Product Design Specifications

Osteochondral Graft Tapping System

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Function: Osteochondral allografts (OCAs) are used to repair chondral defects in young, active patients. The current procedure involves cutting the graft from cadaveric tissue, then using impaction to drive the graft into a low-clearance receiving hole drilled over the defect. The large impulse associated with graft impaction often leads to decreases in grafted chondrocyte viability, and negatively affects procedure outcomes [1]. To avoid deleterious impaction, we created a screw-in system which taps the patient receiving site, and threads the donor graft allowing the graft to be screwed into the patient. Testing revealed that this new system has significantly higher implanted chondrocyte viability when compared to the impaction protocol. A challenge unique to our system, however, is that the one degree-of-freedom (DOF) nature of a screw mechanism limits graft adjustment relative to the traditional two DOF impacted graft. Therefore, the aim of this project is to develop a protocol for threading the graft and receiving site such that desired graft rotation and height can be achieved simultaneously when the graft is fully inserted into the patient.

Client Requirements

1. The protocol must permit a graft height offset from native tissue of no more than ±1.0mm.
2. After graft preparation and insertion, chondrocyte viability must be consistently greater than 70%, which has been shown to be a threshold to successful graft integration [1].
3. The entire system must be sterilized before use in surgery.
4. The threading protocol must be quick and easy to learn so as not to drastically alter the current surgical practice.
5. Damage to the chondral surface must be no greater than what presently occurs during OCA transplantation.

Design Requirements

1. **Physical and Operational Characteristics**
    a. **Performance Requirements**
        i. Threading the graft and receiving site should not damage the articular cartilage
            1. It should limit gouging, scratching, and other mechanical alterations to the native, or graft cartilage.
            2. It should not result in significant chondrocyte death after use
        ii. Insertion of the graft must be easily executed so as to minimize the risk of tissue damage.
        iii. During the procedure, the graft should be easy to insert and remove allowing the surgeon to adjust the graft depth.
        iv. The threading protocol must cut threads in the graft and receiving site that result in predictable graft placement.
    b. **Safety**
        i. The threading system should not increase the chances of postoperative complications, including (but not limited to) infection, tissue death, or graft dislocation.
        ii. Long term, the threaded graft must not lead to an associated cartilage disorder, significant fissuring or fibrous tissue infiltration, or improper tissue integration.
    c. **Accuracy and Reliability**
        i. The threading protocol should allow for successful graft integration into the recipient site. This means that the procedure should maintain at least 70% chondrocyte viability after implantation.
        ii. The measurement protocol should ensure that, after graft insertion, the donor curvature closely matches that of the recipient site within ±1.0 mm of height difference.
    d. **Life in Service**
        i. Non-disposable components must be serializable to allow for repeated use
        ii. Life of device materials will vary depending on chosen stainless steel alloy.
        iii. Disposable components should be minimized in the design to prevent excessive recurring costs.
    e. **Shelf Life**
        i. Capable of storage at room temperature.
        ii. Must be compliant with hospital regulations of storage.
        iii. Shelf life is not likely to present as a significant design consideration.

f. **Operating Environment**
    i. Protocol must not compromise sterility of the device or surgical field.
    ii. Must function within range of operating room temperatures, in addition to *in vivo* conditions.
    iii. Must be usable in concurrence with all other orthopedic tools and materials.
g. **Ergonomics**
    i. The devices must be designed for comfortable handheld use by the orthopedic surgeon during the procedure.
    ii. To promote easy rotation, the tool must be easy to locate over the central-axis of the graft.
h. **Size**
    i. Tools will be appropriately sized for handheld usage by orthopedic surgeon.
    ii. The device should accommodate bone graft sizes 10 mm - 25 mm in diameter and 7 mm - 14 mm deep.
i. **Weight**
    i. Since the device will be hand-held, its total weight should not be so heavy that it is cumbersome, or fatigues the surgeon during use.
j. **Materials**
    i. All materials must pass ISO regulations to corrosion resistance and excessive wear from use [3].
    ii. Tools involved in the procedure must be sterilizable or disposable.
k. **Aesthetics**
    i. Aesthetics will serve as a secondary initiative to the function of the final product.

1. **Production Characteristics**
    a. **Quantity**
        i. One prototype capable of inserting the graft into the patient.
            1. The prototype may have more than one component.
    b. **Components**
        i. The final product must consist of a mechanism for inserting the graft into the recipient hole.
            1. A component must hold the graft in place and align a threading mechanism.
            2. An external threading component must create threads on a harvested graft.

3. An internal threading component must create threads in the patient receiving site.
4. A component will function as a screwdriver to screw the graft into the recipient site.
5. A final component must define the starting threading position on the graft threading component to ultimately allow for predictable graft placement.

2. **Miscellaneous**
    a. **Standards and Specifications**
        i. The final product must comply with the FDA standard for manual surgical instruments as stated by CFR 21 - Subchapter H - Medical Devices [3]
    b. **Customer**
        i. Orthopedic surgeons implanting an osteochondral allograft
    c. **Patient Related Concerns**
        i. Decreasing chondrocytes cell viability leads to diminished graft integrity.
        ii. Unwanted debris and fragments of the graft may be released into the synovial fluid environment and cause other complications.
        iii. A graft with an articular surface homologous to the native tissue is necessary for long term grafting success and patient health.
    d. **Current Systems**
        i. Arthrex Osteochondral Allograft Transfer System (OATS). This system is the prototypical system used in osteochondral transplant procedures (and is most similar to the system Dr. Walczak uses). It uses a sizing guide, guide wire, and cannulating reamer to size, locate, and ream the chondral defect. The allograft is prepared using the hole saw which is guided by a manually held ring. The impaction rods forces the graft into the receiving hole [4].
        ii. Zimmer Chondrofix Osteochondral Allograft. This system uses a hollow punch hammered into the bone to guide the drill bit during receiving site preparation. There is no need to prepare an allograft since it comes with a pre-made, decellularized allograft that fits precisely in the hole created by the punch and drill bit. The graft is inserted the majority of the way using the insertion tool, and is pounded in the reminder of the way using an impaction rod [5].
        iii. COR Precision Targeting System. This is the only surgical system that claims to address chondrocyte viability concerns associated with OCA transplantation. The tool encloses the graft during harvesting and insertion to protect it from mishandeling. The surgical guide also claims to use “low impaction insertion” but does not describe how impaction forces are

minimized relative to traditional tools. Despite the promise with the system, it is not currently in use in human OCA transplantation. [6]

iv. There are no direct competitors, and of the ones currently in use, all rely on graft impaction.

References

[1] 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.

[3] "CFR - Code of Federal Regulations Title 21," *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=888. [Accessed: 10-Oct-2017].

[4] W. Bugbee, "OSTEOCHONDRAL ALLOGRAFT TRANSPLANTATION CLINICAL OUTCOME AND RETURN TO SPORT", *Aspetar Sports Medicine Journal*, vol. 10, pp. 246-251, 2016.

[5] Zimmer, Inc., "Zimmer® Chondrofix® Osteochondral Allograft Surgical Technique", *Zimmer*, 2017. [Online]. Available: http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/surgical-techniques/biologics/zimmer-chondrofix-osteochondral-allograft-surgical-technique.pdf. [Accessed: 04- Oct-2017].

[6] DePuy Synthese Mitek Sports Medicine, "COR ® PRECISION TARGETING SYSTEM Repair of Osteochondral Defects in Canines Repair of Osteochondral Defects in Canines Repair of Osteochondral Defects in Canines."