Plantar Fasciitis Treatment with Particulate Human Amniotic Membrane

1David N. Garras, MD
2Ryan T. Scott, DPM

1Midwest Orthopaedic Consultants, Asst. Professor, UIC, Chicago, IL
2The CORE Institute, Phoenix, AZ
Disclosures

• Both Authors received study materials and product for the purpose of conducting this study. No monetary benefits were received by either authors.
Plantar Fasciitis

- Most common cause of heel pain affecting ~1 million patients/year\(^1\)
- Repetitive trauma resulting in degeneration of the plantar fascia\(^2\)
- Conservative therapies are ineffective in approximately 10-15% of patients\(^3,4\)
  - Orthotics, stretching, night splint, NSAIDs
- Persistent conservative therapy failure necessitates more invasive treatments, however, these therapies can be associated with significant clinical side effects and/or limitations\(^5\)
  - Injections
    - Corticosteroids – Plantar fascia rupture
    - PRP – Minimal clinical data
  - Surgery – biomechanical instability, post-op pain
Amniotic Membrane / Umbilical Cord (AM/UC)

- Placental tissues
  - Immunomodulation of local environment
- Decrease local inflammation
  - ↑ anti-inflammatory signaling
  - ↓ pro-inflammatory signaling
- Mediated by unique extracellular matrix biology⁷
  - HC-HA/PTX3 Matrix Complex
- Promotes a regenerative healing environment
Case Series Overview

• 60 patients (n = 10/treatment)
  
  - 25 mg AM/UC
    - 1 injection
    - 2 injection
  
  - 50 mg AM/UC
    - 1 injection
    - 2 injection
  
  - 100 mg AM/UC
    - 1 injection
    - 2 injection
  
• Visit Schedule
  
  - Baseline, 6, 12, 18 weeks
  
  - Ultrasound-guided injections of micronized AM/UC tissue (CLARIX® FLO, Amniox Medical, Inc., Atlanta, GA) at baseline and 6 weeks (2 injection groups)

• Outcome Measures
  
  - FAAM, Foot pain
Interim Results

• N = 23 patients completed 18 weeks follow-up
  – >50% of patients had pain of longer than 6 month duration and had failed conservative therapies

<table>
<thead>
<tr>
<th># Patients</th>
<th>25 mg – 1 injection</th>
<th>25 mg – 2 injections</th>
<th>50 mg – 1 injection</th>
<th>50 mg – 2 injections</th>
<th>100 mg – 1 injection</th>
<th>100 mg – 2 injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

• Foot and Ankle Ability Measure (FAAM) completed at all visits
• Foot pain reported at all visits
All treatments showed statistically significant reduced foot pain for the 18 week study period. For both 1 injection and 2 injections, 100 mg AM/UC tissue demonstrated the greatest reduction in foot pain.

<table>
<thead>
<tr>
<th>Pain Reduction</th>
<th>25 mg – 1 injection</th>
<th>25 mg – 2 injections</th>
<th>50 mg – 1 injection</th>
<th>50 mg – 2 injections</th>
<th>100 mg – 1 injection</th>
<th>100 mg – 2 injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>60%</td>
<td>56%</td>
<td>65%</td>
<td>70%</td>
<td>72%</td>
<td>87%</td>
<td></td>
</tr>
</tbody>
</table>
Results – FAAM – Activities of Daily Living

- For both 1 injection and 2 injections, 100 mg AM/UC tissue demonstrated the highest FAAM-ADL scores at 18 weeks

<table>
<thead>
<tr>
<th>FAAM % Change</th>
<th>25 mg – 1 injection</th>
<th>25 mg – 2 injections</th>
<th>50 mg – 1 injection</th>
<th>50 mg – 2 injections</th>
<th>100 mg – 1 injection</th>
<th>100 mg – 2 injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>58%</td>
<td>40%</td>
<td>40%</td>
<td>95%</td>
<td>49%</td>
<td>88%</td>
<td></td>
</tr>
</tbody>
</table>
Results – FAAM – Sports

- All treatment groups demonstrated an increase in the FAAM-Sports subscale. In patients receiving two injections, there was a dose dependent increase the FAAM-Sports score.

<table>
<thead>
<tr>
<th>FAAM % Change</th>
<th>25 mg – 1 injection</th>
<th>25 mg – 2 injections</th>
<th>50 mg – 1 injection</th>
<th>50 mg – 2 injections</th>
<th>100 mg – 1 injection</th>
<th>100 mg – 2 injections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>96%</td>
<td>41%</td>
<td>80%</td>
<td>154%</td>
<td>94%</td>
<td>108%</td>
</tr>
</tbody>
</table>
Conclusion

• Injections of micronized human amniotic membrane/umbilical cord (AM/UC) tissue:
  – Significantly decreased pain from baseline
  – Improved overall functional recovery
• Despite low overall patient numbers:
  – Dose dependent trend in AM/UC efficacy (100 mg > 50 mg > 25 mg)
  – Injection dependent trend (2 injections > 1 injection)
• Results are consistent with an earlier study\(^5\):
  – Injection of micronized AM tissue improved patient outcomes similar to steroid injection

• **Overall, these interim results are promising and highlight the potential effectiveness of AM/UC tissues as a treatment for plantar fasciitis**
References