

## ALLOMEND CLINICAL REPORT SERIES

## VOLUME 1 - CASE STUDY

# AUGMENTATION OF THE PLANTAR FAT PAD USING ALLOMEND® ACELLULAR DERMAL MATRIX

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## ABSTRACT

Atrophy, a thinning of the plantar fat pad, can create severe problems, including skin breakdown leading to ulcers, chronic pain due to lesions and a general lack of shock absorption over pressure points in the foot. Allograft can be used to replace or augment tissue in the plantar fat pad, a significant weight-bearing area.

This paper presents two cases in which AlloMend® Acellular Dermal Matrix (ADM) (AlloSource®, Centennial, CO) was surgically implanted to enhance the plantar fat pad to promote healing and reduce pain. In Case 1, the procedure was used to resolve recurrent skin breakdown in the heel. In Case 2, the procedure addressed recurring pain and regrowth of a chronic intractable plantar keratoma in the ball of the foot.

In both cases, after more than one year, the enhanced padding was maintained and the patient symptoms remained resolved.

## Introduction

Atrophy in the plantar fat pad is defined as a degeneration to the point where the thickness is 3 mm or less. These pads provide protection from impact pressure and shear forces. The pads are composed of many honeycomb-style micro-chambers containing fatty tissue. The elastin (collagen) walls of the chambers are flexible and pliant and prevent the fat cushion from flattening out. When the fat pad deteriorates due to age or excessive weight bearing, the outer skin is more vulnerable to shearing and the development of painful scar-like lesions, wounds and ulcers. These can contribute to decreased ambulation, unsteady walking and increased incidents of falling.

Allograft tissue is increasingly used in these cases to augment fat pad tissue, reduce pain and spur the healing of trauma to the plantar aspect of the foot. In this study, two cases are presented in which AlloMend ADM was implanted in the plantar fat pad to help resolve recurring pain and damage that could not be controlled by more conservative measures.

AlloMend ADM, AlloSource's acellular human dermal matrix (AHDM) product, is available in multiple thicknesses and a variety of sizes. It is produced through a proprietary process of cleaning, rinsing and decellularizing human donor dermal tissue, with significant removal of cellular debris (including DNA and RNA), proteins and antigens. The decellularization process also inactivates microorganisms through cellular disruption and, as a result, the likelihood of inflammation or immunogenic rejection response by the recipient is further minimized.

The AlloMend process of manufacture results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties. This processing helps ensure that AlloMend ADM will be readily accepted by the recipient with subsequent revascularization and cell repopulation.

AlloMend ADM (Fig. 1) has proven to be a very robust and resilient dermal matrix product for placement in the most challenging environment, including high-stress areas on the bottom of the foot, while retaining flexibility and pliability characteristics that allow for precise placement and suturing. In biomechanical stretch tests, AlloMend ADM exhibited an ultimate tensile strength (UTS) of 20.7 MPa  $\pm$  2.2, surpassing published UTS data for other leading ADM products. In other tests, it exhibited a suture retention strength as strong as the force of the 2-0 suture that is typically used to place it.<sup>2</sup>



**Figure 1.** AlloMend ADM

## Case Reports

### CASE 1.

The patient was a 62-year-old non-diabetic female weighing 263 pounds (119 kg) with a significant history of plantar left heel complications.

In 2010, the patient underwent a successful triple arthrodesis of the left foot due to severe pronation pain. X-rays of the left heel revealed a large plantar calcaneal spur caused by extreme atrophy of the plantar fat pad. The spur was palpated on the plantar central heel. The blisters and ulcers initially healed with the use of topical therapy and off-loading pads. Although the heel was protected with ¼-inch (6.4 mm) silicone heel pads after the wound had closed, the blister returned and broke down again.

Subsequently, the patient once again developed problems with the plantar left heel, this time while recovering from a triple arthrodesis on the right foot performed in January 2013. In May 2013, she developed plantar heel blisters on the left foot that progressed to ulcers due to increased pressure while the right foot was non-weight bearing.

The patient developed a fibular fracture of the right leg in October 2013 and was weight bearing in a CAM (controlled ankle movement) walker on the right leg until January 2014. During that period, the patient experienced several recurrent breakdowns of the left plantar heel skin due to atrophy of the fat pad and the presence of a large calcaneal spur. It was determined that the spur should be removed and the fat pad augmented with an ADM to prevent a future breakdown.

The surgery was performed in October 2014. A medial plantar heel incision was used and the spur was resected with a rongeur and rasp. The plantar fat pad was augmented by placing AlloMend ADM Extra-Thick (2.0–3.3 mm thick) tissue using a parachute technique across the plantar heel in a layer created below the subcutaneous fat and superficial to the fascia and calcaneus.

The patient remained non-weight bearing for four weeks and the sutures were removed after 21 days. The patient was placed in a running shoe with a silicone gel heel cushion after 28 days. At that time, the patient was approved to put full weight on the foot.

Since that time, the patient has had no recurrent blister or ulcer breakdown of the left plantar heel (**Fig. 2**). After nearly two years, the augmented fat pad on the left heel was determined to be even more substantial than the fat pad on the right heel.



**Figure 2.** Case 1, Left Heal Two Years Post-Operative.

**CASE 2.**

The patient was a 54-year-old female school teacher weighing 195 pounds (88 kg) with a history of pain in her left foot from a chronic intractable plantar keratosis (IPK) sub third metatarsal phalangeal joint (MPJ). She previously had undergone an Austin bunionectomy, a 5th metatarsal head resection, a 3rd metatarsal distal neck osteotomy with screw fixation and a HyprocureR subtalar joint implant on the left foot by another doctor.

The patient continued to experience subtalar joint pain and a recurrent painful plantar 3rd MPJ IPK. The subtalar joint implant and screw in the 3rd metatarsal was removed in January 2012. The recurrent IPK was treated every 4-6 weeks with topical salicylic acid therapy. Offloading techniques were utilized, including orthotics and shoe modification. These provided temporary relief but as the lesion returned it once again became painful. The lesion was approximately 8 mm in diameter and extended full thickness into the dermis layer.

Attempts by the author to reduce the pain using sclerosis injections and an eventual excision of a neuroma in the 3rd IMS in March 2013 did not resolve the pain nor prevent the lesion from re-forming.

In June 2015, the patient underwent surgery by the author to excise the plantar lesion. AlloMend ADM Thick (1.0-2.0 mm thick) was placed below the fat layer augmenting the plantar fat pad. A plantar flap was created to cover the deficit.

The patient remained non-weight bearing for four weeks. After that time, the patient was allowed to bear weight while wearing a running shoe. Sutures were removed after 21 days. A slough of the apex of the skin flap was initially evident and the patient developed a superficial local infection at the site, but that condition responded well to an in-office local incision and drainage along with oral antibiotics.

After more than one year, the lesion had not returned and substantial padding was evident in plantar MPJs 2-3-4 (**Fig. 3**).



**Figure 3.** Case 2, Left Foot, One Year Post-Operative

## Discussion

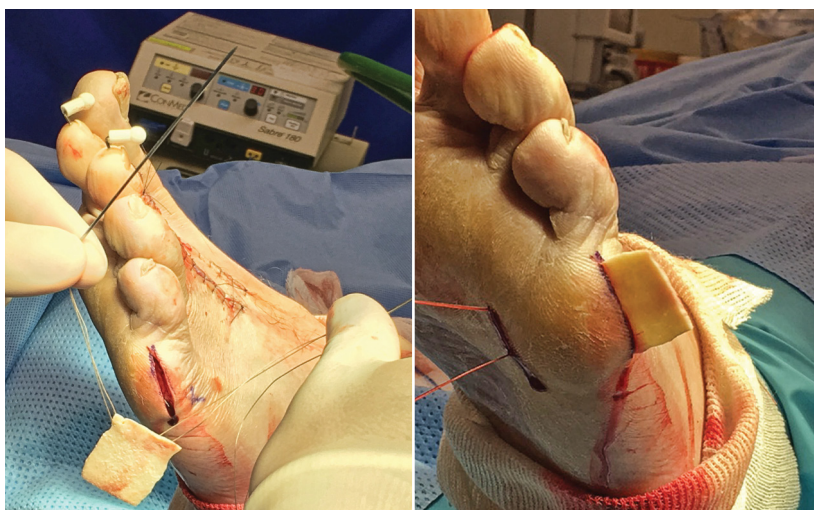
The preferred treatments for plantar fat pad atrophy have evolved. One approach focuses on offloading the site with increased padding, orthotics, braces and footwear modification. Other treatments include liquid silicone injection, autolipotransplantation and resection of bony prominent areas.

Balkin demonstrated that liquid silicone could be a safe, effective and stable material for addressing the loss of plantar fat.<sup>3</sup> After injecting silicone beneath the corns and calluses of 1,585 patients, migration of the silicone fluid was seen as the most significant response, although in cases of minor migration the original calluses remained improved or resolved.<sup>3</sup> Post mortem histopathological findings indicated that silicone fluid was well retained at the deposit site. Characteristics of inflammatory responses, such as an increase in lymphocytes, eosinophils and fibroblasts, were seen infrequently in silicone injected tissue.<sup>3</sup> However safety concerns with silicone remain, primarily related to inflammatory responses, foreign body reactions, migration locally and migration to lymph nodes. Further, the use of injectable silicone or any soft tissue injectable filler in the foot is not currently approved by the Food and Drug Administration.

With autolipotransplantation, suctioned fat is injected into fat pad site in a fan-like fashion. The procedure entails a second surgical donor site on the patient's body, with the associated risks. Another concern with this technique relates to fat resorption. Chairman reported in 1994 that transferred suctioned fat only maintained 32% of its volume and 41% of its thickness when transferred into a host area.<sup>4</sup> This can necessitate multiple applications and possible overcorrections.

Resection of bony prominent areas has been known to reduce plantar foot pain and lesions, such as in a Hoffman-Clayton procedure for severe rheumatoid arthritis deformity in feet. However, in many cases, even with reduction of the bony prominence, pain and lesions may remain due to severe fat pad atrophy.

In 1995, Rocchio reported on the use of ADM in 25 patients to address fat pad atrophy. He used the parachute technique to place the ADM (2 mm thick or 4 mm thick in cases of severe atrophy) in a minimally invasive fashion (demonstrated in **Fig. 4**). Patients were kept non-weight bearing for two weeks and then weight bearing for an additional two weeks. The thickness remained evident up to 12 months after surgery. The patient satisfaction rate was 95.8% at follow up, ranging from one to 27 months post-surgery.<sup>5</sup>



**Figure 4.** Parachute Technique Used for Inserting ADM

In 2012, Mulder reported using ADM on a 27-year-old woman who had lost her heel plantar fat pad in a motor vehicle accident. He used a 4cm X 12cm ADM to successfully replace the tissue. She was kept non-weight bearing for three weeks and allowed to return to shoes after six weeks.<sup>6</sup>

Also in 2012, Schoenhaus-Gold reported on the use of ADM to augment fat pads in diabetics with grade 0 ulcers. She placed the ADM using a modified parachute technique. Patients were partial-weight bearing for two weeks in surgical shoes and placed in running shoes at four weeks.<sup>7</sup>

### Summary

In these two cases, AlloMend ADM was successfully used to augment the plantar fat pad. In both instances, more than a year after placement of the graft, the thickness of the pad has been maintained and the pad shows no sign of breakdown or thinning.

AlloMend ADM appears to be well-suited for plantar fat pad augmentation given that it maintains its physical properties over time, is easily manipulated, incorporates well without resorption and does not elicit an inflammatory response. Unlike injections of silicone or fat tissue, the size and thickness of the implant can be precisely determined. Finally, since it is sutured in place, ADM does not migrate or disperse from the surgical site as can occur with injected silicone.

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James W. Farrell, D.P.M., graduated from the College of Wooster in Wooster, Ohio and received his podiatric training at the William Scholl College of Podiatric Medicine in Chicago. He began his private practice in Rochester, NY in 1985 where he also developed The Foot Performance Center, a clinical gait analysis and orthotic laboratory. Fifteen years later, Dr. Farrell purchased the Skaneateles Foot and Ankle Center, which has expanded to become the Westside Podiatry Center.

Dr. Farrell is a Diplomate of the American Board of Podiatric Surgery and has surgical privileges at Community General Hospital and the Camillus Surgery Center in Camillus, NY, and at Auburn Memorial Hospital in Auburn, NY, where he performs a full spectrum of podiatric surgical procedures.

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