

A Retrospective Clinical Evaluation of the Use of Placental Tissue Matrix in Patients with Chronic Plantar Fasciitis

Jeffrey D Loveland*

Central Tennessee Foot and Ankle Center, Sparta, Tennessee, United States

Abstract

Background: Plantar fasciitis is a common cause of foot and heel pain, affecting over one million people yearly in the United States. Most patients with plantar fasciitis respond favorably to conservative treatments, but these are ineffective in 10-15% of patients. A more invasive option is surgery with the use of placental tissue allograft to supplement/replace damaged or inadequate connective tissue.

Methods: This single-site, retrospective, consecutive case series evaluated safety and efficacy of flowable placental tissue matrix (PTM) in 67 procedures of 65 patients with chronic plantar fasciitis along with partial plantar fasciotomy. Inclusion criteria consisted of plantar fasciitis; failure of \geq 3 conservative treatments; partial fasciotomy with flowable PTM; and \geq 12 months follow-up. The primary outcomes were time to pain-free ambulation and the change in visual analog scale pain score. The secondary outcome was duration of heel pain. All patients underwent partial plantar fasciotomy with injection of 2.0 ccs of flowable PTM into the damaged connective tissues.

Results: The mean preoperative visual analog scale (VAS) pain score was 6.72 ± 0.90 (range from 4 to 8). The mean postoperative VAS score at 4 weeks was 0.37 ± 0.79 , demonstrating a 94.49% decrease in pain (P<0.001), and at 12 weeks was 0.09 ± 0.38 , a 98.66% decrease in pain (P<0.001). Seven patients (10.45%) in the study required additional intervention following application of the flowable PTM with fasciotomy. The average duration of plantar heel pain prior to surgery was 9.48 months (range from 2 to 36 months).

Conclusion: Overall we found that patients with recurrent heel pain secondary to plantar fasciitis reported a significant decrease in pain from prior to surgery to both four and twelve weeks postoperatively. Patients also experienced improved functional recovery following plantar fasciotomy with application of flowable PTM.

Keywords: Placental tissue matrix, Plantar fasciitis, Heel pain, Placental allograft

Level of Evidence: Therapeutic, Level IV, Retrospective

Introduction

Plantar fasciitis is one of the most common causes of foot pain and the most common cause of heel pain, affecting over one million people yearly in the United States [1-3]. 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 [2,4]. Usually selflimiting, plantar fasciitis tends to improve within one year, regardless of treatment. Debilitating heel pain is generally what drives people to seek medical attention.

The plantar fascia is the fibrous tissue originating at the medial tubercle of the calcaneus, which inserts into the transverse ligaments of the metatarsal heads. The fascia divides into five digital bands at the metatarsophalangeal joints, continuing forward to the plantar aspect of the toes, along with a rich network of small plantar nerves [5]. The plantar fascia is composed of medial, central, and lateral bands, with the central plantar fascia the most involved in plantar fasciitis. Plantar fasciitis is a condition of the plantar fascia that can cause severe heel pain in sufferers. Although commonly mischaracterized as "chronic inflammation," the pain from plantar fasciitis is actually a result of collagen degeneration caused by microtears from repetitive stress [6,7].

Up to 10% of the U.S. population will experience plantar fasciitis in their lifetime, typically in the fourth and fifth decades [3]. A recent study found a higher prevalence of plantar fasciitis in those aged 45 to 64 (1.33%) versus those aged 18 to 44 (0.53%) years [8]. Women are affected about 2.5 times as often as men, while race and ethnicity do not impact the incidence of plantar fasciitis. When treating plantar fasciitis, the primary goals for both patient and clinician are typically pain relief and functional improvement [9], both of which were assessed in this study. The majority of patients with plantar fasciitis respond favorably to conservative treatments, such as rest, ice, non-steroidal anti-inflammatory drugs (NSAIDs), stretching, or over-the-counter orthotics, while some patients require physical therapy, corticosteroids, custom arch supports, or night splints. These measures, however, are ineffective in 10-15% of patients [2,4]. In patients for whom the more conservative approaches are unsuccessful, more invasive treatments may be necessary to provide relief. One such option is surgical intervention with the use of allograft derived from placental tissue that is intended to supplement and replace damaged or inadequate connective tissue.

While treatment of plantar fasciitis by fasciotomy alone may be successful in some patients, there are limitations. These limitations include instability, lateral column pain, sinus tarsitis, medial arch pain and fatigue, metatarsalgia, strain along the lesser tarsus, possible secondary stress fractures, continued pain and inflammation [10,11], acute plantar fascia rupture, perifascial edema, pathology related to arch instability [12,13], and decreased arch supporting function of

*Corresponding author: Jeffrey D Loveland, Central Tennessee Foot and Ankle Center, Sparta, Tennessee, United States, Tel: 9317381026; E-mail: lovelanddpm@ yahoo.com

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the planar fascia [14]. These potential complications have led to the implementation of modified or alternative treatment approaches,

including the use of placental tissue in addition to the fasciotomy.

Increasingly, fetal placental tissue has been proposed for use in a range of conditions, including plantar fasciitis. Fetal placental tissue can be classified as amniotic membrane, chorionic membrane, umbilical cord tissue and blood, and amniotic fluid and is known for its therapeutic properties [15,16]. These fetal tissues contain various growth factors, cytokines, and matrix proteins that promote healing differently than adult tissues [17-19]. Fetal tissues not only promote regeneration, but they can decrease both inflammation and scarring [17]. It is these properties that drove the use of fetal tissues initially as treatments for burns and chronic wounds and now as therapies or adjuncts in numerous medical specialties [17,19].

There are a number of advantages conferred by fetal placental tissue. The placental extracellular matrix (ECM) supports healing by promoting tissue reconstruction instead of scar tissue formation. This ECM is rich in growth factors and proteins with anti-inflammatory and anti-fibrotic properties, which down-regulate transforming growth factor beta (TGF-β), suppress pro-inflammatory cytokines, and inhibit matrix metalloproteinases (MMPs) and fibroblast formation in utero [20-22]. Fetal tissues are also non-immunogenic, so there is little risk of reaction or rejection in the patient which can lead to fibrosis and graft failure [22-24]. Additionally, placental ECM is collagen-rich, containing a variety of collagens and fibrous proteins that provide a scaffold structure. Finally, ECM has fibronectin, laminin, integrins, and hyaluronic acid, all of which are important for cellular proliferation and adherence to the scaffold [23,24]. These characteristics of fetal placental tissue imply there would be potential benefit to patients undergoing treatment for plantar fasciitis.

VIAFLOWTM (Wright Medical Group, N.V., Memphis, TN, USA) is a sterile, human tissue allograft, derived from decellularized particulate human placental connective tissue matrix and is intended for homologous use to replace or supplement damaged or inadequate integumental tissue [25]. This substance is composed of pre-mixed, flowable, tissue matrix allografts made from human placental tissues. It can be stored at room temperature for up to five years.

While the therapeutic use of placental tissue has been published across numerous medical specialties [15,16,20,26,27], little has been published in the orthopedic or podiatric literature. In 2018, McIntyre et al. published a comprehensive literature search, of references up to and including 2016, identifying just 6 published human studies and 29 animal studies that investigated the safety and/or efficacy of placental tissues or cells as a therapeutic agent for orthopedic uses [28]. Of the 35 identified studies, very few have evaluated the effectiveness of flowable placental tissue matrix in conjunction with a fasciotomy for plantar fasciitis [17,29].

In this study, we assessed the impact of application of a flowable human placental tissue matrix (PTM) in conjunction with partial fasciotomy for chronic plantar fasciitis. Based on review of the literature and previously conducted studies, we hypothesized that the application of the flowable PTM with partial fasciotomy in the treatment of chronic plantar fasciitis would result in reduction in pain and improved functional outcomes. The primary outcome measure was time to pain-free ambulation and the associated visual analog scale (VAS) of pain score.

Materials and Methods

Study population

To evaluate the safety and efficacy of flowable placental tissue matrix in patients with chronic plantar fasciitis, we reviewed consecutive data from adult patients who underwent surgical correction for plantar fasciitis from August 2016 through January 2019. All patients were treated at the St. Thomas Highlands Medical Center and Central Tennessee Foot and Ankle Center, Sparta, TN The following inclusion criteria were specified: A clinical diagnosis of plantar fasciitis; failure of at least three different conservative treatment measures (stretching exercises, ice massage, NSAIDs, steroid injections, orthotics, physical therapy, or night splints); use of 2.0 cc of flowable PTM during the procedure; and minimum follow-up of 12 months. Patients were excluded if flowable PTM was not used or had less than 12 months of follow-up. Sixty-five patients who had undergone 67 procedures (2 bilateral) for plantar fasciitis with flowable PTM application were identified and added to the sample population.

This single-site, retrospective, consecutive case analysis was designed and implemented by JL who examined all patients, collected all data for the study, and performed all surgical procedures, as well as all chart reviews. As part of routine clinical protocols, the risks, benefits, and alternatives to surgery were explained to all patients prior to surgery, and signed informed consent was obtained. De-identified data of these patients were collected and analyzed in accordance with good clinical practice and the tenets of the Declaration of Helsinki and its amendments. The Western Institutional Review Board (IRB; Puyallup, WA) determined that this research project was exempt from IRB oversight.

Outcome measures

The primary outcome measure was time to pain-free ambulation and the associated VAS pain score. The secondary outcome was the duration of heel pain.

Surgical technique

For this study, a surgical procedure was adapted to address the chronic plantar fasciitis condition of the patients. The surgical approach involved three basic steps and a few minutes to complete the procedure. First, the patient was brought into the operating room and placed under anesthesia. A 4 cm incision was drawn out along the medial aspect along the calcaneal tubercle (Figure 1). Dissection

Figure 1: A 4 cm incision was drawn out along the medial aspect of the calcaneal tubercle, and dissection was carried down to the level of the plantar fascia.



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was carried down to the level of the plantar fascia. Second, a partial release of the medial band of the plantar fascia was performed utilizing sharp scissors (Figure 2). Only the medial band fibers were released, approximately 0.5 to 1 cm in total. After completing the fasciotomy, 2.0 cc of flowable PTM was drawn up with an 18-gauge needle and applied into the connective tissue surrounding the insertion of the plantar fascia with a 21-gauge needle (Figures 3 and 4). Following application, the incision was sutured closed, and a dry, sterile dressing was applied.

Postoperative protocol

Patients were immediately placed in a controlled ankle motion (CAM) boot postoperatively and permitted to weight bear as tolerated. The patients were seen in clinic five to seven days postoperative for a wound check. Sutures were typically removed around two weeks postoperative. The patients could return to normal shoes after the removal of the sutures. All patients were followed for at least 12 months following surgery.

Statistical analysis

Categorical data are presented as counts and rates while continuous



Figure 2: A partial release of the medial band of the plantar fascia was performed utilizing sharp scissors.



Figure 3: Two ccs of cryopreserved placental matrix was injected around the insertion of the plantar fascia.



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data are presented as means and standard deviations. Paired t-test was performed to assess the statistical significance of VAS pain reduction. All statistical analyses were performed using statistical software (SAS, Version 9.4, SAS Inc., Cary, NC).

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Results

Included in the study were 67 joints of 65 patients (15.38% male) with a mean age of 48.06 ± 12.81 (range 18 to 78) who had undergone procedures (2 bilateral) for plantar fasciitis. Of the 67 joints, 33 (50.75%) were right, and 34 (49.25%) were left. All patients received the same treatment - partial plantar fasciotomy with application of 2.0 ccs of flowable PTM into the damaged connective tissues. The average follow-up for these patients was 14 months (range from 12 to 24 months). Table 1 shows patient demographic information and pertinent systemic comorbidities.

A VAS pain score was used to assess patient degree of pain both preoperatively and postoperatively. Patients verbally rated their pain on a 0 to 10 scale. The mean preoperative VAS pain score was 6.72 \pm 0.90 (range from 4 to 8), and the mean postoperative VAS score at 4 weeks was 0.37 \pm 0.79 (range from 0 to 3). The reduction in VAS score from baseline to week 4 was -6.35 ± 1.14 (range from -8 to -3), demonstrating a 94.49% decrease in pain, and is statistically significant (P<0.001). At 12 months, there were only 4 patients that still reported pain. The mean VAS score at 12 months was 0.09 ± 0.38 (range from 0 to 2). From baseline to month 12, the reduction in VAS score was -6.63 \pm 1.01 (range from -3 to -8). This represents a 98.66% decrease in pain from baseline, again at a statistically significant level (P<0.001). All results are summarized in Table 2.

The average duration of plantar heel pain prior to the procedure was 9.48 months (range from 2 to 36 months). Two patients were included that had previous plantar fascial surgeries. One had a partial plantar fascia release four years prior to this procedure, and the other had a partial plantar fascia release one year prior to the procedure. All patients enrolled in the study had attempted and failed a minimum of three conservative treatment modalities with persistent heel pain.

Seven patients (10.45%) in the study required additional intervention following application of the flowable PTM with fasciotomy. Four patients required a follow-up corticosteroid injection

Characteristic	Value
Sex (n, %)	
Male	10 (15.38)
Female	55 (84.62)
Age (y)	
Mean ± standard deviation	48.06 ± 12.81
Median	49
Range	18.0 to 78.0
Laterality (n, %)	
Right	33 (50.75)
Left	34 (49.25)
Comorbidities (n, %)	
Neuropathy	10 (15.38)
Diabetes	11 (16.92)
Hypertension	22 (33.85)
Fibromyalgia	12 (18.46)
Restless leg syndrome	9 (13.85)
Other (COPD x2, atrial fibrillation, ADHD, rheumatoid arthritis x2)	6 (9.23)
COPD: Chronic Obstructive Pulmonary Disease; ADHD: Attention De Disorder.	ficit Hyperactivit

Endpoint		Value
Average duration of pain before surgery (months)	N	67
	$\begin{array}{c} Mean \pm standard \\ deviation \end{array}$	9.70 ± 5.46
	Range	2 to 36
Pre-operative VAS score*	N	67
	Mean ± standard deviation	6.72 ± 0.90
	Range	4 to 8
VAS score*, 4 weeks postoperatively	N	67
	$\begin{array}{c} Mean \pm standard \\ deviation \end{array}$	0.37 ± 0.79
	Range	0 to 3
VAS score* change from baseline to 4 weeks postoperatively	N	67
	Mean ± standard deviation	(- 6.35 ± 1.14)**
	Range	- 3 to - 8
VAS score*, 12 months postoperatively	N	67
	Mean ± standard deviation	0.09 ± 0.38
	Range	0 to 2
VAS score* change from baseline to 12 months postoperatively	N	67
	$\begin{array}{c} Mean \pm standard \\ deviation \end{array}$	(- 6.63 ± 1.01)**
	Range	-3 to - 8
*VAS measured on a scale from 0-10, *P-value<0.0	001	

 Table 2: Study Results (N = 67 joints of 65 patients).

to address persistent pain, and the injection resolved the remaining pain. These steroid injections occurred between 7 weeks and 6 months postoperatively. Interestingly, three of these four patients also reported to have restless leg syndrome (RLS). While there is no clinical trial data linking these two conditions, it is not uncommon for RLS patients to experience concurrent foot problems, and it has been hypothesized that the gait changes, which often accompany plantar fasciitis, can trigger restless leg syndrome [30]. Two other patients required formal physical therapy at 6 and 7 weeks postoperatively, and one patient reported taking NSAIDs to address the remaining postoperative pain.

Of the four patients requiring a steroid injection, one with no significant medical history required a corticosteroid injection approximately seven weeks following application of the flowable PTM because of continued heel pain. This patient's heel pain resolved after the corticosteroid injection, and the patient returned to the office to have the PTM application in the contralateral heel six months later. There were no complications or adverse reactions attributable to the application of the flowable PTM in this study.

Discussion

All patients enrolled in our study had attempted and failed a minimum of three conservative treatment modalities with persistent pain. Treatment modalities included: steroid injection, NSAIDs, stretching exercises, ice massage, orthotics, night splints, and physical therapy. These therapies all have potential limitations or drawbacks. For example, steroid injections in plantar fasciitis play a significant role in short-term therapy,[31] however, several complications have been noted. Complications may include plantar fascial rupture, plantar fat pad atrophy, lateral plantar nerve injury secondary to injection, and calcaneal osteomyelitis [32-37]. Another example would be treatment with a stretching regimen. While stretching shows limited short-term benefit, long-term benefit may be seen if patients are compliant over many months [38]. When patients failed at least three of these more conservative treatment strategies, the next therapeutic step was surgery, specifically fasciotomy with flowable PTM.

All patients in this study received only one application of 2 cc room temperature flowable PTM, in contrast to previous studies in which patients were offered a second injection [17,29,39]. In those studies, smaller amounts of amniotic tissue were applied rather than a high concentration placental tissue matrix.

With respect to safety of flowable PTM in this patient population, there were no adverse reactions in any of the patients that received an injection in the heel region.

There is always a risk of a patient with plantar fasciitis not healing completely following one injection of flowable PTM with fasciotomy. The 90% of patients who had resolution of pain following one injection, as well as the four who improved following steroid injection and the one whose pain resolved with NSAID therapy, have results that can all be attributed to scar tissue and some inflammation from surgery. It is more difficult to explain the two patients for whom physical therapy helped to alleviate soreness.

Although attempts were made to minimize all biases, some of the limitations of this study include small sample size, retrospective nature of the study, and possible patient selection bias. Additionally, the analysis was not done comparing fasciotomy with flowable PTM to another treatment or intervention.

In addressing the lack of a comparator arm, we reviewed the literature to compare our results to published results of plantar fasciotomy outcomes, specifically those studies that included pain assessment via VAS pain score. Since surgery is typically a later treatment step, [2,4,40,41] the literature is quite sparse, particularly with respect to any prospective studies. There are very few studies that prospectively compare conservative treatment options for plantar fasciitis to surgical interventions, and no quality randomized clinical trials that compare the various surgeries as treatment for chronic plantar fasciitis [42].

There are several retrospective reviews [40,43-47] ranging from 26 joints of 23 patients [43] to 83 joints of 79 patients [40]. These studies all measured pain via VAS, with decreases in pain ranging from a 70.59% reduction in pain [45] to an 85.71% reduction [47]. These reductions are all less than the 94.49% decrease in pain measured by VAS in our study. Although methodologies varied across these reviews and when compared to this study, we believe that the addition of flowable PTM to partial plantar fasciotomy may result in a greater decrease in postoperative pain levels.

Conclusion

Patients with recurrent heel pain secondary to plantar fasciitis reported a significant decrease in pain from prior to surgery to four weeks and twelve weeks postoperatively. Patients also experienced improved functional recovery following plantar fasciotomy with application of flowable PTM. These results are very promising for plantar fasciotomy with a single application of flowable PTM for the treatment of chronic plantar fasciitis with minimal complications. Future studies comparing plantar fasciotomy with and without application of flowable PTM would serve to confirm these findings.

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