Osteochondral Transplant Delivery System

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Overview

- Client Overview
- Problem Statement
- Surgical Procedure
- Current Products
- Procedure Challenges
- Previous Design Work
- Design Ideas
- Proposed Final Design
- Fabrication
- Testing

UW BME Design

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

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

Problem Statement

- Osteochondral allograft **(OCA)** transplantation **repairs defects** in cartilage and subchondral bone
- Etiologies include trauma, osteonecrosis, osteoarthritis, and osteochondritis dissecans [1]
- Number of surgeries performed is **increasing by 5% annually** with an expected **3500 annual procedures by 2020**. [2]
- **Overall failure rate is 18%** [3]
- Impaction method **reduces chondrocyte viability** and **limits vertical adjustment** [1]
- Chondrocyte **viability of 70%** is the threshold for procedure success [4]
- Propose a **screw-in allograft** to replace the current press-fit method

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

Approach:

Design a device to allow easy insertion of the graft into a prepared recipient site while minimizing chondral damage

Current Surgical Procedure

- Chondral defect exposed and measured to determine 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)

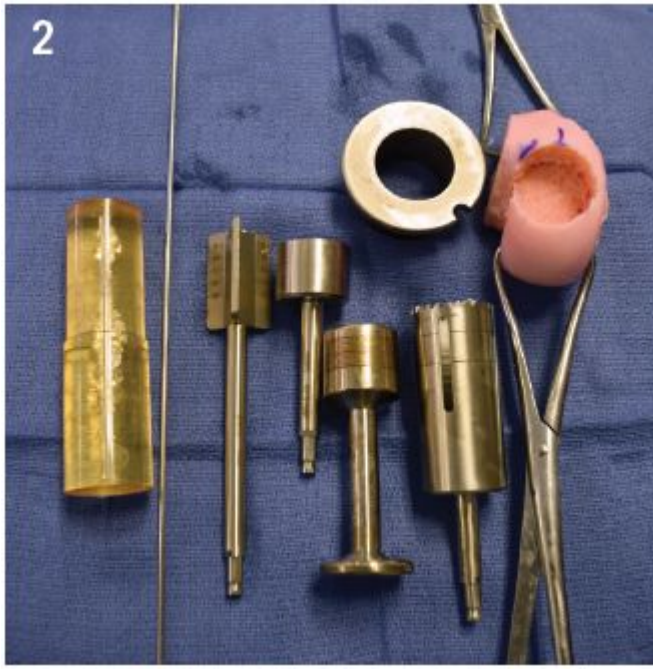
Current Surgical Procedure

- 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)

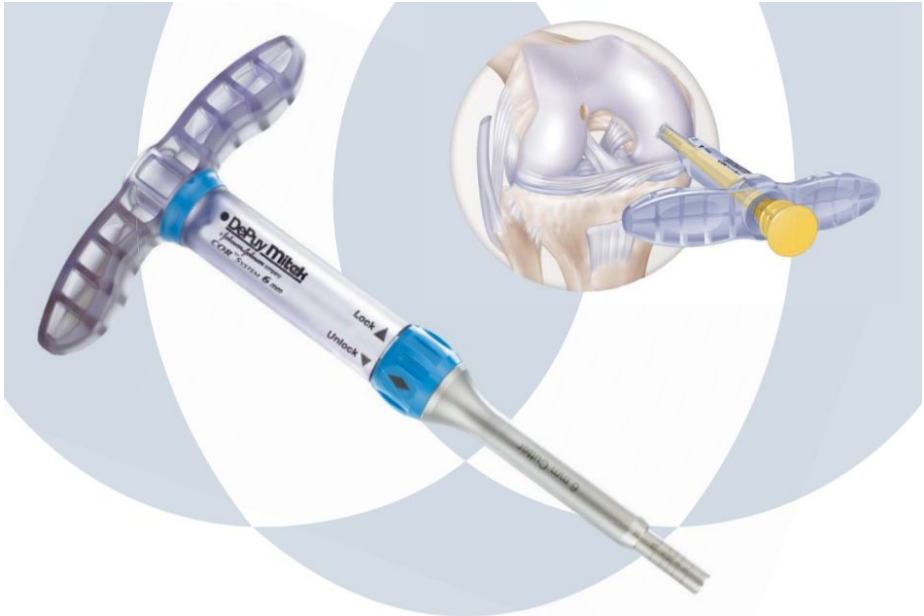
Garrett, J. (2016). *Allograft OATS ® Resurfacing Technique for Articular Cartilage Restoration Surgical Technique*. Atlanta, Georgia: Arthrex Inc.

Current Surgical Systems

Arthrex Osteochondral Allograft Transfer System (OATS)



DePuy Synthes COR ® Precision Targeting System



Procedure Challenges

- Impaction is deleterious to chondrocyte viability [5]
  - Reducing impulse during impaction prevents chondrocyte damage
  - Number of strikes not correlated with chondrocyte death
- Donor chondrocyte viability is a key determinant of OCA success [4]
  - Promote graft integration, and maintain biomechanical function
  - All successful grafts showed viability >70% (t = 6 months)
  - Success factors included hyaline cartilage maintenance, subchondral graft integration, and lack of fibrous tissue infiltration

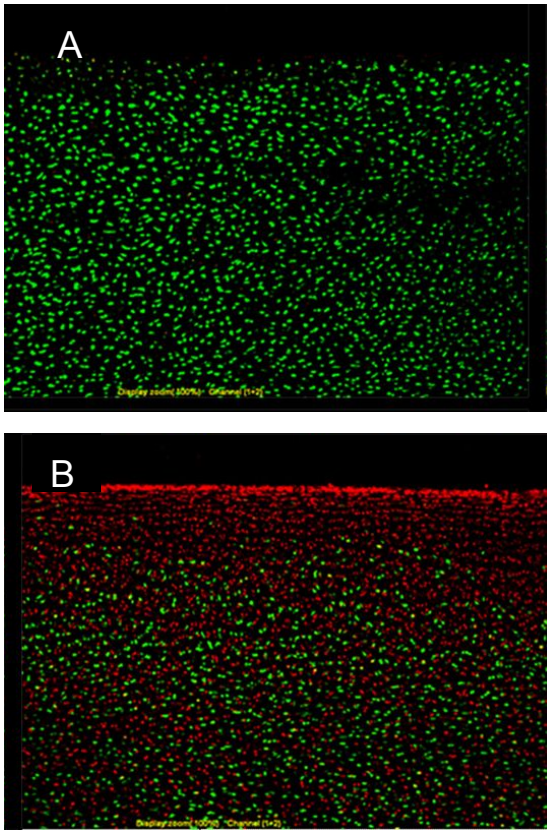


Figure 1. Live/dead stain after chondral impaction [5]
A: Control B: 300 N
Live: **Green** Dead: **Red**

BME 300 Design Work

Design

- Machined tap and die system
- Hand screwed in allografts

Testing

- Live/dead assay of implanted bovine tissue
  - Fluorescence Microscopy
  - ImageJ Analysis

Experimental Group	Threaded Graft Chondrocyte Viability	Impacted Graft Chondrocyte Viability
1	93%	61%
2	99%	61%
3	99%	48%
4	97%	51%
Mean	97%	55%
σ	3.3%	20.4%
p-value	$1.86*10^{-5}$	

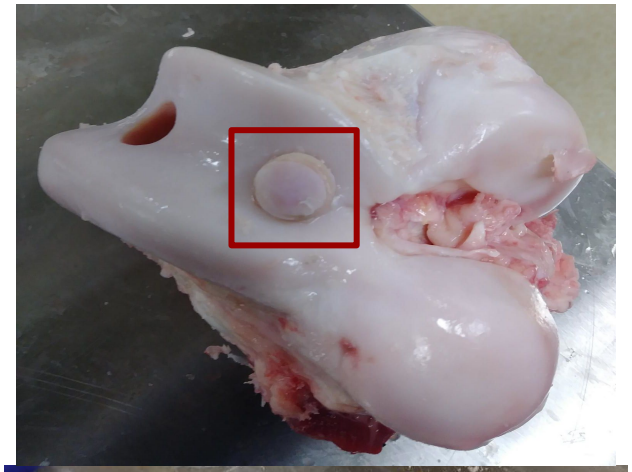
BME 300 Design Work

Shortcomings

- Unable to fully screw allograft flush to native tissue
- Die was inefficient at initiating threads on donor graft

Solution

- Develop tool to ensure full graft insertion
- Refine die and tap to ease thread formation

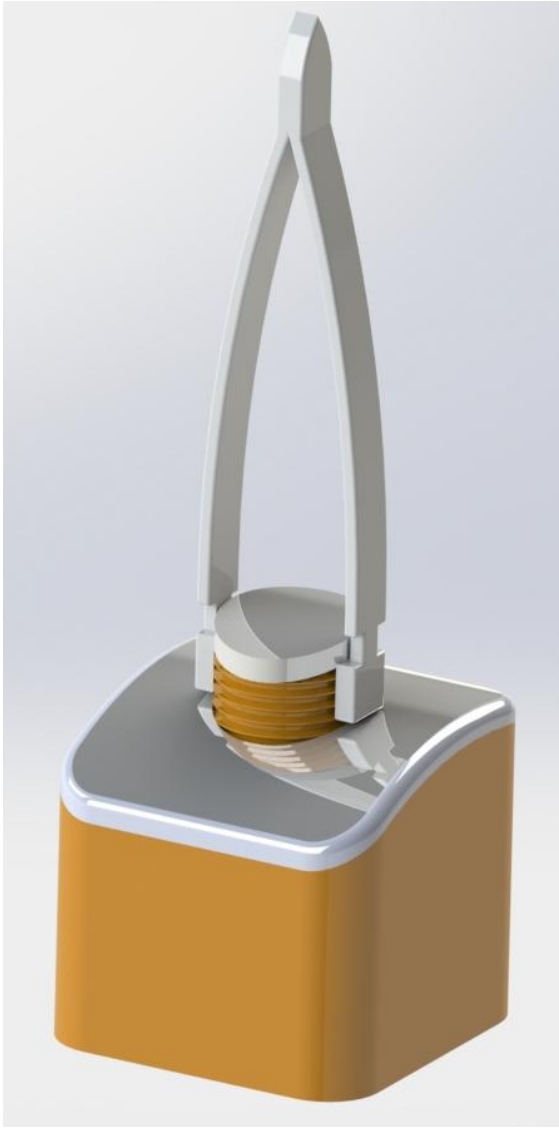


Suction Cup

Criteria	*Weight*	*Rank*	*Score*
Tool Strength	20	2/5	8
Chondrocyte Viability Maintenance	20	4/5	16
Ease of Use (Procedure Integration)	15	2/5	6
Procedure Time	15	3/5	9
Sterilizability	10	5/5	10
Safety	10	4/5	8
Manufacturing Time	5	4/5	4
Cost	5	4/5	4
Total	**100**		**65**

Tweezers

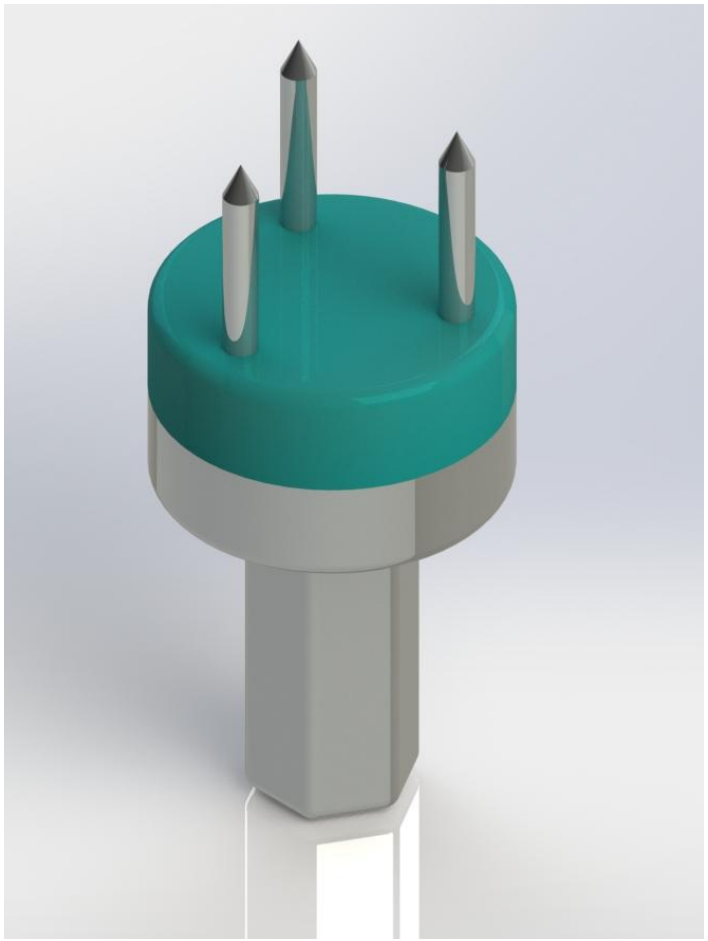
Criteria	*Weight*	*Rank*	*Score*
Tool Strength	20	3/5	12
Chondrocyte Viability Maintenance	20	5/5	20
Ease of Use (Procedure Integration)	15	5/5	15
Procedure Time	15	3/5	9
Sterilizability	10	5/5	10
Safety	10	3/5	6
Manufacturing Time	5	2/5	2
Cost	5	4/5	4
Total	**100**		**78**

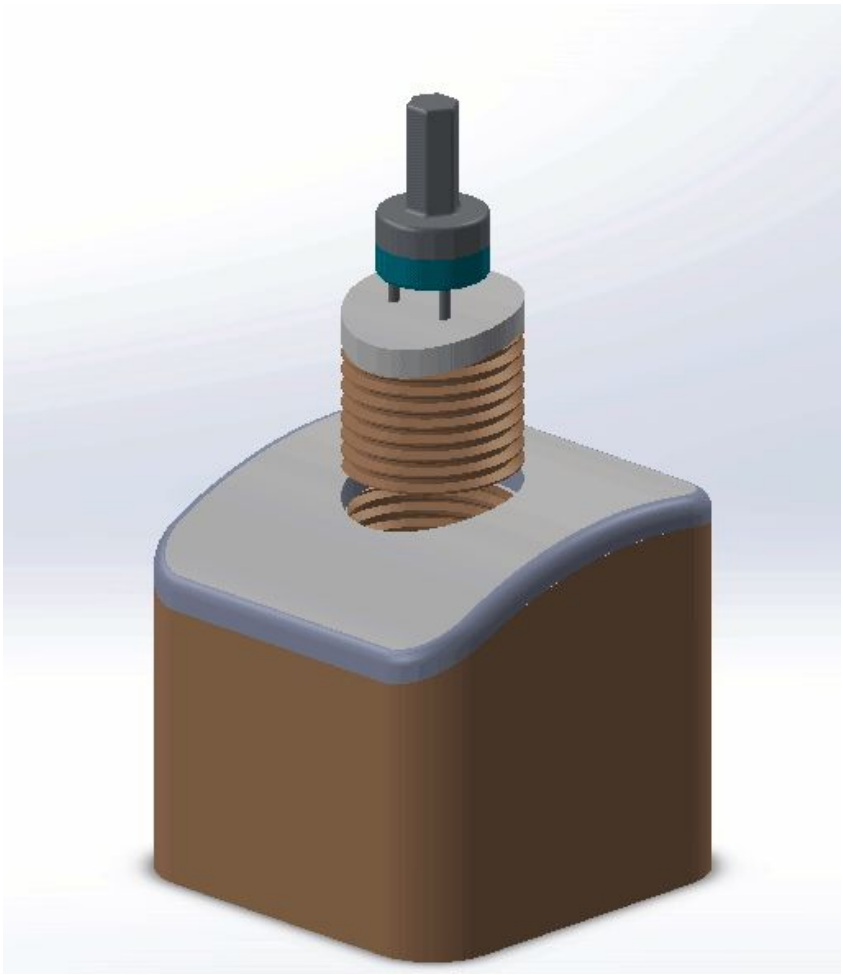


Trident

Criteria	*Weight*	*Rank*	*Score*
Tool Strength	20	5/5	20
Chondrocyte Viability Maintenance	20	4/5	16
Ease of Use (Procedure Integration)	15	5/5	15
Procedure Time	15	4/5	12
Sterilizability	10	5/5	10
Safety	10	4/5	8
Manufacturing Time	5	3/5	3
Cost	5	4/5	4
Total	**100**		**88**

Proposed Final Design





Testing

Surgical Protocol

- Fresh porcine tissue will be obtained from the Clinical Sciences Center
- Subsequent OCA transplant procedures will be performed on porcine knees
  - Standard impaction procedures
  - Threading procedures
  - Control samples
- Chondral biopsy taken from each sample

Confocal Imaging

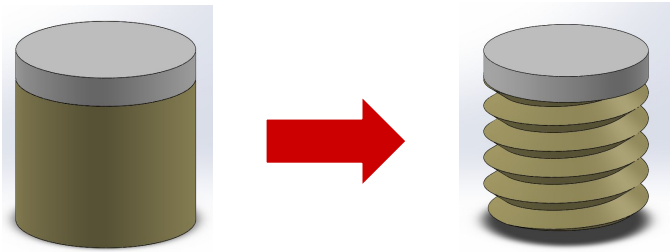
- Samples will be stained with a Calcein AM (live cells) and Ethidium Homodimer-1 (dead cells) to assay cell viability
- Nikon A1RS Confocal Laser Microscope at the UW-Madison Imaging Core

Power Statistics

- Two-sided paired t-test ($\alpha = 0.05$)
- 6 replicate sets
- Sample size equation:

$$n = \left(\frac{t_{\alpha/2,n-1} * \sigma}{\bar{x}}\right)^2$$

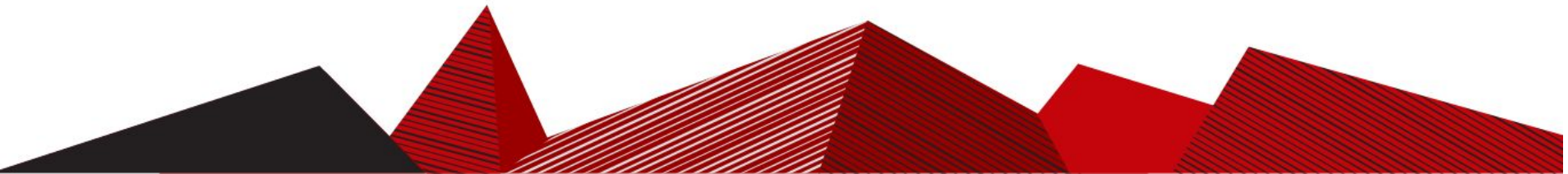
- n = 3 sets
- Doubled this value to increase confidence



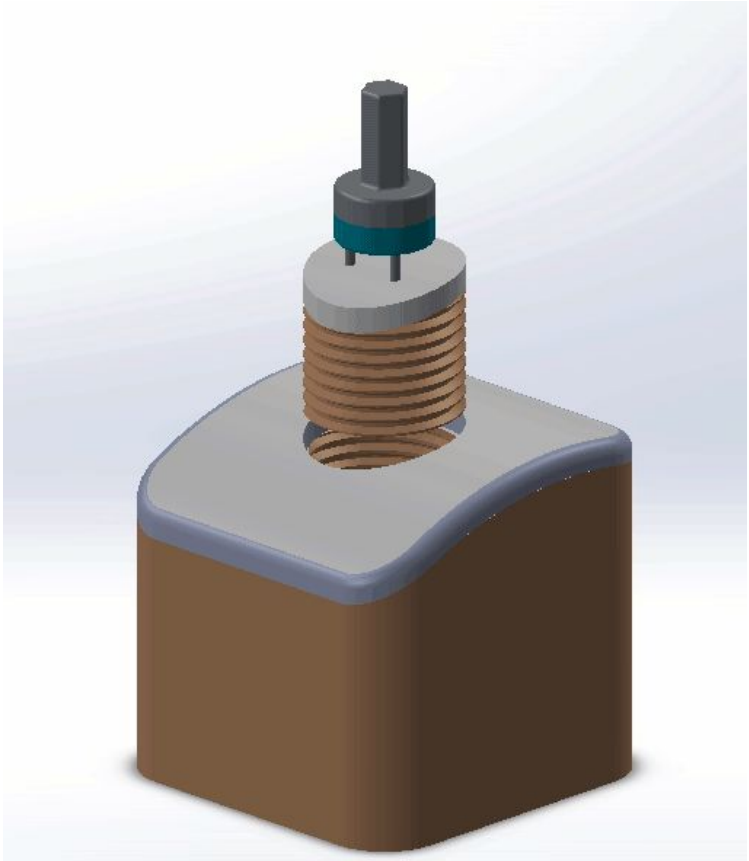
Acknowledgements

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

Thank you!



Questions?



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[3] Chahal J1, Gross AE, Gross C,Mall N, Dwyer T, Chahal A, Whelan DB, Cole BJ.(2013). Outcomes of osteochondral allograft transplantation in the knee.Arthroscopy. 2013 Mar;29(3):575-88. doi: 10.1016.

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[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.