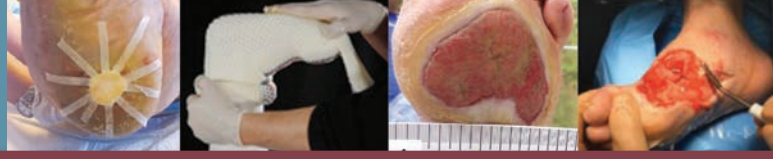

Limb Salvage on Two Chronic Non-Healing Ulcers Using Amniotic Membrane

These cases are examples of clinical success using this modality.

BY MICHAEL FANOUS, DPM, MS, MHA AND MARK ELD

About Amniotic Allografts

Amniotic allografts are products that have been created from the placenta and transformed into viable allografts. Clinicians have used the placental tissues for over a century as a biologic dressing in a broad range of therapeutic applications. Amniotic allograft tissues have been shown clinically and scientifically to support soft tissue repair, reduce inflammation, and minimize scar tissue formation.

Amniotic allografts are derived from tissues acquired from living, healthy donors after full-term pregnancy and a scheduled Caesarean section. These tissues have been minimally processed and preserved to maintain the natural properties of the placental tissues.

Case 1

Medical History

A 61-year-old male presented with a chronic, non-healing ulceration on the dorsal aspect of the first MPJ. The most notable co-morbidities to consider in developing a clinical treatment protocol for this patient were diabetes and the fact that he was HIV+. In evaluating the non-healing ulceration, the extensor hallucis longus tendon was clearly exposed as well as the proximal phalanx of the great toe.

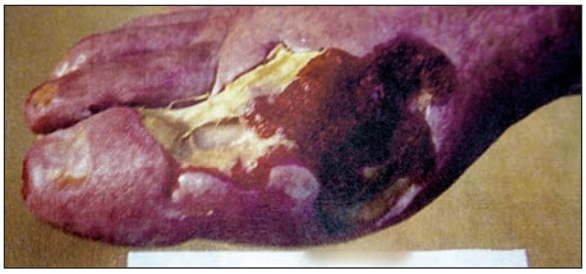

Figure 1: Clinical Observation/Pre Op Diagnosis: A 61-year-old male presented with a chronic, non-healing ulceration on the dorsal aspect of the first MPJ.

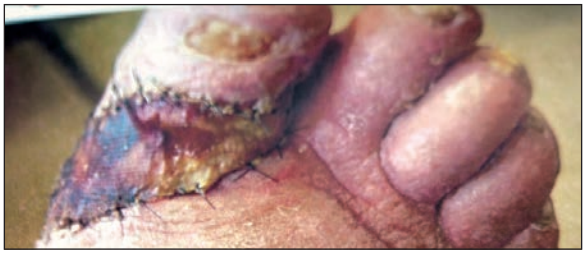

Figure 2: 4 Weeks Post-Op: The Dermal Allograft is still in place and there has been a significant reduction in the size of the wound area.

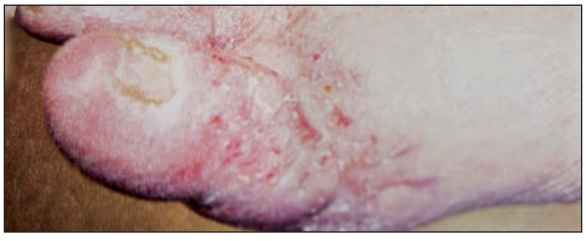

Figure 3: 9 Weeks Post-Op: Upon removal of sutures and dermal allograft, this wound has been fully resolved.

Clinical Treatment Protocol

The patient was prescribed one gram of intravenous Ancef prophylactically. Under general anesthesia, the necrotic tissue was debrided down to the exposed tendon and bone. Good granulation tissue was noted at the base of the dermis and subcutaneous tissues (Figure 1). A dermal allograft was placed over the exposed tendon and bone on the dorsal aspect of the foot. The allograft was secured using 3-0 nylon sutures around the periphery. After securing the dermal allograft, one large BioDRestore flowable amniotic tissue allograft was injected to the margins of the debrided wound. A non-adherent dressing was applied over the dermal allograft.

Post-Operative Clinical Observation

4 Weeks Post-Op: The dermal allograft is still in place and there has been a significant reduction in the size of the wound. The stiches and dermal allograft will remain in place for two to four more weeks. This patient is healing well and no further surgical steps are necessary. It is at this point of the healing process that we re-evaluate the wound and determine if another surgical procedure is needed to debride the wound, apply another injection of the BioD Allgoraft, and placement of the dermal allograft. In this instance, the patient was healing well and another

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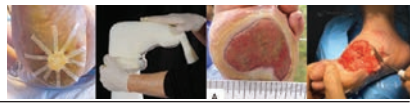

Limb Salvage (from page 150)

surgical procedure was not needed.

Note: *The dermal allograft will turn black and eventually fall off; the key is to ensure that there is no infection, signs of osteomyelitis, or spreading of the wound.*

Conclusion

The use of a dermal allograft alone on the non-healing ulceration in this immune-compromised, diabetic patient would not have healed this wound. The addition of the flowable amniotic tissue allograft around the periphery of the wound provided the necessary active matrix and signal proteins to support tissue repair and regeneration.

Case 2

Medical History

A 53-year-old male presented with a chronic, non-healing wound of the posterior/plantar region of the heel. He stated that he turned over in bed during the evening and heard a loud popping sound. The patient had a history of diabetes, hypertension, neuropathy of both limbs, and ischemia of the lower limb. The patient had severe atherosclerosis and previously had a stent placed in the right superficial femoral artery and popliteal artery.

The patient is a truck driver, and if the limb were amputated, he would no longer be able to continue his career. He was referred to the clinic for a second opinion. In addition to the non-healing wound, it was noted that the Achilles tendon avulsed from the insertion on the calcaneus (Figure 4). Given the patient's co-morbidities, a limb salvage was recommended.

Clinical Treatment Protocol

The patient was placed in a splint at 90 degrees and a wound VAC was placed over the wound. After several months, the tendon re-attached itself and no fixation was necessary. Once the wound VAC and antibiotics were completed, necrotic tissue was visible, and treatment to close the wound with BioDRestore and a dermal allograft was initiated (Figure 5).

Under general anesthesia, the necrotic tissues were removed down to the bed of the dermis. A dermal allograft was cut to the size and shape of the wound and secured using 3-0 nylon sutures around the periphery (Figure 6). After securing the dermal allograft, one large BioDRestore was applied to the margins of the debrided wound. A non-adherent dressing was applied over the dermal allograft.

Post-Operative Clinical Observation

12 Weeks Post-Op: This patient required multiple visits to the operating room due to the size and depth of the wound. At the Week four and Week eight junctures, the patient was brought into the operating room and

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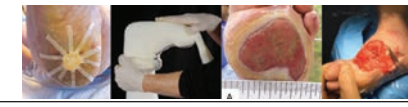

Limb Salvage *(from page 151)*

placed under a general anesthetic. The dermal allograft was removed and the wound was debrided, removing any remaining necrotic tissue. The perimeter area of the wound was injected with BioD amniotic allograft, and a new dermal allograft was placed over the wound. The patient required these two additional surgical debridements and placement of BioDRestore with a dermal allograft to enhance the closure of the wound, as this was a very deep wound with a large surface area.

Note: The dermal allograft will turn black and eventually fall off; the key is to ensure that there is no infection, signs of osteomyelitis, or spreading of the wound.

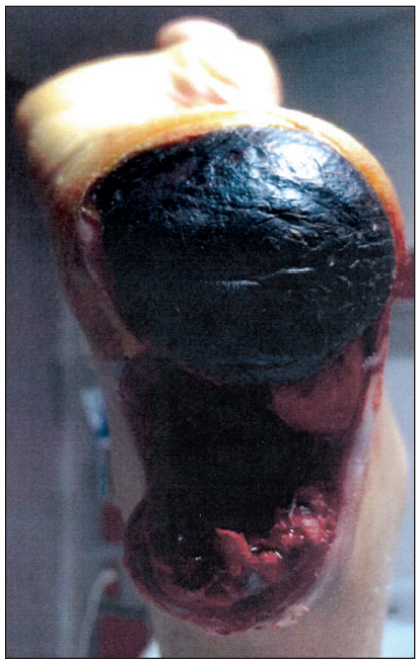

Figure 4: Clinical Observation/Pre Op Diagnosis: A 53-year-old male presented with a chronic, non-healing wound of the posterior/plantar region of the heel.

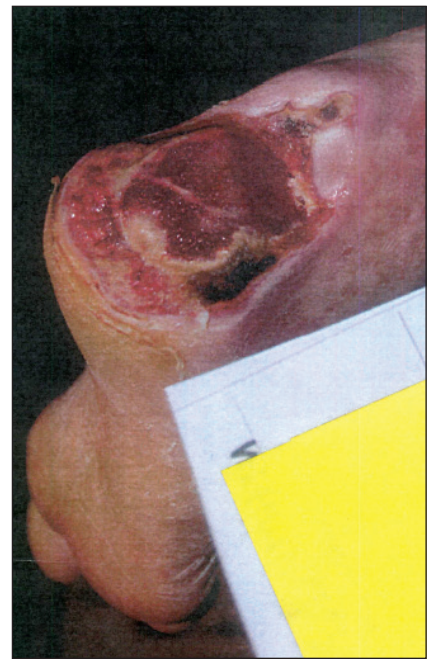

Figure 5: 5 months from Initial Consult: Pre-Operative planning included; splinting at 90˚, placement of a wound vac & antibiotics to get back to healthy granulated skin & tissue.

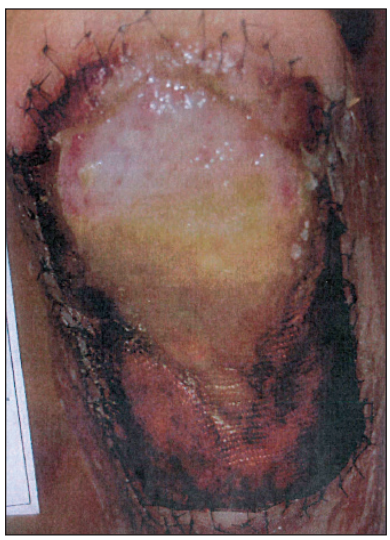

Figure 6: 8 Months from Initial Office Visit and 12th week of Surgical Treatment: Surgical visit to the OR to do debride the necrotic tissue and apply Amniotic Injectable & Dermal Allografting.

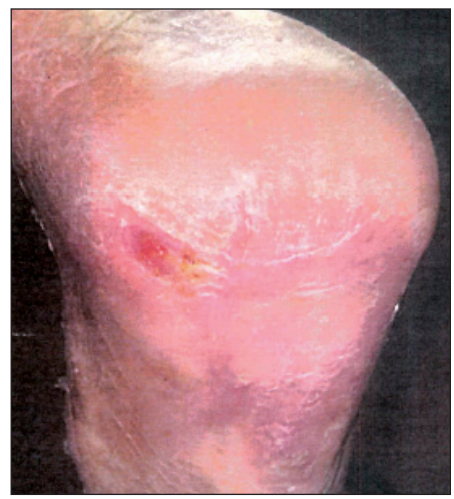

Figure 7: 9 Months from Initial Office Visit and 16 weeks of Surgical Treatment: After nine months of continued treatment, the patient's wound fully resolved.

Conclusion

After nine months of continued treatment ranging from wound VAC, antibiotics, debridement, amniotic tissue allograft and dermal allograft placement, the patient's wound fully resolved. This is a remarkable case study showing that by following a regimented wound protocol, including amniotic tissue, dedicated treatment, and having a compliant patient, this limb was salvaged and the patient was able to return to work and a fully functional lifestyle. It is interesting to note that this patient was originally advised to be sent to the emergency room for a Below the Knee Amputation before he came to my office for a second opinion (Figure 7). **PM**

Mark Robinson contributed to this article.

Disclosure: *Dr. Fanous is a Medical Director for BioD. Mark Robinson is an Independent Consultant.*

Dr. Fanous is a graduate of the Ohio College of Podiatric Medicine. He completed his residency training in Podiatric Medicine and Surgery at USC-County General Hospital in Los Angeles, California. He has earned double master's degrees: a Master of Health Administration (MHA) and a Master of Science in Gerontology (MS) from the University of LaVerne, CA. He was a former Founder and Director of the residency training program and former Chief of Podiatric Surgery at Anaheim General Hospital. He is a professor of surgery at the Academy of Ambulatory Foot and Ankle Surgery. He is currently a Fellow and previously served as President of the Academy of Ambulatory Foot & Ankle Surgery, and he is Chief of Infectious Control at Desert Valley Hospital.

Mark Eld is a national distributor for BioDLogics. He has been working with Dr Fanous for 5 years, specializing in providing him wound care and biologic products. He is trained with VCS certification for HIPAA, O.R. protocol, blood-borne pathogens, aseptic techniques and AATB tissue handling, along with specialized training in surgical techniques of the knee, hip, shoulder and foot and ankle.