

Chronic and Refractory Plantar Fasciitis Treatment with Single-Dose Dehydrated Amniotic Allograft Injection

Myron H. Hansen, DPM, FACFAS; J. Joseph Anderson, DPM, FACFAS
American Foundation of Lower Extremity Surgery and Research

Statement of Purpose

While treatment with conventional Tier 1 and Tier 2 ACFAS Guideline recommendations for plantar fasciitis are effective for many patients, those refractory to therapy, classified as Tier 3, require novel approach to reduce pain, modulate inflammation, and heal soft-tissue damage that is maintained long-term. The study is a single-center case series analyzing ten patients with plantar fasciitis who underwent single-dose injection of dehydrated amniotic membrane.

Methodology & Hypothesis

This single-center, retrospective review of ten patients (age range 27-68) was conducted in Phoenix to identify clinical effectiveness of amniotic membrane injection for chronic/refractory plantar fasciitis with multiple pain and ultrasound assessments over 4 months. Patients had significant baseline pain scores that persisted for 10 months average prior to therapy and failed minimum 3 corticosteroid injections.

Table 1. Patient Demographics

Variable	Average	Range
Age (yr)	46	27-68
BMI	30.2	19.6-46.8
History of Pain (mos)	10.5	7-16
Baseline Pain Rating (0-10)	6.9	6-8
Prior Corticosteroid Injections	3.6	3-5

Table 2. Prior Therapies

Variable	% Patients
Corticosteroid Injection	100
NSAIDS	100
Physical Therapy	100
Orthotics	100
Medrol Pack or OPC Cream	80
Night Splints	70
Cam Walker	20

Procedures

After baseline ultrasound, single-dose dehydrated amniotic injection was applied under ultrasound to area of greatest pain. Lidocaine administered in adjunct to amniotic injection. Patients scheduled bi-weekly follow-up for pain ultrasound measurements.

Literature Review

Plantar fasciitis (PF) has an estimated lifetime risk of 10% in the US population with more than 2 million patients treated every year. Of all patients seeking treatment from a podiatric specialist, approximately 11-15% present with a primary complaint of heel pain.¹ Though conservative treatments have shown outcomes of 46-100%, approximately 25% of patients treated progress to a chronic condition. The repetitive micro-tearing of the plantar fascia causes inflammation and leads to a degenerative process.² The pain associated with chronic injury to the connective tissue becomes more resistant to conventional therapy and recurrence is common.³ Human amniotic membrane has been utilized to treat various medical conditions to include chronic wound care, ophthalmology, periodontal, neurologic and orthopedic surgeries. The soft tissue healing effects seen with human amniotic membrane has been published in the literature for over 100 years. Though the results with various surgical procedures and chronic wound treatments are available, the need to evaluate specific indications and verify outcomes in other common office-based treatment is needed.⁴ A single-center, retrospective review was performed to evaluate the clinical effect, rate, and long term maintenance on pain associated with chronic and refractory plantar fasciitis with a single injection of dehydrated human amniotic membrane. 100% of patients treated with single-dose injection had pain reduction by week 2 and maintained effect over 4 months. The clinical and economic impact of these results suggest that inclusion of amniotic membrane injection into treatment strategy in chronic PF may prevent long-term patient suffering from pain and reduced cost due to repeat office visits or costly surgical intervention.⁵

Results

Single-dose injection of dehydrated amniotic membrane significantly reduced plantar fasciitis pain in 10/10 (100%) of patients. Patients achieved 62% pain reduction by week 2, 96% by week 4, and again had 96% pain reduction at week 6. These results were maintained over 4-month observation period. Fascia decreased 19% overall thickness.

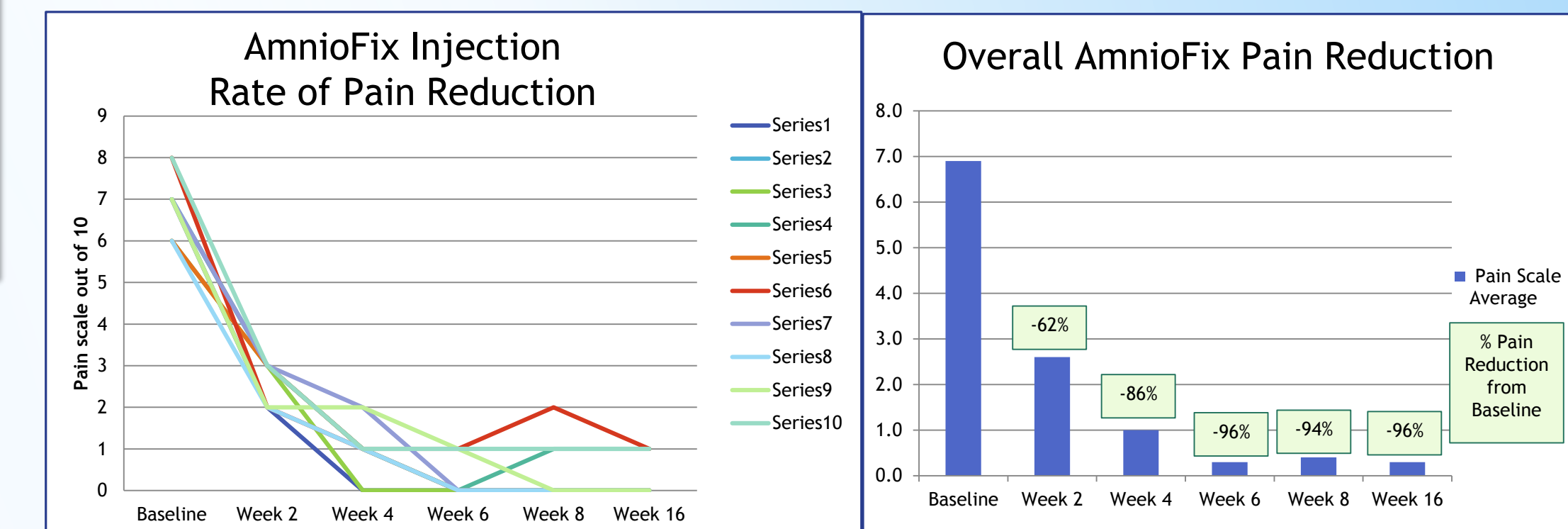
Pre-Injection Ultrasound



Post-Injection Ultrasound



Figures 1 and 2. AmnioFix and Pain Reduction in Plantar Fasciitis.



Analysis and Discussion

Single-dose injection of dehydrated amniotic allograft in patients with chronic/refractory plantar fasciitis produced rapid and sustained pain reduction and inflammation modulation. To our knowledge, this is the first data to demonstrate long-term effect and validate through ultrasound. It is hoped that implementing this treatment earlier will decrease patient suffering, clinic visits, and need for costly surgical intervention.

References

1. Cole C, et al. Plantar Fasciitis: Evidence-Based Review of Diagnosis and Therapy. *Am Fam Physician* 2005;72:2237-2242.
2. Tong KB, Furia J. Economic Burden of Plantar Fasciitis Treatment in the United States. *Am J Orthop* 010;39(5):227-231.
3. The Diagnosis and Treatment of Heel Pain: A Clinical Practice Guideline Revision 2010. *The Journal of Foot & Ankle Surgery* 49 (2010) S1-S19
4. Fetterolf DE, Snyder RJ. Scientific and Clinical Support for the Use of Dehydrated Amniotic Membrane in Wound Management. *Wounds* 2012;24(10):299-307
5. Istwan N. Retrospective Evaluation of AmnioFix Injectable Human Amniotic Membrane Allograft for the Treatment of Plantar Fasciitis. MiMedx Group, Inc. Data on File.