Tissue Augmentation and Replacement of a Heel Fat Pad With a Decellularized Sterile Human Dermal Matrix

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Abstract: The use of xenografts and allografts has been primarily directed at chronic wounds and tendon repair. Currently, there are no known devices in this category that can successfully be used to augment tissue. Patients who have undergone trauma and subsequent surgery, particularly in weight-bearing areas, may experience pain with pressure or ambulation at the site. This report illustrates the use of an allograft for tissue augmentation in a young individual who was involved in a motor vehicle accident resulting in loss of the plantar fat pad. An allograft was successfully used for tissue replacement, thereby reducing pain and facilitating weight-bearing ambulation.

Injuries to the skin, particularly in cases of trauma, may result in physical abnormalities that may affect a patient’s quality of life, be cosmetically unacceptable, and contribute to facilitated tissue breakdown. Plastic surgical reconstruction may partially address the defect but often involves procedures that are cosmetically unappealing to the patient or may leave areas with deficient underlying tissue. For example, the plantar aspect of the foot, when severely traumatized, may result in scarring, contracture, and increased pain when ambulating, particularly when the fat pad has been damaged or is no longer present. While tissue defects in other corporal locations, including the breast, hip, and buttocks, may pose problems specific to those locations, damage to the heel fat pad directly affects the individual’s ability to ambulate, because cushioning is no longer present. Pain with repetitive pressure to the plantar aspect of the foot further contributes to decreased ambulation. Augmentation of the heel pad with a collagen matrix is one method of addressing this issue.

The following case presentation (Case 1) addresses near complete loss of the plantar heel fat pad subsequent to a motor vehicle accident. Tissue augmentation was performed with a novel, decellularized, sterile human dermal matrix. Two other patients who were treated in a similar fashion with similar results are presented in Case 2 and Case 3.

Decellularized human skin has been used for a variety of medical procedures, primarily, wound healing, soft tissue reconstruction, and sports medicine applications. In theory, decellularization serves to remove DNA material and provides a clean scaffold for host cellular and vascular ingrowth. Repair of rotator cuff tears is one of several reported clinical applications. During these
procedures, the dermal matrix is typically used to augment a repair procedure in order to provide biomechanical strength, as well as to support directed healing. Similarly, Achilles and quadriceps tendon augmentation procedures using decellularized human skin are reported. Soft tissue reconstruction procedures are commonly performed with decellularized human skin, including primary, staged, and revision breast reconstruction. In addition, hernia repair using similar materials has been reported. Decellularized human skin is also widely used in the treatment of skin wounds, such as diabetic foot ulcers.

A new, decellularized dermal allograft (DDA) has recently been introduced (DermACELL™, [LifeNet Health, Virginia Beach, VA]). The patented process used to prepare the DDA includes the use of anionic detergents and endonuclease, resulting in a material with more than 97% nucleic acid removal and acellular histological appearance. Additionally, the DDA is preserved and stored at room temperature, allowing the matrix to be maintained and delivered fully hydrated at room temperature to the surgical suite. Finally, the material is terminally sterilized with low-dose gamma irradiation to provide a medical-device grade Sterility Assurance Level of 106.

The use of this collagen-based human dermal matrix to augment the heel fat pad in a post-traumatic injury case is presented.

**Keypoints**

- In theory, decellularization serves to remove DNA material and provides a clean scaffold for host cellular and vascular ingrowth.
- Case 1 addresses tissue augmentation for near complete loss of the plantar heel fat pad subsequent to a motor vehicle accident; Case 2 and Case 3 present 2 other similarly treated patients.

**Case Reports**

**Case 1.** A 27-year-old woman was involved in a motor vehicle accident that resulted in severe trauma to her right lower extremity and foot. The patient was admitted to the emergency room subsequent to the accident. The patient underwent reconstructive orthopedic surgery of the foot, including internal and external fixation.

The patient was kept nonweight bearing until it was determined that all underlying damage had been repaired. At the time of injury, the patient did not have any significant medical history and was not taking any medications. The patient’s social history was also insignificant, and the patient denied smoking or drinking, except on social occasions. Post recovery, the patient was able to ambulate without assistance, but reported severe ongoing pain of the plantar right foot. Pain medication was taken as needed. Pain would subside when the patient was nonweight-bearing. The patient had asked her orthopedic physician if any treatment was available to reduce pain with ambulation, and was subsequently referred to the University of California, San Diego (UCSD) Wound Treatment and Research Center in the Division of Trauma, Department of Surgery.

**Treatment.** Upon presentation to the UCSD Wound Treatment and Research Center, the patient underwent a medical history and physical, as well as complete bilateral lower extremity examination including a biomechanical and gait analysis. Standard weight-bearing radiographs were taken of the feet. The findings were unremarkable, except for musculoskeletal and soft tissue abnormalities of the right foot secondary to trauma, gait, and biomechanical abnormalities, and absence of the right heel fat pad.

The gait examination was consistent with guarding of the right foot with a mild limp, favoring the left extremity. Pain with palpation of the right heel was rated as 6 (on a 1–10 scale with 0 = no pain and 10 = unbearable pain) with deep pressure to the right heel and between 6–8 with ambulation. There appeared to be little tissue present between the heel epidermis and the underlying calcaneus, although no skin breakdown was present on the plantar aspect of the foot. Skin color was normal, but elasticity was decreased.

An approximately 2.5-cm x 0.8-cm, full-thickness ulcer was present on the posterior calcaneus (Figure 1). The wound base was pale pink with evidence of some granulation. There was minimal serous drainage from the wound and no clinical signs or symptoms of infection. Periwound tissue was scarred and tight in appearance. All previous conservative and surgical attempts to close the posterior heel wound had failed (ie, various topical dressings, gels, alginates, collagen dressings, topical growth factors, and a full-thickness skin graft). At the time of presentation, the patient requested that both the heel pain and the posterior heel ulcer be addressed.

After extensive counseling and education on treatment options, it was decided it was in the patient’s best interest to attempt tissue augmentation of the plantar heel with an allograft, while addressing the posterior heel wound with bone marrow aspirate (BMA) and a xenograft. The patient understood and gave written informed consent to the surgery. An outpatient procedure was scheduled during which the patient underwent a right lower extremity block. An incision was made on the lateral aspect of the heel and a 4-cm x 12-cm piece of decellularized dermal...
allograft (DermACELL) was placed directly under the calcaneus extending from lateral to medial (Figure 1).

The skin was repositioned with 2.0 nylon and simple interrupted sutures (Figure 2). Attention was directed to the posterior heel ulcer that underwent sharp surgical debridement. Approximately 1.5 cc of BMA (extracted from the calcaneus) was placed on the wound base and covered with a 3.0-cm x 3.0-cm piece of xenograft (Unite®, Synovis, Irvine, CA), which was attached with staples.

All surgical sites were covered with sterile Restore Ag dressing (Hollister Wound Care, Libertyville, IL), fluffed gauze, and KERLIX™ (Kendall Brands, Mansfield, MA). A posterior bulky splint was applied to immobilize the extremity. When stable, the patient was discharged to home with instructions to remain nonweight bearing and to use crutches when ambulating. The dressings were changed weekly. At week 1, the staples were removed and at week 2 the sutures were removed. The patient was placed in a walking boot 3 weeks postoperatively.

The patient returned to normal shoes at week 6, at which time the patient continued to have a normal, rounded heel contour (Figure 3). The patient was able to ambulate without any pain on the plantar foot. The patient had a 3-month follow-up visit and remained asymptomatic, and was satisfied with both the cosmetic and qualitative (pain reduction) results. The Achilles ulcer site was also closed.

Two other patients were treated in a similar fashion, with similar results.

Case 2. A 25-year-old man presented to the author's clinic 1 year post-trauma with a chief complaint of pain under his left heel during ambulation. The patient had sustained a severe motor vehicle injury, which resulted in extensive hospitalization, as well as traction to his extremity. As a result of the trauma, the patient experienced loss of the heel fat pad and chronic ulceration in the plantar mid-foot area. At the time of presentation, the patient was not on any medications except nonsteroidal anti-inflammatory drugs (NSAIDs) for pain with ambulation. Radiographs and MRI did not suggest any osteomyelitis of the bone.

**Treatment.** The patient agreed to undergo a procedure similar to the first case presented with insertion of the same allograft and wound closure by means of excision and suturing. The patient remained on crutches for the first 3 weeks postoperatively, and was transitioned to a walking boot for 2 additional weeks before returning to his normal shoes. The patient reported approximately 80% pain reduction. Long-term results (>3 months) are not available at this time.

Case 3. A 48-year-old man who sustained a crush injury to his right foot from a motor vehicle accident presented to the author's clinic. The patient was not taking any medication at the time of trauma. As a result of his accident, the patient underwent multiple surgeries for foot reconstruction, including partial amputation, orthopedic bone fixation, and multiple skin grafts. As a result, the patient sustained loss to the plantar area of his foot and had difficulty ambulating without pain.

**Treatment.** The patient requested any procedure that might assist with pain reduction. The use of an allograft to attempt to reduce pain was extensively explained to the patient. He underwent a similar insert of the material as in Case 1; however, the allograft was inserted subfifth meta-

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**Figure 1.** Allograft inserted into the plantar heel area. Small ulceration is present over the Achilles area. This was treated with bone marrow aspirate-derived stem cells and xenograft.

**Figure 2.** Sutured incision site after allograft insertion.

**Figure 3.** Six weeks post surgery. Heel pad present and wound closed.
tarsal. The patient also was kept nonweight-bearing for approximately 3 weeks then put in a similar walking boot. The patient stated he had approximately 75% pain relief in the treated area. Long-term results (>5 months) are not available at this time. The patient was able to reduce his pain medications to NSAIDs postoperatively and no longer required narcotics to control pain.

Case 2 and Case 3 were briefly discussed to support results that were seen in Case 1. It is important to understand that, except with Case 1, results beyond 1 year are not available. The patient in Case 1 is beyond 1 year post surgery and remains pain-free. The remaining 2 cases will require follow-up after 1 year to determine any long-term effects.

Discussion

Tissue augmentation has been performed with various products and techniques. One of the most difficult aspects of surgical intervention is choosing a material or device that will address the defect, provide satisfactory results, and be well tolerated by the patient. Numerous allografts and xenografts are available for use as implants or biological coverings, such as AlloDerm® (LifeCell), GraftJacket® (Wright Medical Technology), OASIS® (Healthpoint Biotherapeutics), Apligraf® (Organogenesis), and now, DermACELL. While all are categorized as “graft materials,” the sterilization process, flexibility, and structure vary significantly among products, particularly with reference to cross-linking, species of origin, methods of sterilization, cellular content, thickness, and conformity to tissue. Incorporation into the host tissue is dependent on the ability of host cells to incorporate and eventually replace the introduced graft. The ability to be rapidly invaded and replaced by the host tissue is of particular relevance to tissue augmentation, because products that do not remain in place are not rapidly invaded and are easily displaced with friction, shear, or pressure, and thus, do not accomplish the desired goal.

A fully sterile, decellularized, and structurally unique allograft was successfully used to correct a plantar defect that had been associated with pain on ambulation.

Keypoints

- Incorporation into the host tissue is dependent on the ability of host cells to incorporate and eventually replace the introduced graft. The ability to be rapidly invaded and replaced by the host tissue is of particular relevance to tissue augmentation, as products that do not remain in place are not rapidly invaded and are easily displaced with friction, shear, or pressure, and thus, do not accomplish the desired goal.
- A fully sterile, decellularized, and structurally unique allograft was successfully used to correct a plantar defect that had been associated with pain on ambulation.

Conclusion

Tissue augmentation is an important component of addressing skin defects, which may present both functional and structural limitations. Allografts with appropriate characteristics and properties offer a means of correcting tissue anomalies. In the case presented, a fully sterile, decellularized, and structurally unique allograft was successfully used to correct a plantar defect that had been associated with pain on ambulation. This allograft should be considered for other locations and types of tissue abnormalities by surgeons addressing similar problems. Long-term follow-up with a larger patient population will be necessary to draw more distinct conclusions regarding this promising material.

References