402 - Excellence - 04 - Graft_Delivery - Executive Summary

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Clinical Background

Osteochondral allograft (OCA) transplantation repairs osteochondral defects resulting from traumatic and idiopathic developmental etiologies by introducing a cadaveric allograft with viable cartilage and subchondral bone. OCA transplantation is typically performed on a young, athletic cohort whose lifestyle demands are incompatible with other cartilage repair techniques.

To repair osteochondral defects, surgeons drill into the defective native bone to prepare a receiving hole while a matching graft is harvested from cadaver tissue. The donor graft is then impacted into the recipient site until it sits flush with the surrounding tissue. The impaction sequence used to seat the graft into the patient underpins all current OCA transplantation systems. Counterproductively, impaction activates necrotic pathways, leading to chondrocyte death. Viable chondrocytes promote host integration while maintaining long-term graft integrity and biomechanical function, all of which determine OCA procedure success (Sherman *et. al*., 2014).

Existing Surgical Systems

There are few options for OCA transplantation surgical systems. Our method most closely mirrors the Arthrex Osteochondral Allograft Transfer System (OATS)--one of the most commonly employed systems for OCA transplantation. The Arthrex OATS system, as with all other systems, relies on impaction which has been shown to inhibit graft viability and long term procedure outcomes. Moreover, impaction does not allow the graft to be removed and adjusted after initial insertion which places great pressure on the surgeons to correctly place the graft on the first attempt.

Device Overview

To address the deleterious effect of impaction on chondrocyte viability, this novel OCA transplant system aims to minimize interaction with the allograft cartilage by creating a screw-in graft. A standard graft receiving site for the allograft is created over the defect before a custom tap threads the prepared hole. The harvested allograft is placed in a guide fixture and a custom die cuts matching threads on the graft. A small pronged graft screwdriver is then inserted into the allograft subchondral bone to screw the allograft into the receiving site.

Device Validation

This surgical system was tested on eight fresh porcine knees: each condyle received either a traditional impacted, or threaded allograft. Cartilage biopsies were taken from each allograft with additional biopsies from each knee for control measurements. Chondrocyte viability (percent living chondrocytes) was assayed using a live/dead stain and revealed that the screw-in graft led to significantly greater chondrocyte viability compared to the impaction method ($p < 0.001$).

To measure how well allograft threading could align the graft in the patient recipient site to match the surrounding articular surfaces, simulated grafts were threaded into a Sawbone model. The rotational deviation from a target surface alignment between the graft and patient was measured to quantify the accuracy with which the allograft could be placed in a patient. These deviation results indicated that the allograft could be placed within a vertical displacement range of ± 0.4 mm from the surrounding surface, which is well within the clinically accepted range of ± 2 mm. More importantly, however, the screw graft can be removed and adjusted. This reduces pressure on the surgeon to achieve perfect graft alignment on the first attempt as they can remove the graft and iteratively refine graft placement accuracy by trimming the subchondral bone until the graft is flush with the native patient cartilage.

The improved graft viability would promote better graft-host integration and improve procedure success rates. Moreover, since the surgeon can adjust the graft after insertion, it allows for easier graft placement and improved surface matching. When considering these improvements together, the threaded graft approach offers notable improvements over traditional OCA transplantation techniques.