

Preclinical Assessment of Bendable Osteochondral Allografts for Patellar Resurfacing

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INTRODUCTION: Osteochondral allograft (OCA) transplantation for joint restoration surgery continues to increase in use and success. However, limitations associated with OCA availability persist, especially for joint surfaces with wide variability in size, contour, and geometry such as the patella. To combat these hurdles in donor-recipient anatomy matching, a novel bendable OCA (BOCA) was developed and validated by *ex vivo* testing. Based on the favorable biomechanical properties of patella BOCA, preclinical testing in a valid animal model was used to assess clinical safety and efficacy with respect to compliance with US Food & Drug Administration (FDA) classification under section 361 of the Public Health Services Act in terms of donor tissue recovery and transport, processing and storage at a tissue bank, and transport for transplantation at a surgery center. For this purpose, we implemented an established canine model to test the hypothesis that recovery, transport, processing, storage in MOPS®, and transplantation of patellar BOCA would not compromise aseptis or chondrocyte viability while allowing for functional integration into recipients when compared to standard patellar shell OCAs.

METHODS: With IACUC approval (#16680), patellas (n=10) were aseptically recovered at the University of Missouri (MU, serving as the organ procurement organization [OPO]) from five adult purpose-bred research hounds (tissue donors) within 24 hours of humane euthanasia performed for reasons unrelated to the present study. Each patella was preserved in MOPS® media in individual containers and transported to Columbia University (CU, serving as the tissue bank). At CU, one patella from each pair was aseptically processed to machine linear grooves (2 mm in width) into the subchondral bone to allow for minor compression and expansion of the patella, creating a BOCA. The other patella from each pair was stored as a standard OCA. All patellas were preserved in MOPS for a total of 33 days. Patellas were transported back to MU (serving as the surgery center) for aseptic OCA transplantation surgery of both stifles (knees) in five adult purpose-bred research hounds (OCA transplant recipients) for complete patellar resurfacing in both knees. After trimming to a final thickness of ~4mm with a sagittal saw followed by subchondral drilling, thorough irrigation, and saturation of OCA bone with autogenous bone marrow aspirate concentrate, patellar OCAs were transplanted into each recipient patella such that each dog received a BOCA (N=5) and a standard Shell OCA (N=5), which were stabilized using bioabsorbable pins (**Figure 1**). Donor patellas were not size-matched to the recipients such that BOCAs were expanded or compressed and Shell OCAs were anatomically positioned for best fit. Dogs were recovered from surgery, provided analgesics and antibiotics, and restricted in activity for 1 month and then provided leash walking, socialization, and enrichment activities. Clinical assessments (i.e., forceplate kinetics, lameness, function, VAS pain, effusion and range of motion scores), radiographic assessments of integration and joint health, and chondrocyte viability analyses of patellar grafts were performed at 3 months post-transplantation. Data were compared for statistically significant differences using either paired t-test (forceplate kinetics, pain and effusion) or Wilcoxon signed-rank test (lameness, function, range of motion) with significance set at $p < 0.05$.

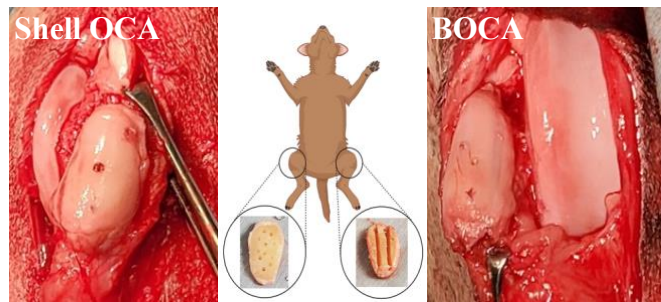


Figure 1: Representative images at surgery of standard shell (nongrooved, nonbendable) patellar allograft and grooved BOCA with machined linear grooves into the subchondral bone of a shell graft.

RESULTS: At 3 months after transplantation, pain and lameness scores were significantly more severe ($p=0.016$ and $p=0.034$, respectively) and function was significantly more compromised ($p=0.043$) for the BOCA knees compared to the Shell OCA knees. Effusion and range of motion metrics were not significantly different between cohorts. Dogs in the BOCA group had lower total pressure index (%TPI) in the affected hindlimbs at 3 months after treatment vs. Day 0 and at 3 months compared to Shell OCA group, but all comparisons were not significant. Radiographic and gross assessments of BOCAs revealed fissuring, fragmentation, and resorption with corresponding trochlear erosions, whereas Shell OCAs showed maintenance of graft articular cartilage integrity, tissue architecture with incorporation, and trochlear cartilage preservation (**Figure 2**). No microbial growth was found in cultures of remnant patellar allografts or MOPS® media samples at time of transplantation or in direct cultures of synovial fluid or patellar samples at 3 months post-transplantation. Viable chondrocytes were noted in all transplanted BOCA and Shell OCAs; however, BOCAs showed changes in cell phenotype and tissue remodeling, while Shell OCAs maintained hyaline cartilage morphology through 3 months after transplantation (**Figure 2 insets**).

DISCUSSION: While BOCAs were able to be safely and effectively recovered and transported, processed and stored, and transported for allograft tissue transplantation in compliance with FDA classification under section 361 of the Public Health Services Act in terms of donor tissue without compromising aseptis or chondrocyte viability, functional integration of BOCAs was not achieved in this preclinical canine model. Based on the fissuring and fragmentation mode of failure noted in BOCAs, the size and number of the machined grooves are being optimized for further preclinical testing such that the potential advantages of bendable OCAs can be realized without compromising their integrity and osteointegration during healing.¹

SIGNIFICANCE/CLINICAL RELEVANCE: Bendable osteochondral allografts can be recovered, machined, stored, shipped, and transplanted to maintain aseptis and chondrocyte viability, but further optimization is required in order to result in effective integration and joint function.

REFERENCE: ¹Peterson CA et al. *Journal of Biomechanics* (2022)

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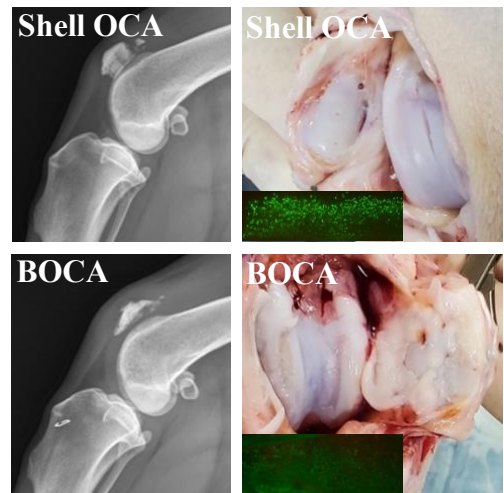


Figure 2: Representative radiographic and gross images of stifles implanted with shell patellar allografts and grooved BOCAs at 3-month post-implantation. **Insets:** Cell viability of respective patellar allografts.