Osteochondral Allograft Transplant Delivery System

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♦ Abstract

Osteochondral allograft transplantation is a surgical procedure of growing popularity in young, active patients. This surgery introduces mature cartilage and subchondral bone to repair chondral defects. Existing surgical systems are detrimental to chondrocyte cell viability and limit vertical graft adjustment--crucial determinants of a successful outcome. Our project validates a design that addresses both challenges by threading the graft and receiving site, producing a screw-in graft. Assessment of chondrocyte viability using live/dead staining shows significant reduction in chondrocyte death in graft threading compared to impaction (n=4, $p<<0.001$). These results are promising, warranting future investigation into this system as a viable surgical alternative.

♦ Motivation and Background

- **Project Motivation**
  - 200,000 cases performed on patients under 25 years old annually [1]
  - 18% procedure failure rate [2]
  - Chondrocyte viability > 70% linked to procedural success [2]
    - Viability reduced by current impaction method
- **Background**
  - Osteochondral Defects
    - Repeated knee injuries and increased loading of the joint cause a separation of cartilage and bone. [3]
    - Leading causes are meniscal tears, abnormal bone growth, and excessive stress.
  - Osteochondral Allograft Transplant Procedure
    - Guidewire is inserted perpendicular to defect.
    - Cannulated dowel reamer removes surrounding tissue along guidewire to a depth of 7-14 mm and diameter of 10-25 mm.
    - Donor plug is harvested from cadaver tissue by passing a surgical hole-saw through a guide ring.
    - The allograft is positioned over the recipient site and impacted in with a hammer and impaction rod. [4]
  - Effect of Impaction on Chondrocyte Viability
    - Impaction impulse activates cell mechanoreceptors
    - Executioner caspases are activated causing apoptosis. [5]

♦ Design Specification

- Design device(s) that create threads in both the recipient and donor sites
- Integrates with current allograft transplant procedures, in terms of workflow and compatibility with surgical environment
- Must comply with current medical and FDA surgical standards

♦ Final Design

Figure 1: Solidworks Prototype Rendering. The bone plug is fixed in supporting cup. The guiding platform ensures axial alignment between the graft and die to produce consistent, accurate threads.

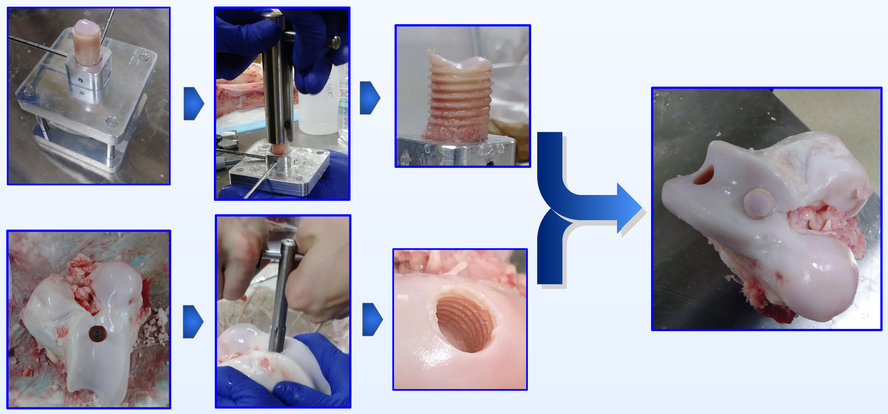

Figure 2: Flowchart of threading and tapping procedure. Following pin fixation of the bone plug within the supporting cup, the die inserted into the guiding platform is used to thread the donor tissue. The tap slides over the recipient site guidewire ensuring perpendicular tapping of the hole. The bone plug is then cut to a desired depth, and manually screwed into the recipient site.

♦ Testing Methods & Materials

Materials

1. 4 fresh bovine feet harvested within 8 hours of death.
2. Osteochondral allograft surgical instrument analogs and prototype tools.
3. DMEM cell media to nourish exposed cartilage.
4. PBS to clean the graft and receiving hole.
5. Calcein AM and EthD-1(Live/dead reagents)
6. Hoechst Stain (Nuclei stain)
7. Agarose gel (4%) to support cartilage cross-sections for imaging.

Methods

1. Obtain sample cartilage for initial assessment of chondrocyte viability.
2. Store the fresh knees in 37°C until testing.
3. Perform simulated surgical procedure.
4. Obtain donor plugs for control, impacted, and threaded samples at 30min post-insertion.
5. Immerse plugs in DMEM media for transportation prior to imaging.
6. Obtain cartilage sample cross-section and stain for 1 hour.
7. Support sample in 4% agarose gel for fluorescent imaging

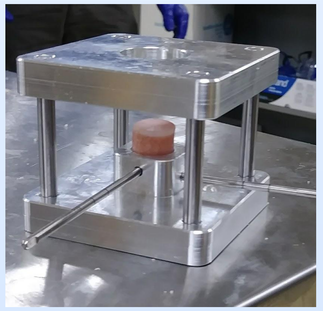

Figure 3: Threading guide with bone plug and cup. The bone plug is screwed into the cup to secure it for threading with the die, which is guided by the hole in the plate above the graft..

♦ Results

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

Table 1: The percent of living chondrocyte cells are recorded for each specimen as well as the averages and standard deviations. A two-variable t-test compared the viability between the two treatments and p-value recorded.

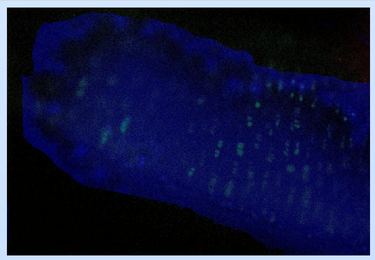

Figure 4: Cross-section of cartilage from a threaded plug. Collected on a fluorescence microscope under 10x magnification.

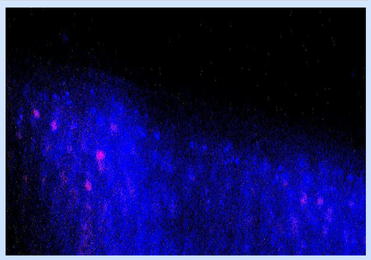

Figure 5: Cross-section of cartilage from an impacted plug. Collected on a fluorescence microscope under 10x magnification.

Blue: Cell nuclei **Red**: Dead Cells **Green**: Live Cells

♦ Conclusions

- Chondrocyte viability tests show a statistically significant reduction in cell death for the threading method compared to impaction.
- Based on the improved cell viability, and if given slight improvements to the current prototype, the screw-in graft method shows great promise in improving this surgical procedure.
- Potential sources of error: variability in plug conditions prior to cartilage harvesting, inconsistency in cartilage harvesting, and suboptimal concentration ratio of cell stain which generated excessive background noise in the imaging.

♦ Future Work

- Prototype Modifications
  - Starter tap and die with tapered threads
    - Aid with cutting initial threads without stripping the bone.
  - Longer handles for the tap and die.
  - Adjustable bottom support in the graft cup.
- Procedure Integration
  - Test the prototype with the real surgical system
  - Assess any increases in procedure duration
  - Assess geometric constraints during implantation
- Testing
  - Revised staining protocol that will more reliably stain the dead cells.
  - Perform imaging with a confocal laser microscope to get better image penetration in the tissue.

♦ References

[1] W. J. Long, J. W. Greene, and F. D. Cushner, "Early Clinical Outcomes Associated with a Novel Osteochondral Allograft Transplantation System in the Knee," *Advances in Orthopedic Surgery*, vol. 2016, p. 1, 2016.

[2] 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.

[3] Drosos GI, Pozo JL (2004). The causes and mechanisms of meniscal injuries in the sporting and non-sporting environment in an unselected population. *Knee,* 11(2), 143-149

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[5] Borazjani BH, Chen AC, Won CB, et al. Effect of impaction on chondrocyte viability during insertion of human osteochondral grafts. J Bone Joint Surg Am 2006;88-A(9):1934-1943.

♦ Acknowledgements

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