Osteochondral Graft Delivery System

Product Design Specifications

Team:
Nicholas Zacharias: Team Leader
Eduardo Enriquez: BSAC
Chrissy Kujawa: BWIG
Rodrigo Umanzor: Communicator
Robert Weishar: BPAG

Date: December 14, 2016

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: $300
- Donor tissue must be placed into donor site with less force required from surgeons during current methods
- 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% viability of chondrocytes on donor graft
    - Procedure must be simple enough to be done in operating room, within the time period of a surgery that takes about 5 hours
    - Bone graft and vice must be held to lie perpendicular so screws on bone graft remain straight
    - Device must be capable of decreasing the force used to insert the bone graft
    - Forces exerted on the bone by the device should not cause any bone chipping, or fragmentation

- *Safety:*
    - Device should not increase chances of infection, increase chances of graft dislocation, decrease chances of surgical success, 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 device should have a success rate that exceeds that of current devices (75-80% success rate)
    - The device should also allow for successful graft implantation, meaning it makes the procedure able to maintain >70% chondrocyte viability, with no greater risk for post-op complications than what already exists
- *Life in Service*:
    - Expensive or specialized components should be reusable, and easily manufactured components should be one time use. Both should be inherently sterilizable. Length of time to be determined with materials chosen
    - If plastic or biodegradable materials are included in the design, then these components may be one-use only
- *Shelf Life:*
    - The device should be capable of storage at room temperature for 9 months unless sterility is compromised before then. No corrosion should be observed on the device during its life of service and must be compliant with hospital regulations
- *Operating Environment:*
    - Product 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, rotational, shear, and compression).
    - Must be able to be used in conjunction with other orthopedic tools, including supports, water, bone glue...etc.
    - Must be able to be operated by an orthopedic surgeon
- *Ergonomics:*
    - Device 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 in compression [24]. 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% viability.
- *Size:*
    - Device will be sized appropriately based on the size of the defect.
    - Range of 5mm-20mm diameter for threading device
    - Depth of at least 10 mm

- *Weight:*
    - Device should weigh 5 lbs or less to be able to be comfortably hand-operated
- *Materials:*
    - Materials 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 product, preferably multiple prototypes for testing
- *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:

- Device should consist of a tap, die, and a bone screwdriver and vices
- 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
    - Device should not release unwanted fragments of bone
    - Required surgery with device should not be more invasive than current procedures
- *Customer:*
    - Orthopedic surgeons implanting an osteochondral graft