A Prospective, Randomized, Blinded, Comparative Study of Injectable Micronized Dehydrated Amnion/Chorion Membrane Allograft in the Treatment of Recalcitrant Plantar Fasciitis

Charles Zelen, DPM1; Attila Poka, MD2; James Andrews, MD3
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Objective

We report the results of a randomized clinical trial examining the efficacy of micronized dehydrated human amnion/chorion membrane (mDHACM) injection as a treatment for chronic refractory plantar fasciitis.1

Methods

An IRB approved, prospective, randomized, single-center clinical trial was performed.

- Forty-five patients were randomized to receive injection of 2cc 0.5% Marcaine pain, then either 1.25cc saline (controls), 0.5cc mDHACM, or 0.25cc mDHACM.

- PF symptoms were evaluated weekly for 6 weeks then at week 8 using American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Scale, Wong-Baker Faces™ Pain Rating Scale.

- QualityMetric’s SF-36v2® Standard Health Survey was completed at baseline and week 8.

Results

- Significant improvement in plantar fasciitis symptoms was observed in patients receiving 0.5cc or 1.25cc mDHACM versus controls within one week of treatment and throughout the study period.

- At one week, AOFAS Hindfoot scores increased by a mean of 2.2 ± 1.74 points for controls versus 38.7 ± 11.4 points for those receiving 0.5cc mDHACM (p=0.002) and 33.7 ± 14.0 points for those receiving 1.25cc mDHACM (p=0.001).

- By week eight, AOFAS Hindfoot scores increased by a mean of 12.9 ± 16.9 points for controls versus 51.6 ± 10.1 and 53.3 ± 9.4 for those receiving 0.5cc and 0.25cc mDHACM respectively (both p<0.001).

- No significant difference in treatment response was observed in patients receiving 0.5cc versus 1.25cc mDHACM.

References


Table 1. Patient Characteristics.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention Group</th>
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<tbody>
<tr>
<td></td>
<td>Controls</td>
</tr>
<tr>
<td>Sample Size</td>
<td>15</td>
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<td>Male gender (%F)</td>
<td>12 (80)</td>
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| Age (years)                     | 55.0 ± 9.9         | 53.0 (33, 80)      | 56.1 ± 12.8        | 55.3 ± 12.9        | 0.158
| BMI (kg/m²)                     | 29.2 ± 6.1         | 27.3 (22.8, 34.8)  | 29.7 ± 5.6         | 32.7 ± 7.2         | 0.216
| PF symptoms (weeks)             | 50.0 ± 13.2        | 26.2 (13.0, 30.4)  | 20.7 ± 8.9         | 16.0 (8, 30)       | 0.615

Conclusions

- Patents receiving mDHACM reported significantly greater reductions in pain from baseline reports (all p<0.001 controls vs. 0.5cc mDHACM, and all p<0.004 controls vs. 1.25cc mDHACM).

- Pain reduction from baseline appears similar for the mDHACM groups.

- Patients receiving mDHACM had significantly greater improvement in physical and mental scores vs. controls (all p<0.002).

- The magnitude of difference between baseline and week 8 appears similar when comparing the mDHACM groups.

Author Affiliation

1. Professional Education and Research Institute, Roanoke, VA. 2. Orthopaedic Trauma Institute, Columbus, OH. 3. Andrews Sports Medicine & Orthopaedic Center, Birmingham, AL.

Figure 1. Mean Difference in AOFAS Hindfoot Score Compared to Baseline Measurement During the Study Period.

- Within each group significant higher scores were observed between baseline and week eight (all p<0.01), although significantly greater improvement was noted in the groups receiving mDHACM vs. controls (all p<0.001).

- Similar improvement in AOFAS Hindfoot scores were observed for those patients receiving 0.5cc or 1.25cc mDHACM at any week.

Figure 2. Wong-Baker Faces™ Score.

- Patients with chronic/refractory plantar fasciitis receiving a single-dose injection of mDHACM allograft experienced significant improvement in symptoms and increased function within 1 week of injection and had continued improvement over the 8 week study period.

- In patients with refractory plantar fasciitis, mDHACM is a viable treatment option.