



CENTRAL | TENNESSEE
FOOT and ANKLE CENTER

A Retrospective Clinical Evaluation of Using Cryopreserved Placental Tissue

Matrix in Treating Chronic Plantar Fasciitis

Jeffrey Loveland, DPM, FACFAS; Philip Basile, DPM, FACFAS; Bryon McKenna, DPM



Statement of Purpose

The object of this study was to evaluate the clinical effectiveness of a human cryopreserved placental tissue matrix as an advanced therapeutic treatment for chronic plantar fasciitis.

Hypothesis: We hypothesized that injection of cryopreserved placental tissue matrix as an advanced treatment for chronic plantar fasciitis would result in similar reduction of pain and functional outcomes as reported in the literature for other advanced therapies for similar patients. **Level IV Retrospective**

Literature Review

Plantar fasciitis is one of the most common causes of foot pain and is the most common cause of heel pain, affecting over 1 million people yearly in the United States⁶. Research has shown that plantar fasciitis is thought to be caused by repetitive trauma to the plantar fascia resulting in degenerative changes to the fascia^{7,8}. The majority of patients with plantar fasciitis respond favorably to conservative treatment, however it is ineffective in 10-15% of patients^{7,8}. These are the patients that require more invasive treatment options, including consideration for possible surgical intervention and possible injection of cryopreserved placental matrix. There are studies that have evaluated the effectiveness of injectable amniotic tissue in the treatment of plantar fasciitis, however more research is needed.

Hanselman et al.¹ performed a randomized controlled, double blinded trial with 23 patients randomized in to 2 groups, c-hAM (N=9) and corticosteroid (N=14). All patients were given injections at the initial visit and offered a 2nd injection at 6 weeks. The primary outcomes were measured utilizing the Foot Health Survey Questionnaire (FHSQ) and visual analog scale (VAS). This was an underpowered study however there was no statistical significance between the corticosteroid group and the c-hAM group with the FHSQ and VAS. They concluded that injection of c-hAM was a safe and comparable treatment option for plantar fasciitis compared to corticosteroid injection.

Zelen et al.⁵ published a randomized controlled prospective study examining the feasibility and effectiveness of using micronized dehydrated human amniotic/chorionic membrane (mDHACM) as an injectable treatment for refractory plantar fasciitis. Patients (N=45) were randomized into 3 treatment groups, control, 0.5cc and 1.25cc of mDHACM. All patients had at least 8 weeks of symptomatic plantar fasciitis and failed at least 3 conservative treatment options without previous injections. The AOFAS hindfoot scale was utilized, at 8 weeks, the control group score improved on average by 12.9, 0.5cc group 51.6 and 1.25cc group 53.3. The conclusion was made that mDHACM injection is a viable treatment option for retractable plantar fasciitis.

Methodology

Population: N=21 patients, 25 procedures (4 bilateral) that have undergone treatment of Plantar fasciitis with injection of cryopreserved placental tissue matrix (cPTM)

Consecutive adult patients who underwent surgical correction of plantar fasciitis were identified via surgical logs between 2016-2017 to achieve the needed sample size.

Study Design: Retrospective multi-center case series

- | | |
|---|--|
| Additional Inclusion Criteria: | Exclusion Criteria: |
| <ul style="list-style-type: none"> Clinical diagnosis of Plantar Fasciitis Treated with 2cc injection of cryopreserved placental tissue matrix Minimum of 10 month follow up | <ul style="list-style-type: none"> Less than 10 months of follow up |

Average Follow Up: 11 months

Procedures: Injection of cryopreserved human placental matrix and partial plantar fasciectomy

Primary outcome: Time to pain free ambulation

Secondary outcomes: Time to treatment, conservative measures exhausted, pain, functional outcomes

Methods: Retrospective chart review of patients meeting the aforementioned inclusion criteria

Conflicts of Interest: Wright Medical Technology (JL), Wright Medical Technology (PB)

Procedure: Placental Tissue Matrix Injection

Step 1

Incision

- Patient is brought to the operating room and placed under anesthesia
- A 4cm incision is first drawn out then performed over the medial calcaneal tubercle
- Dissection is carried down to the level of the plantar fascia



4 cm incision over the medial calcaneal tubercle

Step 2

Medial band partial fasciectomy

- Release part of the medial band of the plantar fascia is performed utilizing sharp scissors
- Only the medial band fibers are released approximately 0.5 cm total



Step 3

Injection of c-hAM

- 2 ccs of cryopreserved placental matrix is injected around the insertion of the plantar fascia
- 18 gauge needle utilized for injection
- Incision is sutured closed and a dry sterile dressing is applied



2 cc of cryopreserved placental tissue

Post-operative Protocol

- Immediately post op, placed in a CAM boot and instructed to weight bear as tolerated
- First post op appointment 5-7 days post op
- Sutures removed around 2 weeks post op
- Return to shoe gear following removal of sutures

Results

Variable	N
Patients	21
Procedures	25 (female = 21, male = 4)
Average age	48.2 years old
Average follow-up	11 months
Average Duration prior to surgery	9.48 months
Diabetic	3
Fibromyalgia	3

Table 1. Patient Demographics

Graph 1. Primary outcome

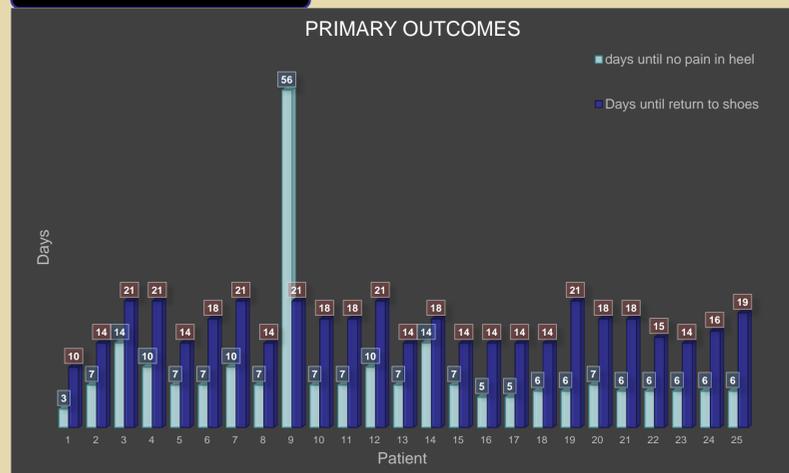


Table2. Primary Outcomes

Variable	N
Avg. days until no pain in heel	9.28 days (3-56 days)
Avg. days return to shoes	16.8 days (10-21)

Analysis and Discussion

The aim of this study was to evaluate the effectiveness of injection of cryopreserved placental tissue matrix as an advanced therapy for chronic plantar fasciitis. A total of 21 patients undergoing 25 procedures were included in the study with a minimum follow up of 10 months and average follow up of 11 months. The average duration post operatively to no pain in the heel was 9.28 days and average return to regular shoe gear was 16.8 days. All patients that were enrolled in the study had attempted and failed a minimum of 3 conservative treatment modalities with persistent pain. Treatment modalities included: steroid injections, NSAIDS, stretching exercises, ice massage, inserts, night splint and physical therapy. The average duration of plantar heel pain prior to injection of placental matrix was 9.48 months. There were 2 patients that were included that had previous plantar fascia surgeries, one had a partial plantar fascia release 4 years prior to the injection and the other had a partial plantar fascia release 1 year prior to the injection. There was one patient that required a corticosteroid injection approximately 7 weeks following the injection of the placental tissue matrix because of continued pain in the heel. This patient heel pain resolved after the corticosteroid injection, the patient had no significant past medical history. There were no complications associated with the injection of the placental matrix in this study.

All patients in this study required only 1 injection of 2 ccs total of cryopreserved human placental matrix in contrast to previous studies in which patients were offered a second injection^{1,5}. The results of this study are very promising for the effectiveness of a single injection of cryopreserved human placental matrix for the treatment of chronic plantar fasciitis with minimal complications. Some of the limitations of this study includes the small sample size of patients at this point, the retrospective nature of this study, and possible selection bias for patients being selected for the procedure although attempts were made to minimize all biases. In conclusion, the injection of placental tissue matrix has significantly decreased pain from baseline and improved functional recovery at an average of 11 months.

References

- Hanselman AE, Tidwell JE, & Satroek RD (2015). Cryopreserved human amniotic membrane injection for plantar fasciitis: a randomized, controlled, double-blind pilot study. Foot and Ankle International, 36(2), 151-8. doi: 10.1177/1071100714552824. Epub 2014 Sep 23.
- Davis JW. Skin transplantation with a review of 550 cases at the Johns Hopkins Hospital. Johns Hopkins Med J. 1910;15.
- Toomey EP. Plantar heel pain. Foot Ankle Clin. 2009;14(2):229-245. doi:10.1016/j.facl.2009.02.001.
- Sabella N. Use of fetal membranes in skin grafting. Med Records NY. 1913;83:478-480.
- Zelen CM, Poka A, Andrews J. Prospective, randomized, blinded, comparative study of injectable micronized dehydrated amniotic/chorionic membrane allograft for plantar fasciitis—a feasibility study. Foot Ankle Int. 2013;34(10):1332-1339. doi:10.1177/1071100713502179.
- Mahowald S, Legge BS, Grady JF. J Am Podiatr Med Assoc. 2011;101(5):385-9Goff JD, Crawford R. Diagnosis and treatment of plantar fasciitis. Am Fam Physician. 2011;84(6):676-82
- Thomas JL, Christensen JC, Kravitz SR, et al.; American College of Foot and Ankle Surgeons Heel Pain Committee. The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. J Foot Ankle Surg. 2010;49(3 suppl):S1-S19
- Donley BG, Moore T, Sferra J, Gozdanovic J, Smith R. The efficacy of oral nonsteroidal anti-inflammatory medication (NSAID) in the treatment of plantar fasciitis: a randomized, prospective, placebo-controlled study. Foot Ankle Int. 2007;28(1):20-23