Meniscal Deficiency: Treatment Options 2016

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ISMF Meeting 2016

Meniscal Transplantation

The Clinical Goal

Preserve the Integrity of the Knee

Evolution of a Concept

- Meniscus Function
- Basic Science of Meniscal Allograft Transplantation
- Tissue Preservation
- Surgical Technique
- Rehabilitation

Meniscal Transplantation

Indications

- Subtotal or total meniscectomy
- Pain secondary to meniscal deficiency
- Grade 3 or less chondromalacia
- Stable knee without malalignment

Meniscal Transplantations

Contraindications

- Rheumatoid Arthritis
- Metabolic Degenerative Disease
- Obesity
- Post-infectious Disease
- Remodeling of the Femoral Condyle

Sizing Considerations

- AP and lateral radiograph with a radiologic marker – Pollard Technique
- Sagittal length medial meniscus is 80% and lateral is 70% of AP tibial plateau dimensions from lateral radiograph
- Width: tibial eminence to periphery of tibial compartment on AP radiographs
- Accuracy of predictability – McDermott, 2004
Radiographs demonstrating sizing measurements

Meniscal Transplantation

Technique

- Double bone plug
- Slot
- Trough

Double Bone Plug

- Commonly used on medial side
- Importance of anatomical placement of both horns
- Concerns about maintaining the appropriate configuration of the meniscus
- Avoids tibial spine debridement
- Fragility of bone plugs and fixation

Trough/Slot Technique

- Can be utilized medially or laterally
- Allow for maintenance of anatomy and meniscus architecture
- Provides excellent bone fixation and stability
- Trough – press fit fixation
- Slot – interference screw fixation
Bone Bridge Fixation

Complications
- Arthrofibrosis
- Meniscal Detachment
- Meniscal Shrinkage
- Meniscal Failure
- Meniscal Extrusion

Pitfalls and Pearls
- Appropriate Surgical Planning
- Don’t Compromise Exposure
- Adequate Fixation Techniques
- Presence of Meniscal Remnant
- Accurate Positioning of Bone
- Anterior Horn Fixation
- Placement of Pull-Through Suture

Rehabilitation
- Early Protected WB; Full WB at 4-6 weeks
- Limited Early Motion
- Similar to Delayed Meniscal Repair
- Use of Unloader Brace
- Early Treatment of Concerns

26 Years of MAT: is it still experimental?
A meta-analysis of 44 trials
- 44 trials, at least 6 months follow-up
- 1136 grafts in 1068 patients
- 678 medial, 458 lateral
- Mean age 34.8 years
- Outcome assessed by 12 scoring systems, 4 imaging modalities, second look arthroscopy, and/or histological analysis
Survival and Reoperation Rates After Meniscal Allograft Transplantation
Analysis of Failures for 172 Consecutive Transplants at a Minimum 2-Year Follow-up

Frank McCormick, MD, MC USNR*,†, Joshua D. Harris, MD‡, Geoffrey D. Abrams, MD§, Kristen E. Hussey, BS∥, Hillary Wilson, BS∥, Rachel Frank, MD∥, Anil K. Gupta, MD¶, Bernard R. Bach Jr, MD∥ and Brian J. Cole, MD, MBA¶

- 32% reoperation rate
- Arthroscopic debridement – 59%
- 95% allograft survival rate at mean of 5 years

Knee Surgery, Sports Traumatology, Arthroscopy
January 2015, Volume 23, Issue 1, pp 310-322
Date: 27 Sep 2014

Meniscal allograft transplantation. Part 1: systematic review of graft biology, graft shrinkage, graft extrusion, graft sizing, and graft fixation
Gonzalo Samitier, Eduard Alentorn-Geli, Dean C. Taylor, Brian Bill, Terrence Lock, Vasilius Moutzouros, Patricia Kolowich

- Donor cells decrease after MAT
- Graft shrinkage in irradiated grafts
- Graft extrusion is common, no clinical impact
- Bone fixation- contact mechanics, less extrusion

Knee Surgery, Sports Traumatology, Arthroscopy
January 2015, Volume 23, Issue 1, pp 323-333
Date: 30 Sep 2014

Meniscal allograft transplantation. Part 2: systematic review of transplant timing, outcomes, return to competition, associated procedures, and prevention of osteoarthritis
Gonzalo Samitier, Eduard Alentorn-Geli, Dean C. Taylor, Brian Bill, Terrence Lock, Vasilius Moutzouros, Patricia Kolowich

- MAT improves QOL at 7-14 years fu
- Associated procedures don’t worsen results
- MAT may prevent progression of AC damage

Knee Surgery, Sports Traumatology, Arthroscopy
January 2015, Volume 23, Issue 1, pp 334-345
Date: 30 Sep 2014

Meniscal Allograft Transplantation: How Should We Be Doing It? A Systematic Review

- Reviewed 41 articles
- Provides pain relief and improved function
- Good results in mid to long term studies

Meniscal Allograft Transplantation
A Systematic Review
Federica Rosso, MD*, Salvatore Bisicchia, MD†, Davide Edoardo Bonasia, MD‡ and Annunziato Amendola, MD, PhD

Long-term Subjective, Clinical, and Radiographic Outcome Evaluation of Meniscal Allograft Transplantation in the Knee
Bart Vundelinckx, MD*,†, Johan Vanlauwe, MD, PhD‡ and Johan Bellemans, MD, PhD†

Long Term Durability

- Does MAT prevent or delay OA?
- The results of complete meniscectomy are well recognized
- Challenge to study
- Role as bridging procedure
Concomitant Procedures

- Ligamentous Reconstruction
- Malalignment Correction
- Articular Cartilage Restoration

Asymptomatic Post-Meniscectomy Knee

- Education about signs and symptoms of knee degeneration
- 45-degree PA radiographs
- Bone Scan
- Articular cartilage tends to rapidly break down, especially in lateral compartment
- Younger patient – strongly consider early intervention

15 yo male s/p subtotal lateral meniscectomy

“Symbiotic” Relationship of Meniscus and Articular Cartilage

Concept of a Functional Unit

MAT Indications

- Subtotal or total meniscectomy
- Grade 3 or less chondromalacia
- Stable knee without malalignment

ACI Indications

- Defect of Articular Cartilage
- Stable Knee without Malignment
- Functional Meniscus
Common Factors in Treatment

- Knee Stability
- Knee Alignment
- Knee Environment

Meniscal Transplantation and ACCI

- Arthroscopic debridement
- Arthrotomy and preparation of tibial bone anchor site
- Meniscal allograft preparation and chondral defect preparation
- Placement and fixation of meniscal allograft
- Completion of ACI procedure

Limitations

- Are the procedures durable enough to allow full return to high demand and high impact sports?
- Long recovery time especially for competitive athlete
- Recreational athlete more likely to return to sports activity
- Important to understand goal of surgery and potential limitations
- Allograft availability
- Insurance approval

Applications - 2016

- Complex injuries to meniscus will continue and be problematic
- Articular cartilage injuries present challenge for the athletic population especially competitive athlete
- Primary goal is not the return to competitive sports but restoration of functional knee
- Challenging population is the adolescent and young adult

CMI - Collagen Meniscus Implant

- Only meniscus implant that is made out of purely biological materials
- Consists of a resorbable and bio compatible collagen matrix
- Arthroscopically implantable
- Adjustable to defect size
- Off-the-shelf supply
- Remaining in use sterile condition

Implant Features

- For use with medial meniscus
- Matrix consists of type I collagen 97.5% highly purified collagen & 2.5% GAGs
- Pore structure optimal for ingrowth of body's own cells (Pore size: ranges from 50-400 µm)
- Cross-linked matrix → degree of cross-linking defines strength & resorption rate of implant
- Matrix is completely absorbable with time
- Stores, transports & storage at +2 to +8°C
Clinical results summarized (1)

CMI has been used clinically for over 18 years. Numerous publications report mid- to longer term results:

- Patients treated with CMI benefit in over 80% of the cases.¹,²,⁴
- Patients have significantly improved knee function (Lysholm), activity levels (Tegner), and pain values from pre- to post-operative.¹,²,³,⁴,⁶
- The functional improvements are maintained over a time period of 10 years.¹,²,³,⁴,⁵,⁶
- Reoperation rate after CMI is around 10-20%.¹,²,⁴ (comparable to meniscus repair)
- Chronic meniscus patients have 3 times less reoperations after CMI than after partial meniscectomy.⁴


Clinical results summarized (2)

Tissue regeneration:

- Significant tissue regrowth in 90% of CMI cases.⁴,⁶
- New meniscus often reduced in size compared to native meniscus, however tissue existent over time period of 5-10 years and remains functional.¹,²,³,⁴,⁶

Radiological evaluation:

- MRI shows normalization of signal over time, however even after 5-10 years, meniscus signal is still not normal.¹,²
- No joint space narrowing and no progressive degenerative changes were observed during 5-10 years follow up.¹,²,⁴,⁶

→ chondroprotective effect

Conclusions: the status of the knee joint is improved or a „steady state“ is reached which enables the knee to function well over a time period up to 10 years.


Ten Year Clinical Publications


- Single surgeon
- Statistically significant improvements in clinical outcomes
- Lysholm scores improved significantly from 60 at pre-op to 88 at final follow-up
- Pain VAS improved significantly from a mean of 55 pre-op to 20 points at final follow-up
- No differences were observed in VAS from 1 year to 10 years of follow-up among surgical and long-term improvements in function
- Most patients showed little or no signs of joint space narrowing
- Safety
- No serious complications warranting repeat surgery.
**Indications**

Chronic case: due to prior meniscectomy

Acute case: due to irreparable tear requiring partial resection

Loss of meniscus tissue

**The consequence of meniscectomy**

"...a tear in a meniscus with degenerative changes might be regarded as the first sign of OA of the joint."

Englund et al. (2001)

Meniscus damage

Joint overload

Cartilage damage

Osteoarthritis (OA)

Total knee replacement

Soaring numbers of meniscectomy procedures imply a growing population suffering symptoms of joint overloading, and OA

**Ideal OA Treatment**

- Clinically significant improvement in knee pain and knee function
- Optimal distribution of medial compartmental loading
- Simple surgical technique and rehabilitation
- Low complication rates
- Ability to delay the need for more invasive surgery (e.g. UKA or TKA)

**The NUsurface® Meniscus Implant**

Non-fixed

- Mobile with anti-migratory features
- No disruption to hard or soft tissues cartilage-like

- Compliant
- Low friction

Bio-stable

- Non-resorbable materials
- Doesn’t require tissue ingrowth to function

**The cushioning effect**

Partial meniscectomy has been shown to lead to a >350% increase in contact forces on the articular cartilage (Seedhom et al., 1979)

NUsurface® meniscus

Post-meniscectomy
How is NUsurface® expected to perform?
- Long-term simulations of use assure durability, low wear and stability in the joint
- Current clinical experience confirms findings from in-vitro tests

Durability
- The implant can withstand long-term loading without being torn

Low wear
- Stable wear rate
- Low reactivity to wear debris

Stability
- Remains in place
- Maintains its biomechanical properties after extended use

NUsurface® Meniscus Implant
- Femur
- Medial Meniscus Rim
- NUsurface® Meniscus Implant
- Left Tibia

NUsurface® Market - Continuum of Care
- Non Invasive
- Minimally Invasive
- NUsurface®
- Invasive
- Uni & Total Knee Arthroplasty

NUsurface® Typical Patient Profile
- Previous partial meniscectomy
- Still in pain
- 50 year old male
- Limited treatment options
- No significant cartilage loss - yet
**Phase II: Multi-Center Trial**

**Patient Population**

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>128</th>
</tr>
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<tbody>
<tr>
<td>Age [mean ± 95%CI (min – max)]</td>
<td>50.4 ± 1.6 (30 – 73)</td>
</tr>
<tr>
<td>Gender [F / M]</td>
<td>54 (42.2%) / 74 (57.8%)</td>
</tr>
<tr>
<td>Body Mass Index</td>
<td>26.7 ± 0.7 (18.8 – 35.1)</td>
</tr>
<tr>
<td>Index Knee [L / R]</td>
<td>65 (50.8%) / 63 (49.2%)</td>
</tr>
<tr>
<td>Previous Partial Meniscectomy</td>
<td>104 (81.3%) / 24 (18.8%)</td>
</tr>
<tr>
<td>Active Smokers</td>
<td>30 (23.4%)</td>
</tr>
<tr>
<td>Study Avg. Follow-up in months [mean ± 95%CI (min – max)]</td>
<td>28.8 ± 2.6 (1 – 57)</td>
</tr>
</tbody>
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**NUsurface® U.S. Clinical Strategy**

- **Two Studies- One Patient Population**
  - SUN Study Single Arm Study - No Control—1 Year
    - 118 NUsurface Patients from all Studies
    - 11 SUN Clinical Sites Being Activated
    - SUN Study starts enrolling January 2016
  - VENUS Study – Randomized Study
    - Non-Surgical Therapy as Control
    - Up to 64 patients in each cohort
    - 10 US Clinical Sites
    - 20 US Patients Treated or Randomized to date

**Meniscal Pathology**

- Meniscal Implant Nu-Ortho
- Leave Alone
- MAT
- Partial Meniscectomy
- Segmental Replacement CMI
- Repair

**Phase II: Multi-Center Trial KOOS Results**

<table>
<thead>
<tr>
<th>KOOS Pain</th>
<th>KOOS Symptoms</th>
<th>KOOS Activity</th>
<th>KOOS Sport</th>
<th>KOOS QoL</th>
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<tbody>
<tr>
<td>Pre-op</td>
<td>1.5 Months</td>
<td>6 Months</td>
<td>12 Months</td>
<td>24 Months</td>
</tr>
<tr>
<td>42.1</td>
<td>56.9</td>
<td>49.2</td>
<td>17.1</td>
<td>22.8</td>
</tr>
<tr>
<td>72.0</td>
<td>73.5</td>
<td>77.7</td>
<td>49.3</td>
<td>54.5</td>
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