Novel Procedure using Viable Allograft for Focal Cartilage Defects

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Considerations for Chondral Lesions

- Marrow Stimulation
- Osteochondral Restoration
- Cell-Based Repair

Microfracture
OATS/mosaicplasty
MACI
Viable 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.
Viable 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
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, 9 M)
- Mean clinical follow-up 24.1 months (12–36 months)
- Mean age 28.1 yrs; Mean BMI 27.9
- Mean defect size 4.58cm$^2$
- 60% patella, 15% MFC, 10% LFC, 10% multiple, 5% Trochlea
- 70% Grade 4A, 20% Grade 3, 10% grade 4B
Patient-Reported Outcome Scores

<table>
<thead>
<tr>
<th></th>
<th>Mean Pre-op score</th>
<th>Mean Final score</th>
<th>p-value</th>
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<tbody>
<tr>
<td>MSF-12</td>
<td>48.77 ± 14.0</td>
<td>55.64 ± 11.7</td>
<td>0.0588</td>
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<tr>
<td>PSF-12</td>
<td>37.30 ± 9.0</td>
<td>51.28 ± 8.8</td>
<td><strong>0.0002</strong></td>
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<tr>
<td>KOOS</td>
<td>49.51 ± 15.2</td>
<td>72.51 ± 24.4</td>
<td><strong>0.0013</strong></td>
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<td>KOOS Symptom</td>
<td>56.43 ± 17.5</td>
<td>84.92 ± 16.1</td>
<td>&lt;<strong>0.0001</strong></td>
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<tr>
<td>KOOS Pain</td>
<td>62.59 ± 16.3</td>
<td>91.72 ± 17.3</td>
<td>&lt;<strong>0.0001</strong></td>
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<td>KOOS ADL</td>
<td>66.27 ± 18.6</td>
<td>93.80 ± 16.1</td>
<td>&lt;<strong>0.0001</strong></td>
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<td>KOOS Sports</td>
<td>30.33 ± 28.7</td>
<td>84.45 ± 27.7</td>
<td>&lt;<strong>0.0001</strong></td>
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<td>KOOS QOL</td>
<td>31.70 ± 24.8</td>
<td>81.30 ± 20.8</td>
<td>&lt;<strong>0.0001</strong></td>
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<td>Lysholm</td>
<td>50.47 ± 21.5</td>
<td>87.23 ± 15.0</td>
<td>&lt;<strong>0.0001</strong></td>
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<td>IKDC</td>
<td>42.14 ± 14.9</td>
<td>86.24 ± 17.2</td>
<td>&lt;<strong>0.0001</strong></td>
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</table>
Radiographic Follow-Up

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

**PRE-OPERATIVE**

**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
References