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. OCA transplantation is typically performed on a young, athletic cohort for whom other cartilage repair techniques are incompatible with their lifestyle demands. A key step underpinning all OCA transplantation procedures is impaction of the allograft into the patient. Counterproductively, impaction activates necrotic pathways, leading to chondrocyte death. Viable chondrocytes promote host integration while maintaining long-term graft integrity and biomechanical function, all of which determine OCA procedure success. To address the deleterious effect of impaction on chondrocyte viability, this novel OCA transplant system aims to minimize interaction with the allograft cartilage by creating a screw-in graft. Simulated OCA transplantations in fresh porcine tissue compared the efficacy of our graft threading system to the current impaction technique and revealed a significantly higher chondrocyte viability with threading ($p < 0.01$; $n = 5$) which would suggest better long-term patient outcomes.

Motivation and Background

- **Background**
  - Osteochondral Defects
    - Traumatic and developmental etiologies prevail.
    - 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 apoptosis pathways. [2]
    - Viable chondrocytes promote host integration
      - Low viability correlates with increased failure rates

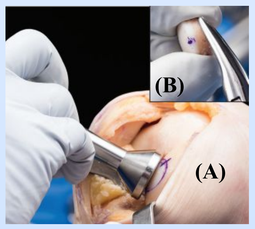

Figure 1: Arthrex Osteochondral Allograft Transplant System (OATS). Impaction rod used to seat the allograft flush with the native tissue (A). Graft chamfering of the subchondral bone to facilitate insertion (B) [3].

- **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
- Must comply with current FDA surgical standards

Final Design

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.

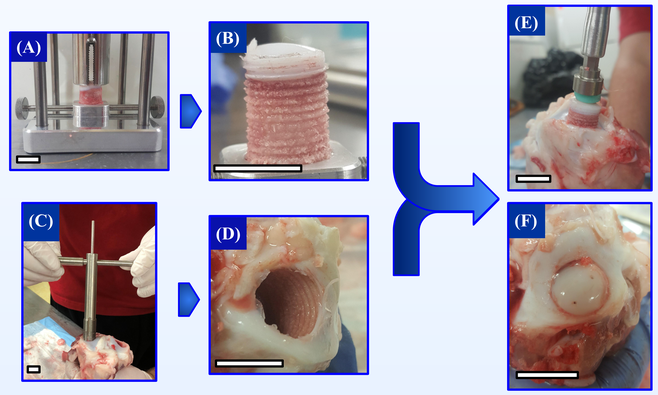

Figure 4: Flowchart of allograft threading and tapping procedure. Following pin fixation of the bone graft within the supporting cup (A), the die inserted into the guiding platform is used to create external threads in the donor tissue (B). The tap slides over the recipient site guidewire (C) ensuring (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 16 mm.

Testing Methods & Materials

Materials

1. 5 fresh porcine knees (3-4 months old) harvested 4 hours after death.
2. Osteochondral allograft surgical instrument analogs and prototype tools.
3. DMEM cell media to nourish cartilage biopsies.
4. PBS to clean the graft and receiving hole.
5. Calcein-AM and Ethidium Homodimer-1 (Live/dead cell stain)

Methods

1. Incubate the fresh knees at 37°C until testing.
2. Perform the simulated surgical procedures (both impaction and threading).
3. Obtain cartilage biopsies for imaging (non-grafted control, impacted, gross threaded, tine-threaded).
4. Stain biopsies in Calcein-AM and EthD-1 with DMEM and PBS for 18 hours before imaging
5. Imaged using A1RS confocal microscope at the UW-Optical Imaging Core.
6. Samples imaged 100 µm from cut surface with FITC and TRITC excitation wavelengths.
7. Chondrocyte viability assessed with custom CellProfiler pipeline.

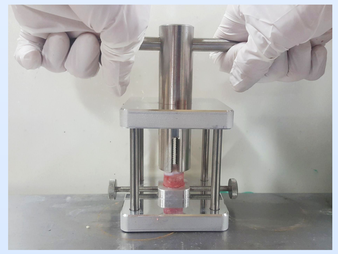

Figure 5: Threading guide with bone graft and holding cup. The bone graft is screwed into the cup to secure it for threading with the die, which is guided by the hole in the plate above the graft..

Results

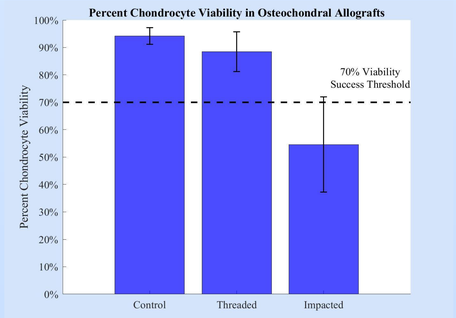

Figure 6: Graph showing the mean chondrocyte viability for each treatment group: non-impacted control, threaded allograft, and impacted allograft. Error bars indicate standard deviation. Dashed line indicates the necessary chondrocyte viability threshold associated with successful procedure outcomes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

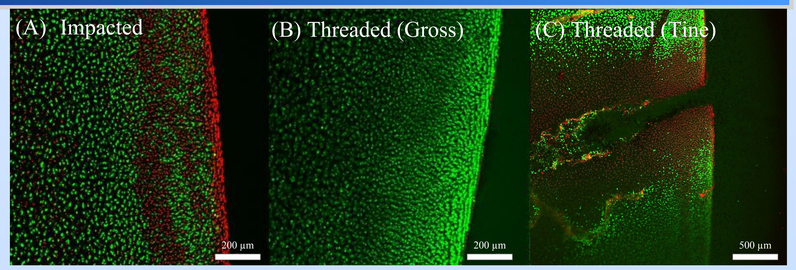

Figure 7: Cross sections of graft cartilage biopsy collected with confocal microscopy (Nikon A1Rs Confocal Microscope; UW Optical Imaging Core) 18 hours after staining. (A) Impacted graft under 10x magnification. (B) Threaded graft under 10x magnification. (C) Threaded graft at the insertion point of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

Conclusions

- Chondrocyte viability tests showed a reduction in cell death for the threading method compared to impaction.
  - One-tailed paired t-test; $n = 5$; $p = 0.0098$.
- No significant difference between threaded and control viabilities
- Gross cartilage integrity remains high despite the chondrocyte death within 400 µm of the tine insertion site.
- Sources of Error:
  - Could not rigorously quantify impaction forces to ensure that they fell within a clinically relevant range.
  - Use juvenile porcine tissue which was much softer than the bone used in human OCA transplantations.

Future Work

- Address the issue of allograft cartilage geometry alignment with native tissue.
  - Requires training in the OCA transplantation procedure to accurately match the patient geometry.
- Perform testing on tissue that is consistent with the material properties of human bone.
  - Porcine bone tissue is less dense than the bone typically used in this operation.
  - Using denser bone in testing allows for more precise cutting of the threads without tear-out of the bone.
- Obtain access to the commercially available OATS or other similar OCA transplantation surgical kit to ensure that the impaction method used in surgery does significantly reduce chondrocyte viability.

References

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