ZIMMER BIOMET

Osteochondral Allograft (OCA) Kit

ADVANCING THE SCIENCE OF CARTILAGE REPAIR

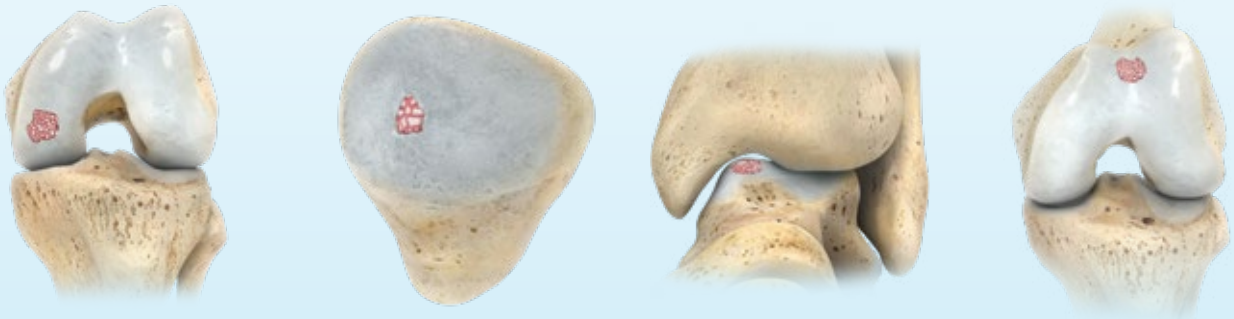
OSTEOCHONDRAL ALLOGRAFT (OCA) KIT

Zimmer Biomet's OCA Kit is an osteochondral allograft containing fresh young allograft cartilage and cancellous chips for treatment and repair of osteochondral deficiencies that can occur in multiple anatomic locations, such as the knee, hip, ankle and upper extremities. It allows for a single-stage procedure with fibrin fixation, eliminating the need for harvesting autograft or a periosteal flap - thereby reducing donor site morbidity and saving time in the OR.

The kit offers an Early Intervention option that can limit the need for further surgical intervention and potentially divert the progression of these lesions.

Advantages:

- Includes young allograft cartilage, which contains 10x greater chondrocyte density than adult tissue and does not elicit an allogeneic immune response[1-3]
- Implanted in a single-stage procedure with fibrin fixation - no need to harvest a periosteal flap, tissue or cells from areas of undamaged cartilage
- Survivorship at 5 years 85% in knee and 89% in ankle[4,5]
- Significantly reduce pain and improve function for at least 5 years[4,6]



Cartilage Injury and Treatment

There are over 600,000 cartilage procedures performed in the US annually.[7] Some of the clinical challenges with these procedures are the variation in size and severity of the lesions and the fact that spontaneous cartilage repair rarely happens due to no blood vessels and low cell density in cartilage.[8]

The OCA Kit cartilage graft consists of young living articular cartilage, which displays beneficial properties similar to those of articular cartilage found in young, healthy joints. The modular graft makes it possible to address deficiencies of various sizes and shapes.

Young Allograft Cartilage Tissue

In comparison with using adult articular cartilage, which has limited capacity for self-repair[9], young living articular cartilage contains 10x greater chondrocyte density than adult tissue and does not elicit an allogeneic immune response.[1-3]

Comparison of Young versus Adult Bovine Cartilage[9]

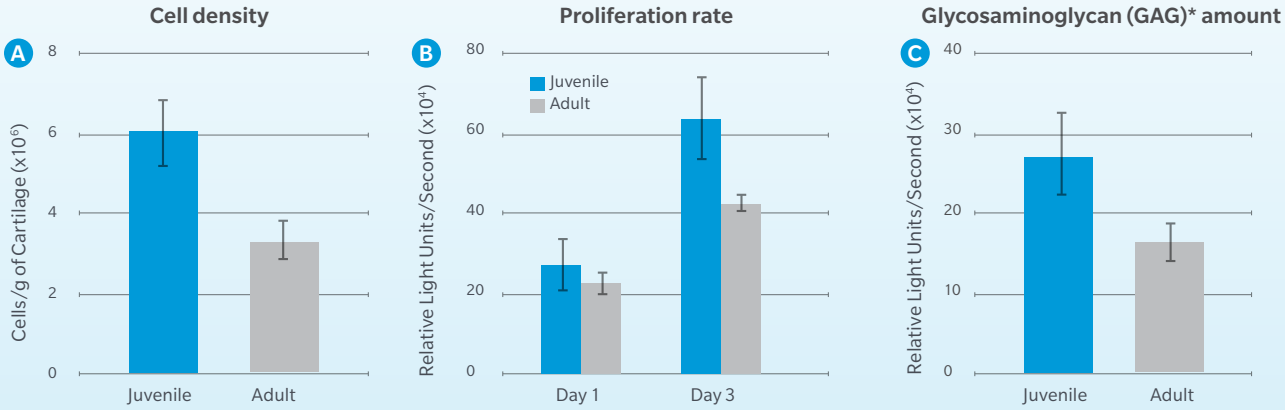
A study comparing young versus adult bovine cartilage demonstrated:

A. Juvenile bovine cartilage has significantly higher cell density than adult cartilage ($p<0.05$)

B. Juvenile bovine chondrocytes have significantly higher proliferation rate than adult chondrocytes (Day 3, $p<0.01$)

C. Juvenile chondrocytes synthesize significantly greater amount of glycosaminoglycan (GAG)* than adult chondrocytes ($p<0.05$)

Young versus adult bovine cartilage**



A naturally occurring carbohydrate found in cartilage and is used as a biomarker that indicates chondrocytes' matrix generating potential.
*** Human cartilage may not repsond the same as bovine cartilage.*

CLINICAL EXPERIENCE

Zimmer Biomet's Young Allograft Cartilage

Zimmer Biomet's young allograft cartilage has been used to treat focal defects in a wide range of anatomical applications, including:

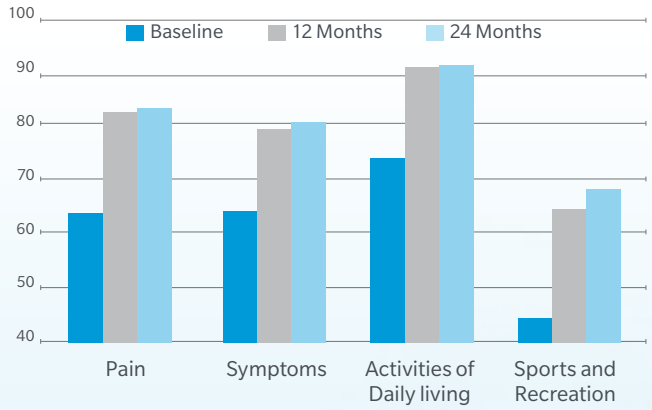
- Knee (i.e., condyle, trochlea, patella, tibial plateau)
- Foot and ankle (i.e., talus, MPJ)
- Elbow
- Shoulder (i.e., humeral head, glenoid)
- Hip (i.e., acetabulum, femoral head)

Zimmer Biomet Longitudinal studies in the knee and ankle demonstrated 85% and 89% graft survivorship at 5 years respectively.[4,5]

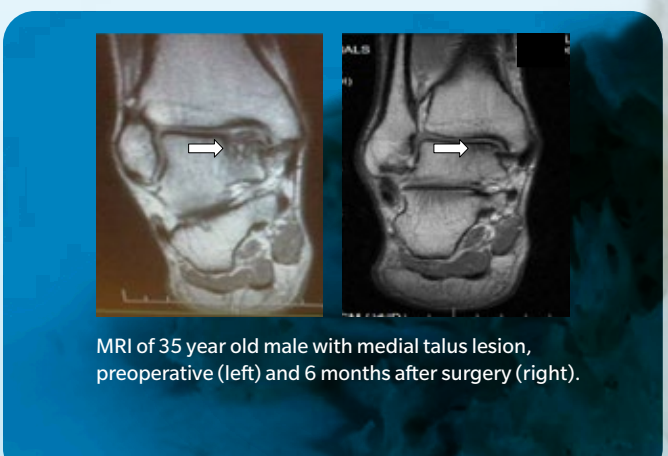
SURVIVORSHIP AT 5 YEARS

Clinical trials on Zimmer Biomet's young allograft cartilage in both the ankle and knee demonstrate significant improvement in patient reports of pain, function and activity scores (KOOS, AOFAS, FAAM, VAS pain scales).[6,11,12]

Patient reported KOOS sub scores of independent study utilizing Zimmer Biomet young allograft cartilage to treat lesion in the knee[6]



Outcome scores in 25 knee patients 24 months following implant of Zimmer Biomet's young allograft cartilage. Significant improvement over baseline is seen for pain, symptoms, functions and sports ($p<0.05$).



MRI of 35 year old male with medial talus lesion, preoperative (left) and 6 months after surgery (right).

Comparing Cartilage Defect Repair Treatment Alternatives

	Defect Characteristics	Tissue Characteristics	Procedure Characteristics
Autologous Chondrocyte Implantation (ACI)	Chondral femoral defects; routinely 5 to 10 cm^2	Adult autologous chondrocytes	One or two-stage surgical procedure, fixation from scaffold or cover subsequent reoperations common[5]
Bone Marrow Stimulation*	Chondral; limited treatment area < 2 cm^2	No tissue implanted, fibrous repair tissue[6-7]	Single stage surgery, simple technique, may be done arthroscopically
Osteochondral Autograft	Osteochondral; limited treatment area < 2 cm^2	Adult autologous tissue from non-weight bearing surface	Single stage complex procedure, perpendicular access to defect required, donor site morbidity
Osteochondral Allograft	Osteochondral; large defects > 2 cm^2	Adult allograft tissue, risk of disease transmission, typical wait period for graft availability	Single stage complex procedure, perpendicular access to defect required
Micronized Cartilage Matrix (BioCartilage®)	Chondral; limited treatment area < 2 cm^2	Dehydrated, micronized adult cartilage	Single stage surgery, augment to bone marrow stimulation procedures, no published clinical evidence
OCA Kit	Osteochondral defects up to 5 cm^2	Juvenile (≤ 13 yrs) hyaline cartilage	Single stage surgery, simple technique with fibrin fixation, may be done arthroscopically, used in multiple joints including knee (patellofemoral & condyle)

** e.g., debridement, microfracture, chondroplasty, subchondral drilling, etc.*

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