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THE FISCHELL DEPARTMENT of BIOENGINEERING

UNIVERSITY OF MARYLAND

Scapholunate Ligament Augmentation System for Rapid Functional Restoration

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Clinical Need

Objective

Devise a novel ligament augmentation device applicable to complete tears of the scapholunate ligament (SLL) with or without scaphoid and lunate malalignment. This device will allow flexibility and range of motion during the healing process while providing a secure connection between the scaphoid and the lunate able to withstand normal tensile loads.

Background

- Scapholunate Ligament (SLL) is primary stabilizer of the wrist
  - Cup shape ligament composed of 3 sections
  - Flexion and radial-ulnar deviation
- Stage 2, 3, and 4 Scapholunate Dissociation (SLD): Complete rupture of SLL with intact cartilage.
  - Stages 2 and 3: aligned scaphoid and lunate
  - Stage 4: malaligned scaphoid and lunate [3].
- Improper healing can result in:
  - Reduced range of motion and weakness
  - Long term osteoarthritis
  - Scapholunate advanced collapse (SLAC)

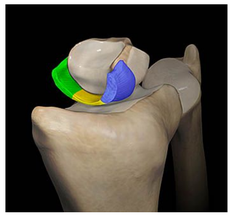
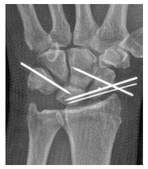


Figure 1: Cross section of SLL. Dorsal (blue), Proximal (yellow), Volar (green)

Motivation: Inadequate Surgical Solutions

- Multitude of current surgical repair procedures
- Current procedures have inadequate long term results
  - Pinning → reduced range of motion and flexibility
  - Suturing → inadequate strength
  - Rate of retear high after surgical repair
  - Inability to return to peak performance



Device Design

After surgical repair of the scapholunate ligament in stage 2 SLD, our intraosseous device will be placed to augment the weakened ligament, allowing for optimal healing. For stage 3 and 4 SLD, the irreparable ligament will be replaced by our device. The device will be secured internally into both the scaphoid and the lunate, and the polyethylene sutures will hold those internal connections in tension to bear wrist loading.

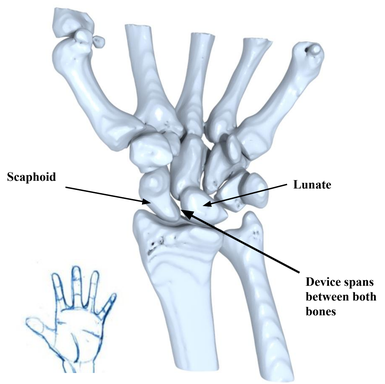


Figure 2: Anatomy of a patient's left hand shown palm out. CAD model developed based on an anonymous CT scan provided by our clinical mentor

3 Key Design Features

Strength: Able to bear as much tensile load as the SL ligament (260N) [4].
Flexibility: Allow rehabilitation exercises to begin within 2 weeks of surgery.
Bone Health: Small device for minimal drilling of bone, as drilling may cause bone weakness or osteonecrosis in rare cases[6].

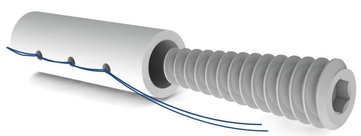
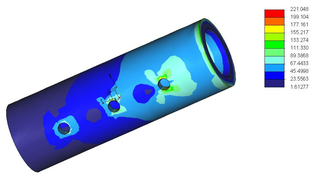


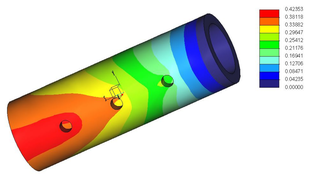
Figure 3: Solidworks render of our device, consisting of a polypropylene spacer, a tapered peek headless screw, and polyethylene suture wires

Mechanical Testing

Finite Element Analysis

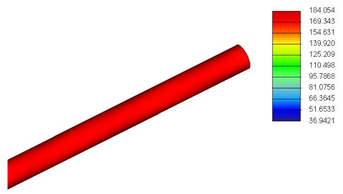
Model device simulated in tension at the maximum required force capabilities of an intact Scapholunate Ligament, 260 N [4].

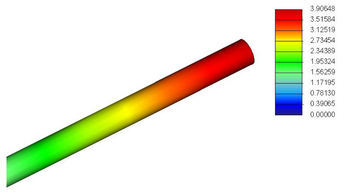




Max Stress: 221 MPa **Max Displacement**: 0.4 mm

Polypropylene spacers show high stress-bearing capabilities and low displacement
Polyethylene suture will be limiting factor for stress and displacement



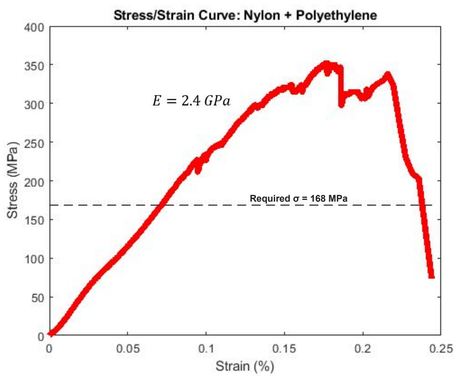


Max Stress: 184 MPa **Max Displacement**: 3.9 mm

Polyethylene spans between scaphoid and lunate 4 times in our device, increasing the effective cross sectional area of the sutures by a factor of 4

To model this for stress testing, cross sectional area in model is multiplied by 4

Tensile Testing



Device tested under tensile loads until failure. Peak stress was 352 MPa (524 N), well above the required 168 MPa (260 N).

Stress-strain curve and Young's Modulus are characteristic of Polyethylene

$$\sigma_{Req} = \frac{260\ N}{4 \times [\pi \times 0.00035^2]} = 168\ MPa \qquad FOS = \frac{F_{fail}}{F_{allow}} = \frac{542\ N}{260\ N} = \frac{352\ MPa}{168\ MPa} = 2.1$$

Conclusion

Our clinical mentor provided us with a unique challenge: combining **strength** and **flexibility** in our device. Using the engineering design process we were able to implement a feasible and reproducible solution which met both of these requirements

Conclusions

- Elimination of pinning, increased flexibility
- Ability to withstand expected loading of 260 N with a safety factor of 2.1
- We learned:
  - Access to medical-grade, sterile materials and cadaver specimens provides a significant barrier to entry in the field of medical device design
  - The process of innovating medical technologies can be extensive and time consuming, but in the end it is rewarding
  - Identifying a need, generating a concept, developing strategies and planning, and integrating the parts of the new device require teamwork and dedication

Ethical Implications

- Surgeons must learn new surgical procedure
- Higher level of confidence in athletes returning to preinjury level of competition
- Expensive procedure, patients unable to afford surgery can be subject to increased progressive arthritis and wrist pain
- Invasive surgery is associated with increased risk to patients such infection and osteonecrosis in rare cases

Future Work

Additional Testing

- Perform in vitro force analysis tests with cadavers for accurate mechanical model
- Conduct animal in vivo studies to study host immunological response and other potential risks associated with materials or design of the device
- Analysis of stress-strain curve for anatomically sized model
- Insert device into cadaver hand model with appropriate surgical tools

Design Modifications

- Completely bioresorbable design to address stage 2 SLD
- Revise the cylinder design to an expandable sheath to facilitate insertion, similar to existing screw-in-sheath constructs used in ACL reconstruction such as IntraFix®

FDA Approval

- FDA approval once appropriate test in animal models and cadavers are performed to determine that device is at least as safe and effective as other available devices [5]
- Submit Premarket Notification 510 (K)

Acknowledgements

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Abstract

The scapholunate ligament serves a critical role in stabilizing the wrist and providing support during physical activities. However, its prominent role and complexity within the carpal system make ruptures of the scapholunate ligament (SLL) one of the most common and complicated types of wrist injuries. Multitudes of methods exist to surgically repair the system to regain functionality, but these methods are inadequate, and many have long term side effects such as high retear rates, reduced range of motion and flexibility, and an inability for the patient to return to peak performance. The current procedures are highly dependent on the stage of the scapholunate dissociation (SLD). The six stages are categorized by quantifying the degree of tear (complete or partial), the repairability of the ligament, alignment or malalignment of the scaphoid, and cartilage health. Our device will be applicable to complete tears of the ligament with and without malalignment of the scaphoid, which correspond to stages 2 through 4. Our team proposed to work towards solving this medical problem with applications of mechanics and surgical engineering principles. Under the guidance of our clinical mentor, Dr. R. Frank Henn III, an orthopedic surgeon at the University of Maryland School of Medicine, we designed a reliable method for surgically augmenting the ruptured scapholunate ligament to restore functional mobility without sacrificing long term stability. Our intent was to establish a method of repair that is common across orthopedic practices and replaces the multitude of less desirable methods used today. The purpose of our device is to augment the scapholunate ligament as it heals for stage 2 SLD or to replace the native ligament for stages 3 and 4 SLD. Our design consists of two spacers made of polypropylene that can be inserted into the scaphoid and lunate. Much like drywall anchors, these spacers expand with the insertion of polyether ether ketone (PEEK) screws and are held in tension with polyethylene suture. The maximum force the native SLL ligament can withstand is 260 N. Both FEA simulations and mechanical testing have shown our device is capable of holding far greater loads than required, with a safety factor above 2. Our device provides the load-bearing capabilities to effectively hold the scaphoid and lunate in tension while providing the flexibility necessary to return to functional movement quickly.