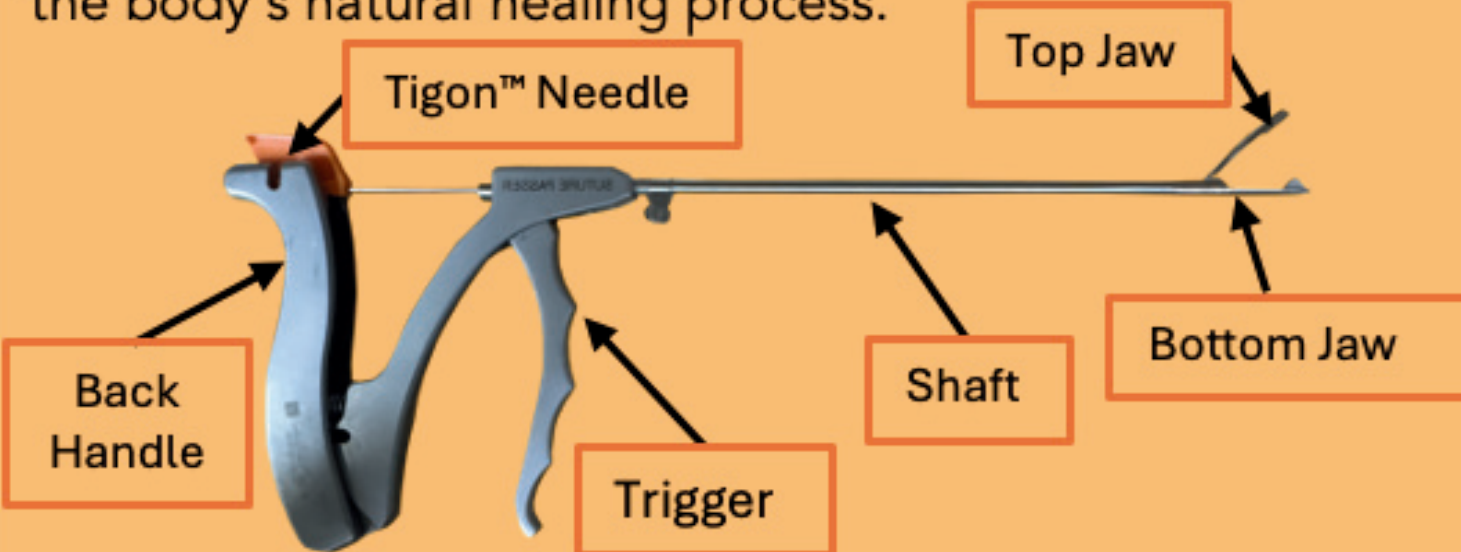


Background

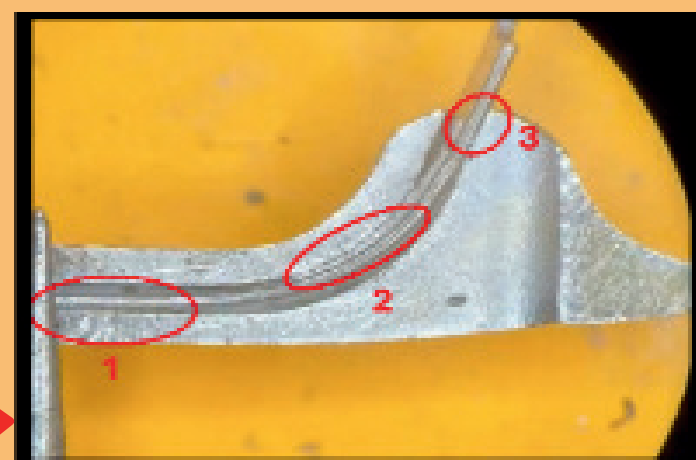
Tigon Medical's suture passer is a surgical instrument used in arthroscopic procedures to pass suture thread through tissue during rotator cuff repair surgeries, aiding the body's natural healing process.



Our focus was to improve the needle's success in fully passing through rotator cuff tissue and recapturing the suture by redesigning key components for better usability, performance, and surgeon satisfaction.

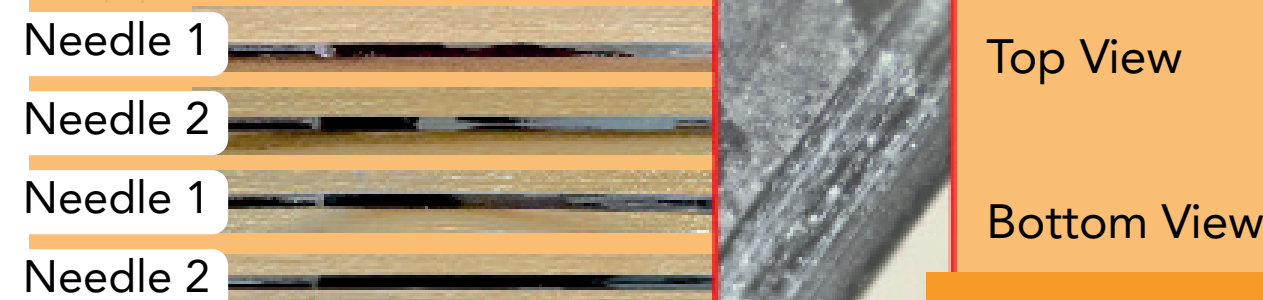
Problem Definition

Surgeons reported suture passer failing to puncture tough rotator cuff tissue during procedures, wasting time in the operating room.



Front Section View of Bottom Jaw:
Three major locations of friction

Friction Level: Low to High

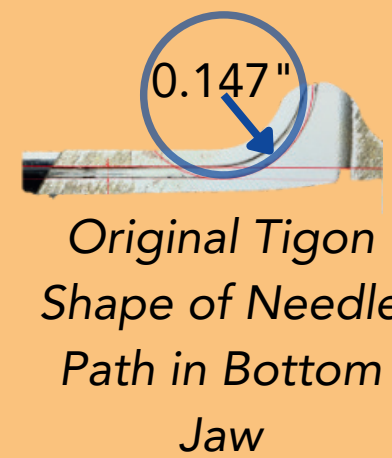


Friction Testing on Two Needles
Coated with Dykem

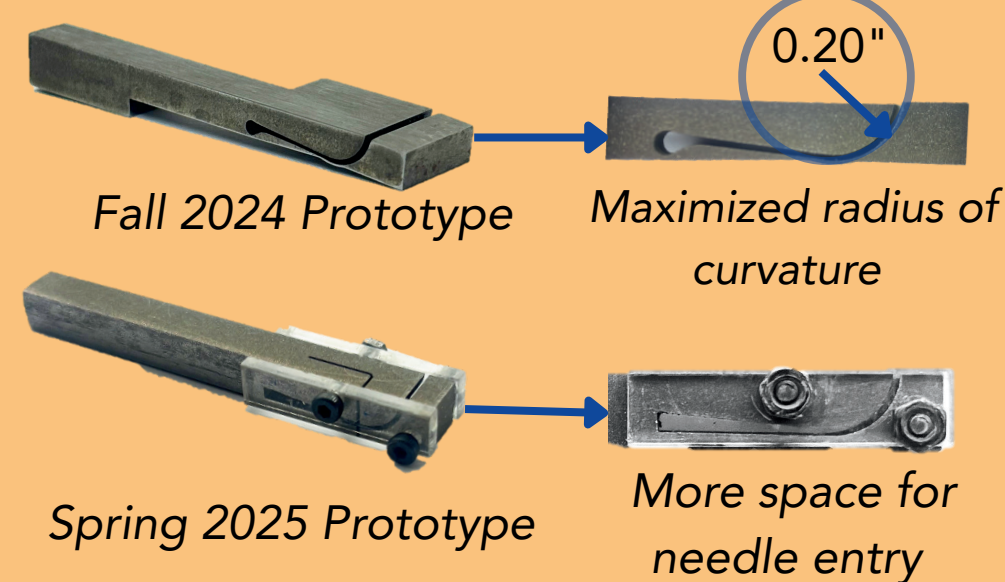
Objective:
Increase success rate of suture passing by reducing friction in needle path and required puncture force

Prototyping

1. Lower Jaw Redesign

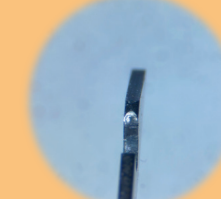


Original Tigon
Shape of Needle
Path in Bottom
Jaw



2. Needle Sharpening

Original
Tigon
Needle Tip



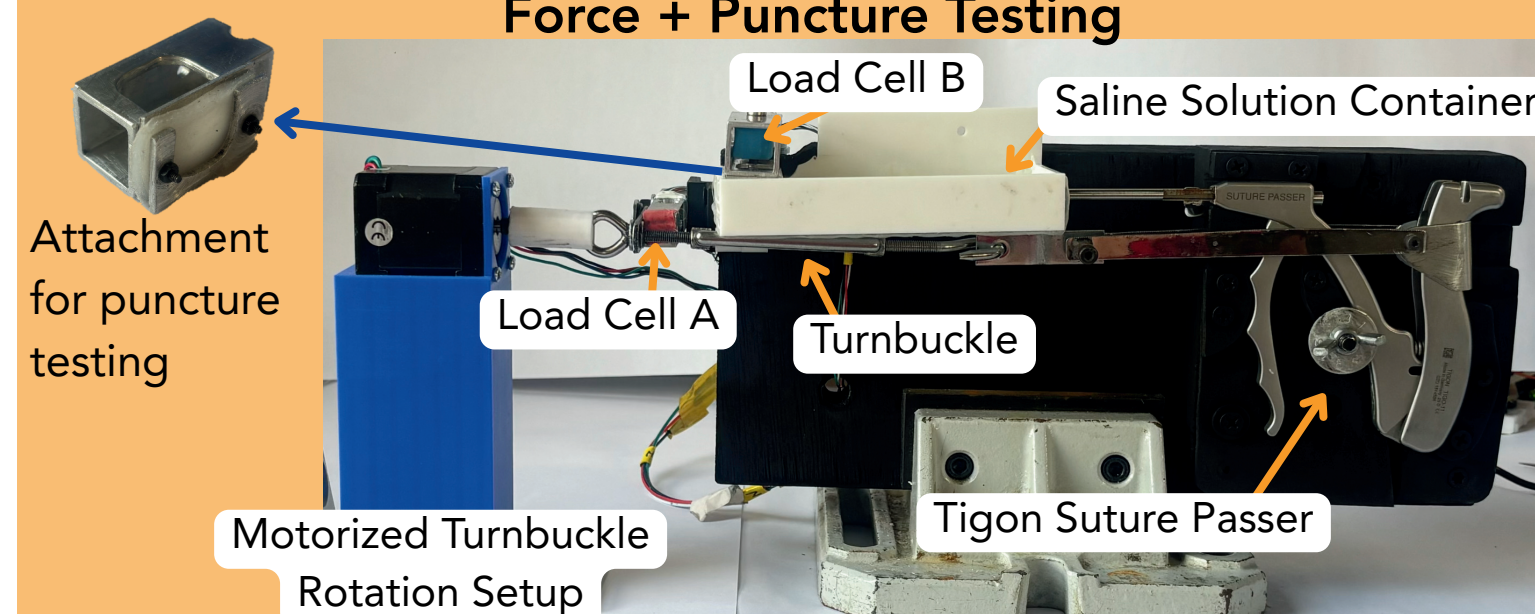
Sharpened
Needle Tip



Front View: Needle
sharpened to diamond
tip, less successful than
alternatives

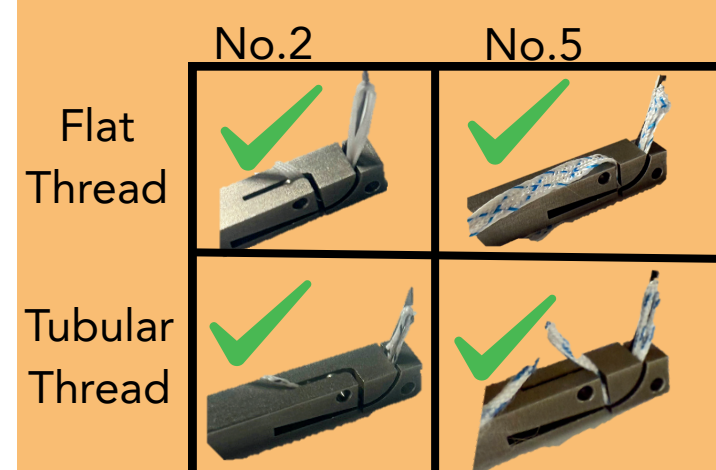
Testing

Force + Puncture Testing

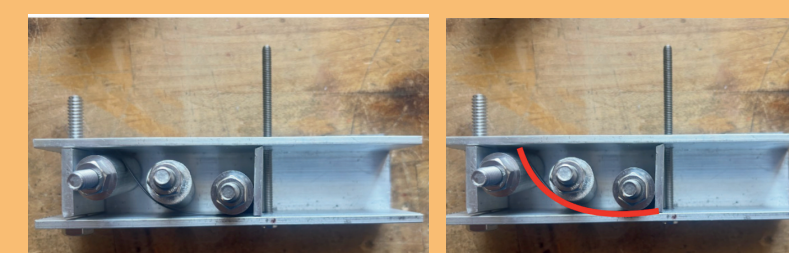


Force Testing Setup

Suture Compatibility Testing



Nitinol Training



Nitinol can be trained to change
shape at specific temperature.

Solutions

1. J-Path in Bottom Jaw

Force Transmission from Handle
Compression to Needle Ejection
increased **215%**



Greater Likelihood of Successful Puncture

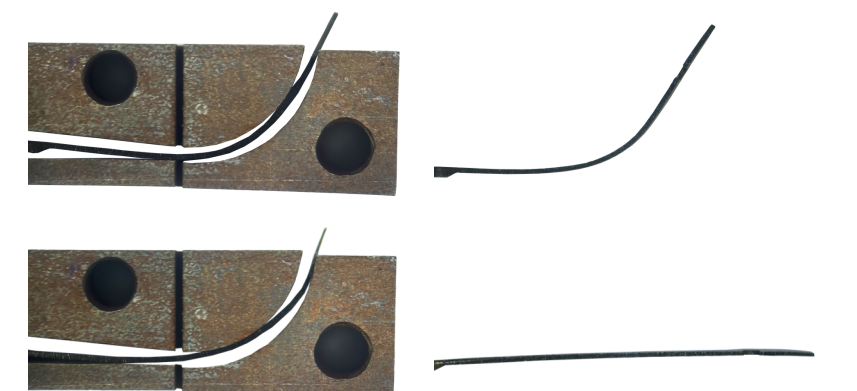
2. Needles Sharpened to 30°-35°

Stainless Steel Needles	Puncture Force (lbs)	Standard Deviation
Control	0.94	0.25
30° Sharpened	0.47	0.15
35° Sharpened	0.50	0.17
45° Sharpened	0.67	0.27

**50%
Lower
Necessary
Puncture
Force**

3. 45°C Trained Nitinol

Trained



Untrained

Conclusion

Puncture Rotator Cuff Tendons	✓	Single Hand Operation	✓
Self - Capture	—	Tigon Needle Compatible	✓
Needle Ejects 10 Times Before Being Replaced	✓	Fit Through 7mm Cannula	—
Suture Compatible	✓	Sterilizable	—

Dashed requirements need further iteration with more budget and access to operating room.

Acknowledgements: Stephen Belkoff, Rich Bauernschub, Melinda Tiao, Joe Korn, Stipe Iveljic