Meniscus Allograft Transplantation

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  - Ossur Inc.

Overview

- Current Evidence
- How should we do it?
  - Myers systematic review
  - International Meniscus Reconstruction Experts Forum (IMREF) Consensus Statement

International Meniscus Reconstruction Experts Forum (IMREF) 2016 Consensus Statement on the Practice of Meniscal Allograft Transplantation

- Meniscal Allograft Transplantation: How Should We Be Doing It? A Systematic Review
  - Myers, Smith, Hoang, R., Ashton, M. L., & Attrill, M.
Current Evidence

- 44 papers. 1136 grafts in 1068 patients, 1st case 1984
- If good at 2 years then Lysholm score maintained

- 1,332 patients (1,374 knees), 35 studies
- Mean follow-up 5.1 years
- Failure rate: 10.6% at 4.8 years (new replacement or removal)
Current Evidence: 1st RCT!!

- A Pilot Randomised Controlled Trial Comparing Meniscal Allograft Transplantation to Physiotherapy
  - Tim Spalding, Nick Smith, Nick Parsons, David Wright, Peter Thompson, Andy Metcalfe, Charles Hutchinson, Matt Costa

- Is MAT Chondroprotective?
- Is there clinical benefit over non operative treatment?

Funded by:

Methods

- Comprehensive cohort design (RCT and PG)
- Recruitment target: 36 (Pilot study)
  - Stratified for malalignment
- Primary Outcome:
  - Change in KOOS4 and IKDC scores at 4, 8 and 12 months
  - RCT and PG groups pooled if not significantly different (agreed a priori)

Inclusion
- Aged 16 – 50 years
- Symptomatic meniscal deficient knee compartment
- Surgeon deems they would benefit from MAT

Exclusion
- Need for ligament surgery
- Significant bare bone in ipsilateral compartment
- Previous cartilage modifying procedures

Interventions

Meniscal allograft transplantation
- Frozen non-irradiated MAT
- Soft tissue fixation with bone tunnels
- Osteotomy for malalignment
- Standardised rehabilitation

Personalised knee therapy
- Initial 1 hour session with senior knee physiotherapist
- Exercise prescription and further physio (min 3 months)
- Off-loading knee brace for malalignment

Spalding Verdonk et al 2015
Results

Assessed for eligibility
(n=52)

Entered RCT (n=21)
Entered PG (n=15)

18 total
(11 RCT, 7 PG (2 loss fu))

Analysed 12 months
(7 RCT, 6 PG)

20 total
(13 RCT, 7 PG)

Entered RCT (n=21)
Entered PG (n=15)

13 total
(7 RCT, 6 PG)

Analysed 12 months
(11 RCT, 7 PG (2 loss fu))

Baseline Demographics

<table>
<thead>
<tr>
<th></th>
<th>RCT</th>
<th>Preference group</th>
<th>RCT</th>
<th>PKT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>27.5</td>
<td>MAT 27.5</td>
<td>32.1</td>
<td>MAT 26.4</td>
</tr>
<tr>
<td>Male/Female</td>
<td>10/0</td>
<td>MAT 8/3</td>
<td>9/3</td>
<td>PKT 3/6</td>
</tr>
<tr>
<td>Left/Right</td>
<td>2/8</td>
<td>MAT 6/5</td>
<td>2/4</td>
<td>PKT 3/6</td>
</tr>
<tr>
<td>Medial/Lateral</td>
<td>1/9</td>
<td>MAT 5/8</td>
<td>1/5</td>
<td>PKT 3/6</td>
</tr>
<tr>
<td>Meniscal/ meniscectomy</td>
<td>1/9</td>
<td>MAT 3/8</td>
<td>3/6</td>
<td>PKT 3/6</td>
</tr>
<tr>
<td>Normal/ Malalignment</td>
<td>7/3</td>
<td>MAT 7/4</td>
<td>4/2</td>
<td>PKT 4/5</td>
</tr>
<tr>
<td>Initial injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mechanism</td>
<td>Sport: 9</td>
<td>RCT 10</td>
<td>Sport: 3</td>
<td>PKT 1</td>
</tr>
<tr>
<td></td>
<td>Trauma: 1</td>
<td>RCT 10</td>
<td>Trauma: 1</td>
<td>PKT 1</td>
</tr>
<tr>
<td>Mean time from initial injury to assessment (time's)</td>
<td>7.6</td>
<td>RCT 7.7</td>
<td>9.2</td>
<td>PKT 7.4</td>
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<tr>
<td>Cartilage volume (mm3)</td>
<td>2824</td>
<td>RCT 2776</td>
<td>2429</td>
<td>PKT 2222</td>
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<tr>
<td>KOOS4</td>
<td>36.3</td>
<td>RCT 47.6</td>
<td>55.4</td>
<td>PKT 57.6</td>
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<tr>
<td>Lysholm</td>
<td>52.9</td>
<td>RCT 48.6</td>
<td>55.2</td>
<td>PKT 57.6</td>
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<tr>
<td></td>
<td>57.9</td>
<td>RCT 58.7</td>
<td>64.6</td>
<td>PKT 69.1</td>
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</tbody>
</table>

Change in KOOS4 Scores

*p=0.03
**Summary of clinical evidence**

- Good long term outcomes if graft still intact by 2 years
- 1st RCT suggests MAT may be better than non-operative treatment alone
  - Currently underpowered

**MAT – How Should We Do It?**

- **Indications**
  - Pain following subtotal or total meniscectomy
  - Chondroprotection/cartilage repair
  - Instability

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**Change in IKDC Scores**

- MAT
- PKT

<table>
<thead>
<tr>
<th>Time</th>
<th>MAT</th>
<th>PKT</th>
</tr>
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<tbody>
<tr>
<td>BL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8m</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12m</td>
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8/8/2017
## Indications

### Ranking of indications

<table>
<thead>
<tr>
<th>Indication</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>Total</th>
<th>Score</th>
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</thead>
<tbody>
<tr>
<td>Stability in combination with ACL reconstruction in patients with meniscal deficiency</td>
<td>4</td>
<td>13</td>
<td>12</td>
<td>11</td>
<td>49</td>
<td>2.22</td>
</tr>
<tr>
<td>Unicompartmental pain secondary to meniscal deficiency</td>
<td>85.0%</td>
<td>93.0%</td>
<td>93.0%</td>
<td>9.0%</td>
<td>91.8%</td>
<td>3.92</td>
</tr>
<tr>
<td>Concomitant procedure to articular cartilage</td>
<td>0.0%</td>
<td>96.0%</td>
<td>78.0%</td>
<td>26.0%</td>
<td>11.0%</td>
<td>2.24</td>
</tr>
<tr>
<td>Touraine OA</td>
<td>2.23%</td>
<td>67.78%</td>
<td>28.89%</td>
<td>65.11%</td>
<td>43.87%</td>
<td>1.75</td>
</tr>
</tbody>
</table>

Based on current clinical evidence showing improvements in outcome following MAT IMREF recommends the following main indications:

1. **Unicompartmental pain** in face of total or subtotal meniscectomy
2. As concomitant procedure with articular cartilage repair
3. As concomitant procedure to revision ACL reconstruction to aid in joint stability

## MAT – How Should We Do It?

**Indications**
- Pain following subtotal or total meniscectomy
- Chondroprotection/cartilage repair
- Instability

**Ideal patient**
- Age < 40
  - Physiological age vs. chronological
  - Minimal chondrosis
    - OAR≥0.66 grade IIIa
  - Stable knee
    - DR ligament reconstruction
  - No malalignment
  - No obesity
  - Not obese and well motivated

## Joint Restoration Philosophy

**Biomechanics**
- Realignment Osteotomy
- Ligament Reconstruction
- Meniscus Allograft Transplantation

**Biology**
- Articular Cartilage Repair
- Adjuvant Therapies
- 16 year old male
- Hockey
- PLC injury plus lateral meniscus tear
- Failed repair – referred for repair plus PLC recon
- PLC recon October 2012
- Good recovery post op

SS – The ideal candidate.....

SS - MRI

- Develops lateral knee pain
  - ADL’s
    - No sport
- MAT in Feb 2014
- Good recovery
  - Back to hockey
Asymptomatic Knee?

- Why do it?
  - OA prevention?

- Limited evidence that MAT reduces the risk of OA development

Meniscus deficiency is an indication for MAT however it should not be considered as a routine procedure in the asymptomatic patient.

Pre op Considerations

Cartilage Repair?

- When performing an articular cartilage restoration procedure, IMREF recommends performing MAT in the absence of a functional meniscus in the involved ipsilateral compartment.

OA?

- IMREF recommends caution if performing MAT in knees with moderate to severe radiographic OA (ie, Kellgren-Lawrence grade >3).

Pre op Considerations

Sizing

- Options
  - XR – Pollard
  - Anthropometry
  - MRI (most accurate)
    - Most use contra-lateral MRI

Pre op Considerations
Pre-op Considerations

Viable Grafts?

- Verdonk
  - No difference in outcome with viable compared to frozen grafts

Sterilization

- Most want non-irradiated frozen grafts
  - Gamma radiation
    - 3.6 mrad to kill HIV
  - Chemical and ultrasound washes
    - Many include terminal radiation

- Risk of bacterial infection
  - CDC estimates 1/2,200
  - AATB 192 cases, 1/7,000
  - Industry 1/1.5-2.5 million

- Risk of viral infection
  - Reduced with NAT/PCR
  - HIV 1/8 million

Surgical Technique

- Soft Tissue vs. Bone Fixation
  - Based on current evidence, IMREF accepts that there is no superiority of one surgical technique of another (bone vs. soft tissue)

The American Journal of Sports Medicine

Prospective comparative study between two different fixation techniques in Achilles allograft transplantation

For information: Anthony Sheehan, MD
Sports Medicine & Shoulder Center
251 S. Roberta St., Suite 101
Fresno, CA 93702
(559) 448-4400

Surgical Technique
Surgical Technique

Alignment
• Verdonk 2006
  – Better results with HTO
• ElAttar et al.
  – Meta-analysis – 19% osteotomy
• Gomoll 2009
  – HTO + cartilage
• Stone 2010
  – No osteotomy
  – No difference
• Consensus
  – Mechanical axis alignment should be evaluated when considering MAT and realignment osteotomy be considered if there is mechanical axis deviation

Post op Considerations

• Rehabilitation
  – No real consensus
  – May be different depending on fixation technique
  – Follow similar lines to meniscal repair
    • Period of protected weight bearing
    • Limit deep flexion
    • 3-4 months return to light activities
    • 6 months – Sport specific training and RTS
• IMREF recommends an individualized return to sport prescription based upon functional assessment.
Post op Considerations

- **Return to contact sport**
  - 13 patients, mean age 19
  - 4 had grade IV lesion treated with O-C allograft
  - 3 required further op: revision, repair, partial resection
  - Rehab: 2/52 brace, 3/12 sport training, 4/12 full contact
  - 77% (10/13) returned previous level of activity
    - Mean time: 16 months
    - X-Ray: K-L grade: 5 progressed
    - 93% had high satisfaction scores

Post Operative Assessment

- **Pre and post operative outcome scores should be collected**
  - KOOS, WOMET, Marx Activity, EQ-5D

- **Routine 2nd look arthroscopy not recommended**

- **IMREF suggests surgeons performing MAT consider MRI to assess graft healing and position at 1 and 2 years postoperatively**
  - Relative Percentage Extrusion (RPE)

Post Operative Assessment

- **Relative Percentage Extrusion**

Relative % extrusion = $\frac{A}{(A+B)} \times 100$
Graft Failure?

Yes

No

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Definition of Failure

- Mechanical failure
  - AGREED
  - Complete removal of graft including arthroplasty

- Clinical Failure
  - NOT AGREED
  - No consensus on clinical failure but should include MRI, PROMS

Future Perspectives

- International registry
- Multicenter RCT
- Methods of fixation to avoid extrusion
- Biologics to improve healing, graft survival and OA progression
- Asymptomatic knee
  - Biomarker assays
  - Functional imaging
Summary

• MAT no longer experimental
  – 20 year outcomes available
  – Many areas to work on to improve outcomes

• Good 2 year outcome a predictor of long term success

• Key is patient selection and counseling
  – Return to sport

• Attention to accurate sizing and graft procurement important

• Data collection is of paramount importance

• Await further level 1 evidence

Thank you!

Acknowledgements

• Tim Spalding
• IMReFgroup

http://www.djopublications.com/ebook
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