

# Novel Procedure Using Viable Allograft for Focal Cartilage Defects

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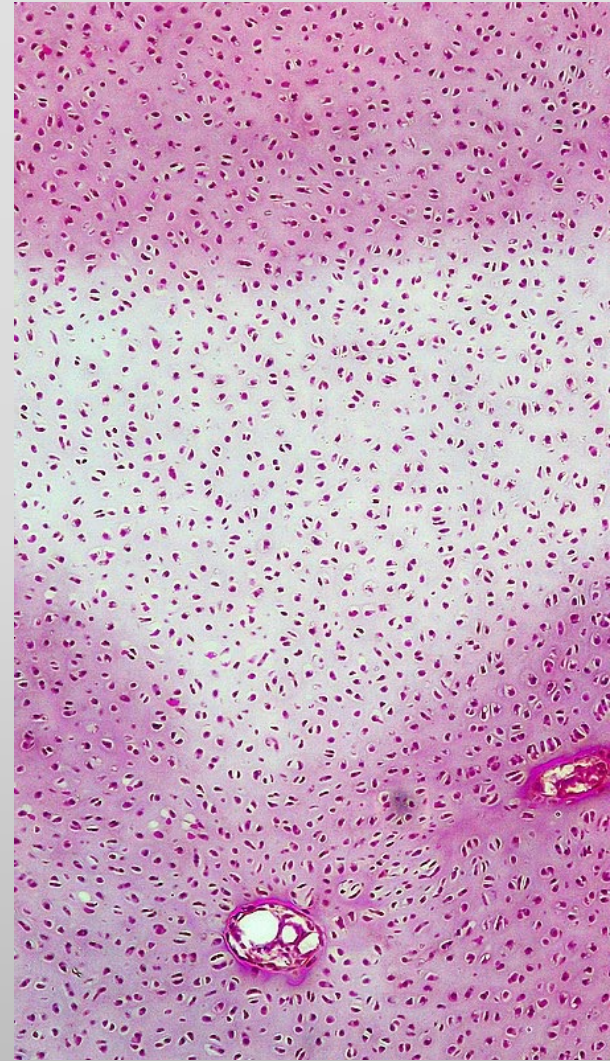


# Disclosures

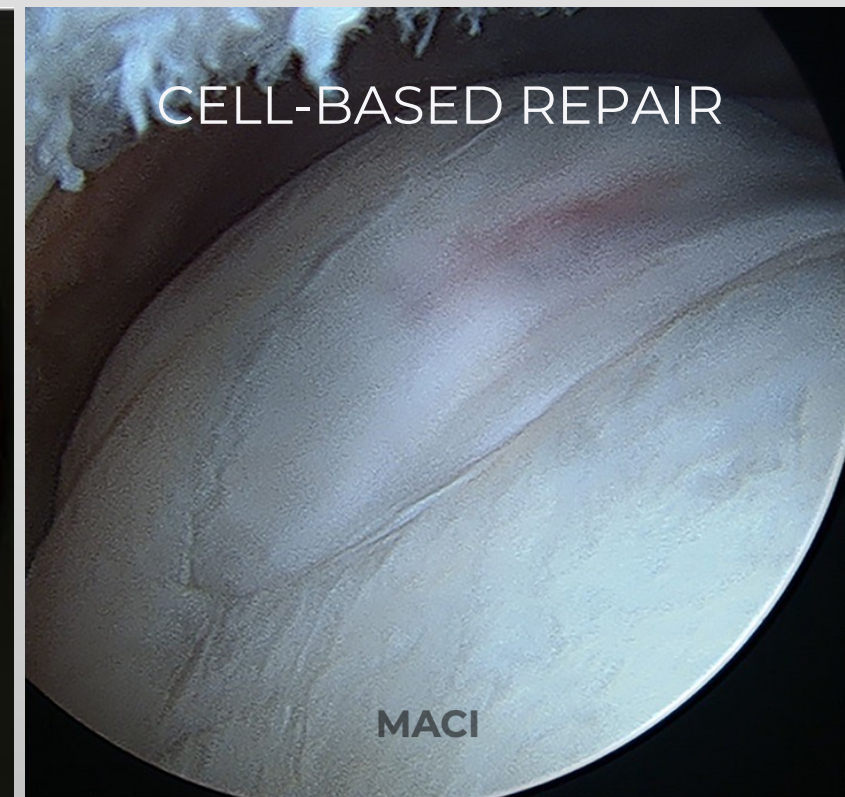
- Authors
  - Consultant
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    - Depuy/ Mitek
    - Zimmer
  - Fellowship Support
    - Arthrex
    - Smith and Nephew
    - Conmed
    - Mitek
- Please see meeting guide for full list of disclosures

# Chondral Defects

- Complex architecture of hyaline cartilage
- Synergistic interactions of ECM proteins+ chondrocytes-->organized chondral repair and regeneration
- Goals of surgical treatment: replace or restore damaged cartilage
- Treatment strategies considerations:
  - Age and activity level
  - Location and size of defect
  - Meniscal status
  - Limb alignment
  - Concomitant pathology
  - Comorbidities



# Considerations for Chondral Lesions



## OSTEOCHONDRAL ALLOGRAFT TRANSPLANTATION (OCA)

- Single-stage, biomechanically stable, large lesions
- Potential for rejection
- Risk of graft failure in older patients with prior knee surgery

## MATRIX-ASSOCIATED CHONDROCYTE IMPLANTATION

- 1<sup>st</sup> line treatment
- Excellent results at long term follow up
- Requires 2-staged surgery

## Ideal Procedure

- Type II collagen regeneration
- Staging
- Lesion size/location
- Pricing
- Ease of use



## OSTEOCHONDRAL AUTOGRAFT TRANSFER (OATS)

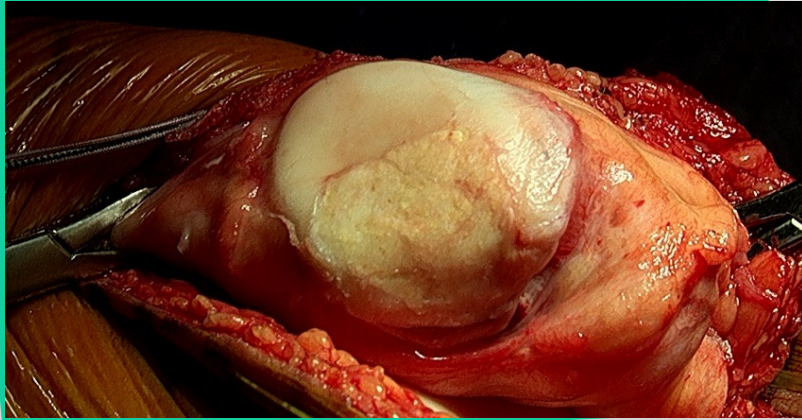
- Biomechanically stable autologous hyaline cartilage
- Potential donor site morbidity & fibrocartilage formation at plug periphery

## MICROFRACTURE

- Ideal for small lesions
- Single-stage, arthroscopic
- Autologous fibrocartilaginous cells  
Concerns regarding durability

- Single-stage option
- Variable sized lesions
- Easy-to-handle material
- Biomechanically stable
- Type II collagen regenerated

# 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 5cm<sup>2</sup> while matching the articular surface contour**

# Basic Science



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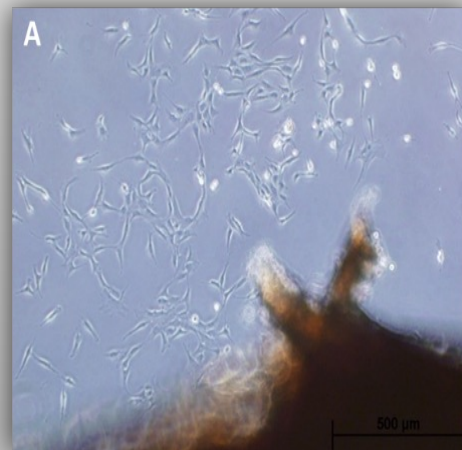
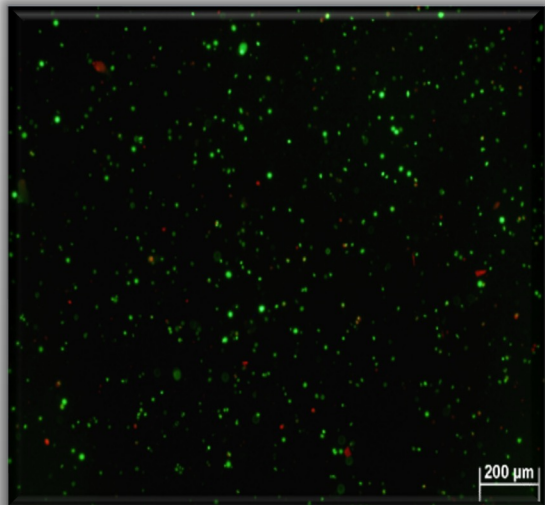


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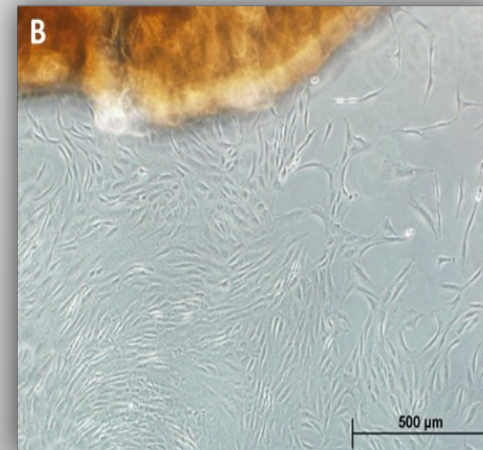


# In-Vitro Viability Assessment

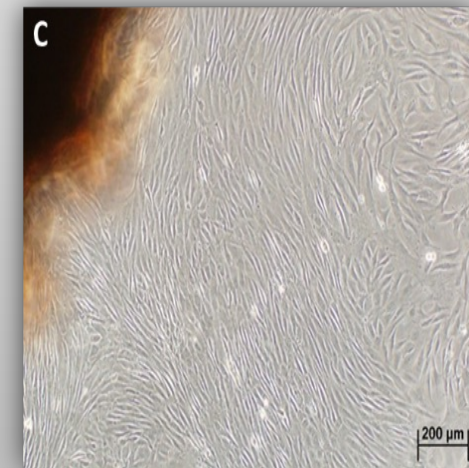
- Cryopreserved chondrocytes within cartilage fibers demonstrated **87% cell viability** after thawing
- Further demonstration of survival at 12 months with proliferation and confluency on tissue medium



Day 14



Day 21



Day 24



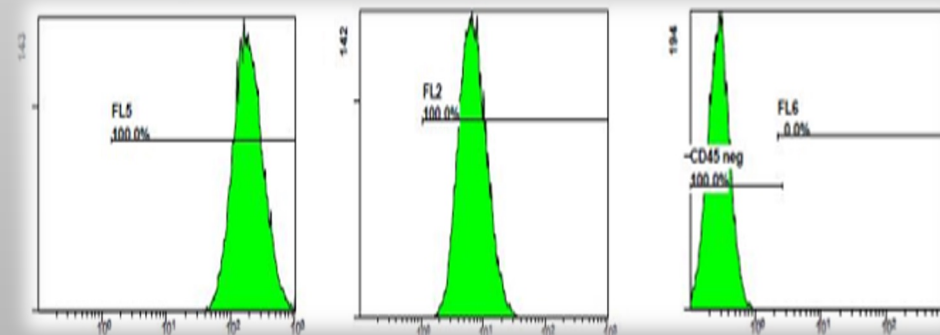
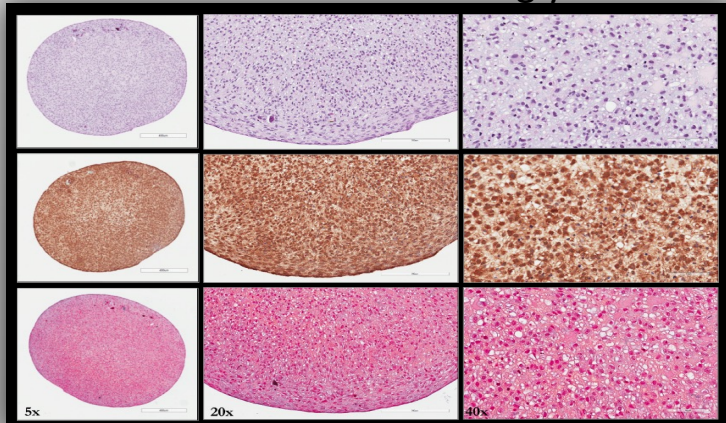
# Viability Cartilage Allograft

- Viability Characterization

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



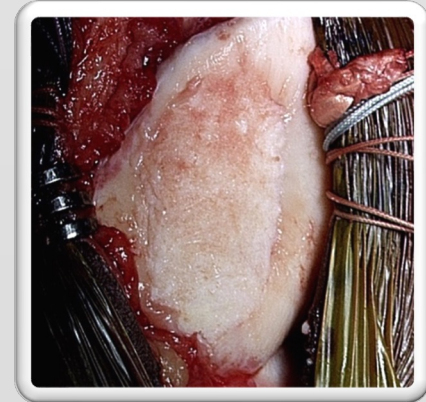
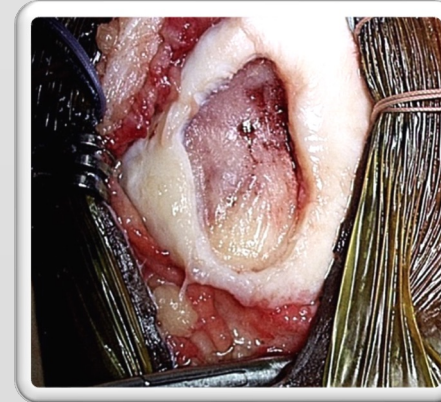
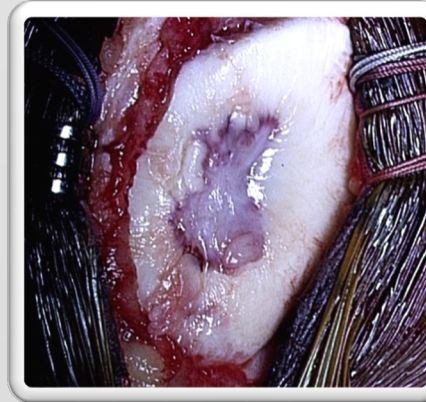
# Clinical Study



# 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
- Hypothesis → VCA is a safe single stage procedure for isolated chondral defects with results comparable or better than other single stage procedures

# Methods



- IRB approved prospective case series
- ICRS grade 3 or 4 focal unipolar chondral defects of patella, MFC or LFC (August 2018- January 2020)
- VCA treatment performed by senior sports medicine trained surgeon
- All patients followed standardized post operative protocol
- Outcome Measures:
  - IKDC, Tegner, Lysholm, KOOS, SF-12
  - Collected at pre-op and post op:
    - 6wk, 3mo, 6mo, 12mo, 18mo, 24+mo
  - Primary outcome measure:
    - Clinically significant improvement >12 points on KOOS subscales
- Radiographic + MR monitoring (MOCART)

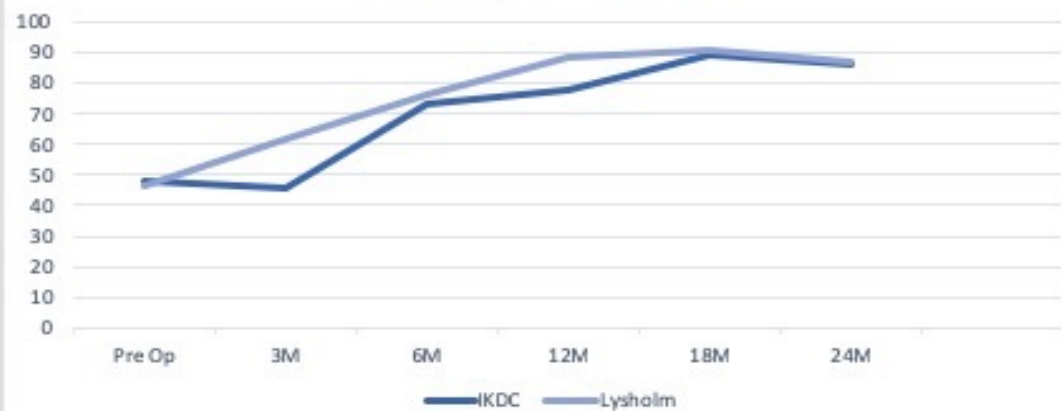
# Results

- 20 Knees (11 F, 9 M)
- Mean clinical follow-up 24.1 months (12-36 months)
- Mean age 28.1 yrs; Mean BMI 27.9
- Mean defect size 4.58 cm<sup>2</sup>
- 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	<b>0.0002</b>
KOOS	49.51 ± 15.2	72.51 ± 24.4	<b>0.0013</b>
KOOS Symptom	56.43 ± 17.5	84.92 ± 16.1	<b>&lt;0.0001</b>
KOOS Pain	62.59 ± 16.3	91.72 ± 17.3	<b>&lt;0.0001</b>
KOOS ADL	66.27 ± 18.6	93.80 ± 16.1	<b>&lt;0.0001</b>
KOOS Sports	30.33 ± 28.7	84.45 ± 27.7	<b>&lt;0.0001</b>
KOOS QOL	31.70 ± 24.8	81.30 ± 20.8	<b>&lt;0.0001</b>
Lysholm	50.47 ± 21.5	87.23 ± 15.0	<b>&lt;0.0001</b>
IKDC	42.14 ± 14.9	86.24 ± 17.2	<b>&lt;.00001</b>

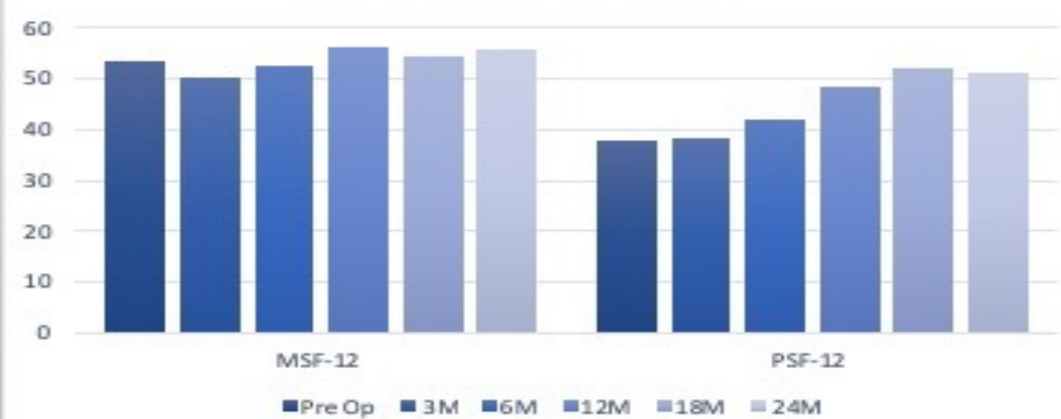
### IKDC & Lysholm Scores



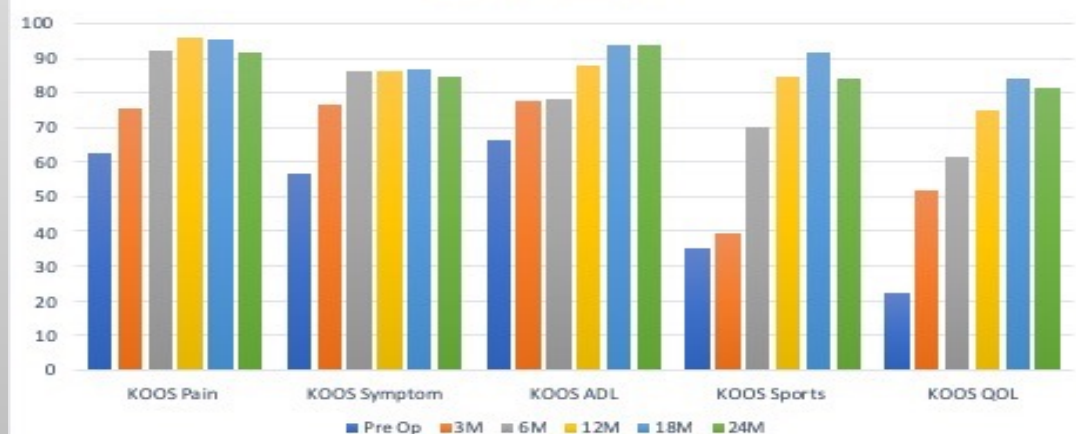
### Knee Pain Frequency



### MSF-12 & PSF-12 Scores

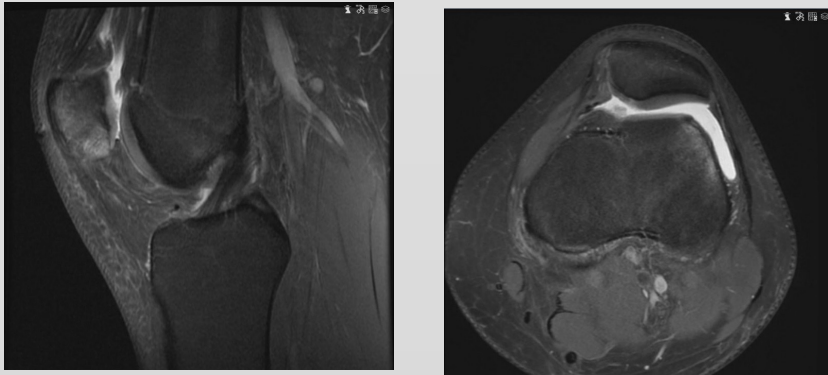


### KOOS Subscales



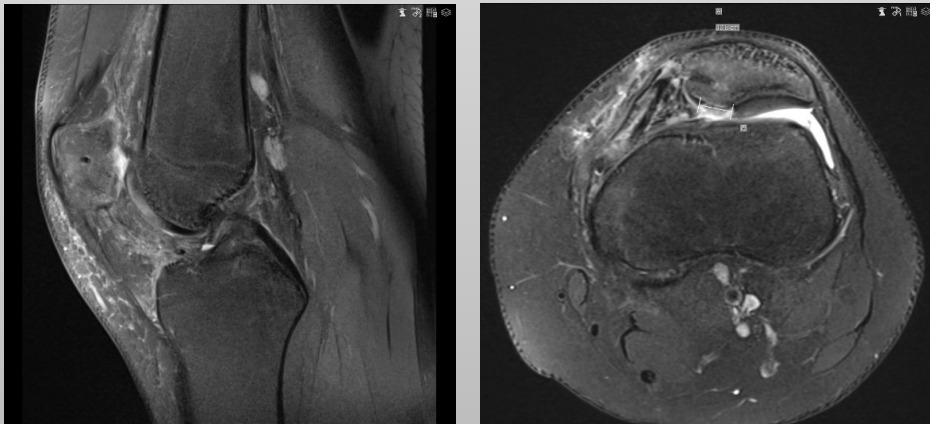
# Radiographic Follow- Up

## Pre-Operative

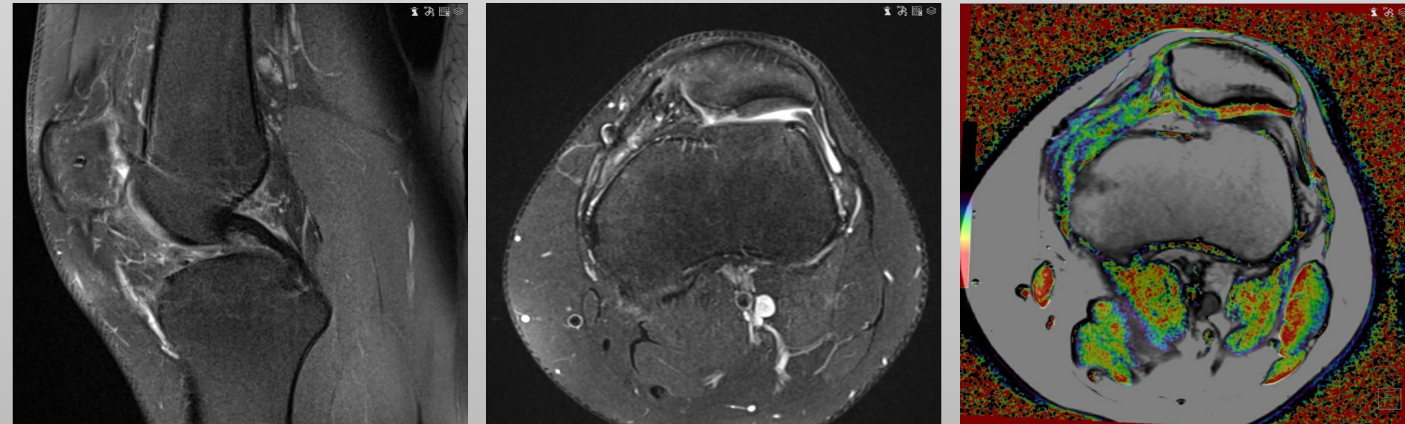


- 100% had evidence of allograft incorporation
- Average MOCART 2.0 score 63.3
- Improved degree of intrasubstance signal heterogeneity+ minimal underlying subchondral edema

## 3 Months



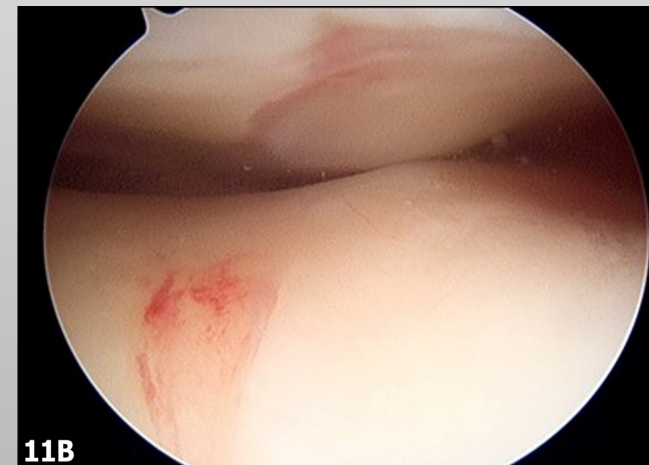
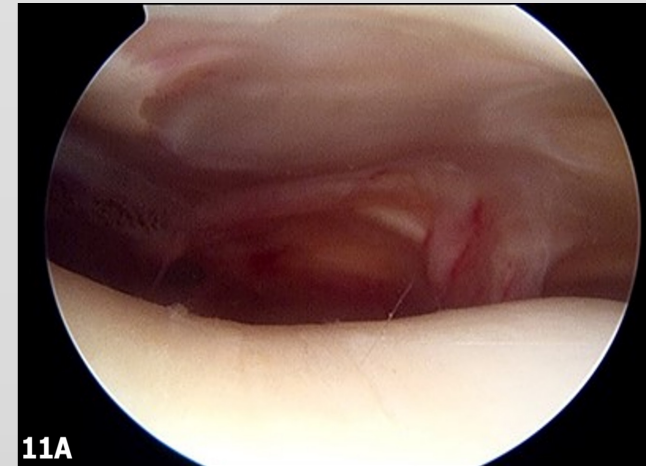
## 6 Months





# Second Look Arthroscopy

- Patient requiring lysis of adhesions at 3 months post op
- Brittberg score 11/12
- Excellent early incorporation into native cartilage with retained contour and no delamination



# Conclusion

- Novel VCA with significant improvements in post-operative outcome scores with mean 2-year follow up
- Good radiographic and arthroscopic incorporation of graft
- Potential benefits:
  - Cartilage fibers + allograft matrix shown in vitro to have viable chondrocytes
  - Putty-like handling properties to chondral defects of variable size in single stage
- Future studies
  - Compare with OATS, OCA, and MACI