Osteochondral Graft Delivery System

Product Design Specifications

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Function: Osteochondral allografting is a common procedure performed on patients that require replacement of diseased bone. Current methods of implantation require the application of mechanical forces that have a detrimental effect on the live chondrocytes present on the implant. Maximizing the amount of viable tissue during and after the surgery is a crucial factor for the success of the procedure. Hence, the client requests a delivery system that will reduce the amount of mechanical forces required to securely place the implant into the donor site.

Client Requirements:

- Budget: $250
- Donor tissue must be placed into donor site with less than 165 N of force applied to the articular cartilage layer (the average impaction force for current procedures)
- Must securely fit into donor site while keeping chondrocyte cell viability >70% during and after the procedure.
- Delivery system must only require the use of sterile tools available in a surgery room, or must be made to to fit surgical standards.

Design Requirements:

- *Performance Requirements:*
    - Application of bone graft should result in approximately 70 - 90% viability of chondrocytes on donor graft.
    - Procedure must be simple enough to be done in operating room, within 5 hours (the time period of a surgery).
    - Bone graft and vice should be positioned perpendicular (relative to each other) so screws on bone graft remain straight.
    - System must be capable of decreasing the 165 N used to insert the bone graft.
    - Forces exerted on the bone by the device should not cause any bone chipping, or fragmentation and minimal damage to the articular cartilage.

- *Safety:*
    - The delivery system should not increase the chances of infection, graft dislocation, or create complications post-op.
    - Our device has failed if, postoperatively, the graft does not exhibit proper integration into the native tissue, if the hyaline cartilage is not properly maintained, if an associated cartilage disorder develops, or if significant fissuring, fibrillation, or fibrous tissue infiltration occurs.
- *Accuracy and Reliability:*
    - The delivery system should have a success rate that exceeds that of current devices (75-80% success rate)
    - The delivery system should also allow for successful graft implantation with no greater risk for post-op complications than standard practice
- *Life in Service*:
    - Expensive or specialized components should be reusable and easily manufactured components should be one time use. Both should be sterilizable. Length of time to be determined with materials chosen
    - If plastic or biodegradable materials are included in the delivery system, then these components may be one-use only
- *Shelf Life:*
    - The delivery system should be capable of storage at room temperature for 9 months unless sterility is compromised before then. No corrosion should be observed on the delivery system during its life of service and must be compliant with hospital regulations
- *Operating Environment:*
    - The delivery system has to be sterile while in use
    - Should operate in temperatures typical of an operating room (20-23 °C), with humidity of 20-60%
    - All pieces will have to withstand the forces exerted on them during operation (tension, torsion, shear, and compression).
    - Must be able to be used in conjunction with other orthopedic tools, including supports, water, and bone glue.
    - Must be able to be utilized by an orthopedic surgeon
- *Ergonomics:*
    - The delivery system should be able to be used easily by surgeon without damage during operation. 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 MPa 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 less than 70% viability.
- *Size:*
    - The delivery system will be sized appropriately based on the size of the defect.
    - Range of 5mm-20mm diameter for threading bone graft
    - Height of graft must be at least 10 mm
- *Weight:*

    - Components of the delivery system are appropriately weighted for use by an orthopedic surgeon
- *Materials:*
    - Materials used in the delivery system should comply with medical standards set out by the FDA
    - Reusable materials must be sterilizable
- *Aesthetics, Appearance, and Finish:*
    - No color or aesthetics
    - Function over form

Production Characteristics:

- *Quantity:*
    - 1 final delivery system, preferably multiple testing using delivery system
- *Target Product Cost:*
    - TBD
- *Standards and Specifications:*
    - Implanted allograft should be in compliance with the FDA regulations under Section 361 of the Public Health Service Act as monitored by the Tissue Reference Group . All surgical tools should comply with the code of federal regulations under Title 21 with the FDA.

Characteristics:

- The delivery system should consist of a tap, die, vices and a bone screwdriver
- Must be made of surgery-grade material
- Various devices to stabilize tools will be necessary
- *Patient-related concerns:*
    - Completed bone graft must not cause pain
    - Allergies, immune response hemocompatibility, and biocompatibility
    - Allograft should not release unwanted fragments of bone
    - Required surgery with the delivery system should not be more invasive than current procedures
- *Customer:*
    - Orthopedic surgeons implanting an osteochondral graft will be the intended user