

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

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## Background

- Plantar fasciitis (PF) is a common, painful, and often frustrating condition seen frequently by the foot and ankle surgeon.
- Failure of conservative management may indicate the need for surgery.
- However, specialized treatment that can reduce inflammation and promote healing may be a possible alternative prior to surgical intervention.

### Human Amniotic Membrane

- Human amniotic membrane has been used to enhance healing for >100 years.<sup>1</sup>
- In vivo* and *in vitro* studies have shown that the biochemical properties of amniotic membrane help to reduce inflammation and enhance soft tissue healing.<sup>2</sup>
- Repair is mediated through contained growth factors including EGF, TGF- $\beta$ , FGF which are known to stimulate epithelial cell migration and proliferation, and PDGF A and B which stimulate many metabolic processes, including general protein and collagen synthesis, collagenase activity, and chemotaxis of fibroblasts and of smooth muscle cells.<sup>3</sup>

### Dehydrated Human Amnion/Chorion Membrane

- The PURION<sup>®</sup> Process is a method of gently cleaning, drying, and sterilizing human amnion/chorion membrane.
- The dehydrated human amnion/chorion membrane (dHACM) allograft material can be micronized to create a powder that can be suspended in saline for injection.

### References

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- Parolini O, et al. Human term placenta as a therapeutic agent: from the first clinical applications to future perspectives. In: Berven E. editor. *Human Placenta: Structure and Development*. Nova Science Publishers, 2010: 1-48.
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## Purpose

- 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.<sup>4</sup>

## 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 plain, then either 1.25cc saline (controls), 0.5cc mDHACM, or 1.25cc 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<sup>™</sup> Pain Rating Scale.
- QualityMetric's SF-36v2<sup>®</sup> 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  $\pm$  17.4 points for controls versus 38.7  $\pm$  11.4 points for those receiving 0.5cc mDHACM ( $p < 0.001$ ) and 33.7  $\pm$  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  $\pm$  16.9 points for controls versus 51.6  $\pm$  10.1 and 53.3  $\pm$  9.4 for those receiving 0.5cc and 1.25cc mDHACM respectively (both  $p < 0.001$ ).
- No significant difference in treatment response was observed in patients receiving 0.5cc versus 1.25cc mDHACM.

mDHACM = AmnioFix<sup>®</sup> MiMedx Group, Inc., Marietta, GA  
AmnioFix<sup>®</sup> and PURION<sup>®</sup> are registered trademarks of MiMedx Group, Inc.  
Study sponsored by MiMedx<sup>®</sup>, Marietta, GA

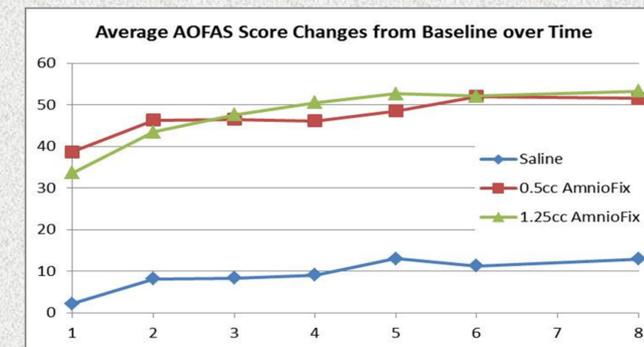


Table 1. Patient Characteristics.

Variable	Intervention Group			p-value
	Controls	0.5cc mDHACM	1.25cc mDHACM	
Sample Size	15	15	15	
Female gender (#/%)	12 (80)	7 (47)	10 (67)	0.158
Age (years)	50.5 $\pm$ 9.9 53.0 (33, 63)	56.1 $\pm$ 12.8 60.0 (30, 72)	51.3 $\pm$ 12.9 55.0 (26, 71)	0.360
BMI (kg/m <sup>2</sup> )	29.2 $\pm$ 6.3 27.3 (22.3, 42.3)	29.7 $\pm$ 5.6 28.7 (22.5, 43.6)	32.7 $\pm$ 7.2 32.5 (21.8, 50.5)	0.261
PF symptoms (weeks)	20.6 $\pm$ 13.8 16.0 (8, 51)	24.2 $\pm$ 13.0 21.0 (8, 48)	20.7 $\pm$ 8.9 16.0 (8, 40)	0.613

mDHACM = micronized dehydrated human amnion/chorion membrane. BMI = body mass index. PF = plantar fasciitis. Data presented as #/% or mean  $\pm$  SD, median (minimum, maximum), as indicated.

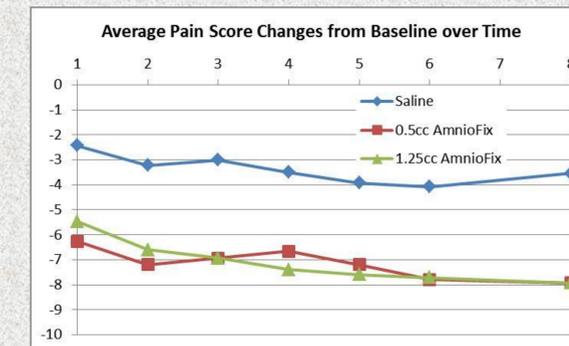
Figure 1. Mean Difference in AOFAS Hindfoot Score Compared to Baseline Measurement During the Study Period.



- Within each group significantly higher scores were observed between baseline and week eight (all  $p \leq 0.01$ ), 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.

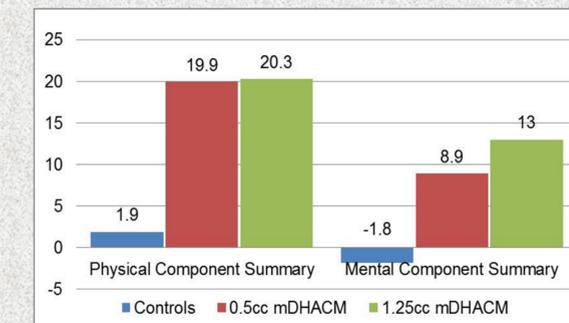
## Results

Figure 2. Wong-Baker FACES<sup>™</sup> Score.



- Patients 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.

Figure 3. QualityMetric's SF-36v2<sup>®</sup> Standard Health Survey.



- Patients receiving mDHACM had significantly greater improvement in physical and mental scores vs. controls (all  $p \leq 0.002$ ).
- The magnitude of difference between baseline and week 8 appears similar when comparing the mDHACM groups.

## Conclusions

- 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.

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