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## Case Reports and Series

## Open Surgical Implantation of a Viable Intact Cryopreserved Human Placental Membrane for the Treatment of Recalcitrant Plantar Fasciitis: Case Report With Greater than 2-Year Follow-Up Duration

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## ABSTRACT

Plantar fasciitis is one of the most common conditions encountered by a podiatric physician. Although most individuals respond well to traditional conservative and surgical remedies, a portion of patients will exhaust all available treatment options and will experience ongoing pain that can ultimately affect their quality of life. There has been an increase in scientific and clinical research surrounding the medical use of human placental membranes (HPMs) and many of these point-of-care allografts are now commercially available. We present the case of a 53-year-old female with chronic plantar fasciitis for whom both conservative therapies and surgical treatments of 1 year's duration had previously failed. After open revision with implantation of viable intact cryopreserved human placental membrane (vCPM; Grafix<sup>®</sup>, Osiris Therapeutics, Inc., Columbia, MD), the patient was able to resume her full-work duty with minimal symptoms at the 12- and 24-month follow-up examinations. This case report highlights the use of HPMs as an adjunct approach in the treatment of recalcitrant plantar fasciitis and the need for continued research.

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Plantar fasciitis is one of the most common causes of heel pain, affecting approximately 2 million people in the United States and resulting in >1 million visits to physicians annually (1,2). Plantar fasciitis is the result of repetitive loading and subsequent strain on the plantar fascia, which, in turn, elicits microtrauma to the fascia (3,4). Although 90% to 95% of patients with plantar fasciitis will experience resolution of symptoms within 1 year with conservative regimens, patients with unresolved or worsening symptoms experience chronic plantar fascia pain for which current surgical treatments have had limited efficacy in addressing and resolving the underlying etiology (5–8). For chronic cases of plantar fascia pain for which both conservative and surgical treatment protocols are inadequate in providing relief, human placental membrane (HPM) usage offers an alternative solution.

The amniotic membrane is the innermost tissue layer of the placenta, which is abundant in multipotent stem cells and various bioactive factors that promote and facilitate the innate tissue repair process (9,10). These factors are inclusive of fibronectin, laminin, and various collagen types (including collagen types III, IV, and V) (10). Other components in the amniotic membrane, such as intact 3-dimensional architecture of extracellular matrix (ECM) and viable cells such as fibroblasts and mesenchymal stem cells, have been correlated with decreased fibrosis and reduced bacterial load in wounds. In addition, these components have been noted for their unique capabilities of pain suppression and promotion of tissue repair (9–12). Owing to its capacity for aiding in regeneration and the healing processes, the use of HPM is a potential alternative therapy for degenerative tissue disorders such as plantar fasciitis. In the present case report, we present our results with a case involving amniotic membrane placement by way of open plantar fasciotomy revision after unsuccessful primary endoscopic plantar fasciotomy (EPF).

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## Case Report

A 53-year-old Hispanic female, with a body mass index of 27 kg/m<sup>2</sup> and without significant medical history, employed as a janitor at a local

hospital, presented to the podiatry clinic with complaints of sharp right heel pain and palpable lumps along the plantar medial foot arch. The classic symptoms of plantar fasciitis were noted during the patient interview, including pain with morning steps, pain located at the plantar medial arch, and pain with prolonged activity. Using a numeric rating scale (NRS-11), the patient reported a baseline clinical pain measurement of 8 of 10 (13). On physical examination, it was also determined that the patient had a gastrocnemius equinus deformity and experienced an intensified sharp pain on physician palpation of the medial plantar calcaneal region.

The patient's initial treatments included nonsteroidal antiinflammatory drugs, stretching programs, and rest, to which the patient was reportedly compliant yet found no improvement in function or reduction in pain which remained at 8 of 10 after 4 weeks. Once the poor response to first-line conservative measures was demonstrated, treatment was advanced to adjunct physician-prescribed therapies, including prefabricated foot orthotics and a series of 4 corticosteroid injections (0.5 cc triamcinolone acetonide injectable suspension [40 mg/1 ml] with 2.5 cc 0.5% bupivacaine plain) localized to the area of maximal tenderness. During a 6-month period, the patient continued to experience discomfort without relief of symptoms, and the NRS-11 clinical assessment of pain continued at the level of 7 of 10.

Subsequently, right EPF, in conjunction with percutaneous Achilles tendon lengthening (TAL), was performed 9 months after the patient's initial presentation. The patient was placed in a posterior splint and instructed to remain non-weightbearing for 2 weeks postoperatively. The skin sutures were removed on postoperative day 14, and the patient began full weightbearing activities in a controlled ankle motion boot. At 4 weeks postoperatively, the patient was transitioned to regular running shoes and reported a slight attenuation of symptomatic pain with an overall improvement from her baseline condition. The NRS-11 clinical assessment of pain had decreased to 4 of 10.

At 10 weeks after surgery, the patient reported that her pain level with ambulation was worsening compared with at the previous visit. At 14 weeks postoperatively, the patient reported sharp pain at the insertion site of the plantar fascia comparable to her preoperative condition, and she rated her pain as 7 of 10. Thereafter, her level of pain ranged from 6 of 10 to 8 of 10 and persisted for the first 6 months after the EPF-TAL surgery. At best, her overall daily heel pain had only decreased approximately 25% after 1 year of treatment, including surgery. At no time did the patient ever experience radiating pain or paresthesia suggestive of tarsal tunnel syndrome or plantar nerve entrapment.

At this point, and after discussion of the potential benefits and risks, postoperative course, and expectations, the decision was made to undertake open plantar fasciotomy combined with the placement of a viable intact cryopreserved human placental membrane (vCPM; Graftix<sup>®</sup>; Osiris Therapeutics, Inc., Columbia, MD). The patient provided informed consent, and the procedure was scheduled (Fig.). As a part of the surgical revision procedure, a plantar-medial transverse skin incision was made just distal to the heel weightbearing surface. Dissection through the subcutaneous layer was continued until the plantar fascia was sufficiently visualized. The deep plantar fascia displayed fibrosis and hypertrophy and was palpably indurated. The medial third of the plantar fascia was transected, and the vCPM was placed on the superficial surface of the fascia, covering the area of the transection. The subcutaneous tissue and skin were closed as separate layers at the site of incision. The patient was initially placed in a posterior splint and instructed to be non-weightbearing on the operated foot. After 2 weeks, the patient was transitioned to partial and then to full weightbearing in a controlled ankle motion boot, at which time she rated her heel pain as 7 of 10. The patient's skin sutures were removed at 3 weeks postoperatively, at which time she rated her heel pain as 5 of 10. At the 6-week follow-up assessment, the surgical site dem-

onstrated minimal edema and only slight tenderness. She rated her heel pain as 3 of 10 on the NRS-11.

At the 6-week postoperative examination, the patient was instructed to transition back to regular shoes at her own discretion. At 12 weeks postoperatively, the patient reported an intermittent pain level of 3 of 10 and had resumed her previous work duty without limitations. Finally, by the 12-month postoperative follow-up visit, she was fully active without restrictions and had resumed her pre-heel pain active lifestyle. She rated her pain as 2 of 10. During the ensuing year, the patient continued to improve, and she related no activity limitations and reported that her residual pain was perhaps 10% of that before treatment. The patient's final postoperative outcome after open plantar fasciotomy release with placement of a vCPM graft resulted in satisfactory recovery with a >90% decrease in pain and discomfort.

## Discussion

Despite the wide variety of conservative management modalities available for plantar fasciitis, progression to a chronic condition can still occur. For such patients, surgery is one of the alternative treatment options available. However, as many as 50% of patients will reportedly be left unsatisfied after their surgical interventions (14). Clinically, the degree of symptom severity and an increased duration of persistent symptoms preoperatively contribute to less successful outcomes after fasciotomy to treat chronic plantar fasciitis (14). As was exhibited by the failed initial surgical intervention in the present case study, surgery alone, whether endoscopic or not, will not always be clinically successful. We believe that in such cases, the area of pain might have been incised (released), but the abnormal healing process innate to chronic damage of the plantar fascia has not been addressed, resulting in complications such as hypertrophy, scarring or fibrosis, and pain.

In the present case, it was thought that placement of vCPM would minimize the potential surgical complications and would address the underlying etiologic issues of recalcitrant plantar fasciitis and therefore optimize patient outcomes. It has been theorized that the pain stemming from plantar fasciitis is rooted in abnormalities of the plantar fascia caused by repetitive microtrauma and stress (4,11). Initially, the microtrauma to the fascia elicits a reparative function by way of an acute inflammatory process, which is evidenced histologically by the infiltration of leukocytes and the development of tissue fibrosis and associated edema (8). This acute process permits increased synthesis of granulation tissue to successfully balance the matrix degradation caused by the microtrauma (8), thereby permitting regeneration of a competent matrix, a crucial component of healing. In contrast, with consistent trauma (e.g., a chronic process), the physiologic response required for normal healing becomes impaired.

The shift from acute to chronic plantar fasciitis is evidenced histologically by the ongoing infiltration of macrophages, lymphocytes, and plasma cells into the plantar fascia tissue. Inhibition of the mitogenic activity of fibroblasts, reduced growth factor levels, and abnormally elevated levels of matrix metalloproteinases, which degrade the ECM components, contribute to the pathologic process in which matrix degradation is favored over competent tissue generation (5,11). Eventually, the normal fascia is replaced by angiofibroblastic hyperplastic tissue that subsequently spreads to the adjacent tissue, creating a self-perpetuating circle of degeneration with widespread effects that progress with time (15).

In addition to tissue inhibitors of metalloproteinases, the components found in fresh HPM include a 3-dimensional ECM, growth factors, and viable epithelial cells, fibroblasts, and mesenchymal stem cells (10). The antiinflammatory, antimicrobial, and angiogenic properties of HPM might contribute to the host's natural tissue repair process (10). In larger randomized studies, commercialized HPM products have been

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