



# Polymeric Meniscus Replacement Attached with Antiparallel-Barbs Protruding from Anchor



BME 490 | Team 14: The Bee's Knees

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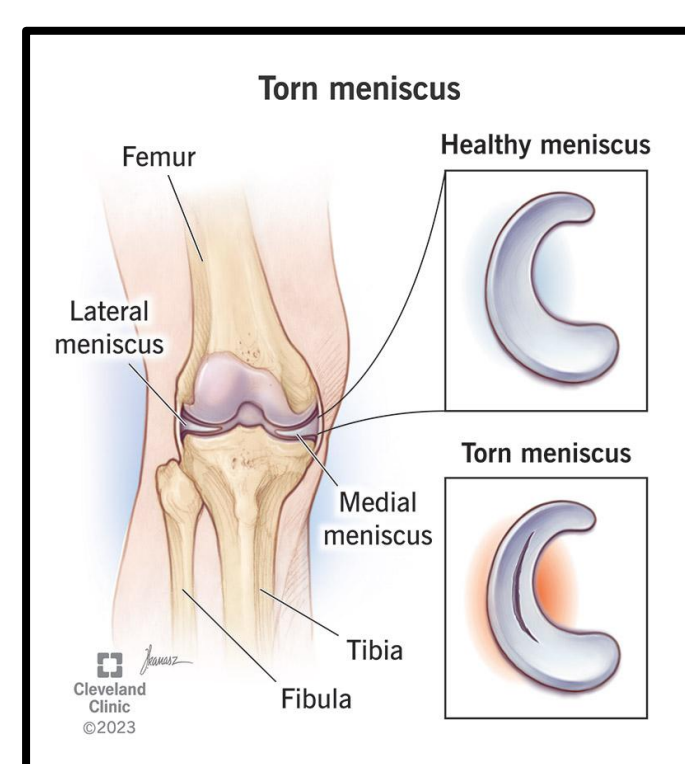
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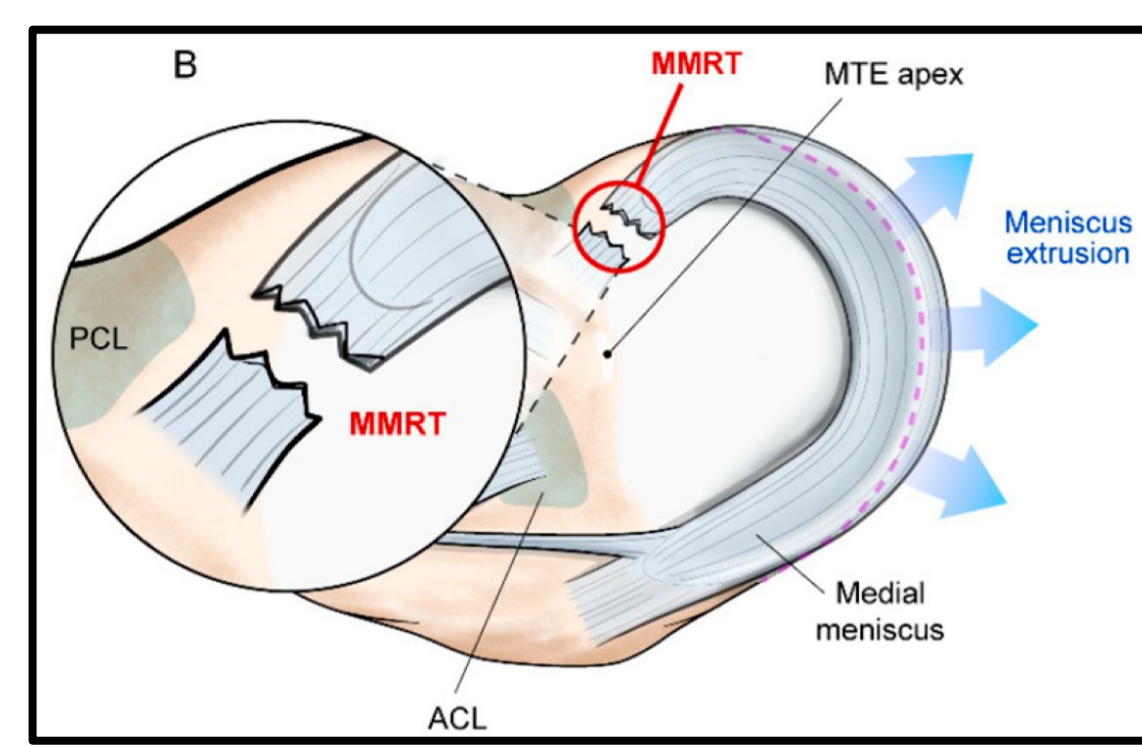
## Introduction and Background

The meniscus is a section of cartilage attached to the tibial plateau inferior to the femur. The meniscus comprises of two sections: the medial meniscus and the lateral meniscus, focusing on stability and movement respectively (Fig 1). Overall, the core function of the meniscus is to work as a shock absorbent and to transmit forces to the knee, increasing joint stability.

Meniscus tears are a relatively common injury among young, athletic adults, that limits the load-bearing ability of the knee [1]. These tears limit the ability of the meniscus to generate hoop forces, or circumferential force that distributes loading across the knee joint (Fig 2). Meniscus replacement offers an alternative to meniscectomy, opting to mimic the structure and function of the tissue. Currently, there are no FDA approved meniscus replacements on the U.S. market available for patient use, highlighting the clinical need for a an effective replacement available to patients. Most products in development or those available in other countries attach to the tibia through screws or simply don't connect at all [3]. However, hoop force generation is only achievable by stable connection to the tibia. Here, a novel polymeric meniscus replacement is designed to attach to the tibia using a non-damaging, secure method to replicate the meniscus.



**Figure 1:** Anatomy of meniscus. Physiology of healthy and torn meniscus [1].

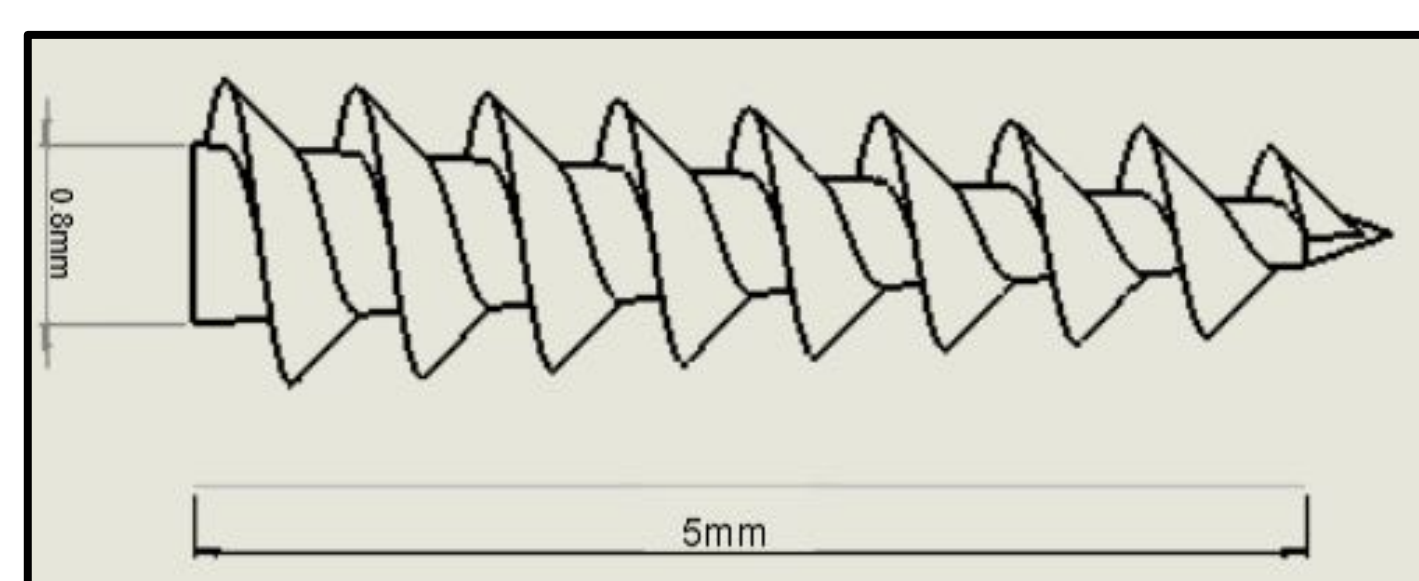


**Figure 2:** Medial meniscus root tear (MMRT) which causes a loss of hoop tension that results in meniscus extrusion [2].

## Mission Statement

The Bee's Knees aim to develop a novel and stable meniscus that causes minimal tissue damage. A secure attachment method that integrates with local tissue that follows class III FDA regulations will be developed.

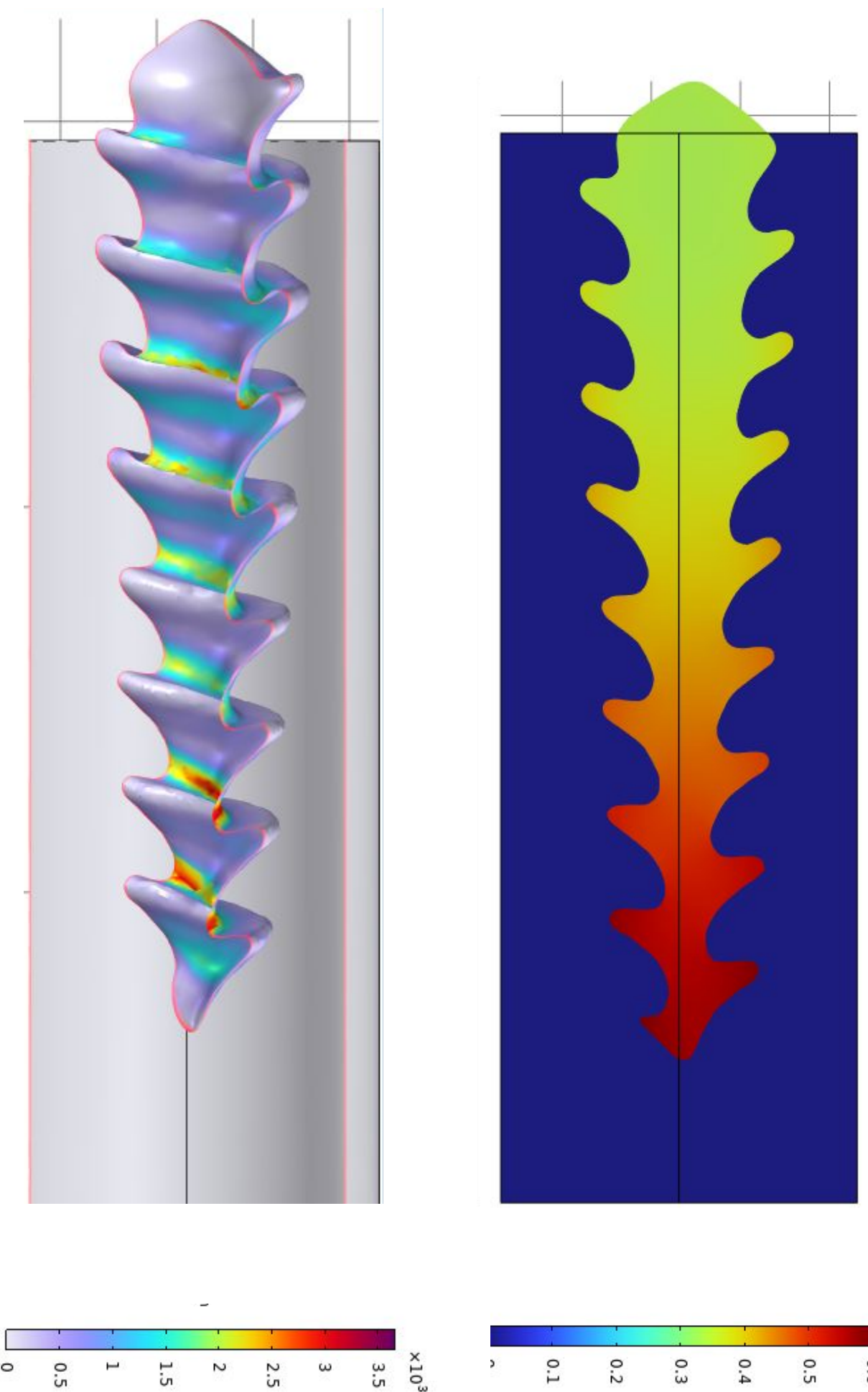
## Final Technical Models



**Figure 3:** Technical drawing of final anchor prototype with dimensions made with Solidworks.

Simulations were done with COMSOL. The screw was embedded in a cylinder, and the material of the screw was set to have the same parameters as our polyurethane and the material of the cylinder mimicked meniscus root. The force that was applied was 100 N/m<sup>2</sup> straight up and out of the cylinder across the entire surface of the anchor.

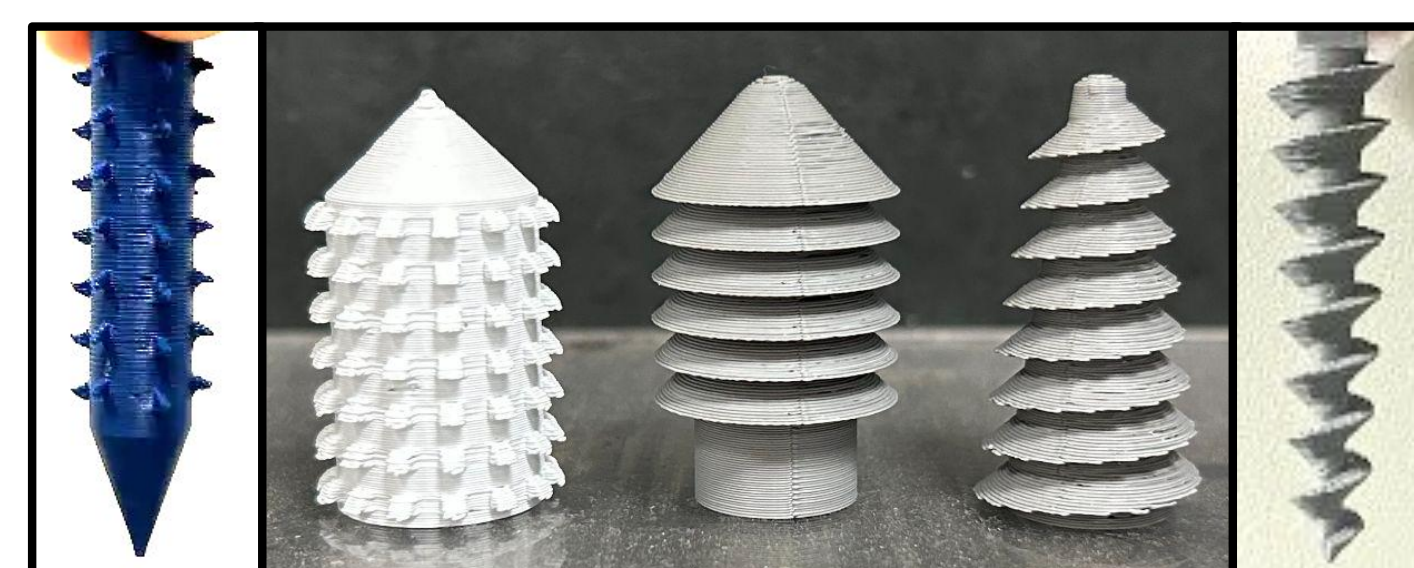
Figure 4 shows that the screw did get pulled out of the cartilage about 0.25mm, and that a lot of stress was put on the bottom of the screw. Figure 5 shows that the bottom of the screw was displaced more than the top screw.



**Figure 4:** Von Mises Stress (N/m<sup>2</sup>) and deformation

**Figure 5:** Displacement Magnitude (mm)

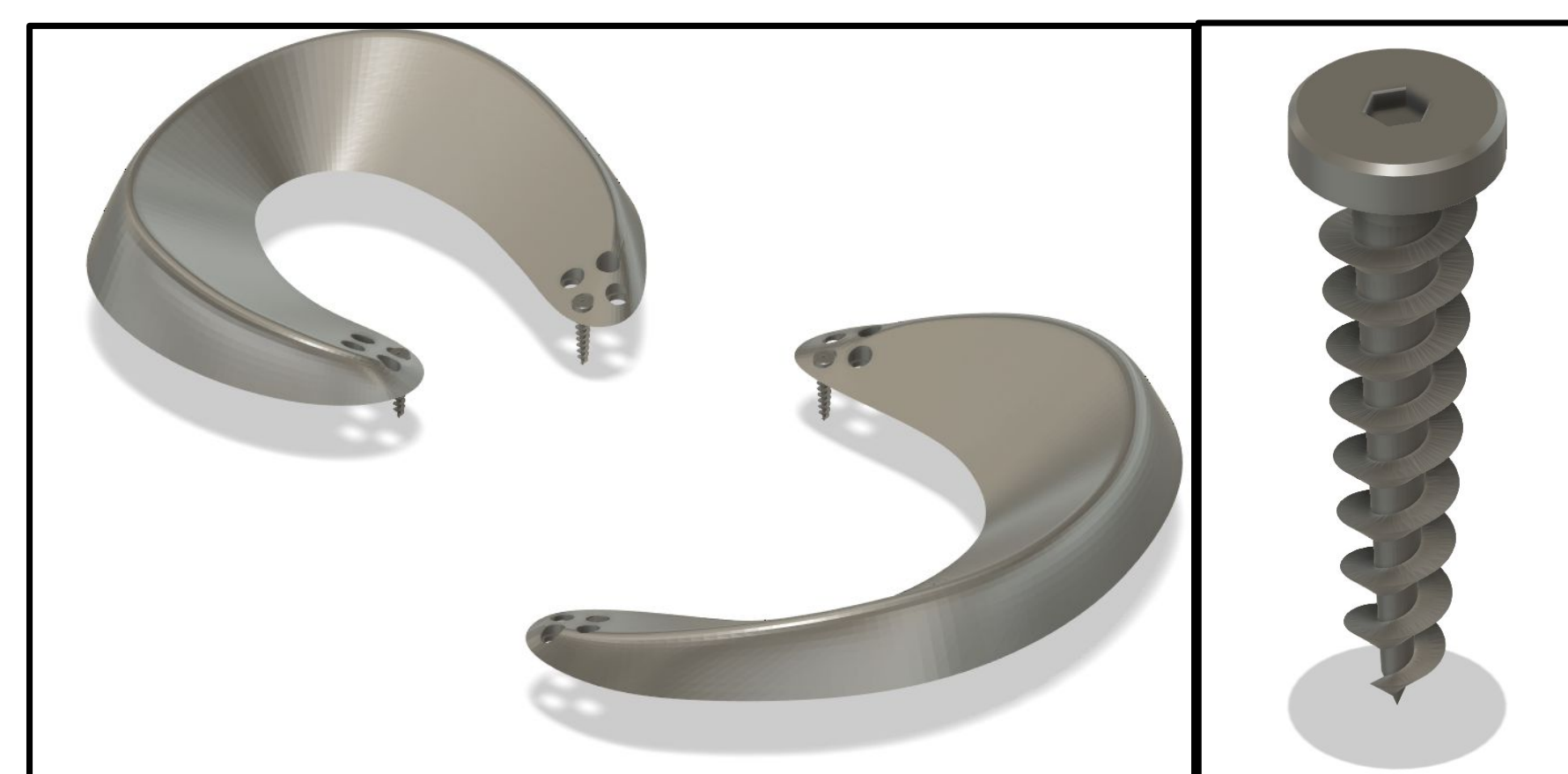
## Prototype



**Figure 6:** Anchor design evolution. From left to right, the designs are antiparallel barbs, parallel barbs, conical bowl shape, screw anchor, and wood screw



**Figure 7:** 3D print, silicone mold of print, polyurethane prototype.

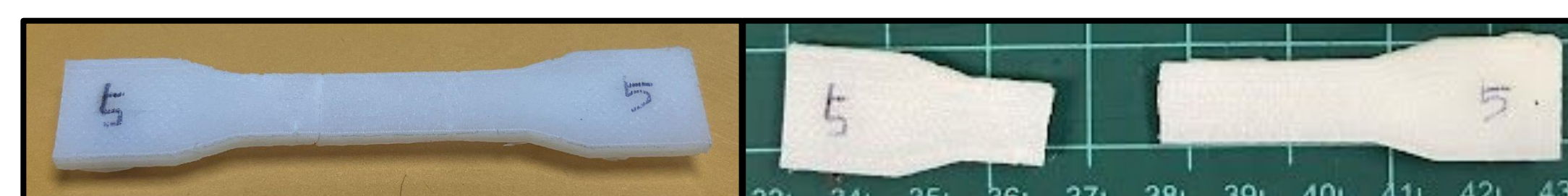


**Figure 8:** 3D model of the final, gamma prototype

Designs were 3D printed prior to silicone mold development, with a multitude of analyzed designs (Fig. 6). These prints were used to develop silicone molds, in which polyurethane was poured into to develop casts for testing (Fig. 7). The first type of test was the tensile test, in which polyurethane dogbone samples were made using the previously described methods (Fig. 9).

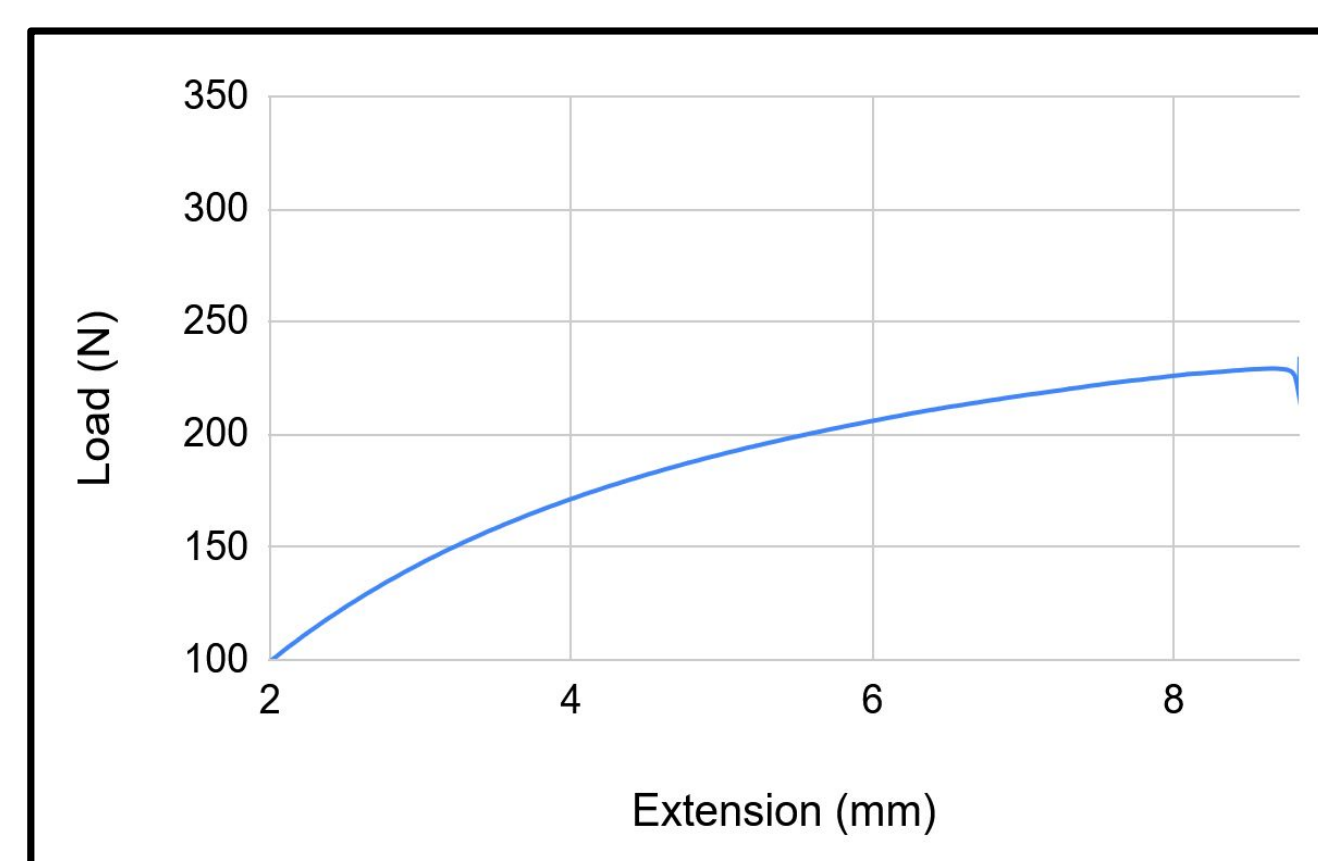
The second test was the pull-out test, in which the final design of 5mm screws upscaled 10x were used (Fig. 10). These screws were placed into synthetic cartilage, which incorporated 1-5 mm thread segments with silicone to mimic randomized cross linking in the meniscus roots. These tests determined the gamma prototype, which has been 3D printed (Fig. 8).

## Verification Results

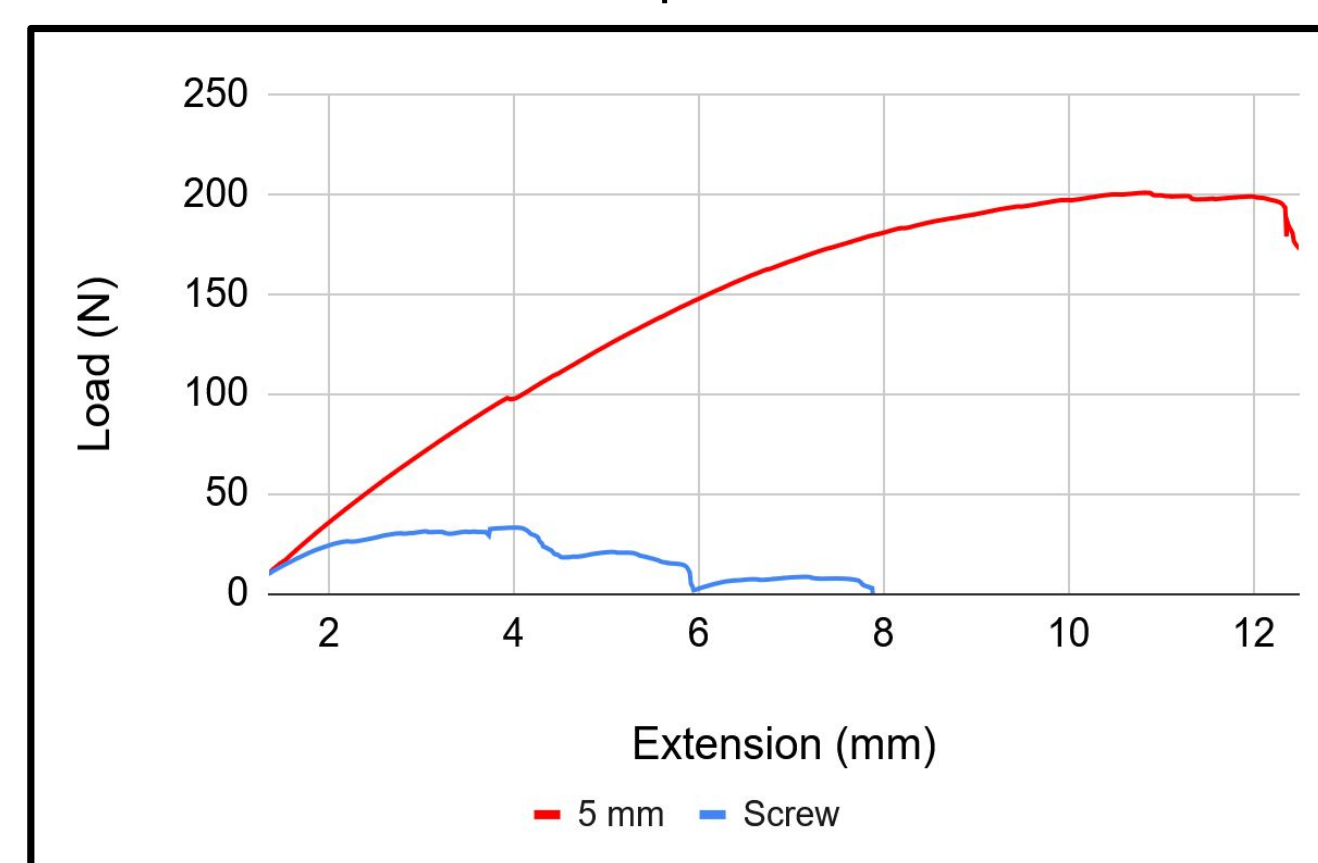


**Figure 9:** Polyurethane dogbone before and after tensile testing.

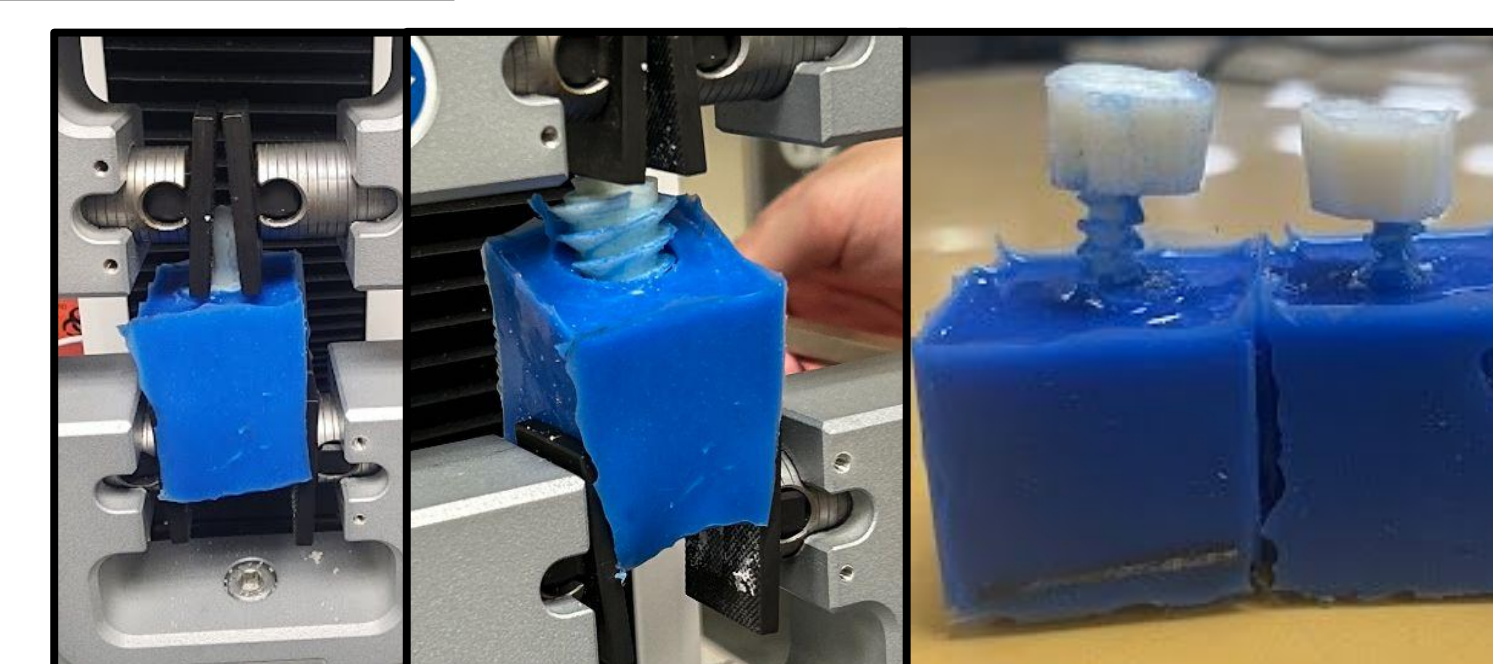
Tensile testing yielded a Young's modulus of 127.12 ± 26.54 MPa for PU specimens, compared to a Young's modulus of 122.6 ± 49.6 MPa for the native meniscus (Figure 12). Pull-out testing yielded a pull-out stress of 1.80 ± 0.72 MPa for PU wood screws, 0.93 ± 0.13 MPa for 2 mm PU anchors, and 4.06 ± 0.15 MPa for 5 mm PU anchors (Figure 14).



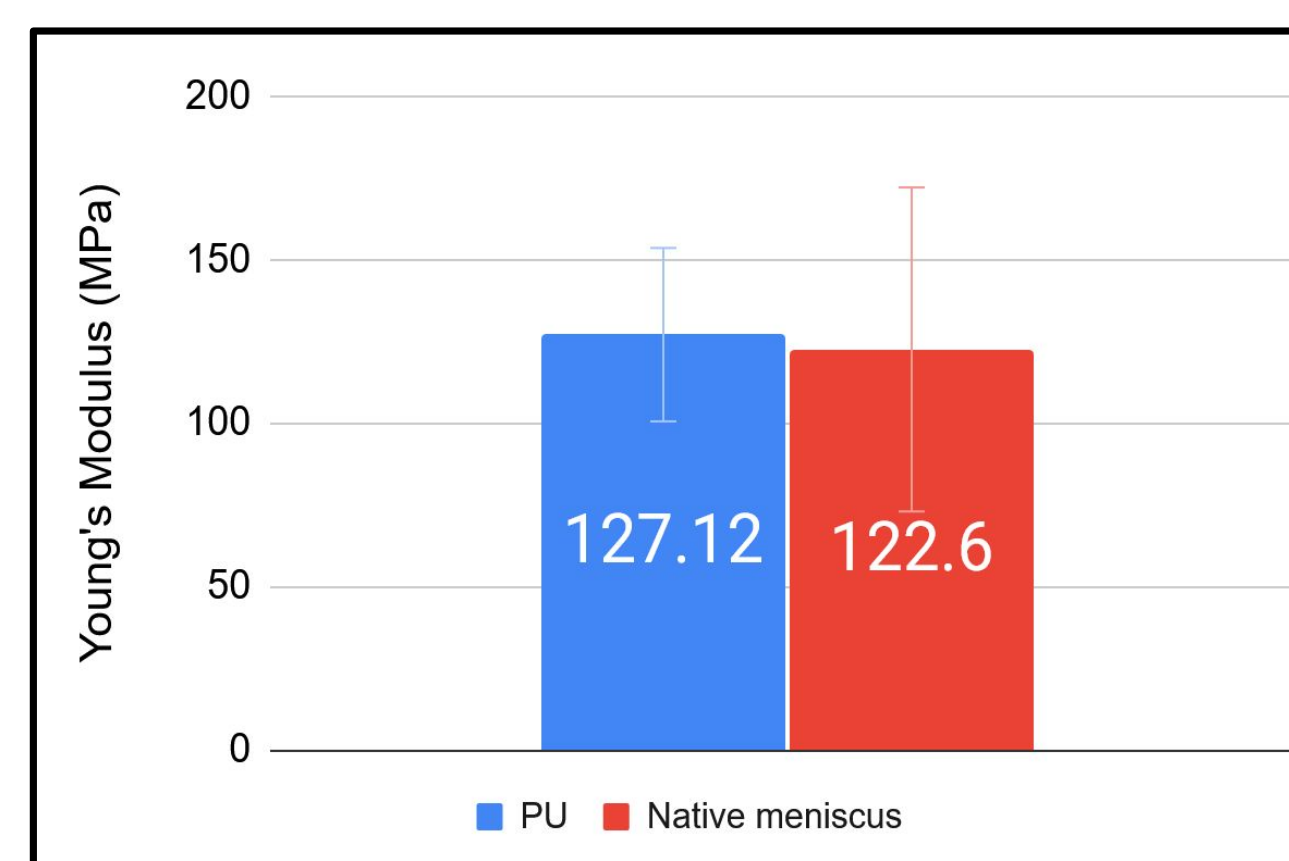
**Figure 11:** Tensile force and displacement curve of PU specimens



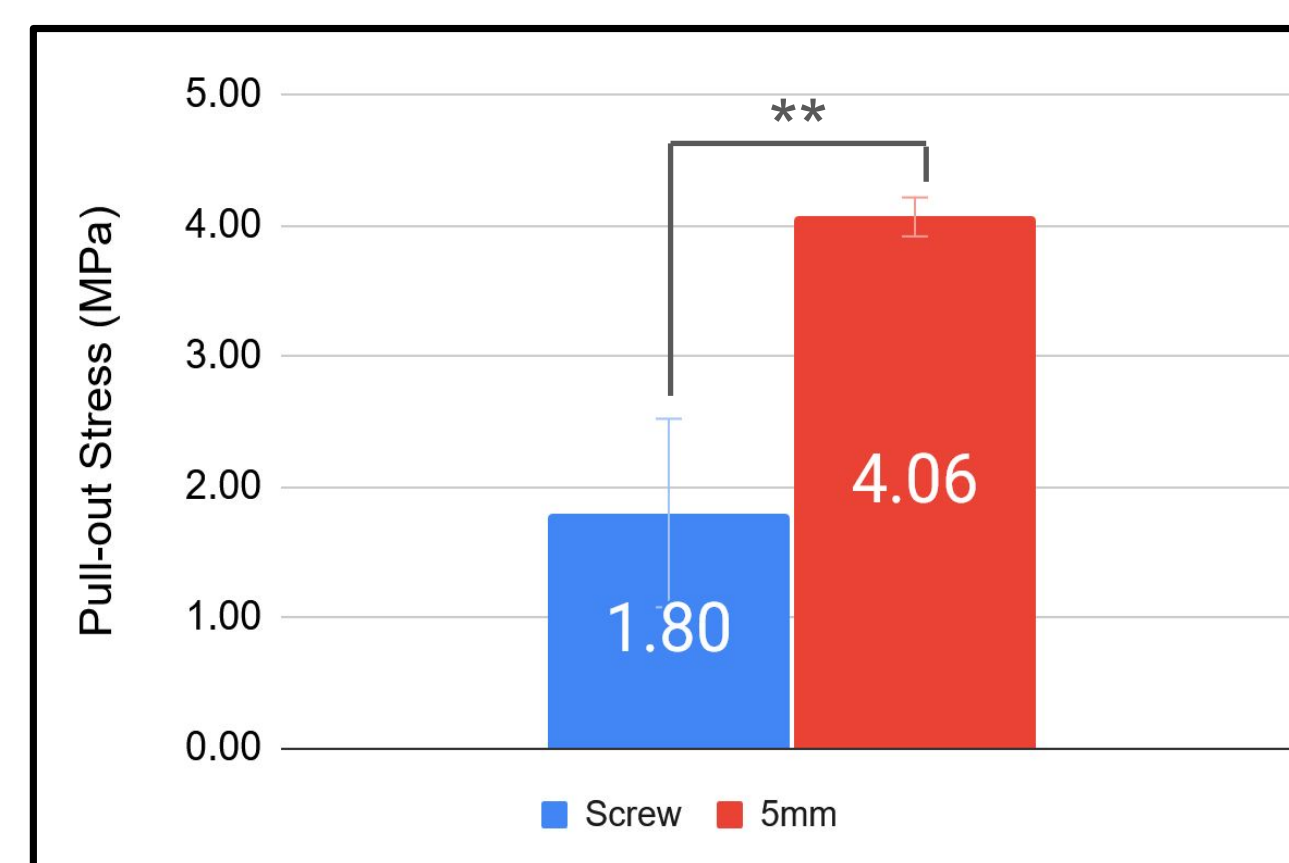
**Figure 13:** Pull-out force of 5 mm PU anchors and PU wood screw anchors. Red = 5mm Blue = Wood Screw



**Figure 10:** Pull-out setup for PU anchors embedded in silicone.



**Figure 12:** Young's modulus of PU specimens vs native meniscus



**Figure 14:** Pull-out stress of PU screws 5 mm PU anchors and PU wood screw anchors embedded in silicone.

## Final Product Specifications

### Patient Critical Requirements

#### Safety and durability

- Ultimate tensile strength of  $40 \pm 8$  MPa and shear strength of  $\geq 6.35$  MPa
- Frictional coefficient of 0.02-0.05
- Generation of hoop forces through attachment to native meniscus roots.

#### Clinical performance

- Stable in vivo for >15 years with little mechanical degradation
- Recovery time of 4-6 weeks, full recovery of 3-6 months
- Does not cause significant cell death or inflammation from wear particle generation

### Secondary Requirements

#### Replicate meniscus anatomy

- 4.4-5 grams mass
- 45.7 mm length, 27.4 mm width, 5.2-6.9 mm thickness (medial)
- 35.7 mm length, 9.3 mm width, 3.8-6.2 mm thickness (lateral)
- 3-5 mm depth into meniscal roots for attachment

#### Material specifications

- ~\$95 to purchase 95A liquid polyurethane (3 lbs)
  - High hydrophilicity to mimic lubrication of meniscus
- ~\$35 for 30A silicon rubber for molding
- 3D printer filament (ABS used in this experiment)

### Test Results

- Shear modulus of 1.753 MPa
- Ultimate tensile strength of 59.57 MPa
- Young's Modulus of 127.12 MPa
- Average pull-out stress of 0.935 MPa in 2mm, and 4.07 MPa in 5mm (w/o failure)

## Design Status and Future Steps

The anchors that attach the artificial meniscus to the meniscal roots have been designed after several rounds of iteration, with initial testing looking positive. Pullout force and young's modulus were determined with Instron testing, with the design of attachment methods being improved upon and verified with testing.

Next phases include cyclical testing to ensure durability, insertion and pullout testing with cartilage to confirm modeled results, and repetition of all testing with the scaled down model with higher quality materials to confirm results. Additionally, next steps include fully designing of the anchor's connection to the artificial meniscus, and determine the specifics of sewing the artificial meniscus into capsule for stability, which should be mechanically similar to techniques within other meniscus repair.

As the Bee's Knees Meniscus is a Class III device due to it being inserted into the body long term, and its potential risk for serious injury. Further it would require Pre-Market Approval, because of the use of novel attachment methods within the implant, as well as the high potential for harm, which requires significant animal and clinical trials to show evidence for the device's safety and efficacy.



## References

- [1] "What is a Torn Meniscus?," Cleveland Clinic. Accessed: Sep. 17, 2025. [Online]. Available: <https://my.clevelandclinic.org/health/diseases/17219-torn-meniscus>
- [2] M. S. Kim, Y. In, H. Kim, J. Jeong, and S. Sohn, "Why Hoop Tension Matters: A Biomechanical Perspective on Medial Meniscus Posterior Root Tears—A Narrative Review," *Bioengineering* (Basel), vol. 12, no. 6, p. 638, June 2025, doi: 10.3390/bioengineering12060638.
- [3] T. R. Carter, "Report on Evolving Indications, Technique, and Outcomes of Novel And Surgical Procedures-NUsurface," *Curr Rev Musculoskelet Med*, vol. 18, no. 4, pp. 115–122, Jan. 2025, doi: 10.1007/s12178-025-09944-z.

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