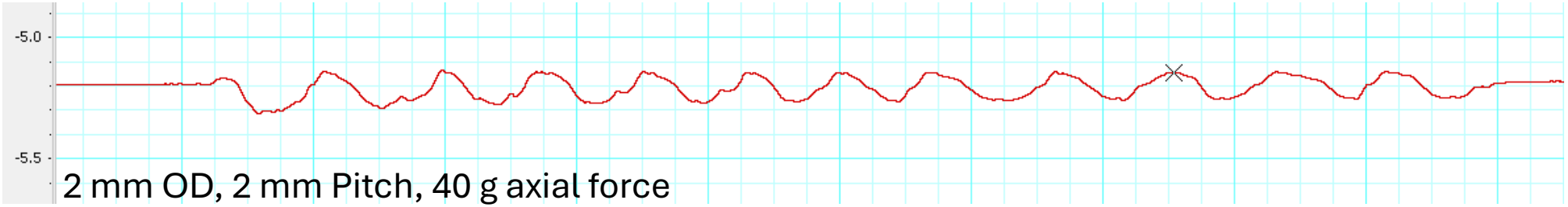

1 mm OD, 1 mm Pitch, 20 g axial force




1 mm OD, 2 mm Pitch, 20 g axial force




2 mm OD, 1 mm Pitch, 60 g axial force

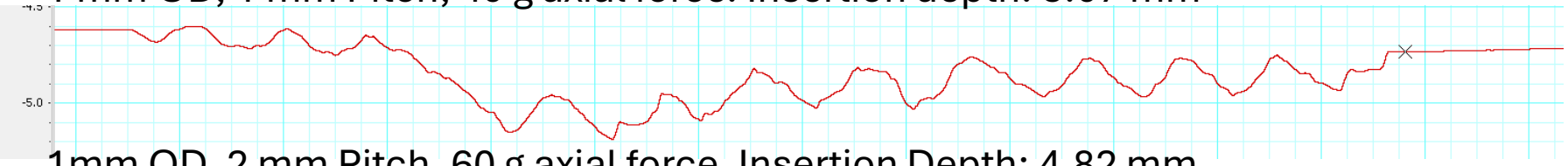



2 mm OD, 2 mm Pitch, 40 g axial force

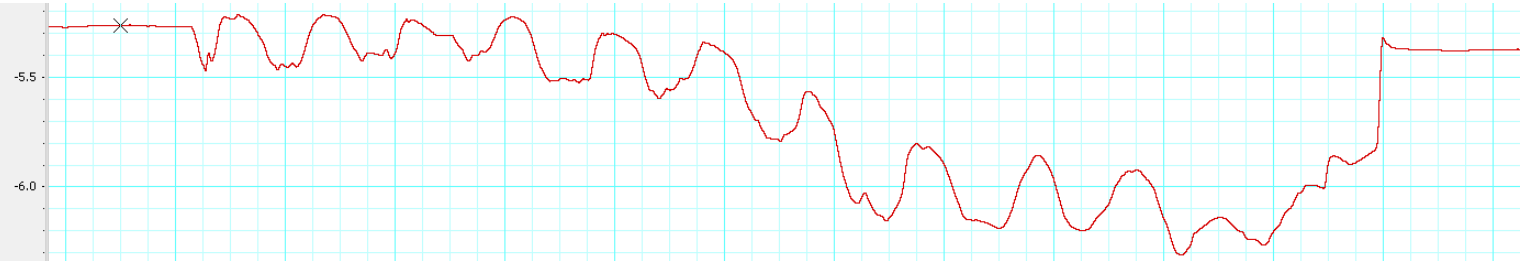

1 mm OD, 1 mm Pitch, 20 g axial force. Insertion depth: 2.56


1 mm OD, 1 mm Pitch, 40 g axial force. Insertion depth: 5.07 mm

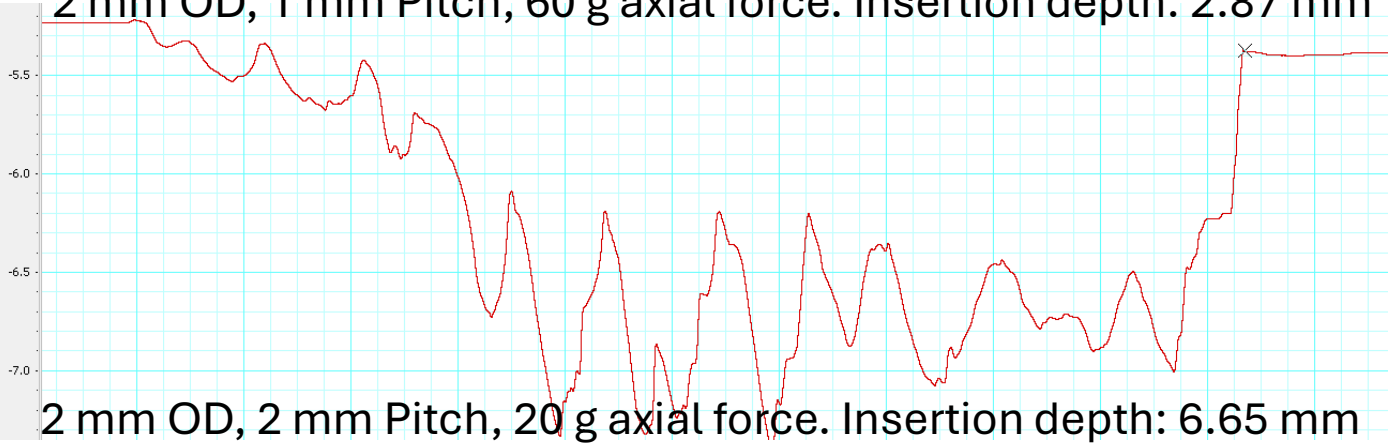
Successful




1mm OD, 2 mm Pitch, 60 g axial force. Insertion Depth: 4.82 mm

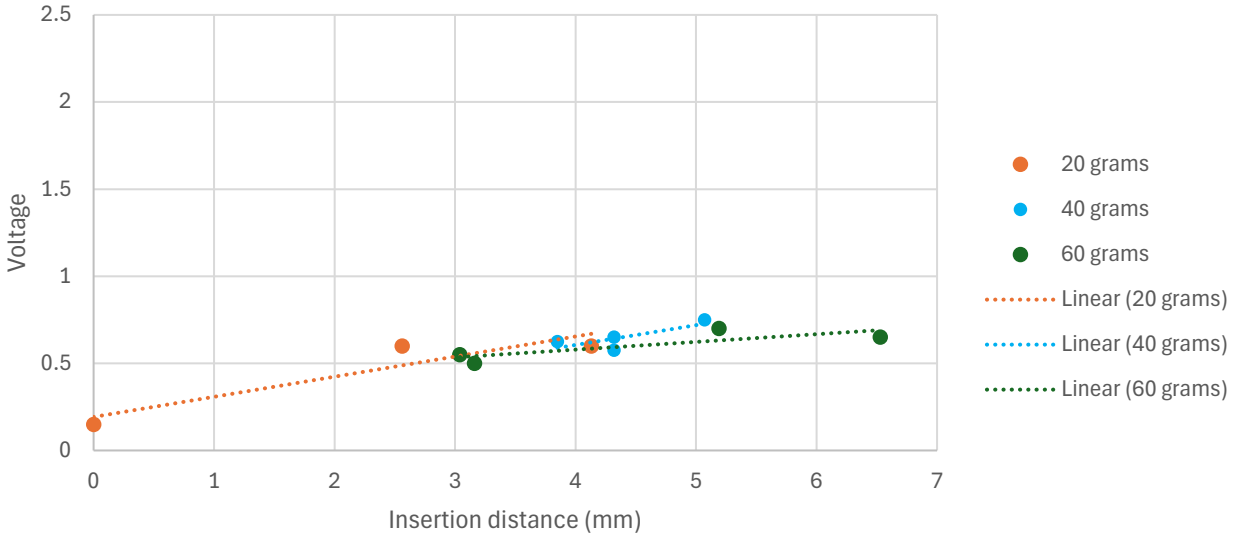



2 mm OD, 1 mm Pitch, 60 g axial force. Insertion depth: 2.87 mm




2 mm OD, 2 mm Pitch, 20 g axial force. Insertion depth: 6.65 mm

## 1 mm OD, 1 mm Pitch

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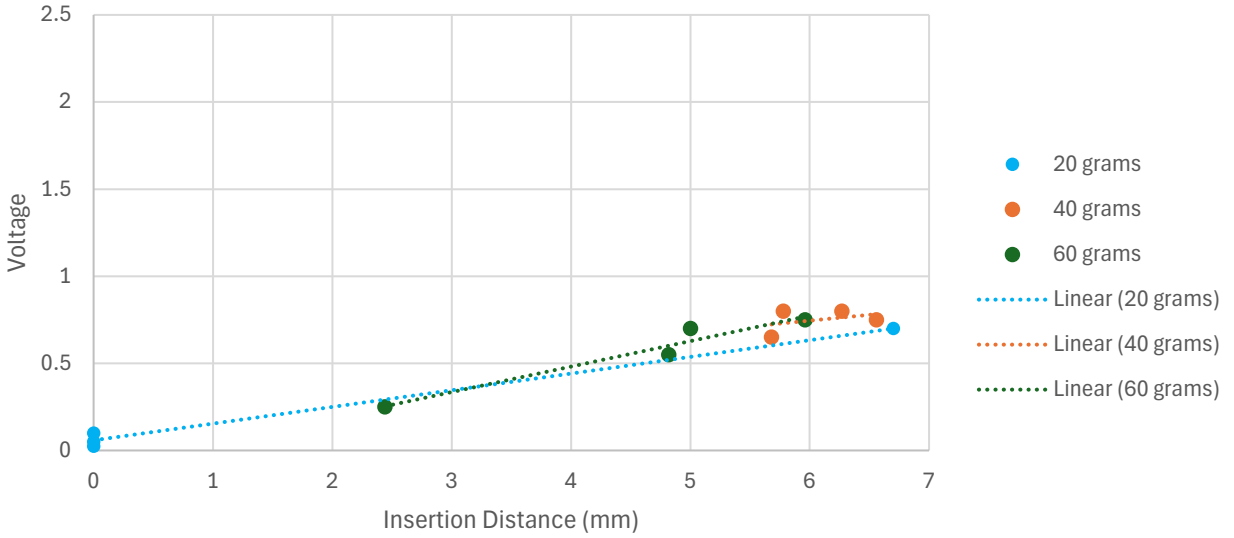
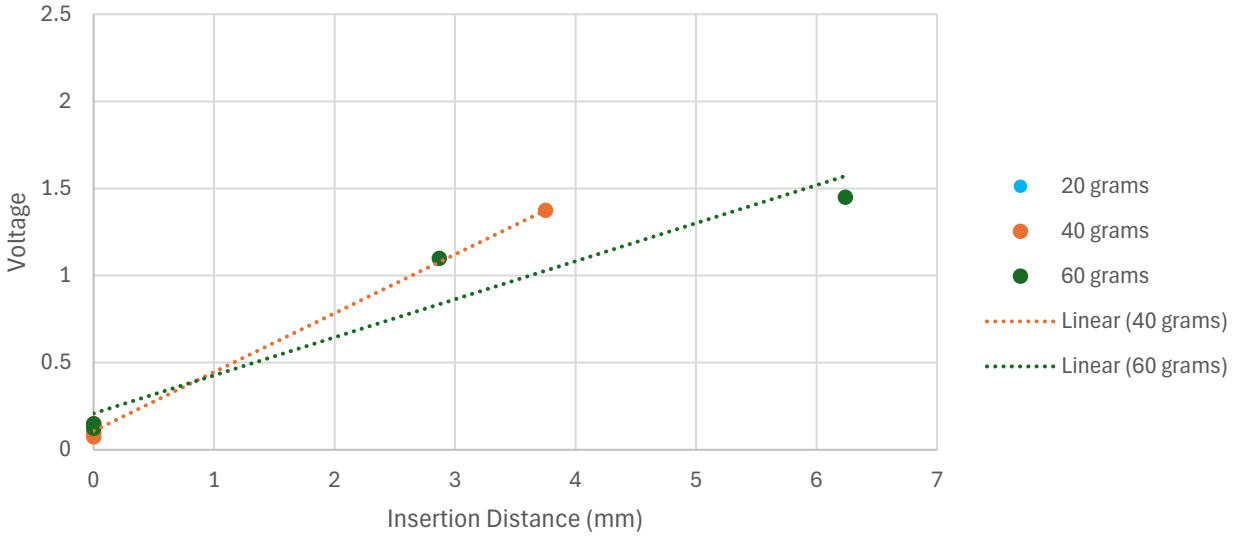
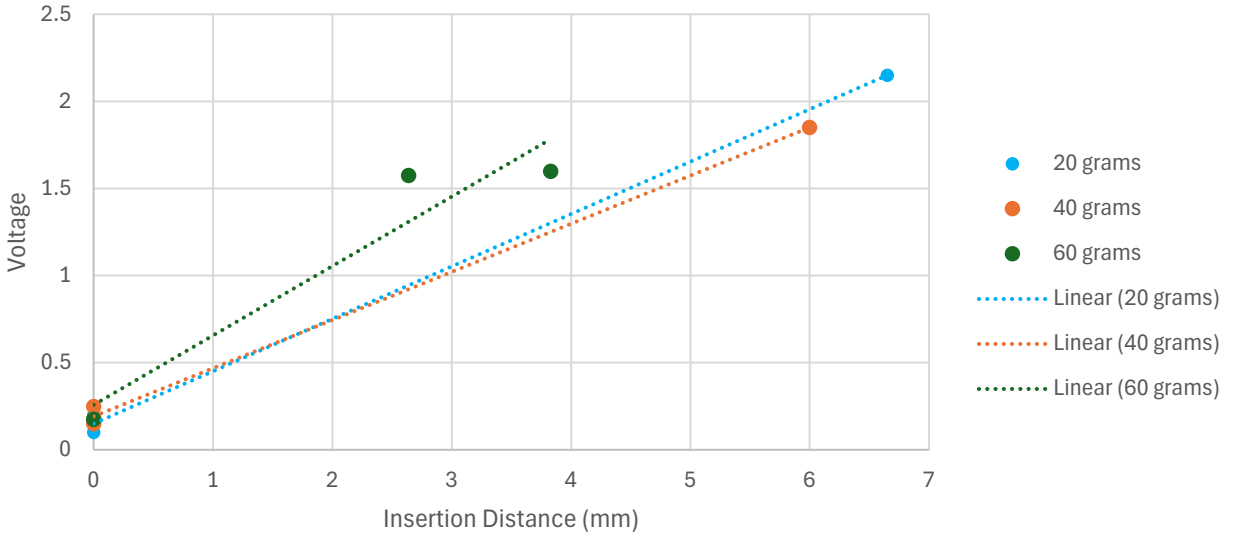



## 2 mm OD, 1 mm Pitch




## 2 mm OD, 2 mm Pitch



# Discussion

# Test Setup works

- The benchtop testing setup can quantifiably measure differences in insertion behaviors
- Various test show that the setup is robust and accurate
- The current data cannot necessarily be analyzed to determine which leads are the most successful

# Limitations

- The setup is not perfect – torque measurement shows that there must be lack of concentricity somewhere in setup
- Eraser is not the same as septum tissue – drill, entanglement, and screwdriver behaviors are not shown
- Further experimentation on septum tissue is needed to make conclusions about the impacts of physical dimensions of leads