Osteochondral Allograft Transplant Delivery System

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Abstract

Osteochondral allograft (OCA) transplantation repairs osteochondral defects resulting from traumatic, and idiopathic developmental etiologies by introducing a cadaveric allograft with viable hyaline cartilage and subchondral bone. A key step underpinning all OCA transplantation procedures is impaction of the allograft into the patient which can cause unintended chondrocyte death. To address the deleterious effect of impaction on chondrocyte viability, this novel OCA transplant system aims to bypass impaction using a screw-in graft. Previous work has demonstrated that chondrocyte viability is maintained using this novel approach. However, the screw-in method presents a unique challenge in achieving desired graft alignment as rotation and vertical translation are fully coupled in a screw. Through graft threading testing, it was found that these grafts can be inserted with < 1 mm of height offset from the surrounding surfaces. These results show that although threading presents a graft alignment challenge, the resulting alignment errors are clinically insignificant.

Background and Motivation

- **Background**
  - Osteochondral Defects
    - Arise from traumatic and developmental etiologies.
    - Typically 10-25 mm in diameter.
    - Devastating to quality of life. [1]
  - OCA Transplant Procedure
    - Guidewire is inserted over the defect to guide reamer-removal of afflicted tissue.
    - A hole-saw cuts the donor graft from cadaver tissue.
    - The allograft is impacted into the recipient site. [1]
  - Effect of Impaction on Chondrocyte Viability
    - Impaction activates necrotic pathways. [2]
    - Viable chondrocytes promote host integration
    - Low viability correlates with increased failure rates

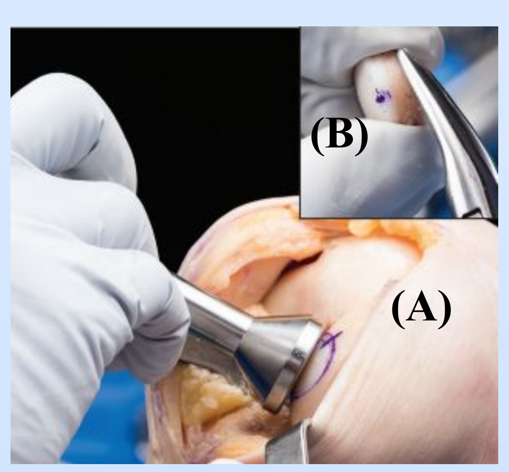

Figure 1: Arthrex Osteochondral Allograft Transplant System (OATS). Impaction rod used to seat the allograft flush with the native tissue (A). Graft chamfering of the subchondral bone to facilitate insertion (B) [3].

- **Project Motivation**
  - Increasingly popular procedure [4]
    - Projected 3500 cases performed annually by 2020 and increasing by 5% annually.
  - 18% failure rate dependent on defect etiology [5]
  - Current impaction method limits chondrocyte viability
    - Chondrocyte viability >70% linked to procedure success [6]

Design Specifications

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

Previous Design Work

Figure 2: Solidworks Prototype Rendering. The bone graft is fixed in supporting cup. The guiding platform ensures axial alignment between the graft and die to produce consistent, accurate threads.

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

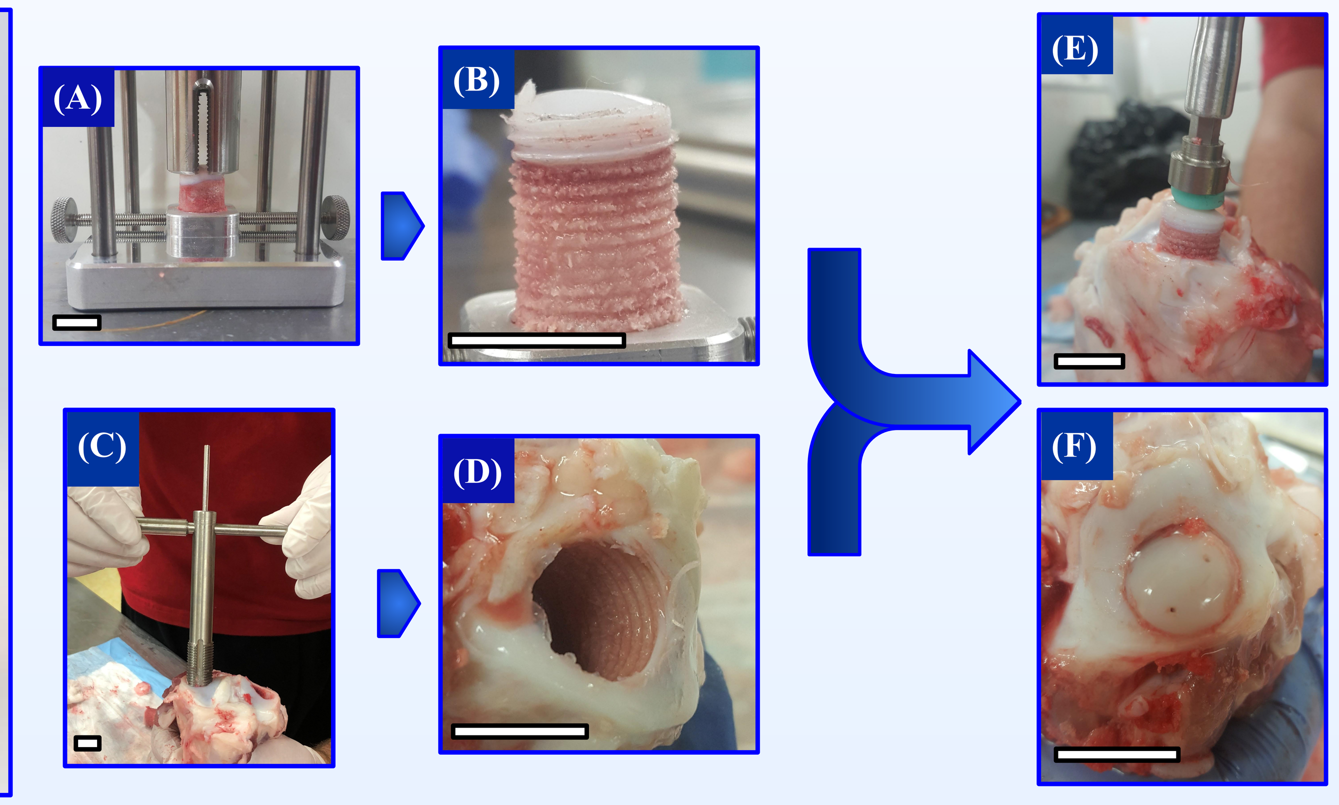

Figure 4: Flowchart of allograft threading and tapping procedure. Following pin fixation of the bone graft within the supporting cup (A), the die inserted into the guiding platform is used to create external threads in the donor tissue (B). The tap slides over the recipient site guidewire (C) ensuring (perpendicular tapping of the hole) and is used to create internal threads in the recipient site (D). The bone graft is then cut to a desired depth, and manually screwed into the recipient site (E) until it sits flush with the native tissue (F). All scale bars are 15 mm.

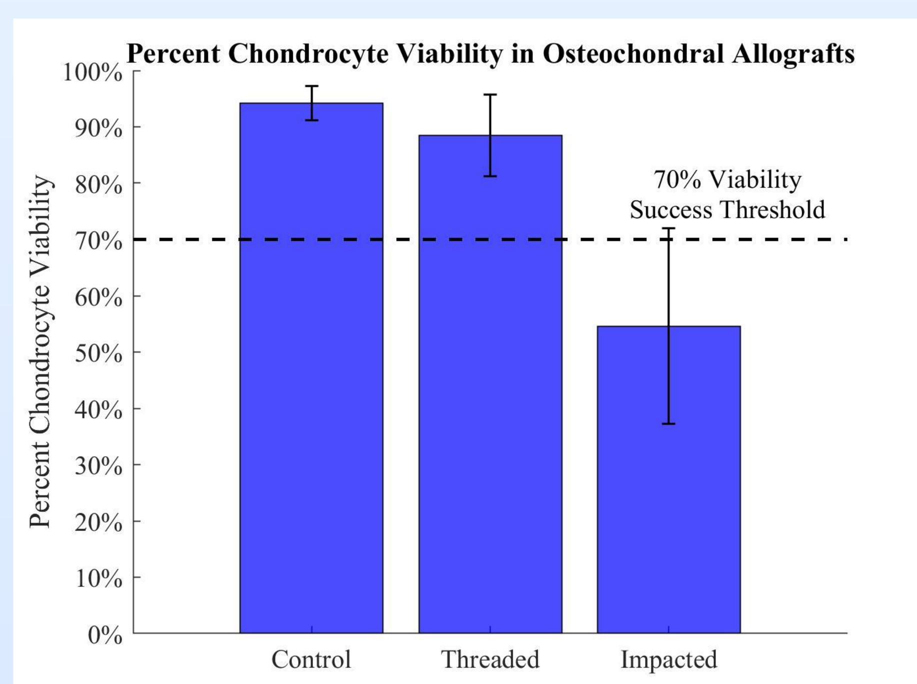

Figure 6: Graph showing the mean chondrocyte viability for each treatment group: non-impacted control, threaded allograft, and impacted allograft. Error bars indicate standard deviation. Dashed line indicates the necessary chondrocyte viability threshold associated with successful procedure outcomes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

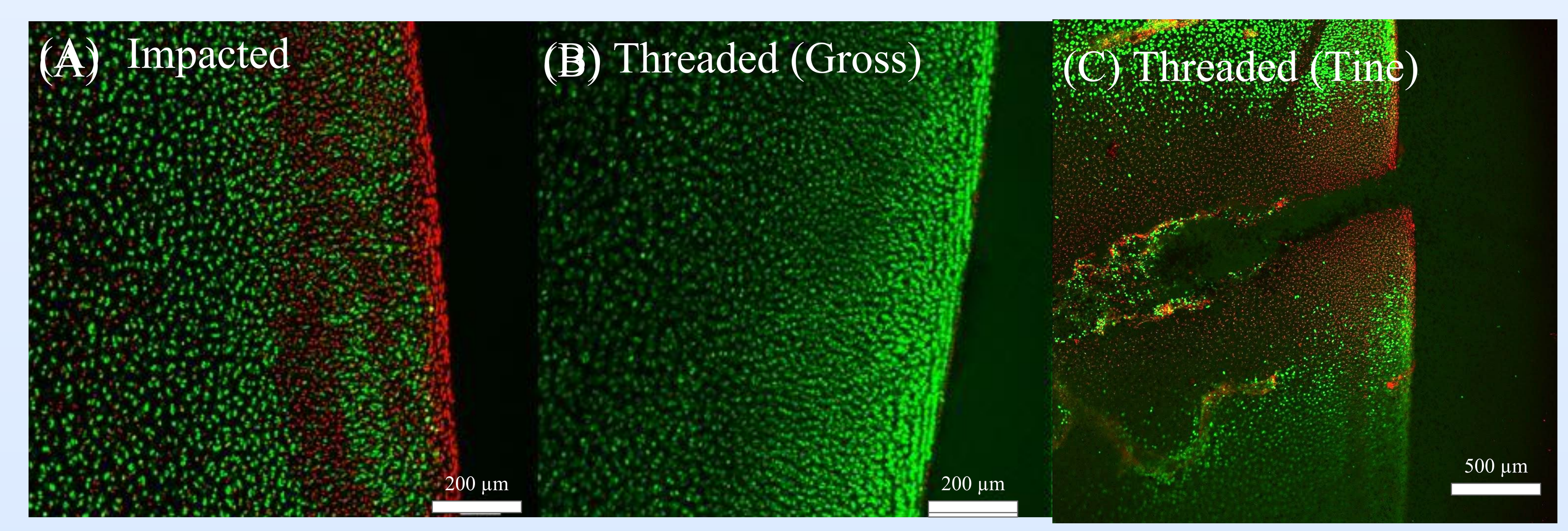

Figure 7: Cross sections of graft cartilage biopsy collected with confocal microscopy (Nikon A1Rs Confocal Microscope; UW Optical Imaging Core) 18 hours after staining. (A) Impacted graft under 10x magnification. (B) Threaded graft under 10x magnification. (C) Threaded graft at the insertion point of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

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

Testing Methods and Materials

Rotational Alignment Testing

1. 26 grafts were harvested from a saw bone 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

Results

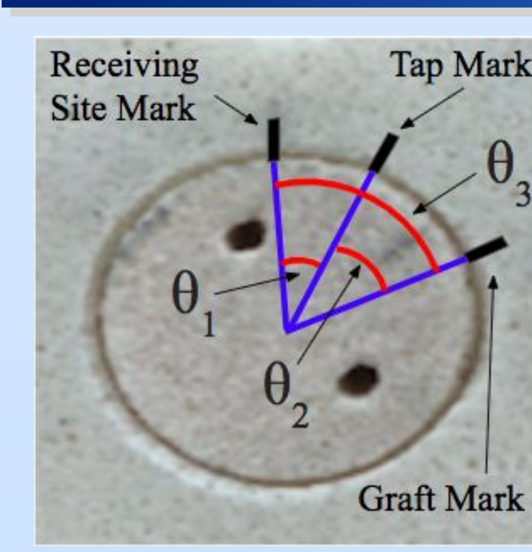

Figure 8: Sawbone graft inserted into sawbone receiving site. The receiving site mark indicates the intended position for the tap and graft alignment marks. The tap mark indicates the tap position when fully inserted, and the graft mark shows the alignment when the graft is fully inserted. θ_1: tap angle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

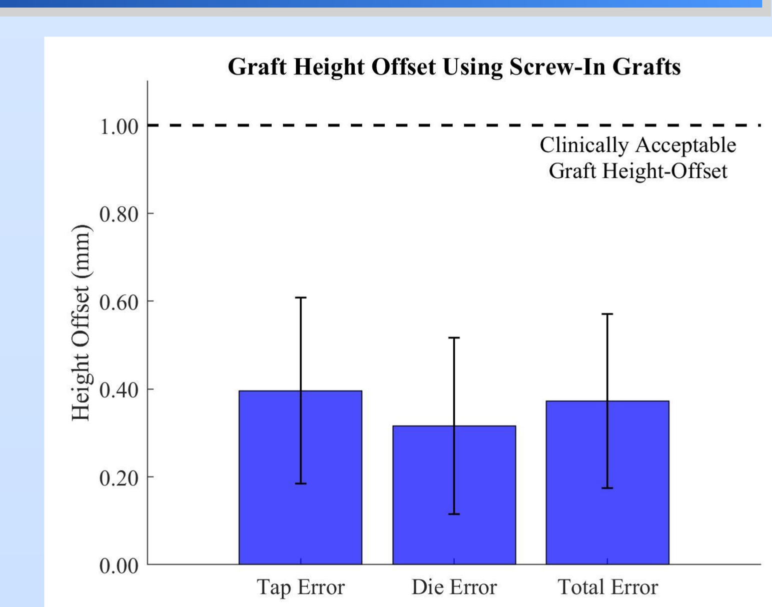

Figure 9: Mean height offset between the graft and receiving site as a result of measured angle difference (n=26). Error bars indicate one standard deviation. The total height difference was less than the clinically acceptable graft height-offset threshold of 1mm.

Discussion

- The average offset angle of 88.4° in SawBone Model
  - Translates to +/- 0.37 mm in graft height offset
- Thread quality depended on applied pressure during threading.
- Received positive feedback from an independent orthopedic surgeon at UW Health.
  - Mechanical insertion of the graft was a good feature as it prevents graft loosening.
  - Tool was intuitive and simple to use.

Laser Scanning

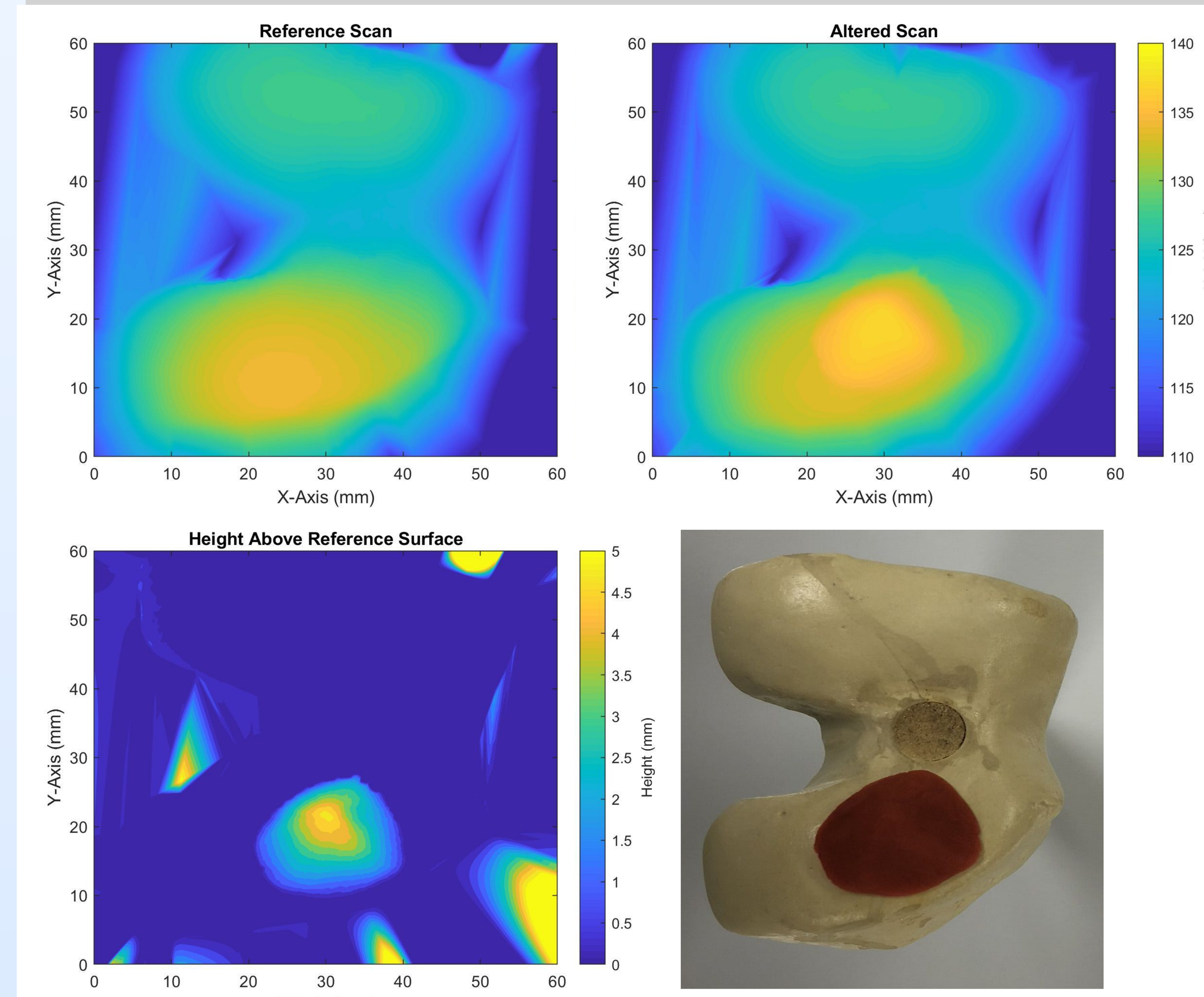

Figure 10: Laser measurements of simulated graft height offset above articular surface in a model femur. The reference scan is the geometry of the unaltered bone. The altered scan shows the bone with the simulated graft and this height offset is quantified by subtracting the reference scan from the altered scan. Image depicts the altered bone model.

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

Future Work

- Compare graft threading system to commercial OATS impaction system.
- Train orthopedic surgeons to implement graft threading technique.
- Improve staining and sectioning protocol for assessing chondrocyte viability post-insertion.

References

[1] Sherman, *JAAOS*, 2014. [2] Borazjani, *JBJSA*, 2006. [3] Garrett, *Allograft OATS ® Resurfacing Technique for Articular Cartilage Restoration Surgical Technique*. Atlanta, Georgia: Arthrex Inc, 2016. [4] Mccormick, *AJARS*, 2014. [5] Chahal, *Arthroscopy*, 2013. [6] Cook, *AJSM*, 2016.

Acknowledgements

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