#14

Polymeric Meniscus Replacement Attached with Antiparallel-Barbs Protruding from Anchor

BME 417 | Team 14: The Bee's Knees

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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.

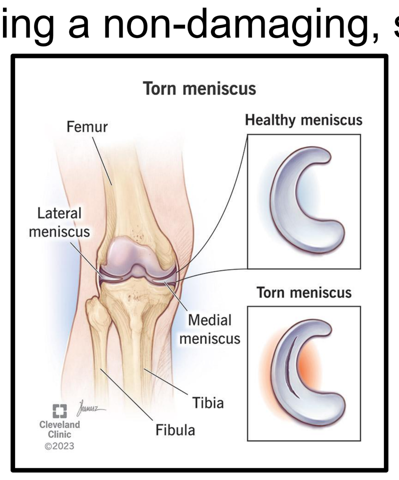


Figure 1: Anatomy of meniscus. Physiology of healthy and torn meniscus [1].

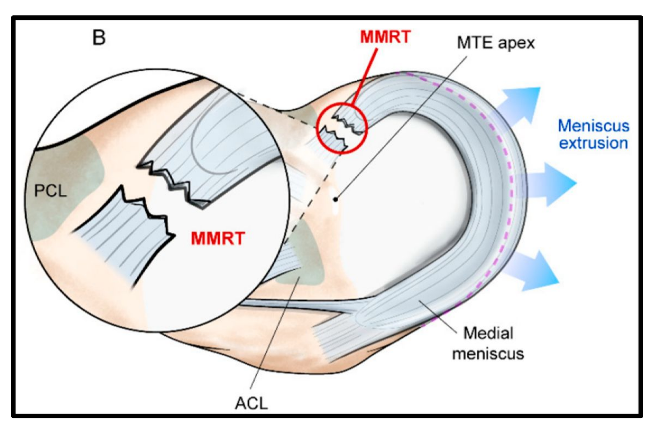


Figure 2: Medial meniscus root tear (MMRT) which causes a loss of hoop tension that results in meniscus extrusion [2].

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 II FDA regulations will be developed

Project Planning

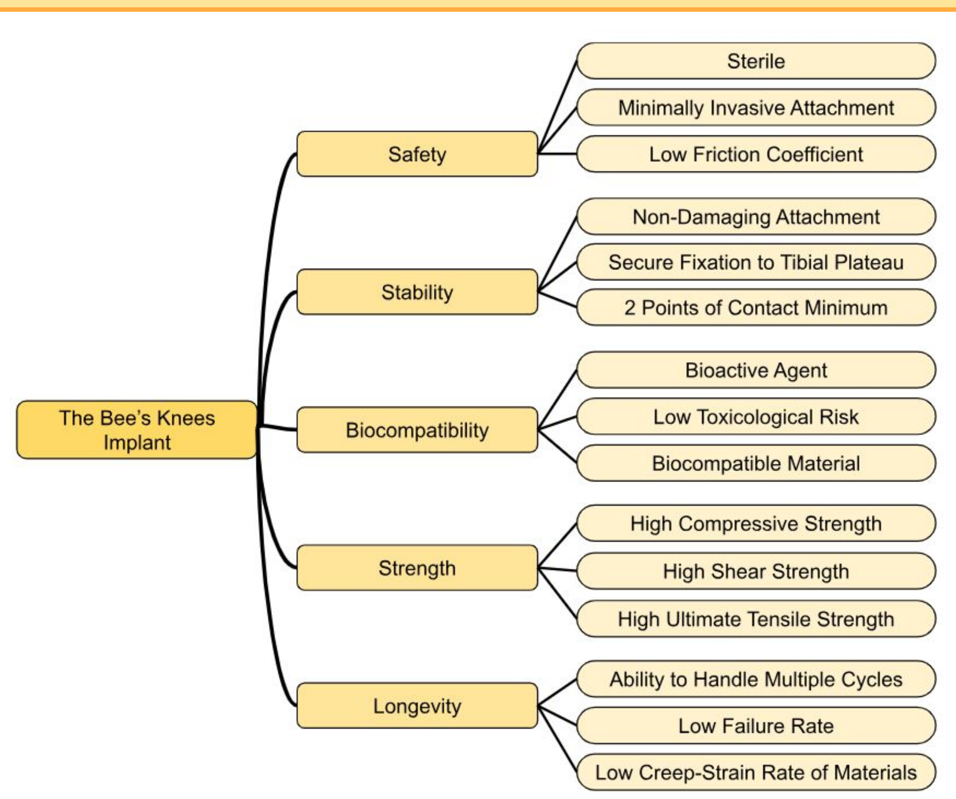
Completed phases

Project Selection and Planning (AUG - SEPT 2025) → Concept Development (SEPT 2025) → Concept Selection and evaluation (OCT 2025) → Technical Refinement (NOV 2025)

Upcoming phases

Regulatory Documentation → Comprehensive Documentation → Device Verification → Testing, Validation, and Clinical Evaluation

Design Inputs



Device Concept and Design

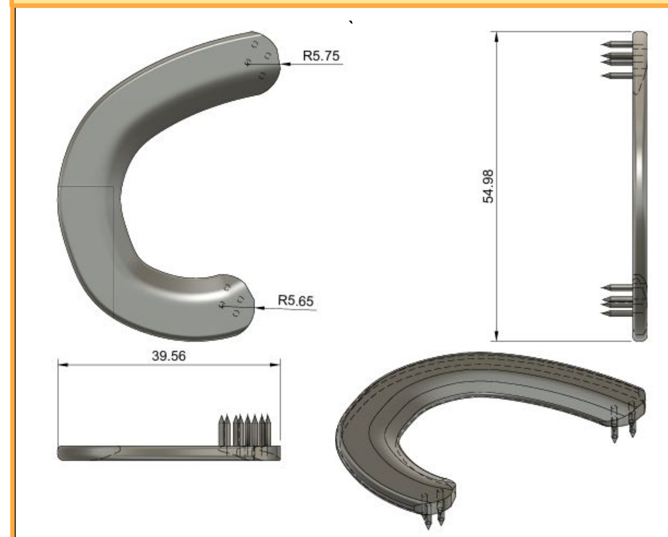


Figure 3: Right Medial Meniscus Implant Model with dimensions (mm)

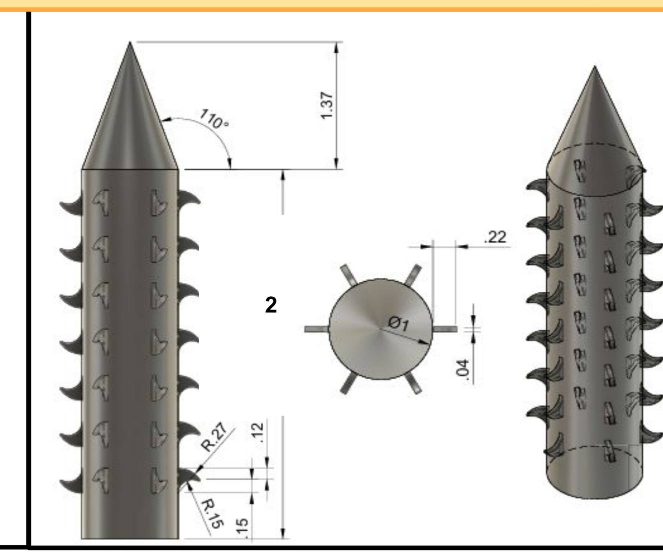


Figure 4: Anti-movement Protrusion Model (deployed) with dimensions (mm)

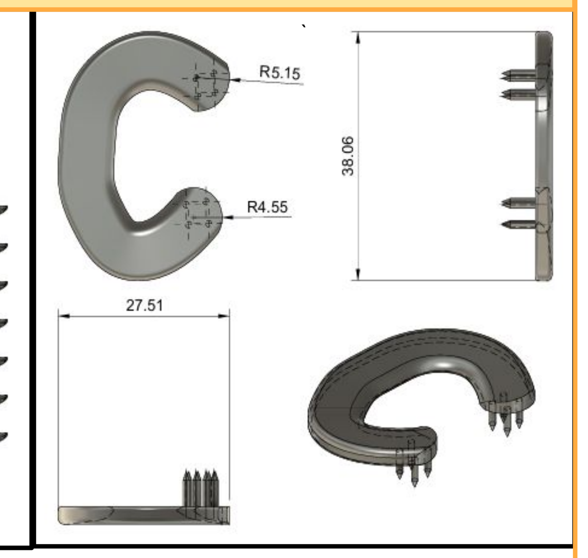


Figure 5: Right Lateral Meniscus Implant Model with dimensions (mm)

The meniscus implants will be custom made for each individual, as the anatomy of the knee joint varies widely between people. The Anti-Movement Protrusions, however, will be a uniform size, but their configuration will also be custom made. These protrusions will consist of 6 columns of antiparallel curves fins, in order to stop the implant from becoming dislodged, as well as to hinder the implant's ability to penetrate further into the tissue.

Product Architecture and Technical Models

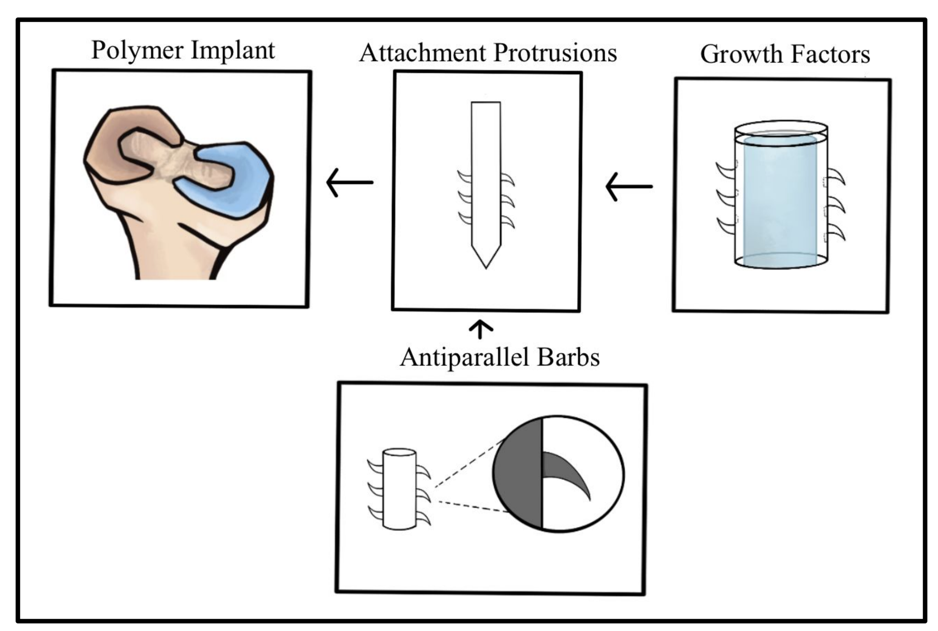


Figure 6: Product architecture of artificial meniscus

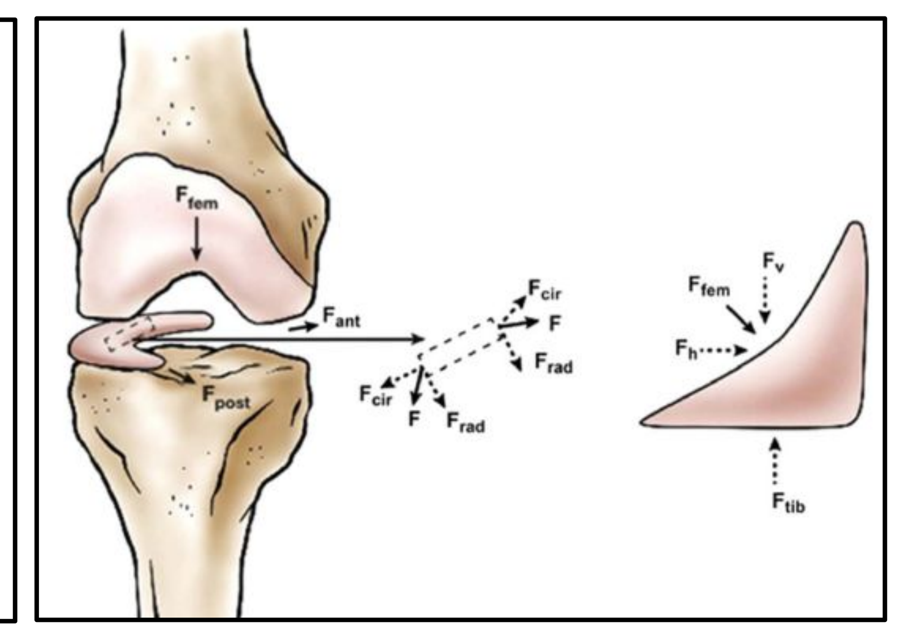


Figure 7: Free body diagram showing the force distribution of meniscus [4]

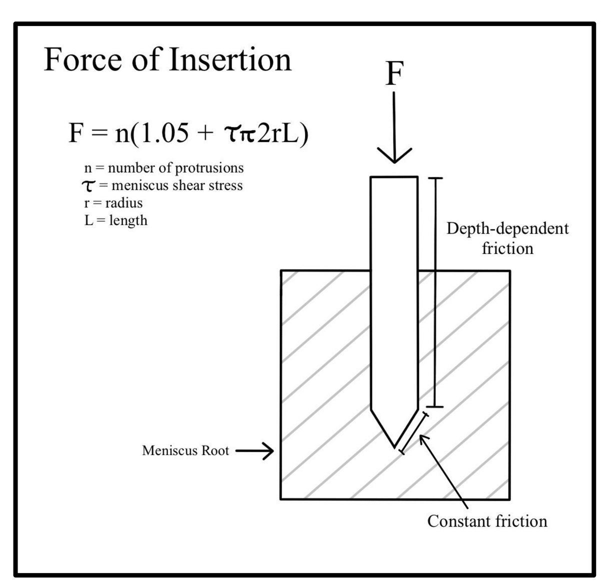


Figure 8: Insertion force required for anchor insertion without spikes released

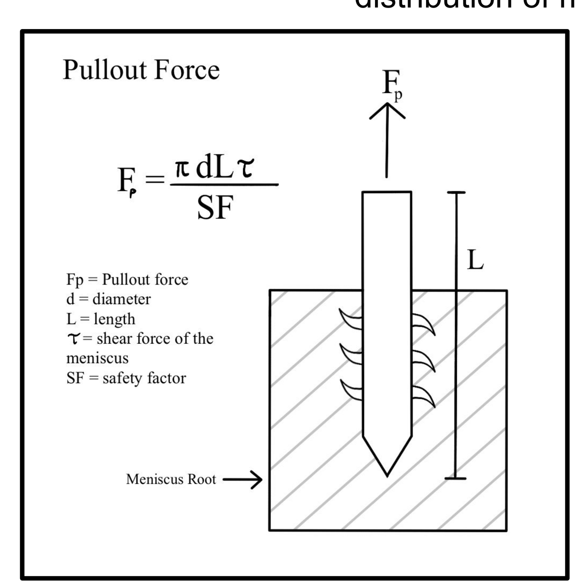


Figure 9: Pull-out force of anchor once barbs are released

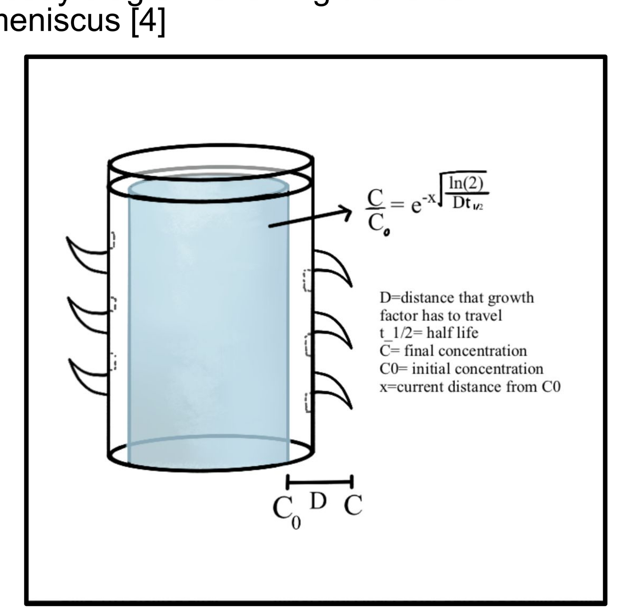


Figure 10: Growth factor release from anchor coating

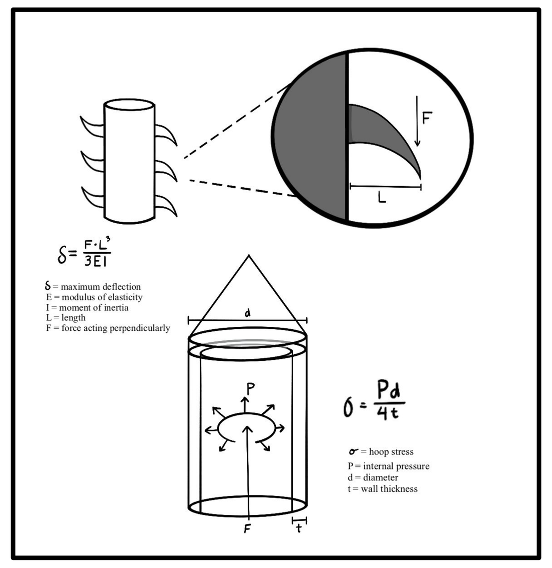


Figure 11: Hoop stress of anchor and max deflection of barbs

The meniscus implant will be secured via protrusions covered in antiparallel barbs, that release to secure the implant (Figure 6). The protrusions will also be coated in a growth factor to repair any damage done by the barbs (Figure 7). The most vital part of our artificial meniscus is its force distribution as shown of the natural meniscus in Figure 8. Additionally, the penetration force during the initial surgical procedure is modeled by Figure 9, while the removal force is modeled by Figure 10.

Final Concept Product Specifications

Patient Critical Requirements

Safety and durability

- Ultimate tensile strength of 40±8 MPa, compressive strength of >18.10 MPa, shear strength of >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)

Material specifications

- ~$3,000 to produce full implant
- High hydrophilicity to mimic lubrication of meniscus

Design Status and Future Work

Design Status:

- Determined secure and novel fixation method for artificial meniscus.
- Completed market research to find competitive gaps and ensured no patent infringement
- Researched and selected optimal material to mimic low friction of meniscus
- Discussed methods for growth factor release

Future Work:

- Determine best method for barb release and growth factor release
- Run simulations in Ansys or similar to model different forces on the knee, meniscus, and attachment
- 3D print preliminary physical prototypes
- Instron testing and force gauges to ensure strength of implant and fixation, and create methods for testing durability over millions of cycles

Design for Manufacturing with Costs

The cost of creating the body of the implant will be around $45 for 3D printing materials alone [5, 6, 7, 8]. Growth factors scale up the price significantly, often costing $100 for 10 ng [14]. Assuming we are covering between 30-140 mm^2, we will need between 1-5 uL of 0.1 mg/mL solution [15]. This is 0.1-0.5 ug of growth factors, or $1000-5000, averaging $3000.

The production cost of the implant is estimated to be $3,000 [9]. Since the price of a meniscus tear surgery is around $5,000-$10,000 the price of the implant should be around this range to in order to keep up with the competition [10].

Assuming that half of meniscus repair surgeries recipients receive this implant, and that it is sold for $9,000, the total annual profit would be around $180 million [11, 12, 13].

References

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[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.

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