

Novel Procedure using Viable Allograft for Focal Cartilage Defects

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Considerations for Chondral Lesions

MARROW STIMULATION

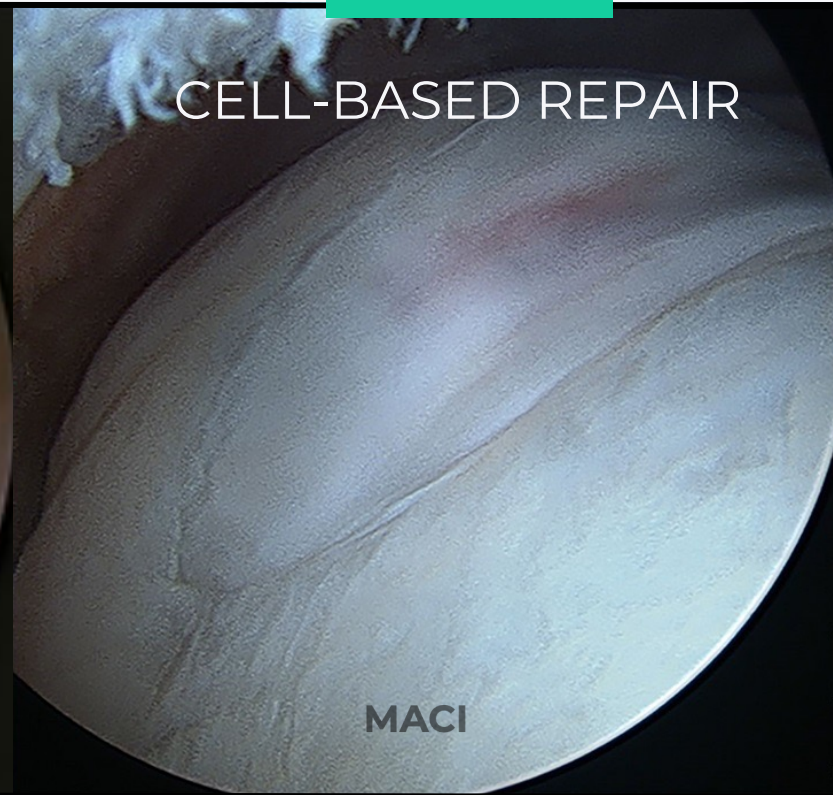
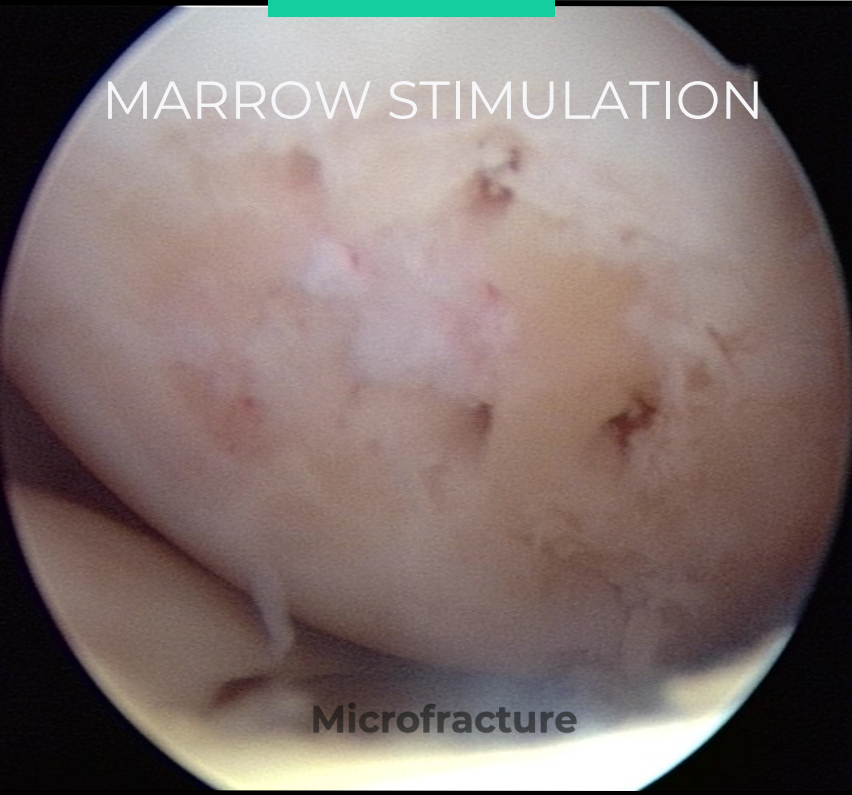
Microfracture

OSTEOCHONDRAL
RESTORATION

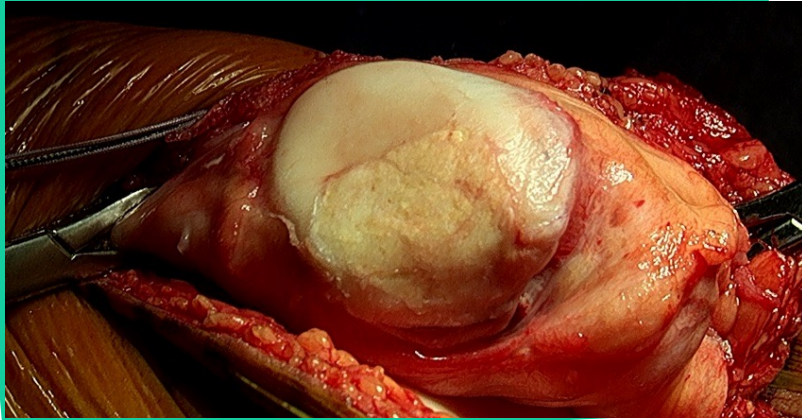
OATS/mosaicplasty

CELL-BASED REPAIR

MACI



Viabile Cartilage Allograft



- Hyaline cartilage fibers are cryopreserved
- Aseptically processed



Thawed at room temperature



Cartilage fibers are rinsed with normal saline



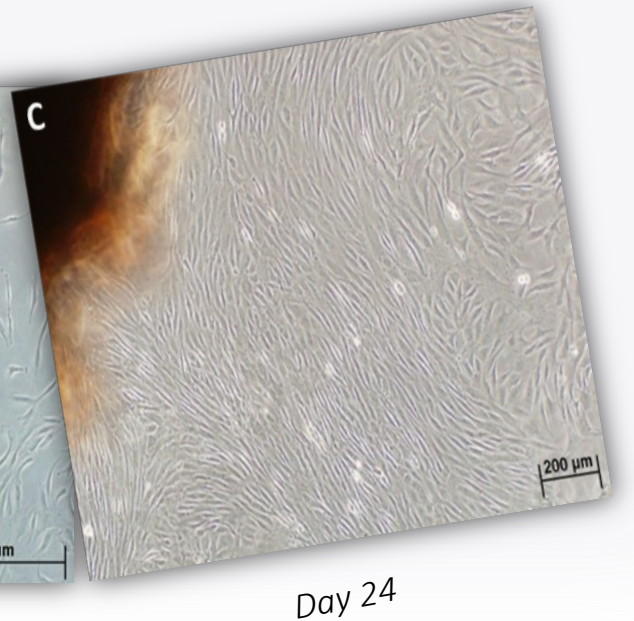
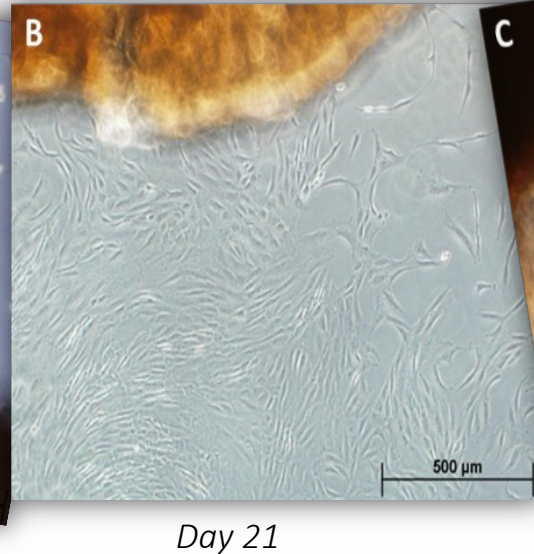
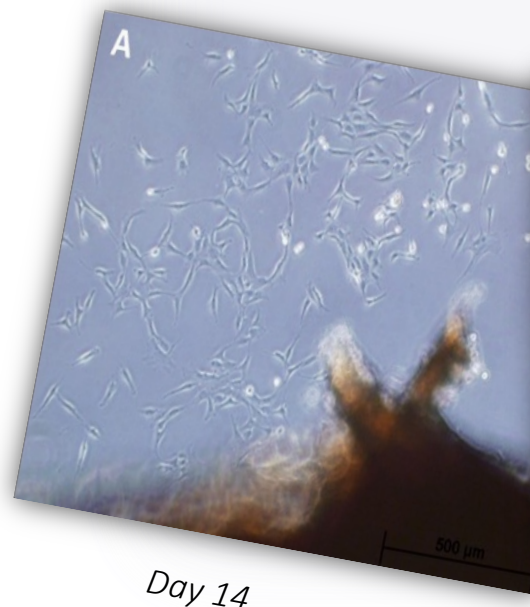
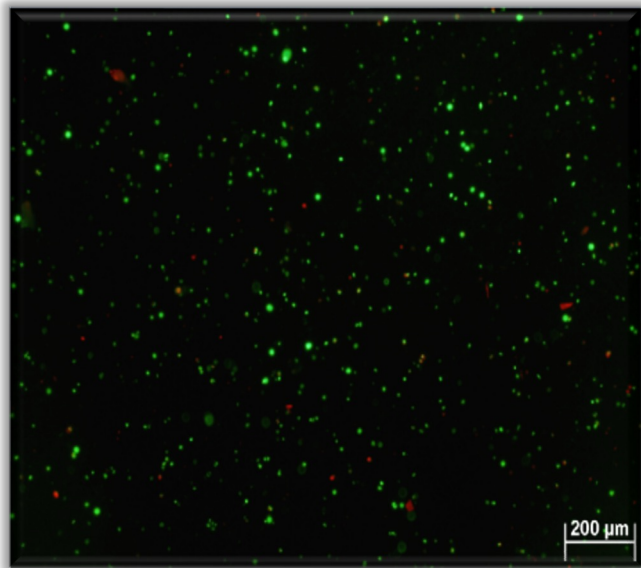
Mixed with cartilage allograft matrix to form a putty-like material



Molded to fill cartilaginous defects up to 5cm² while matching the articular surface contour

In-vitro Viability Assessment

- Cryopreserved chondrocytes within cartilage fibers demonstrated **87% cell viability** after thawing
- Further demonstration of survival at 12 months with proliferation and confluency on tissue medium



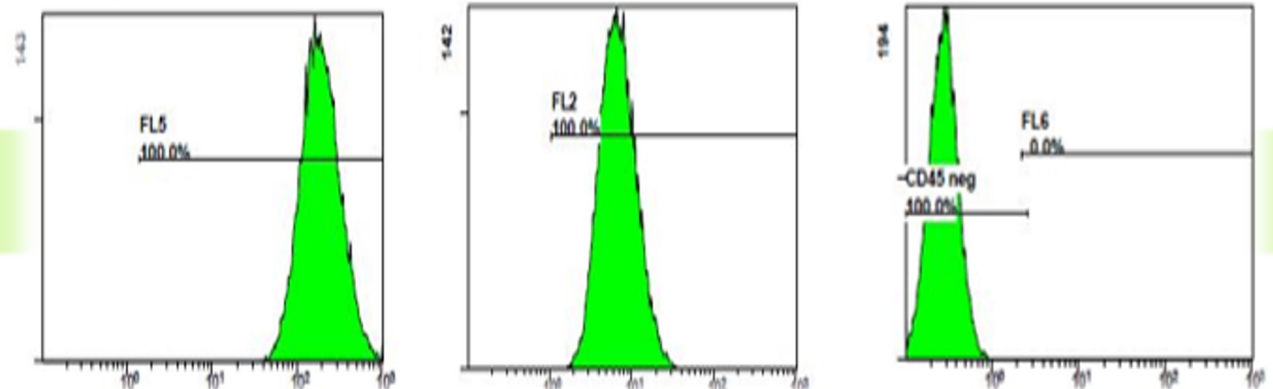
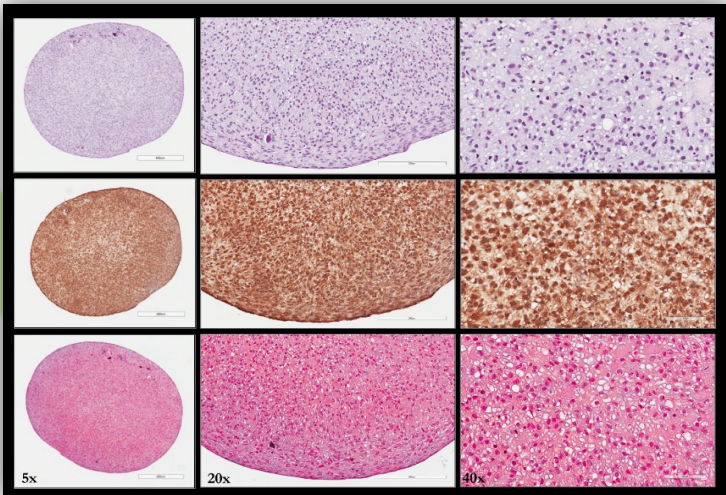
Viability Cartilage Allograft

VIABILITY CHARACTERIZATION

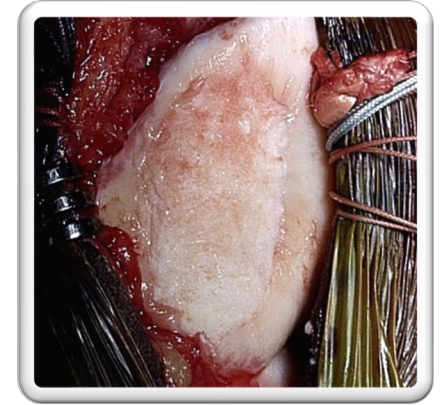
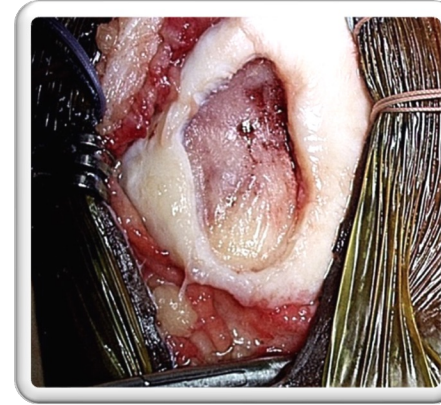
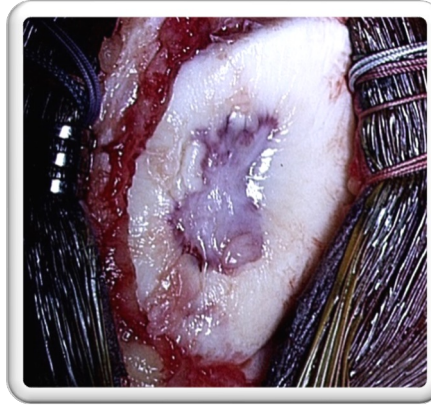
- Viable cartilage fibers stored 6-12 months -79°C
- Post-thaw viable chondrocytes
 - Migrating & proliferating
 - Functional viable cells
- Viable cartilage fibers produced:
 - Collagen II
 - Proteoglycans

CELLULAR CHARACTERIZATION

- Normal chondrocytes express:
 - CD44 + CD49e (CD45 unviable)
- Cells from cryopreserved viable cartilage fibers expressed:
 - CD44 + CD49e
 - No CD45
- Homogenous population of chondrocytes



Methods



STUDY PURPOSE

- To evaluate the safety and performance of VCA through preclinical and clinical studies.
- To evaluate patient outcome scores after hyaline cartilage restoration through a single-stage procedure
- Prospective case series
- ICRS grade 3 or 4 focal unipolar chondral defects of the patella, MFC, or LFC (Aug 2018 – Jan 2020)
- VCA treatment performed by senior sports medicine trained surgeon
- Outcome measures: IKDC, Tegner, Lysholm, KOOS, SF-12
- Radiographic + MR monitoring

Methods

POST-OPERATIVE PROTOCOL

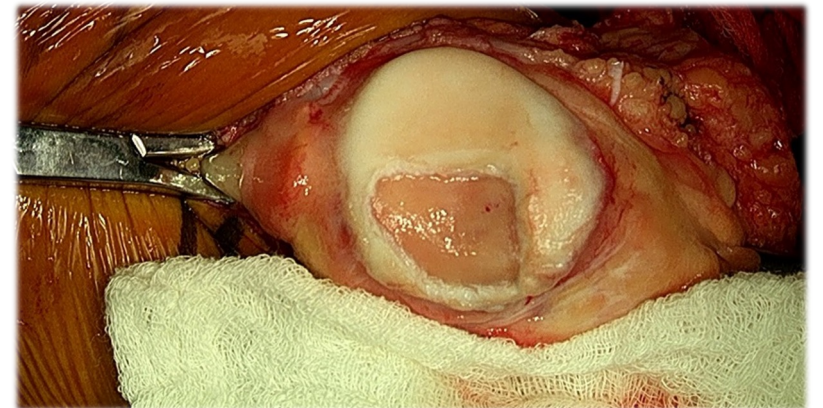
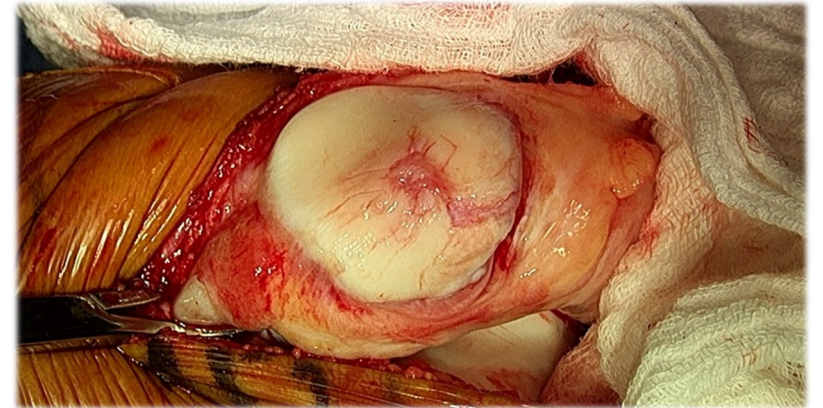
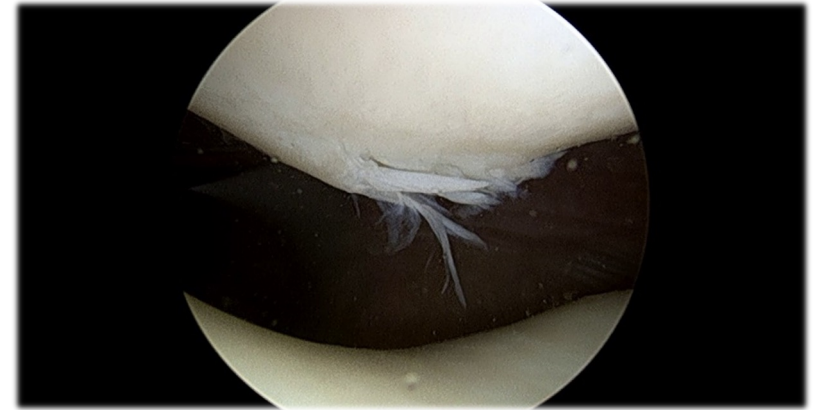
- ROM restricted post op x 6d in HKB locked at 10 degrees hyperextension → CPM initiated POD7 x 4 wks
- Patellofemoral lesions remained locked in extension x 6 wks
- Open chain activity limited x 3 months post op
- TTWB (25%) post op □ 50% WB wks 2-4 → 100% WB at 6 wks
- Full flexion initiated at 6 wks
- Running initiated 3 months
- Sport-specific training at 4-6 months

OUTCOME MEASURES

- Pre-op and Post-op 6wk, 3mo, 6mo, 12mo, 18mo, 24mo+
- Paired samples t-test using SAS v9.4 with alpha set at 0.05
- Primary outcome measure: clinically significant improvement >12 points on KOOS subscales

Results

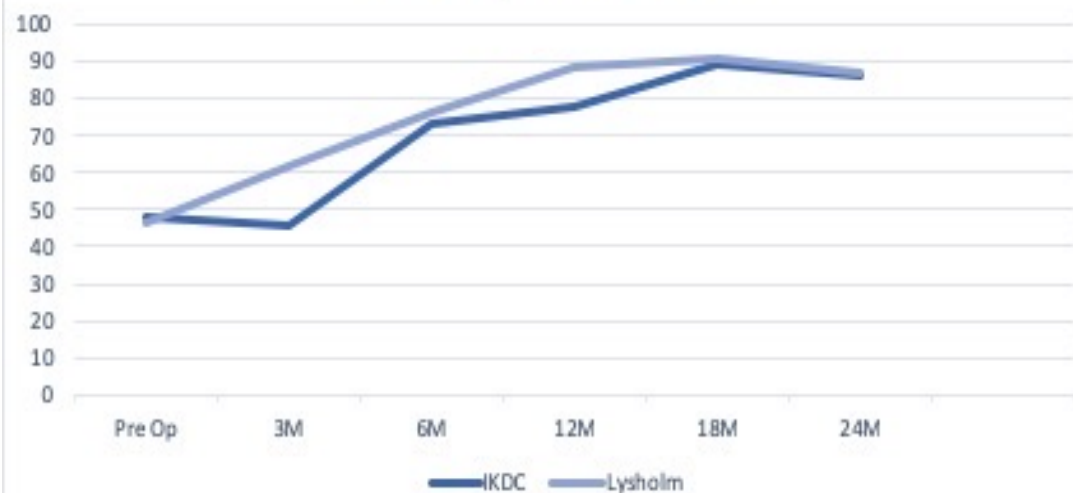
- 20 knees (11 F, 9M)
- Mean clinical follow-up 24.1 months (12–36 months)
- Mean age 28.1 yrs; Mean BMI 27.9
- Mean defect size 4.58cm²
- 60% patella, 15% MFC, 10% LFC, 10% multiple, 5% Trochlea
- 70% Grade 4A, 20% Grade 3, 10% grade 4B



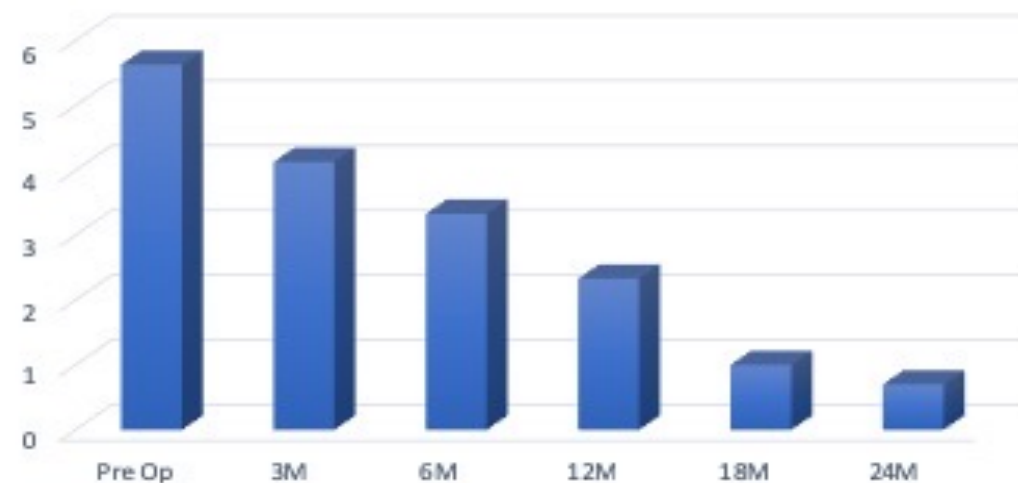
Patient-Reported Outcome Scores

Mean functional score difference between pre-operative and at final follow-up			
	Mean Pre-op score	Mean Final score	p-value
MSF-12	48.77 ± 14.0	55.64 ± 11.7	0.0588
PSF-12	37.30 ± 9.0	51.28 ± 8.8	0.0002
KOOS	49.51 ± 15.2	72.51 ± 24.4	0.0013
KOOS Symptom	56.43 ± 17.5	84.92 ± 16.1	<0.0001
KOOS Pain	62.59 ± 16.3	91.72 ± 17.3	<0.0001
KOOS ADL	66.27 ± 18.6	93.80 ± 16.1	<0.0001
KOOS Sports	30.33 ± 28.7	84.45 ± 27.7	<0.0001
KOOS QOL	31.70 ± 24.8	81.30 ± 20.8	<0.0001
Lysholm	50.47 ± 21.5	87.23 ± 15.0	<0.0001
IKDC	42.14 ± 14.9	86.24 ± 17.2	<.00001

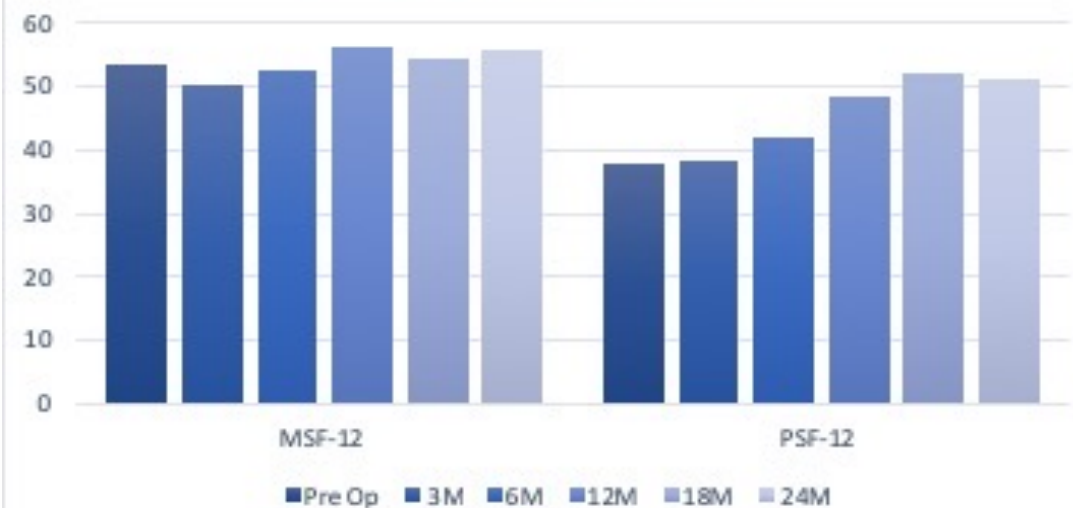
IKDC & Lysholm Scores



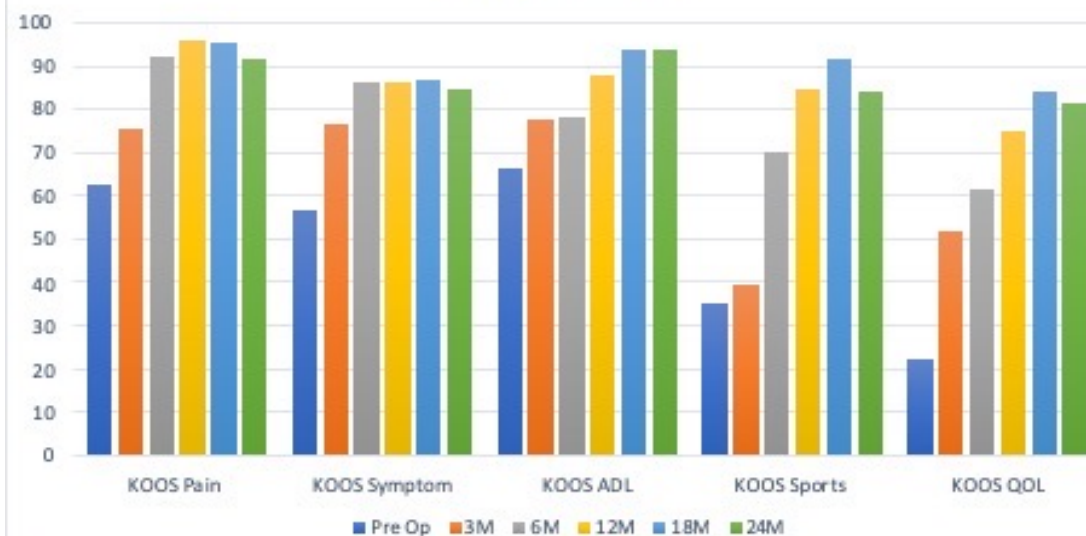
Knee Pain Frequency



MSF-12 & PSF-12 Scores

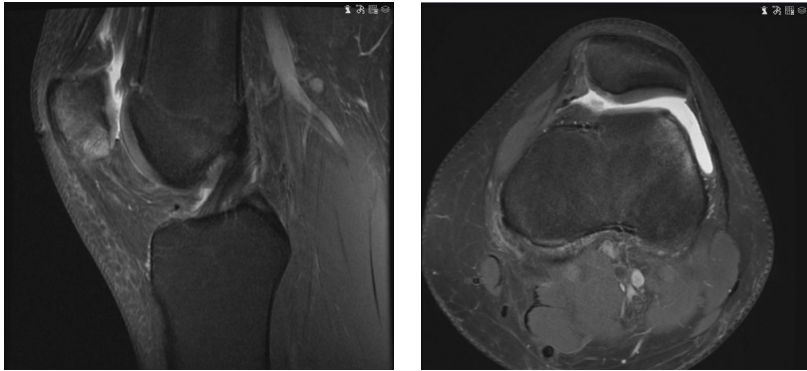


KOOS Subscales



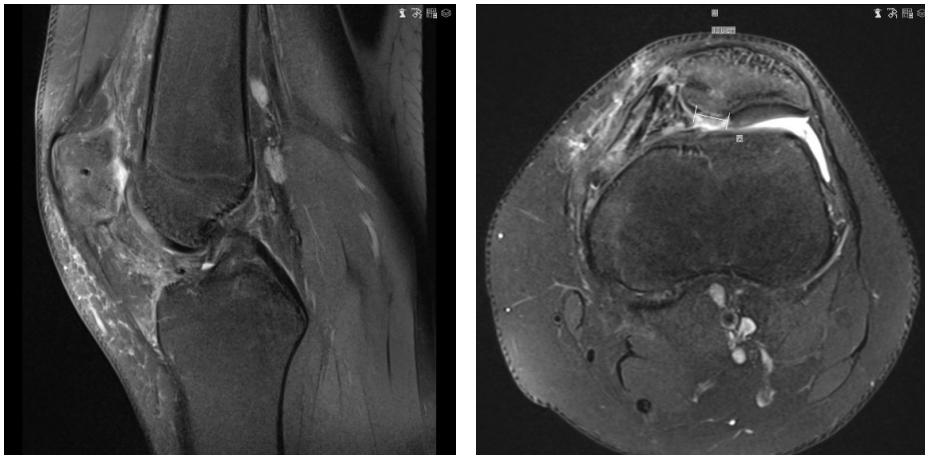
Radiographic Follow-Up

PRE-OPERATIVE

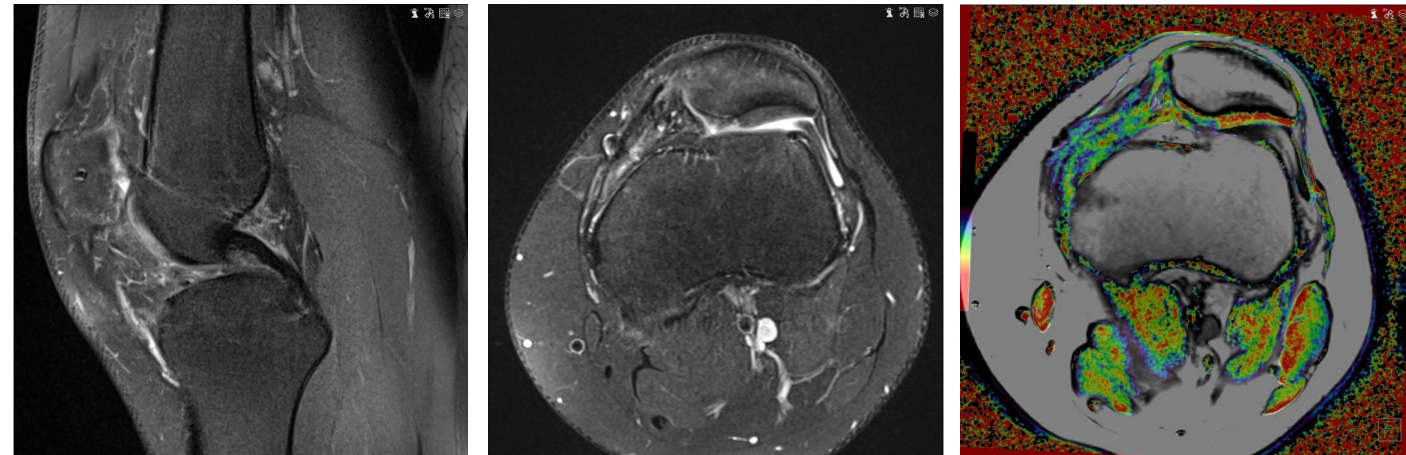


- 100% had evidence of allograft incorporation
- Average MOCART 2.0 score **63.3**
- Improved degree of intrasubstance signal heterogeneity + minimal underlying subchondral edema

3 MONTHS



6 MONTHS



Key Findings

- The first cohort to date with mean 2-year post-operative outcome scores and radiographic follow up of VCA allograft solution for cartilage repair
- Viability
 - In-vitro VCA characterization
 - Animal study safety characterization
 - Clinical study demonstrated improvement in functional outcomes

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