Plantar Fasciitis Treatment with Particulate Human Umbilical Cord/Amniotic Membrane

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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 biology
  - HC-HA/PTX3 Matrix Complex
- Promotes a regenerative healing environment
Case Series Design

- 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
Results

- N = 53 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>53</td>
<td>8</td>
<td>8</td>
<td>9</td>
<td>9</td>
<td>10</td>
<td>9</td>
</tr>
</tbody>
</table>

- Foot and Ankle Ability Measure (FAAM) completed at all visits
- Foot pain reported at all visits
Results – Foot Pain

- 25 mg – 1 injection
- 25 mg – 2 injections
- 50 mg – 1 injection
- 50 mg – 2 injections
- 100 mg – 1 injection
- 100 mg – 2 injections

1 Injaction

2 Injections

- 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></td>
<td>57%</td>
<td>66%</td>
<td>68%</td>
<td>60%</td>
<td>73%</td>
<td>70%</td>
</tr>
</tbody>
</table>
Results – FAAM – Activities of Daily Living

- 25 mg
- 50 mg
- 100 mg

1 Injection

2 Injections

- 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>48%</td>
<td>135%</td>
<td>49%</td>
<td>72%</td>
<td>71%</td>
<td>102%</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 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></td>
<td>176%</td>
<td>420%</td>
<td>102%</td>
<td>395%</td>
<td>377%</td>
<td>107%</td>
</tr>
</tbody>
</table>
Conclusion

• Injections of micronized human amniotic membrane/umbilical cord (AM/UC) tissue:
  – Significantly decreased pain from baseline
  – Significantly improved overall functional recovery from baseline
    (with the exception of 25mg/1 injection)

• 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\textsuperscript{5}:
  – Injection of micronized AM tissue improved patient outcomes similar to steroid injection

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