Osteochondral Allograft Transplant Delivery System

Team: Alexander Teague, David Fiflis, Alexander Babinski, Zachary Wodushek
Client: Dr. Brian Walczak, DO, Department of Orthopedic Surgery and Rehabilitation, University of Wisconsin-Madison
Advisor: Tracy Puccinelli, PhD, Department of Biomedical Engineering, University of Wisconsin-Madison

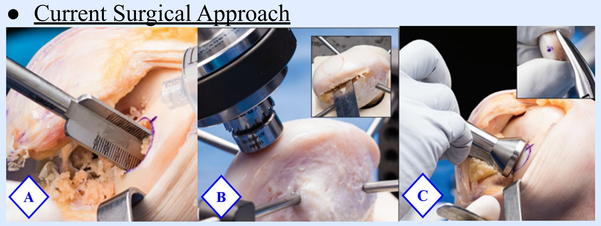
Abstract

Osteochondral allograft (OCA) transplantation repairs defects in cartilage and its underlying bone by implanting a fresh cadaver allograft with viable cartilage and bone tissues. A key step in OCA transplantation is inserting the graft into the patient using impaction. These allograft impaction forces result in cartilage death which can lead to premature graft failure. To minimize allograft damage, this novel OCA transplant system aims to bypass impaction using a screw-in graft. Testing in porcine knees showed that threading maintains cartilage viability better than traditional impaction. Evaluating graft placement accuracy showed that grafts can typically be inserted to within ±0.36 mm of the surrounding surface, which is well below the ±1 mm clinical target. Surgeon feedback indicated the tools are intuitive to use, and integrate well with the current workflow. Present work addresses both cartilage viability and graft placement accuracy to show that allograft threading is indeed a viable alternative to traditional impaction.

Background and Motivation

Background

- Osteochondral Defects
  - Arise from trauma, and abnormal developmental.
  - Typically 10-25 mm in diameter.
  - Devastating to quality of life. [1]
- Current Surgical Approach



(A) Drilling the patient graft receiving site.
(B) Harvesting donor graft with surgical hole saw.
(C) Impacting donor graft into patient receiving site.

- Current Procedure Shortcomings
  - Graft impaction reduces cartilage viability
    - Can result in poor graft integration
  - Impaction limits post-implantation graft adjustment
    - Can negatively affect joint loading
  - Low viability and altered joint loading can increase graft failure rates.

Project Motivation

- 3500 yearly cases (by 2020) with 5% annual growth [4].
- 18% failure rate dependent on defect etiology [5]
- Current impaction method limits chondrocyte viability
  - Cartilage viability >70% promotes grafting success [6]
- Limited graft adjustment complicates procedure

Design a system to address current procedure limitations

Design Specifications

- Design a device to screw the graft into the threaded receiving site
- Minimize damage to cartilage to promote high viability
- Integrate with current surgical workflow and instruments
- Achieve threaded graft placement accuracy of ± 1 mm.

Design Overview

Figure 2: Graft threading fixture. The graft is fixed in supporting cup. The guiding platform ensures axial alignment between the graft and die to cut accurate threads.

Figure 3: Solidworks rendering of graft screwdriver used to insert the allograft into the recipient site of the patient.

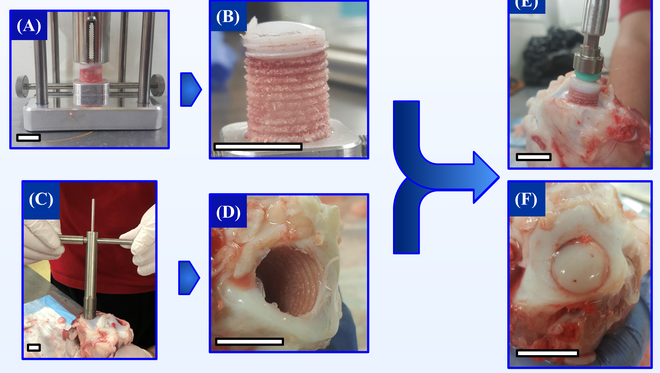
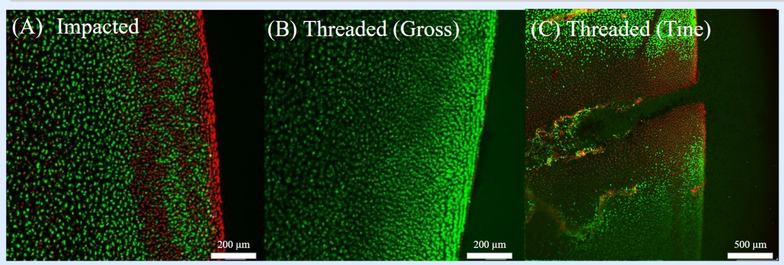


Figure 4: Flowchart of allograft threading and tapping procedure. The bone graft in the supporting cup and the die is guided to cut external threads on the graft (A/B). The tap slides over the recipient site guidewire to cut accurate internal threads in the patient (C/D). The bone graft is then cut to length and manually screwed into the recipient site (E) until it sits flush with the native tissue (F). All scale bars are 15 mm.

Viability Testing



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

Figure 7: Cross sections of graft cartilage biopsy collected with confocal microscopy (Nikon A1Rs Confocal Microscope; UW Optical Imaging Core) 18 hours after staining. (A) Impacted graft under 10x magnification. (B) Threaded graft under 10x magnification. (C) Threaded graft at the insertion point of the graft screwdriver under 4x magnification. Articular surfaces of each biopsy are on the right side of each image.

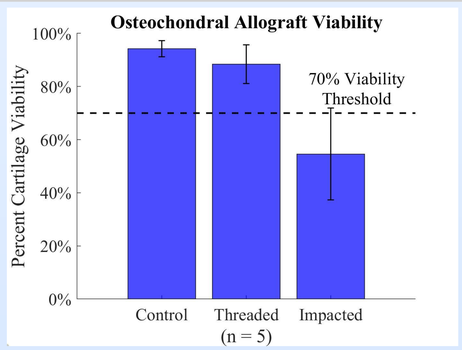


Figure 6: Mean cartilage viability for each treatment group: non-impacted control, threaded allograft, and impacted allograft. Error bars indicate standard deviation. Dashed line indicates the necessary chondrocyte viability threshold associated with successful procedure outcomes [6].

Graft Placement Evaluation

Rotational Alignment Testing

1. 26 grafts harvested from a SawBone block and threaded with the die.
2. The threading start site was marked on the graft.
3. 26 receiving sites were created in the saw bone and threaded.
4. The threading start site was marked on each receiving site.
5. A graft was fully inserted into each receiving site.
6. The rotational offset of graft insertion (Fig 8) was then measured using ImageJ and translated to a height offset using the thread pitch (1.5mm/360°).

Materials

- SawBone-Solid Rigid Polyurethane Foam (20 pcf)
  - Mimics cancellous bone mechanical properties

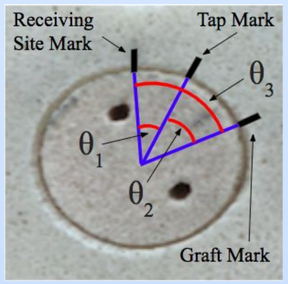


Figure 8: Sawbone graft inserted into a receiving site. The receiving site mark indicates the intended position for the tap and graft alignment marks. The tap mark indicates the tap position when fully inserted, and the graft mark shows the alignment when the graft is fully inserted. θ_1: tap angle error. θ_2: die angle error. θ_3: total angle error.

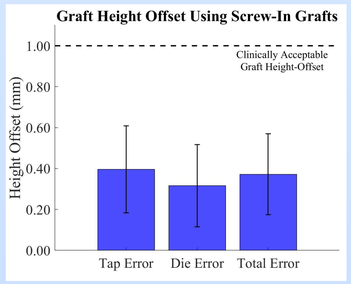


Figure 9: Mean height offset between the graft and receiving site as a result of measured angle difference (n=26). Error bars indicate one standard deviation. The total height difference was less than the clinically acceptable graft height-offset threshold of 1mm.

Current Work

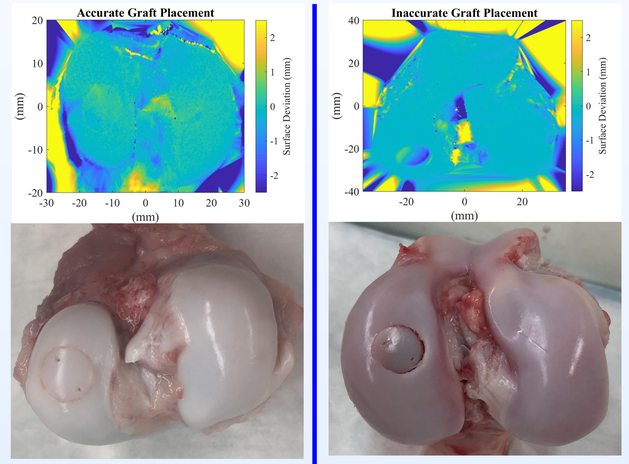


Figure 10: Laser measurements showing surface deviation from native cartilage of an accurately placed graft, and an inaccurately placed graft. Large deviation (height difference) magnitudes indicate poor graft placement accuracy. Images of the scanned femur are included below the surface deviation plots to show grafting accuracy in the tissue.

- Laser scanning method used to measure graft height offset.
  - Compares grafted surface to ungrafted reference surface.
- Used to validate graft placement accuracy in tissue.

Surgeon Feedback

- Received positive feedback from an independent orthopedic surgeon at UW Health.
  - Mechanical insertion of the threaded graft is desirable to prevent graft loosening.
  - Tool was intuitive and integrates with current workflow

Discussion

- This novel screw-in approach is a drastic improvement over current OCA transplantation methods
  - Significantly improves chondrocyte viability
  - Correct placement of the graft to less than ±1 mm
  - Allows surgeon to adjust graft after insertion

Future Work

- Perform additional surgeries to further validate the system
  - Evaluate both cartilage viability and graft placement
  - Compare to commercial OATS impaction system
  - Train orthopedic surgeons on the threading technique
  - Incorporate more representative live tissue models

References

[1] Sherman, *JAAOS,* 2014. [2] Borazjani, *JBJSA*, 2006. [3] Garrett, *Arthrex Inc.*, 2016. [4] Mccormick, *AJARS*, 2014. [5] Chahal, *Arthroscopy*, 2013. [6] Cook, *AJSM*, 2016.

Acknowledgements

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