Osteochondral Graft Tapping System

Preliminary Product Design Specifications

September 22nd, 2017

Team: Alex Teague
Josiah Wolf
Grace Li
David Fiflis
Zach Wodushek

Function: Osteochondral allografts are used to repair chondral defects in young, active patients. The currently accepted practice involves cutting the graft from cadaveric tissue then using impaction to drive the graft into a low clearance receiving hole drilled over the defect on the patient's articular cartilage. The large forces associated with graft placement often lead to decreases in grafted chondrocyte viability, and negatively affect procedure outcomes. To increase the number of successful procedures, our client envisions a screw-in graft that bypasses the need for damaging impacts. Thus, we are to design a system that will allow the graft and recipient site to be tapped, and allow the graft to be easily screwed into place.

Client Requirements

1. The grafted plug must be removable from the recipient site so the depth of the graft can be adjusted.
2. After graft preparation and insertion, chondrocyte viability must be consistently greater than 70%, which is the accepted threshold for procedure success [1].
3. The entire system must be sterilized before use in surgery.
4. The system must be quick to use, and easy to learn so as not to drastically alter the current surgical practice.

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 not gouge, scratch, or result in mechanical alterations to the native, or grafted cartilage.
            2. It should not result in significant chondrocyte death after use.
        ii. The threading must be easily executed so as to minimize the risk of damaging the graft tissue.
        iii. During the procedure, the graft should be easy to insert or remove allowing the surgeon to adjust the graft depth.

iv. The system must reliably cut threads that are perpendicular to the central axis of the reamed hole and cylindrical graft to ensure proper alignment.
v. The graft threading system must accurately cut threads that engage properly so that the graft will not loosen after the procedure.

b. Safety

i. The delivery system should not increase the chances of postoperative complications, including infection, tissue death, or graft dislocation.
ii. Long term, the 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 device should have a success rate that exceeds that of current procedures(less than 24% failure)
ii. The device should also allow for successful graft integration into the recipient site. meaning that the procedure should be able to maintain at least 70% chondrocyte viability prior to implantation

d. Life in Service

iii. Specialized or irreplaceable components must be sterilizable for repeated use
iv. Life of device materials will vary, but must be inherently resistant to corrosion

d. Shelf Life

i. Capable of storage at room temperature
ii. Must be compliant with hospital regulations of storage

e. Operating Environment

i. Method of implantation must not compromise sterility
ii. Must function with range of operating room temperatures, in addition to *in vivo* conditions
iii. All components must withstand tension, compression, rotation, and torsional forces exerted upon them during function and implantation
iv. Must be usable in concurrence with all other orthopedic tools and materials such as bone cement and lubricant

f. Ergonomics

i. The device must be designed for comfortable handheld use by the orthopedic surgeon during the procedure
ii. Device should be easily adjusted for different sized defects and bone grafts
iii. Forces placed on the cancellous bone of the graft should not exceed 6.6 MPa from torsional stress, 3-20 MPa in tension, and 1.5-50 in compression. Cortical bone is stronger than cancellous, so force limitations inherently include the cancellous bone. The forces applied to

the articular cartilage should not exceed those at which there is <70% chondrocyte viability.

g. **Size**
    i. Tools will be appropriately sized for handheld usage by orthopedic surgeons
    ii. Bone graft sizes must range between 10mm - 25mm in diameter and 10mm deep. The prototype will make a graft that is 15mm in diameter, but should be designed in such a way that future iterations can be made in various sizes (i.e. 10mm, 15mm, 20mm, 25mm).
h. **Weight**
    i. The device must be weighted for use by an orthopedic surgeon with a general guideline of five pounds or less
i. **Materials**
    i. All materials must comply with current medical and FDA surgical standards
    ii. Any material that will be inserted and remain in the human body must be biocompatible
    iii. Tools involved in the procedure must possess the ability to be sterilized or be disposable
j. **Aesthetics**
    i. Aesthetics will serve as a secondary initiative to the function of the final product
    ii. The final product will follow the ergonomic guidelines above

2. **Production Characteristics**
    a. **Quantity**
        i. One prototype capable of properly preparing the graft
    b. **Components**
        i. The final product should consists of a tap, die, and a bone screwdriver and possibly vices to hold the graft during preparation.

3. **Miscellaneous**
    a. **Standards and Specifications**
        i. The final product must comply with FDA standards for manual surgical instruments
    b. **Customer**
        i. Orthopedic surgeons implanting an osteochondral graft
    c. **Patient Related Concerns**
        i. Decreasing chondrocytes cell viability over-time may lead to diminished performances
        ii. Unwanted debris and fragments of the graft may be released into the synovial fluid environment and cause other complications.

d. Competition

i. Oscillating Saw- Many medical device companies produce such a product with little variation as to the function of this device. One such company is ScienceMedic Co. LTD which produces a pneumatic and battery powered version of this saw which is activated by a trigger, and held like a common power drill. At the end of the device is a saw which oscillates in the horizontal plane at a controlled frequency this product is used in association with other saws in a typical osteochondral allograft procedure.

ii. Reciprocating Saw- This is a common product produced by many medical device companies with little variation in function. One company which produces this instrument is Kaiser Osron. They offer both an autoclavable and disposable version of their Ultramax3 reciprocating saw, which are both battery powered. This product is shaped in like a standard power drill, and is activated by a trigger. The blade on the end of the saw functions like a jigsaw vibrating forward and backward along the axis of the blade.

iii. Reamers

1. Cannulated dowel- This type of reamer is composed of a solid cylindrical piece which rotates about its axis. This device is passed along a guidewire, which has been inserted into the center of the recipient site, to a depth of a 6-12 mm clearing the affected tissue from the site.
2. Donor- This type of reamer is composed of a hollow cylindrical piece which rotates about its central axis. The reamer is passed over a guidewire inserted into the donor tissue to a depth equal to that removed from the recipient site, thus removing an intact piece of donor tissue which is complementary to the reamed recipient site.

References

[1] J. L. Cook *et al.*, "Importance of Donor Chondrocyte Viability for Osteochondral Allografts," (in English), *American Journal of Sports Medicine,* Article vol. 44, no. 5, pp. 1260-1268, May 2016.