Osteochondral Transplant Delivery System

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Client: ***Dr. Brian Walczak, DO***
Advisor: ***Dr. Tracy Puccinelli, PhD***

Client Overview

- **Dr. Brian Walczak, DO**
  - Orthopedic Surgeon
  - Faculty, University of Wisconsin School of Medicine and Public Health
- **Specialties**
  - Joint Preservation
  - Knee Arthroscopy
  - Pediatric Sports Medicine

Proposes a novel approach to osteochondral allograft (OCA) transplantation

University of Wisconsin Hospitals and Clinics Authority, "Brian E. Walczak, DO," *UW Health*. [Online].

Current OCA Transplantation Procedure

- Chondral defect is exposed and measured to determine the appropriate tool size (A)
- Guidewire is drilled into the center of the defect and surgical reamer removes defective tissue (B)
  - Depth markings on the reamer allow surgeon to drill to the proper depth
- Depth measurements taken about donor hole (C)

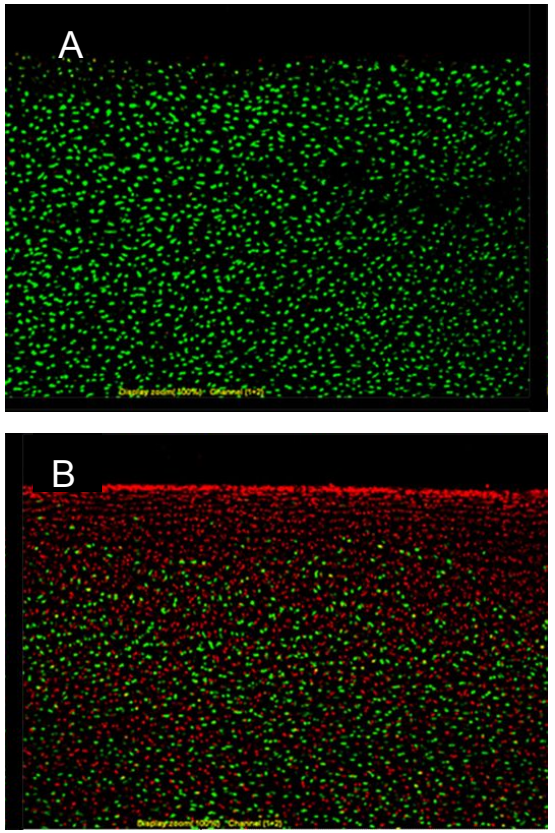
Current OCA Transplantation Procedure

- Allograft harvested from cadaver condyle using hole-saw and oscillating saw (D)
  - Graft height trimmed to match depth of receiving hole
- Impaction rod and hammer secure the donor graft in the receiving hole (E)
- Donor graft aligned within ±1mm of native cartilage (F)

Garrett, J. (2016). *Allograft OATS ® Resurfacing Technique for Articular Cartilage Restoration Surgical Technique*. Atlanta, Georgia: Arthrex Inc.

OCA Transplant Challenges

- **Impaction is deleterious to chondrocyte viability**
  - Reducing impulse during impaction prevents chondrocyte damage
- **Donor chondrocyte viability is a key determinant of OCA success**
  - Promotes graft integration, and maintains biomechanical function
  - All successful grafts showed viability >70% (t = 6 months)



Live/dead stain after chondral impaction [5]
A: Control B: 300 N
Live: **Green** Dead: **Red**

Problem Statement

- Number of surgeries performed is **increasing by 5% annually** with an expected **3500 annual procedures by 2020**. [1]
- **Overall failure rate is 18%** [2]
- Current impaction method **reduces chondrocyte viability** [3]
- Chondrocyte **viability of 70%** is the threshold for procedure success [4]
- Design a device to allow easy insertion of the graft while minimizing chondral damage

"Osteochondral Allograft Transplantation (OCA)," *Illinois Sports Medicine and Orthopaedic Centers*. [Online]. Available: [Accessed: 05-Oct-2017].

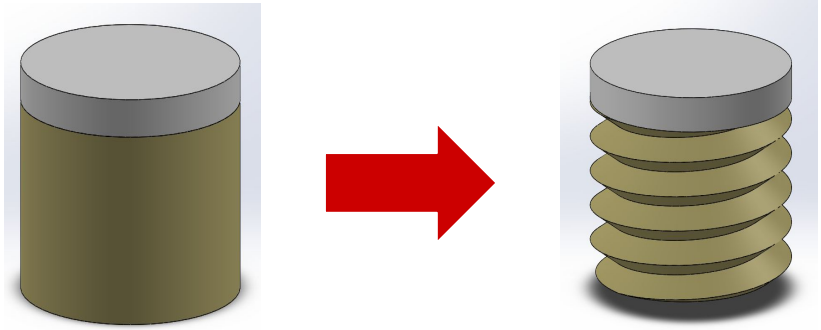
Approach

*We propose a **screw-in allograft** to replace the current impaction method.*

Past Work: OCA Threading Prototype

Cadaver Graft Threading

- Stainless steel die
- Graft holding cup
- Threading alignment guide



Idealized Graft Threading

Graft Threading Alignment Guide

Past Work: OCA Threading Prototype

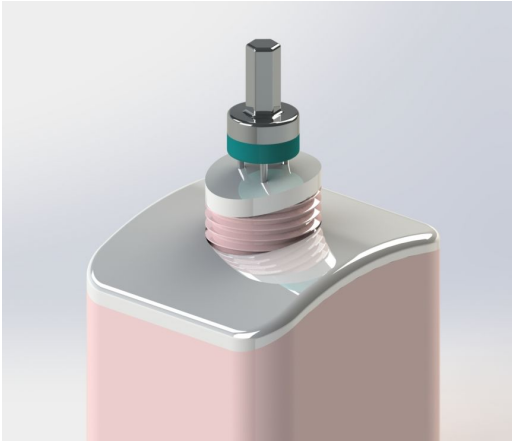
Patient Receiving-Site Threading

- Stainless steel tap
- Guide-wire alignment for threading accuracy

Wire Guided Tap

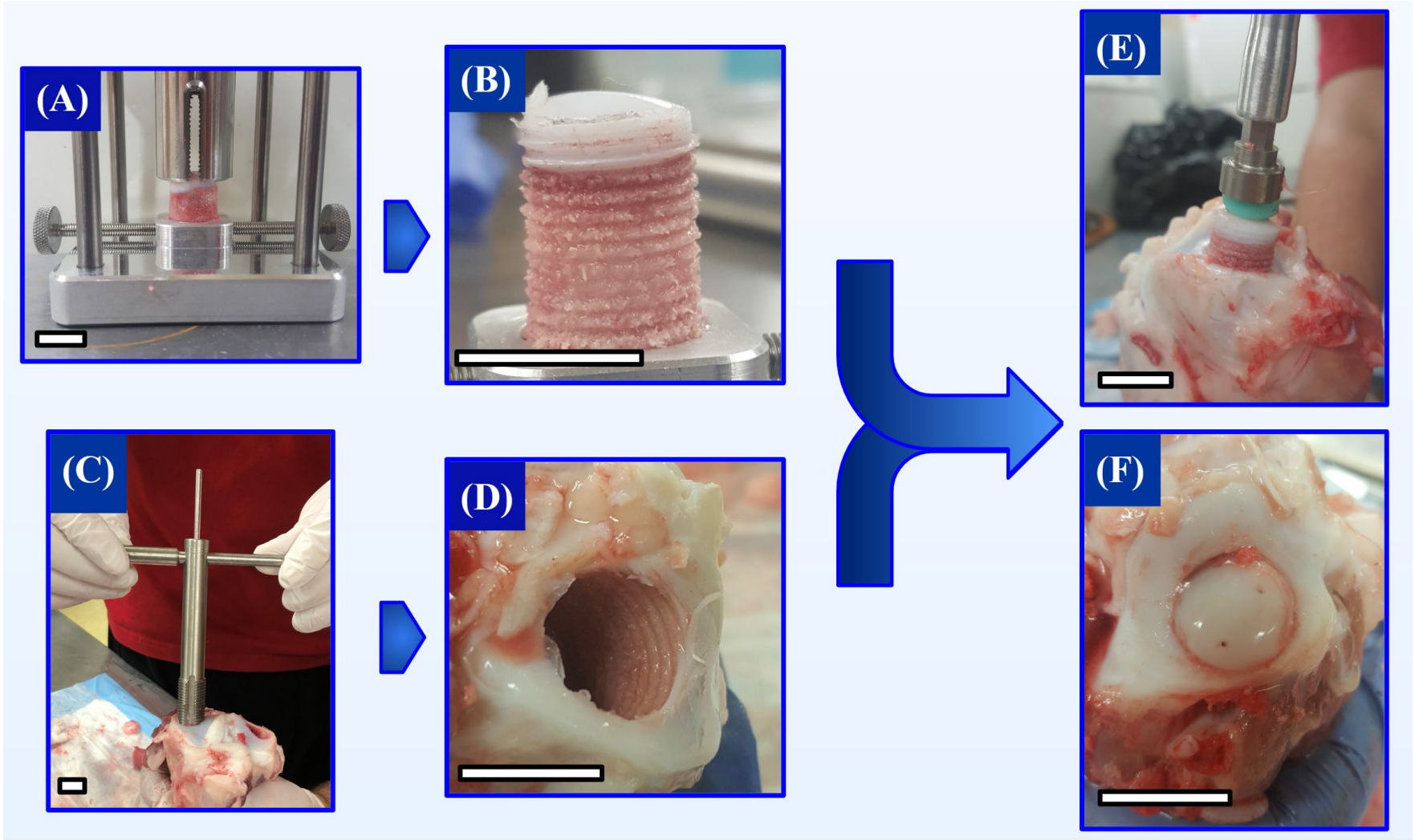
Graft Insertion Screwdriver

- Stainless steel construction
- Tines insert into the subchondral bone
- Turns the graft into the patient



Graft Insertion Screwdriver

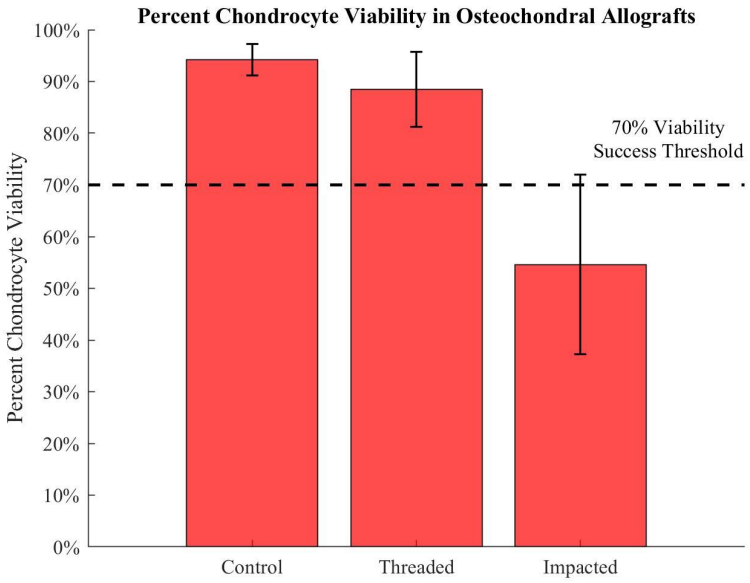
OCA Threading Workflow

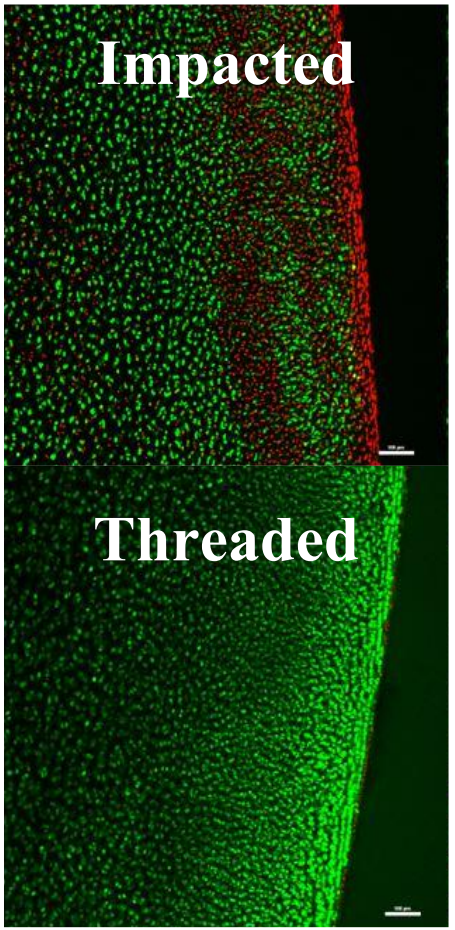


*All Scale bars 15mm

Past Work: Chondrocyte Viability Evaluation

- Live/dead assay of implanted porcine tissue
  - Confocal microscopy
  - Cellprofiler viability analysis

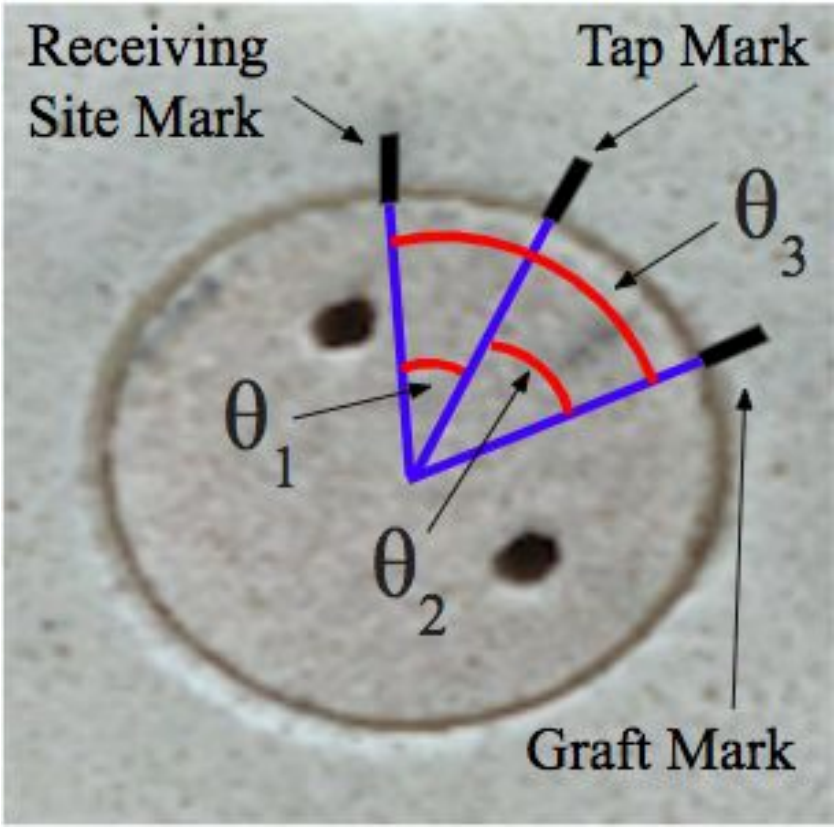


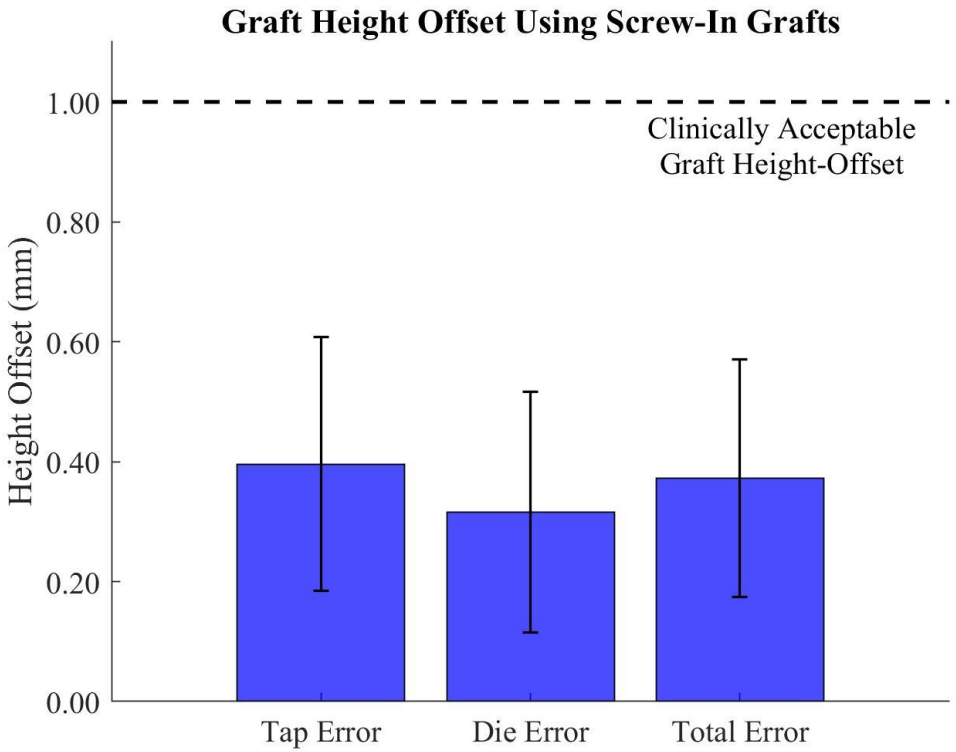


Live/dead stain after graft implantation

Live: **Green** Dead: **Red**

Past Work: Graft Height Offset Evaluation



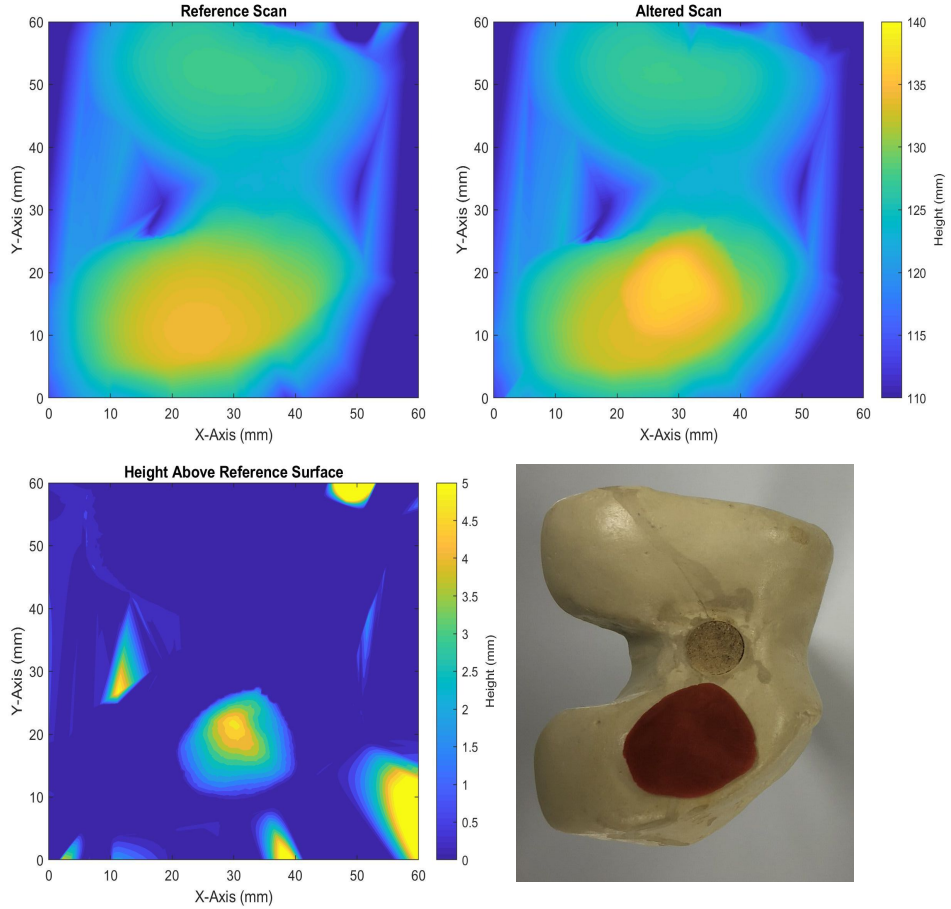


Project Outlook

- ✓ Successfully shown that graft threading maintains chondrocyte viability.
- ✓ Graft threading still allows for accurate graft placement.
- ❑ Future Aims:
  1. Use laser scanning in animal models to evaluate height offset
  2. Evaluate chondrocyte viability in additional surgeries
  3. Have Orthopedic surgeons use our system

Aim One: Laser Scanning

- Quantify graft placement using 3D laser scanning
- Assess maximum graft height above reference surface
- Extend testing to *ex-vivo* animal model
- Ensure that grafts can be inserted to within 1 mm.



Aim Two: Live Dead Assay

Biopsy Harvests

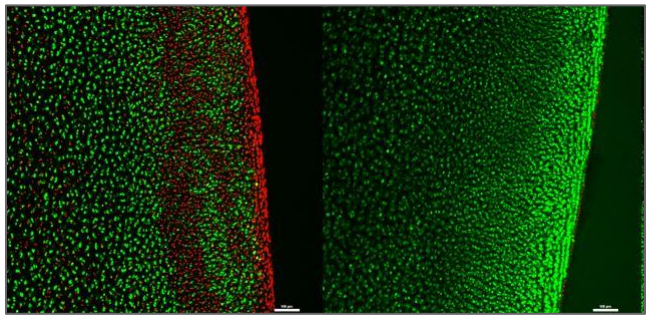
1. Ungrafted Segment (Control)
2. Impacted Graft (Standard of Care)
3. Threaded Graft (Novel Strategy)
4. Tine Insertion Points

Imaging Plan

- UW Optical Imaging Core
- A1RS confocal Microscope
- Calcein-AM/EthD (live/dead)

Analysis

- CellProfiler pipeline previously developed by our team
- Quantify cell viability based on live and dead events



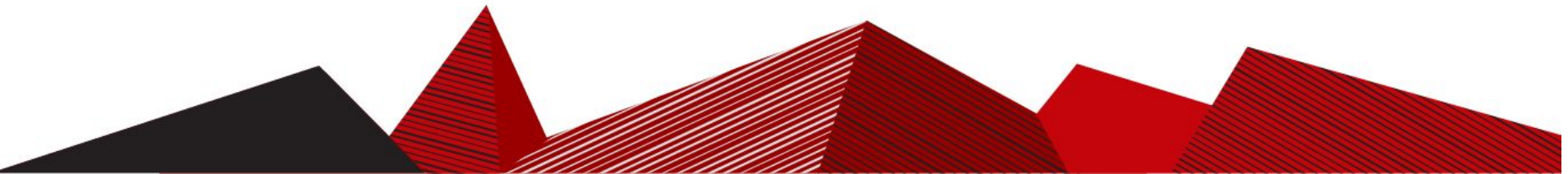
CellProfiler

Aim Three: Surgeon Training

- Train orthopedic surgeons to use our system
  - Simplified procedure in Sawbone
  - Received positive preliminary feedback

- Develop a survey
  - Obtain quantitative data using a Likert scale
    - E.g. strongly agree, agree, disagree, strongly disagree
    - *This system integrates well with the current surgical workflow.*
    - *This system is easy to learn.*
- Incorporate design improvements

- Stretch goal: have surgeons perform our animal tissue testing
  - Would provide data that carries more weight for publication
  - Difficult to coordinate schedules



Timeline and Budget

- Tissue Availability For Viability Testing:
  - Feb 6 (Finish any additional fabrication by this date)
  - Feb 12
  - Mar 15
  - More after spring break?
- Budget is Negotiable
  - $950 spent to date
  - Pigs tissue is donated
  - Minimal fabrication required
  - Anticipated costs for staining: $700
  - Miscellaneous supplies: $75

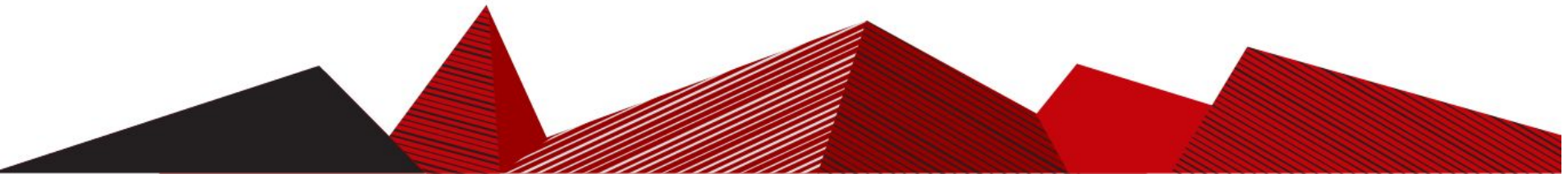
Week:	Feb. 4	Feb. 11	Feb. 18	Feb. 25	Mar. 4	Mar. 11	Mar. 18	Mar. 25	Apr. 1	Apr. 8	Apr. 15	Apr. 22	Apr. 29
Grafting Procedures													
Laser Scanning Testing													
Teach Surgeons and Solicit Feedback													
Summarize Results for BME Presentation													
Project Writing and Wrap-Up													

*Blue is definite events
*Orange is potential events depending on tissue availability

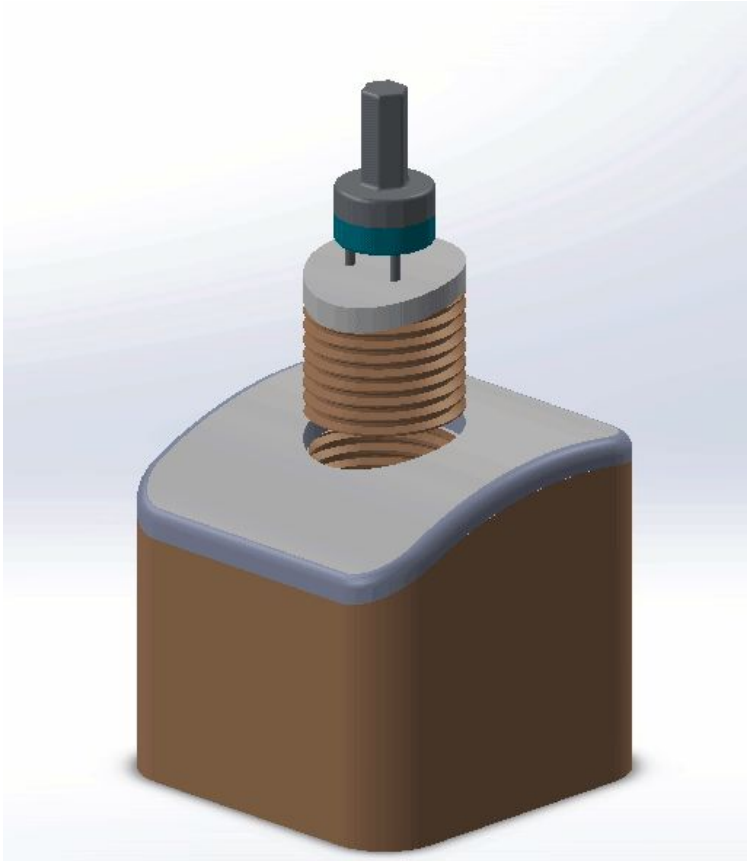
Acknowledgements

We would like to thank our advisor Dr. Puccinelli, and our client Dr. Walczak for their help with the design process.

Thank you!



Questions?



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[3] F. Mccormick et al., "Trends in the Surgical Treatment of Articular Cartilage Lesions in the United States: An Analysis of a Large Private-Payer Database Over a Period of 8 Years," Arthrosc. J. Arthrosc. Relat. Surg., vol. 30, pp. 222–226, 2014.

[4] Cook JL, Stannard JP, Stoker AM, et al. Importance of donor chondrocyte viability for osteochondral allografts. Am J Sports Med. 2016 May;44(5):1260-1268

[5] Kang RW, Friel NA, Williams JM, Cole BJ, Wimmer MA. Effect of impaction sequence on osteochondral fraft damage: the role of repeated and varying loads. Am J Sports Med. 2010 Jan;38(1):105-113.