301 - Tong - 30 - 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 hyaline cartilage and subchondral bone. OCA transplantation is typically performed on a young, athletic cohort for whom other cartilage repair techniques are incompatible with their lifestyle demands. 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*., JAAOS 2014).

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 is used to thread the prepared hole. The harvested allograft is placed in the guide fixture and a custom die is used to cut the matching threads on the graft. A small pronged device is then inserted into the allograft subchondral bone, acting as a screwdriver, to insert the allograft into the receiving site flush with the surrounding tissue.

Device Validation

This surgical system was tested on six fresh porcine knees: each condyle received an OCA transplantation with either the current impaction method, or with our novel threading system. Cartilage biopsies were taken from each allograft with additional biopsies taken from each knee for control measurements. Chondrocyte viability (percent living chondrocytes) was assayed using a live/dead stain and confocal microscopy and revealed that the screw-in graft yielded graft cartilage with significantly higher chondrocyte viability than the current impaction method ($p<0.05$).

Existing Surgical Systems

There are numerous options currently available for OCA transplantation surgical systems. Our method mirrors procedure themes found across all systems, but most closely reflects 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 to place the graft which has been shown to inhibit long-term grafting success. Our system departs from traditional impaction methods and instead employs a threading mechanism to prevent the detrimental effects of impaction on chondrocyte viability and graft integration.

Commercial Opportunity

OCA transplantation is becoming more prominent among the active young-adult population (20-50 years old) since osteochondral defects do not lend themselves well to other chondral repair procedures given patients' high expectations for recovery. Consequently, the number of OCA transplantation procedures performed is increasing by 5% annually with an expected 3500 procedures to be performed in 2020 (McCormick *et. al.*, Arthroscopy 2014). By avoiding impaction of the articular cartilage and preserving chondrocyte viability, our screw-in graft can promote improved long-term graft maintenance that exceeds that of currently available surgical systems.