MENISCAL SCAFFOLDS

2014 Update

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Disclosure:
The Following Relationships Exist

• Consult
  – Pierce Surgical
  – Cayenne Medical
  – Orteq
  – Parcus Medical
  – Zimmer
  – Ceterix

• Research and education support - none
Meniscus Preservation

• *Patients want to know will be used to replace tissue that is removed?*

• Ideally, replacing lost tissue would:
  – Re-establish normal joint load transmission
  – Prevent DJD

• Some patients develop pain following a meniscectomy
Option #1: Meniscal Allograft

• Replace entire meniscus
  – Remove remaining normal tissue

• Large operation
  – Mini-open & bone-tunnels

• Donor matching

• Disease transmission & immune reactions
Option #2: Meniscal Scaffolds

- **Not** currently approved for use in USA

- Used in Europe, Asia & South America
Option #2: Meniscal Scaffolds

- No allograft tissue
- Off-the-shelf device
- No bone tunnels required
- Procedure ~ like repairing bucket handle
- Replaces only excised portion of meniscus
Meniscal SCAFFOLDS

• Do not provide mature tissue immediately
• Support cellular & vascular ingrowth
• Enable physiologic replacement of lost tissue
Scaffold Indications

- Symptomatic knee post-meniscectomy
- Stable rim with intact anterior & posterior horns
- Meniscal defect > 25mm
- ICRS ≤ 3
- Age < 50 y/o
Implantation Procedure

1. Debride torn meniscus
2. Measure defect
3. Shape & size implant
4. Suture in place
Typical Case for Scaffold

- 36 y/o male
- Medial knee pain with vigorous walking
- Normal alignment
- Ligaments ok
CMI (formerly Menaflex)

- CE approval 2003
  - > 3000 cases
- FDA Approved - 2008
  - Rescinded - 2010
- Purchased out of bankruptcy by Ivy Sports Medicine
- Lawsuit with FDA
- Type I collagen derived from irradiated bovine tissue
- Bioresorbable: 12-18 months
- Separate medial & lateral implants
## CMI Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>F/U</th>
<th>CMI</th>
<th>Results</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>JSJS 2008 Rodkey</td>
<td>5 yrs</td>
<td>Acute - 157</td>
<td>CMI ↑ activity, ↓ pain in chronic group only</td>
<td>Acute did same as meniscectomy</td>
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<tr>
<td></td>
<td></td>
<td>Chronic - 153</td>
<td>(≤ 3 scopes)</td>
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<tr>
<td>AJSM 2011 Zaffagnini</td>
<td>10 yrs</td>
<td>17 CMI vs.</td>
<td>CMI - ↓ pain</td>
<td>CMI → Less joint space narrowing</td>
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<td></td>
<td>16 meniscetomy</td>
<td>↑ IKDC, Tegner, SF-36</td>
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<tr>
<td>Arthroscopy 2011</td>
<td>10 yrs</td>
<td>25 Medial only</td>
<td>Good/excellent - 83% Lysholm same @ 1 yr and 10 yrs</td>
<td>MRI – all lost scaffold volume</td>
</tr>
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<td>Monilau</td>
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<tr>
<td>AJSM 2011</td>
<td>2 yrs</td>
<td>24 Lateral only</td>
<td>↓ pain and ↑ function in 96%</td>
<td>No cartilage deterioration</td>
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<td>MRI → Implants reduced in size or resorbed</td>
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Actifit Implant

- Biocompatible, porous, acellular scaffold
- Aliphatic polyurethane
- Degrades over 5 years
- Flexibility & high suture pull-out strength → easy to handle/insert
- Medial & lateral implants
- CE approved 2008 (>1900 cases)
- Also: Chile; South Africa; Asia
Meniscal Scaffolds – Early Experience

• Scaffold for knee pain in 23 patients
  – 12 CMI – 11 Actifit

• 21/23 (91%) improved @ 2 years

• 2nd look scope @ 1 year - 14 patients
  – ACTIFIT: 4/5 (80%) > 50% infill
  – CMI: 4/9 (44%) > 50% infill

• MRI @ 19 months → no progression of chondral wear

Spalding, Knee 2012
Conclusions

• Scaffolds offer solution for post-meniscectomy knee pain
• Successfully used by European colleagues since 2003
• Studies show improvement in pain & functional knee scores
• Early results promising in preventing degenerative changes
USA Pivotal Study

• FDA has approved a phased pivotal study designed to demonstrate superiority of ACTIFIT over partial meniscectomy

• For MEDIAL side only

• Patients with post-meniscectomy pain

• 10-12 centers across the country