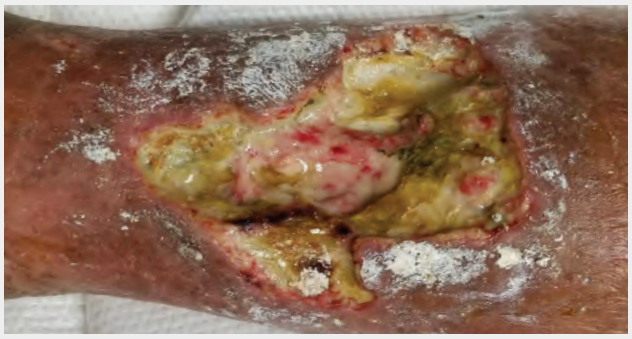
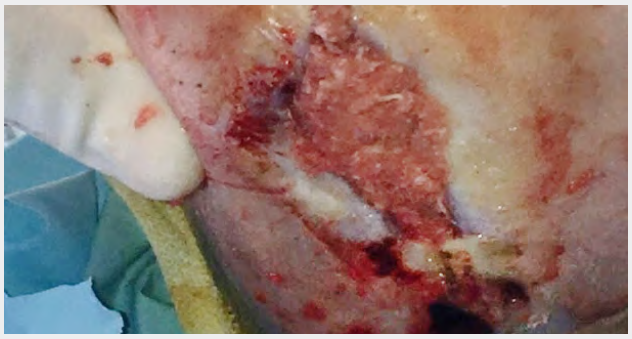
VOLUME 1 | EDITION 1

MIMEDX PLACENTAL-BASED ALLOGRAFTS

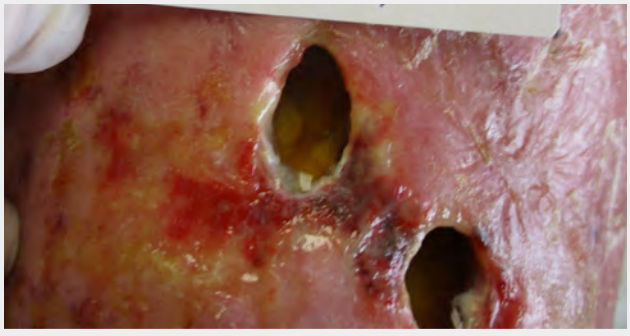
SURGICAL LOWER EXTREMITY CASEBOOK



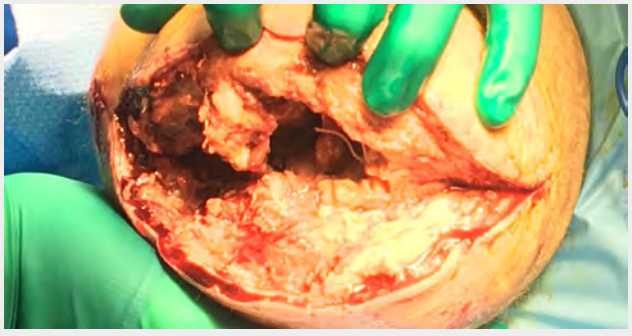
BILATERAL LIMB SALVAGE WITH AMNIOFILL®, AMNIOFIX®, AND NPWT



NON-HEALING CALCANEAL TUNNELING WOUND WITH AMNIOFILL



DEEP TUNNELING LOWER EXTREMITY ABSCESS WOUNDS WITH AMNIOFILL



LOWER EXTREMITY AMPUTATION WITH AMNIOFIX

SB933.001

Bilateral Limb Salvage with AmnioFill, AmnioFix, and NPWT

John A. McFate, MD | Cosmetic and Reconstructive Plastic Surgery | Austin, TX

Challenge

Managing complex wounds of the lower extremities in a healing-impaired patient secondary to delayed presentation and rhabdomyolysis.

Many factors, such as: age, obesity, diabetes, malnutrition, smoking, immunosuppression, etc. can interfere with one or more phases of the healing process, thus causing improper or impaired wound closure.[1] Studies have shown a direct correlation between the number of comorbidities and clinical outcomes. A significant rise in complications, length of stay, and mortality rates are associated with the rise in number of patient comorbidities.[2-4]

Clinical History

A 67-year-old male with multiple medical comorbidities, while at home, tripped over his dog, fell and became trapped on the floor with no one to help him. Two days later he was found by neighbors and taken to the emergency room. He was admitted to the hospital for acute renal failure, rhabdomyolysis, and was managed medically. The patient's comorbidities included hypertension, morbid obesity, and a history of deep venous thrombosis, pulmonary embolism, aortic dissection, and smoking. Consequently, the patient developed full thickness wounds on both legs, and local wound care was managed by the physical therapy wound care team of the hospital.

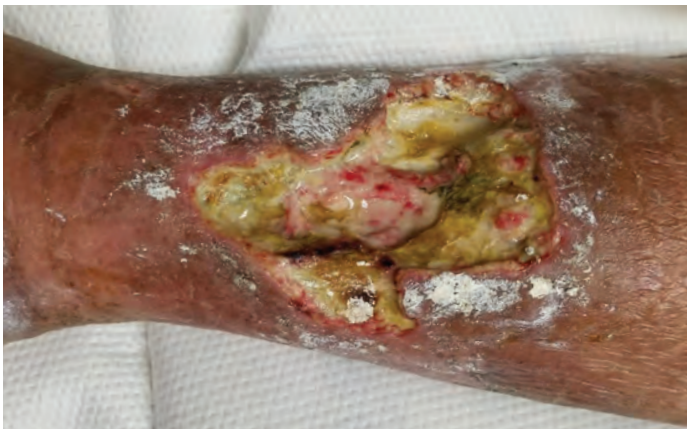


Figure 1: RLE wound at consultation

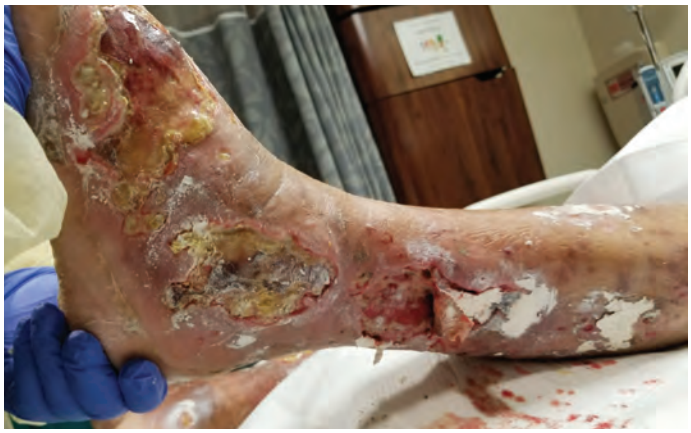


Figure 2: LLE wounds at consultation

Approximately two weeks after presentation in the ER, plastic surgery consultation was requested because the acute wounds on his lower extremities (LE) significantly worsened, and the patient developed fevers. Upon examination, the patient had a weakly palpable dorsalis pedis artery pulse on both feet, several non-healing wounds with significant depth, surface area, edema, and wound infection (Figures 1 & 2).

The right lower extremity (RLE) had a full thickness wound approximately 10 cm x 12 cm in size and 2 cm deep on the medial and anterior aspect of the pretibial area, down to visible muscle with fibrinous tissue and purulent drainage. The left lower extremity (LLE) had multiple partial thickness wounds

sized 9 cm x 5 cm, 10 cm x 7 cm, 10 cm x 5 cm, but with less depth than the RLE. Additionally, there was necrosis and deep purulent drainage on the left foot, third lower digit. A full vascular work-up was completed, but no vascular intervention was required. The patient was informed that it was still unclear whether the limbs would be salvaged.

Surgical Intervention

Due to the risk of infection and the possibility of bilateral leg amputations, the surgical plan was an amputation of the non-viable LLE third lower digit, and multiple stages of thorough debridement of all wounds, application of AmnioFill and/or AmnioFix, and negative pressure wound therapy (NPWT). AmnioFill is a placental-based tissue matrix in a particulate configuration to replace or supplement damaged or inadequate integumental tissue in acute and chronic closures. The product provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[5-7] AmnioFix is a dehydrated human amnion/chorion membrane allograft in sheet and micronized/injectable configurations. AmnioFix sheets provide a semi-permeable protective barrier that supports the healing cascade. It also protects the wound bed to aid in the development of granulation tissue in acute and chronic closures. AmnioFix provides a human biocompatible ECM and retains 300+ regulatory proteins.[5-7] The goal of this treatment plan was to build up the wound and improve the integrity of the tissue until definitive coverage with skin grafting was possible.

Three days after the consultation, the patient was taken to the OR for sharp and hydrosurgical debridement of necrotic fat and tissue, and amputation of the LLE third digit. Cultures were taken which ruled out osteomyelitis. Post-debridement, the RLE wound was area was 24 cm x 14 cm and 2 cm deep, while the LLE area was 22 cm x 5.5 cm, but with less depth. Using forceps, 3,000 mg of AmnioFill was placed dry onto the RLE and 2,000 mg onto the LLE. Approximately 5-10 cc of saline was then applied on top of the AmnioFill on each leg to provide some cohesiveness and improve engagement with the deeper areas. Additionally, AmnioFix sheets and AmnioFix Injectable were applied to cover some of the smaller area wounds. The wounds were covered with non-adherent gauze and NPWT (set at 125 mm Hg) and left intact and untampered with for one week. The patient remained in the hospital and the same process was repeated weekly for the next two weeks (Figures 3 & 4).

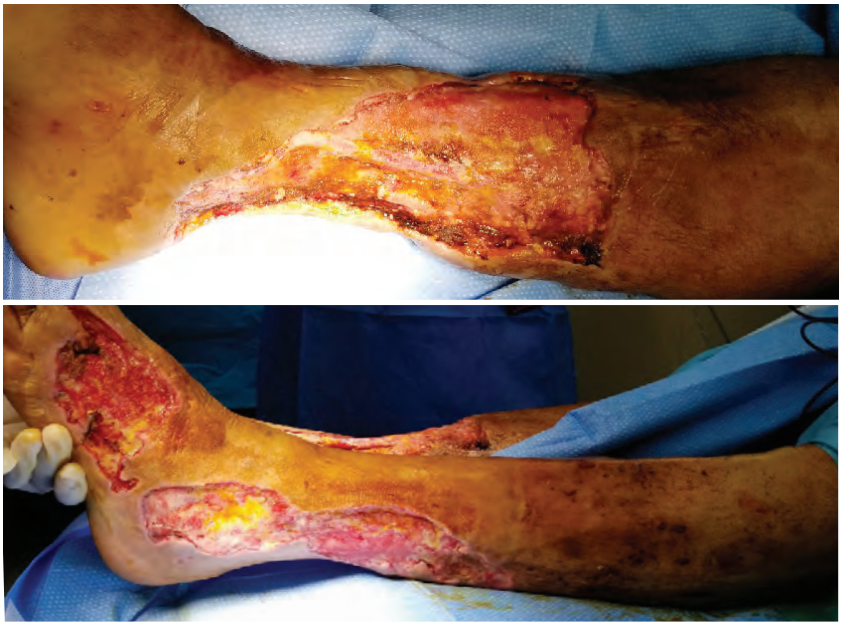


Figure 3: RLE and LLE 5 days after initial surgery. S/P One debridement and one AmnioFill treatment

Figure 4: (from left to right) AmnioFill, AmnioFix (sheet), and AmnioFix Injectable

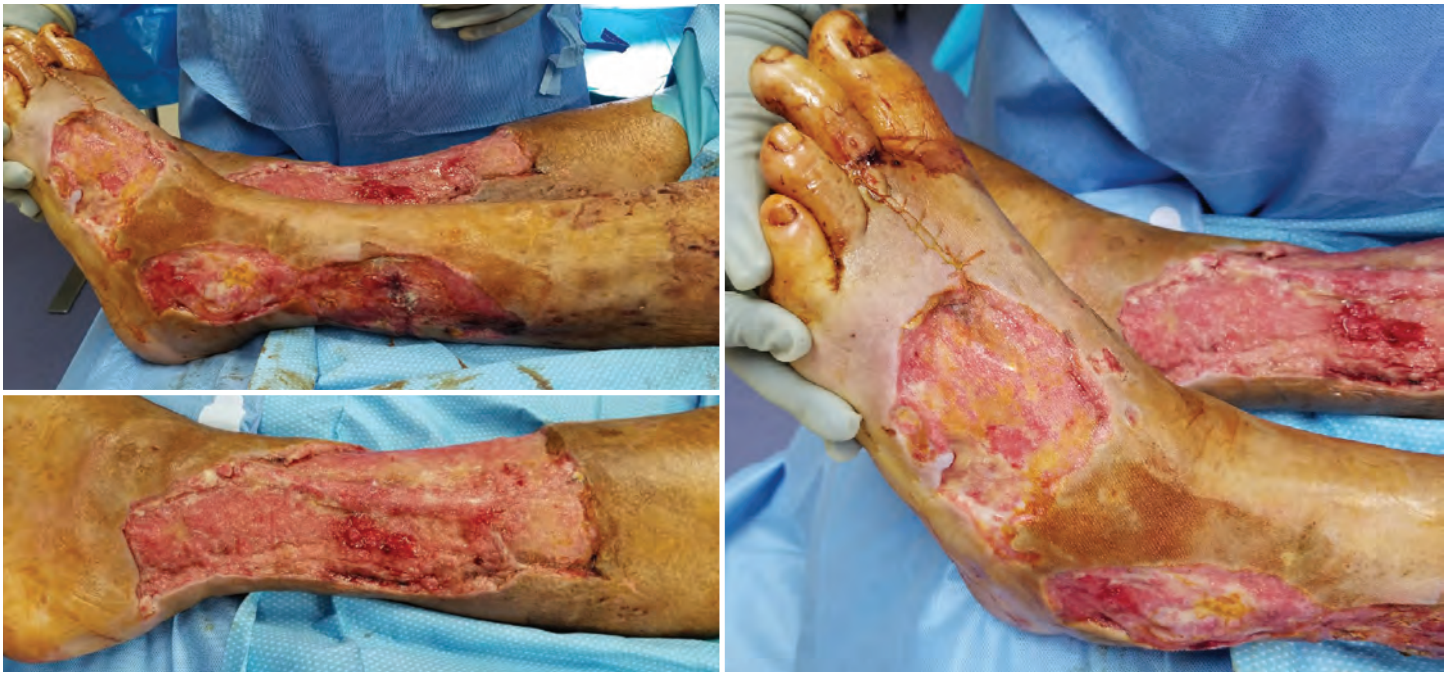


Figure 5: RLE and LLE two weeks after initial surgery. S/P two debridements and two AmnioFill treatments

Each time, the area and depth of the wounds decreased, thereby decreasing the amount of AmnioFill required to 1000 mg per leg, and supplemented with AmnioFix Injectable and/or sheets. The sheets were cut and tailored to fit the flat wound areas where needed. The patient was discharged on Day 21, and continued NPWT and outpatient rehab for four weeks.

Six and a half weeks after the initial procedure, the wound beds were ready for skin grafting (Figure 6), but a holiday delayed scheduling until Week 8. Skin grafts of 22 cm x 9 cm, 23 cm x 4 cm , and 6 cm x 5.5 cm were placed on the RLE, LLE, and dorsum of the foot, respectively. Additionally, due to the severity of the case and the patient's comorbidities, two 9 cm x 20 cm and one 6 cm x 10 cm AmnioFix sheets were simultaneously placed on the skin grafts and donor sites. The skin grafts were covered with non-adherent dressings and NPWT, while the donor sites were dressed with non-adherent gauze, anti-microbial dressings, and bandages.

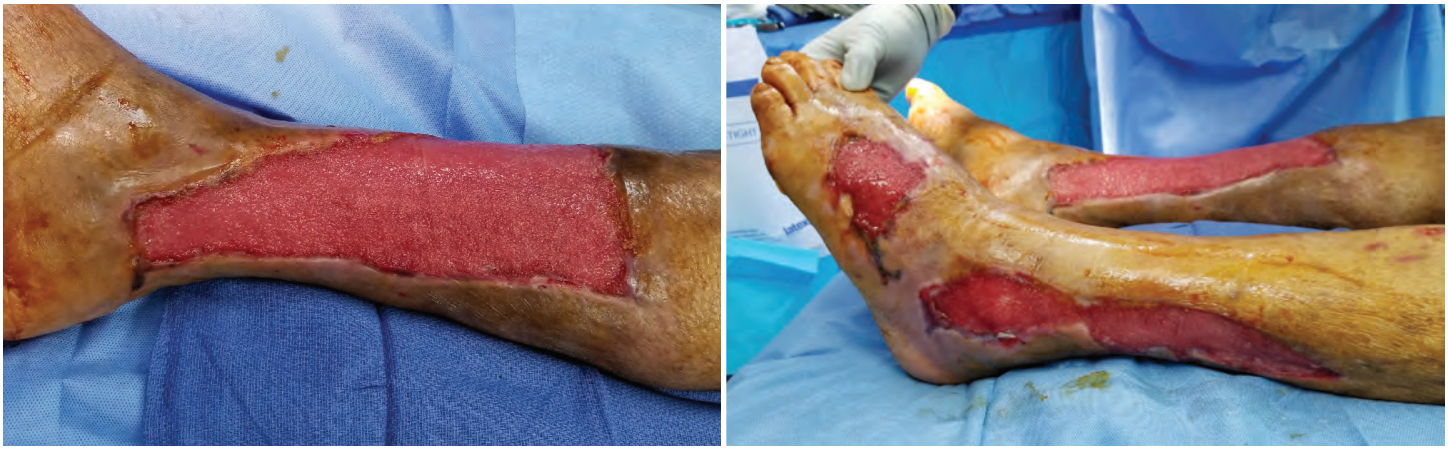


Figure 6: RLE and LLE prior to skin grafting. 6.5 weeks post initial debridement

Follow-Up

Six days post-skin grafting (Figure 7), NPWT dressings were removed and skin graft take was successful. Donor sites, that received AmnioFix sheets, closed in less than two weeks without any complication. All prior wounds continued to be stable at 12 Weeks (Figure 8).

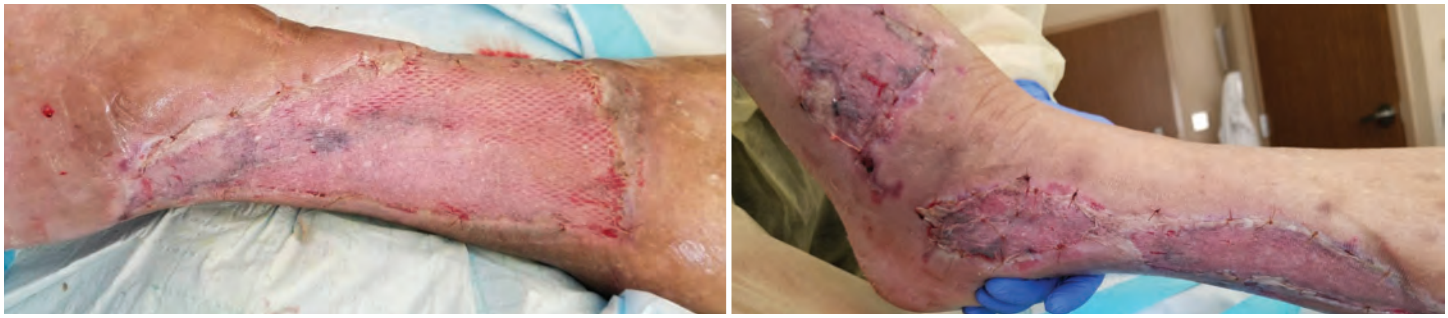


Figure 7: RLE and LLE six days S/P split thickness skin grafting (STSG)

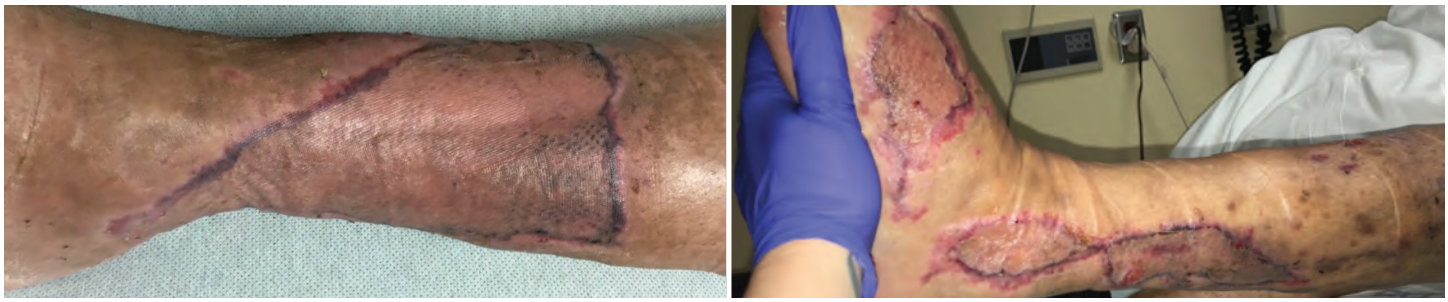


Figure 8: RLE and LLE five weeks S/P STSG. Wounds closed and stable

Conclusion

The severity of the patient's condition and risk of bilateral lower extremity amputations warranted use of advanced wound therapies. In this case example, the use of AmnioFill and AmnioFix, in conjunction with serial debridement and negative pressure vacuum therapy helped:

- Reduce the size and depth of large area wounds
- Decrease length of stay by as much as a month or more
- Avoid bilateral lower extremity amputations

Deep Tunneling Lower Extremity Abscess Wounds with AmnioFill

Megan Oltmann, DPM, AACFAS | Cleveland, OH

Challenge

Filling in a large volume defect after evacuating liquefactive necrosis of fat.

Clinical History

The 59-year-old male presented in the emergency room, and was admitted to the hospital with a deep leg abscess and cellulitis to the lower left extremity and venous stasis ulcers to both legs. The patient had not had any medical care in more than 20 years. Following work up, the patient was diagnosed with high blood pressure as well as pre-diabetes.

The patient was taken into surgery and three pockets were created on the anterior left leg for drainage (Figure 1). There was extensive liquefactive necrosis of fat. Wounds were thoroughly debrided, packed, and dressed. Cultures returned negative. Patient was discharged and placed on two weeks of oral antibiotics.

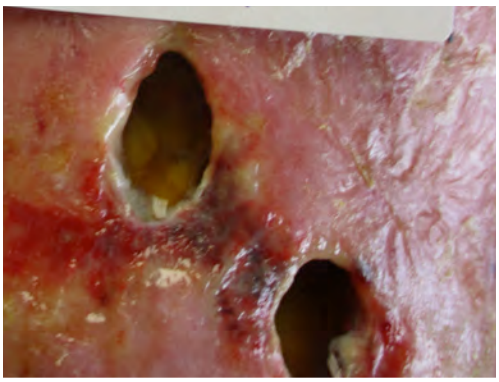


Figure 1: Deep tunneling wounds after abscess drainage

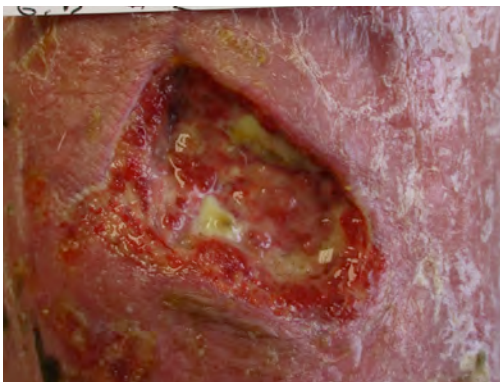


Figure 2: Large defect after joining of two tunneling wounds areas

Figure 3: AmnioFill

At follow-up five weeks later, one wound pocket was closed, but two previously separate wounds became one large and deep wound on the anterior left shin (Figure 2). An additional pocket was created to drain more liquefactive necrosis of fat.

Surgical Intervention

The patient was taken to the OR the following week for sharp debridement. AmnioFill (500 mg) was packed into the deep, anterior LLE wound, which was 7.3 cm x 5 cm x 1.5 cm, as well as the additional drainage site. AmnioFill is a placental-based tissue matrix in a particulate configuration to replace or supplement damaged or inadequate integumental tissue in acute and chronic closures. The product provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[5-7] All wounds were dressed with a petroleum impregnated gauze, calcium alginate with silver, and bandaged with a dry sterile dressing.

Follow-Up

The patient was released and followed by Home Health Care (HHC) for dressing changes. Wound closure progressed nicely, but then slowed when HHC placed an incorrect dressing that trapped moisture and macerated the area. At three weeks post AmnioFill application, the deep wounds were granulated to the level of the skin in most areas despite the dressing change error (Figure 4).

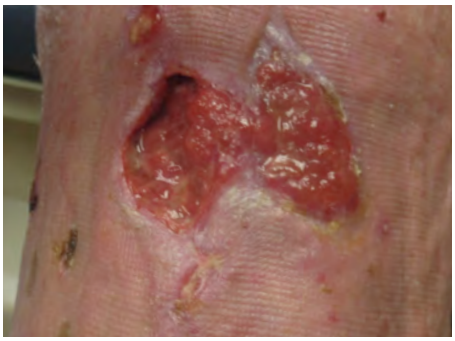


Figure 4: Week 3, post use of improper dressing over area where AmnioFill was placed

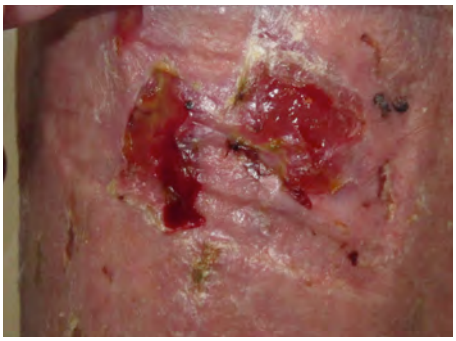


Figure 5: Week 6, continued closure despite improper care

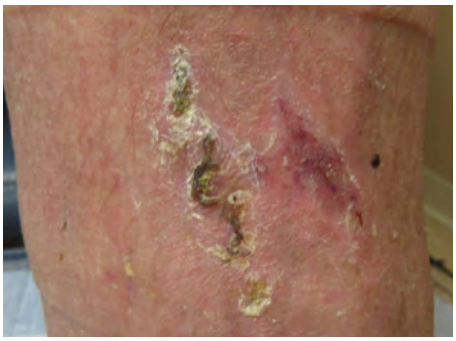


Figure 6: Week 8

The patient continued closure with compression dressings and another round of antibiotics (Figure 5). At 8 Weeks post AmnioFill application, the deep wounds (7.3 cm x 5 cm x 1.5 cm) were fully closed despite challenges with aftercare (Figures 6-8). Composite dressings were used until VLU wound closure, and the patient will continue with lifelong compression stockings.

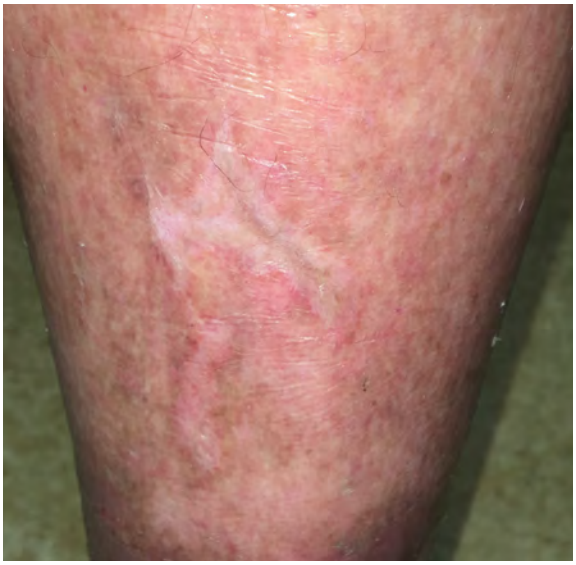


Figure 7: Five months after complete closure

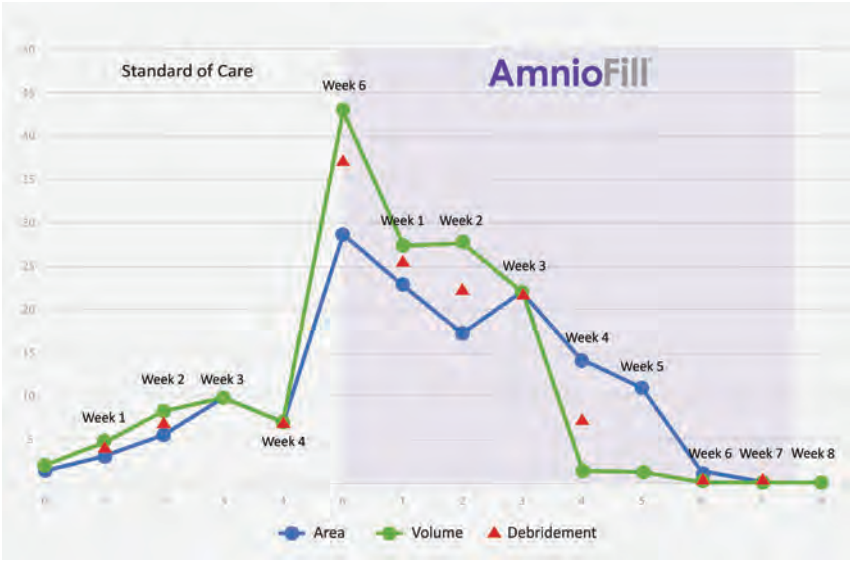


Figure 8: Wound size and volume decreased after AmnioFill treatment highlighted

Conclusion

One application of AmnioFill helped to replace and supplement damaged and inadequate integumental tissue. The product also filled in the deep and wide wounds despite challenges with patient health and improper aftercare by home health care providers.

Non-healing Calcaneal Tunneling Wound with AmnioFill

Khalid Husain, DPM | Arlington Heights, IL

Challenge

Treatment of a non-healing tunneling calcaneal wound of 12 months' duration, not responsive to the application of various advanced therapies.

Clinical History

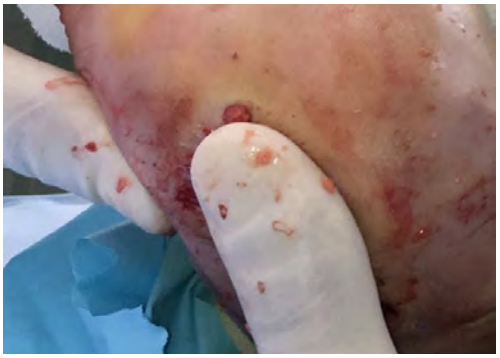
A 64-year-old male with a 20 year history of Type II diabetes mellitus with, moderate sugar control and severe peripheral neuropathy, developed a wound on right heel, complicated by osteomyelitis, 12 months prior to his evaluation visit.

The patient's past medical history included mild hypertension, hypercholesterolemia and chronic renal insufficiency without the need for dialysis. With concerns that the wound was severe enough to require lower extremity amputation, the patient was admitted to the hospital. He subsequently had surgical debridement, revascularization of the right lower extremity, and a partial calcanectomy. The resulting 8 cm x 8 cm x 4 cm deep wound was treated with a bilayer wound matrix and he was discharged to a Skilled Nursing Facility with negative pressure wound therapy prescribed. Over the next 10 months the wound decreased in size to 2 cm x 2 cm x 0.5 cm deep. However, the closure progress stalled and the wound began tracking deeper with concerns for underlying infection. A thorough debridement was done in the office and biopsy came consistent with osteomyelitis.

Surgical Intervention

The patient was taken back to the OR for additional debridement and AmnioFill treatment to fill the defect. AmnioFill is a placental-based tissue matrix in a particulate configuration to replace or supplement damaged or inadequate integumental tissue in acute and chronic closures. The product provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[5-7] After debridement, the wound was approximately 2 cm x 1.5 cm and 1.5 cm deep down to the calcaneus. 250 mg AmnioFill was mixed with 2-3 cc of sterile saline to create a "paste-like" consistency. After about two minutes, the AmnioFill adhered to itself nicely and was easily scooped out using a Freer Elevator, and applied and densely packed into the defect (Figures 1-3). The wound was covered with a non-adherent gauze, a composite dressing, surgical strips, and standard gauze.

Figure 1: AmnioFill



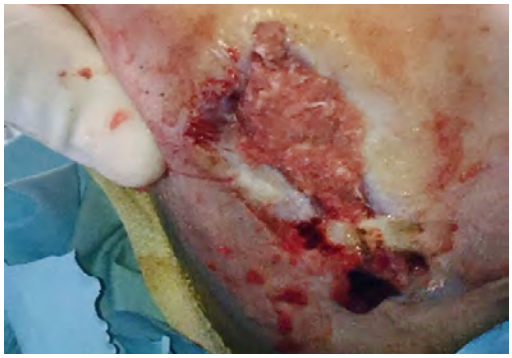


Figure 2-3: AmnioFill application

Follow-Up

At the three day follow-up, the AmnioFill appeared to begin integrating into the wound with early signs of granulation tissue formation. The wound was covered with a hydrogel dressing, non-adherent gauze, and standard gauze and the patient was given instructions for offloading and weekly follow-up visits (Figure 4).

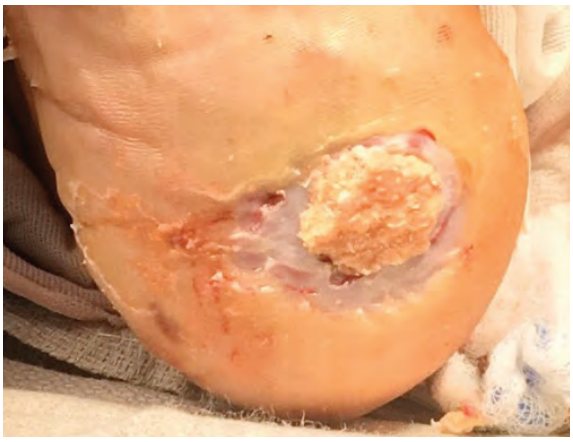


Figure 4: Day 3 follow-up

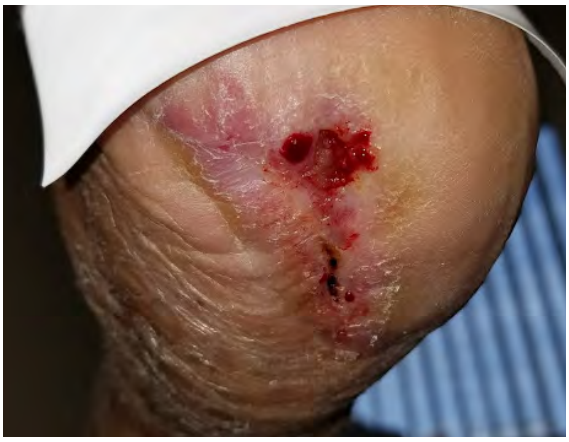


Figure 5: Week 6

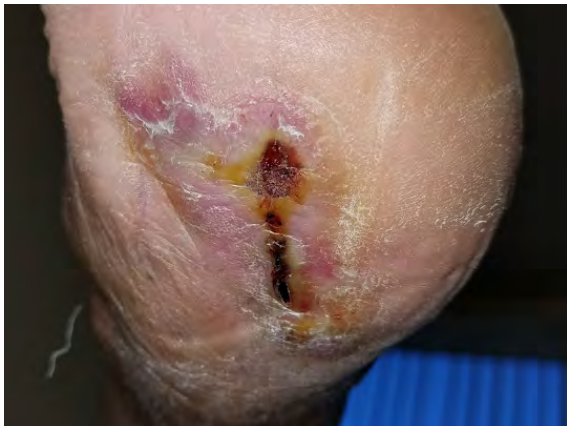


Figure 6: Week 7

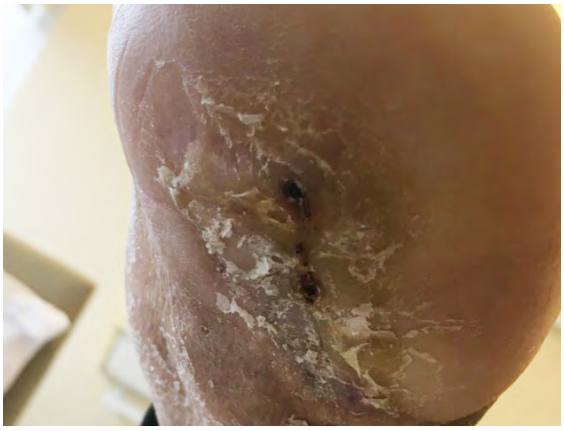


Figure 7: Final closure at Week 8

Conclusion

At the one and two week follow-ups, the wound continued to progress toward closure with healthy, pink granulation tissue noted, indicating further AmnioFill integration into the wound bed. The wound continued to progress nicely until final wound closure at Week 8 (Figures 5-7).

Lower Extremity Amputation with AmnioFix

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Huntsville, AL

Overview/Discussion

Chronic wounds, with or without concomitant infection, have been and will continue to be a significant problem in our complex patient population. Nicotine use, peripheral neuropathy, controlled and uncontrolled diabetes, and peripheral vascular disease are only a few of the risk factors that lead to the often unsuccessful eradication of infection and the persistent presence or recurrence of wounds. Whether failure of treatment comes from patient non-compliance or the natural evolution of their medical diagnoses, surgeons continue to look for new knowledge and technology to improve outcomes in these complex situations.

Clinical History

This patient is a 74-year-old male with a complex medical history including chronic obstructive pulmonary disease, obesity, peripheral vascular disease, peripheral neuropathy, and hypertension. He also has an 80 pack-per-year smoking history and is currently smoking two packs of cigarettes per day. He had a below knee amputation one year prior to presentation secondary to chronic osteomyelitis and non-healing wounds on his foot. His surgical site underwent secondary closure twice (Figure 2) and had been dehisced for approximately six months (Figure 3) at his initial visit. The extent of the wound was the complete surgical incision and the distal two inches of tibia was exposed circumferentially.

Treatment

The patient was taken to the operating room for conversion of his below knee amputation to an above knee amputation. Smoking cessation and follow-up compliance was discussed extensively pre-operatively. The above knee amputation incision dehisced within three weeks of surgery. The patient continued to smoke two packs of cigarettes per day. He underwent two more surgical debridements with secondary wound closures. The surgical plan for the fourth above-knee procedure (Figure 4) included extensive debridement, deep tissue cultures, use of AmnioFix (Figure 1) and a layered wound closure. AmnioFix is a dehydrated human amnion/chorion membrane allograft. AmnioFix sheets provide a semi-permeable protective barrier that supports the healing cascade and protects the wound bed to aid in the development of granulation tissue in acute and chronic closures. AmnioFix provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[5-7] After sharp debridement and extensive irrigation, a 6 cm x 6 cm AmnioFix sheet was placed superficial to the muscle layer that had been repaired by myodesis. The subcutaneous layer was reapproximated with non-absorbable suture and the skin closed with nylon suture.

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Follow-Up

The patient continued to take the same antibiotics for three weeks and also continued physical therapy. Smoking cessation education was emphasized, again, unsuccessfully. The nylon sutures were removed on post-operative day 16. A 2 mm sinus presented within the lateral aspect of the incision. This was treated with ¼ inch packing changed twice daily and closed successfully via secondary intent within two weeks (Figure 5).

Figure 1: AmnioFix sheet

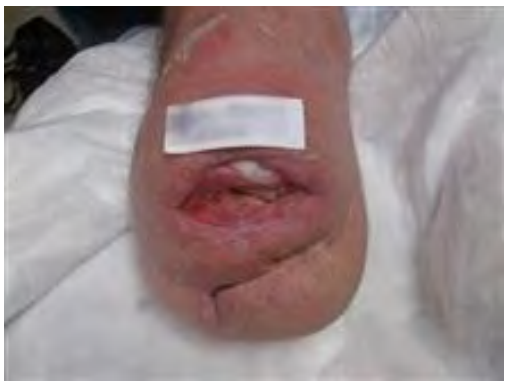

Figure 2: Below knee amputation post-operative wound dehiscence on surgical day of debridement and repeat primary closure

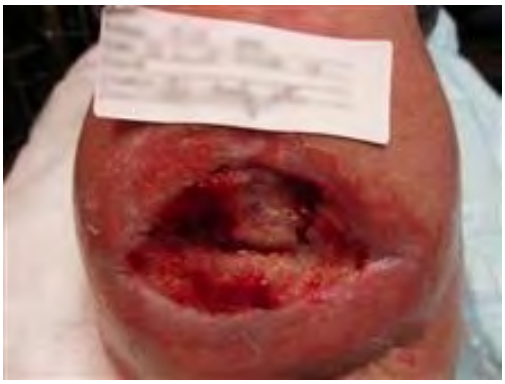

Figure 3: Wound dehiscence less than a month after surgical debridement and primary closure

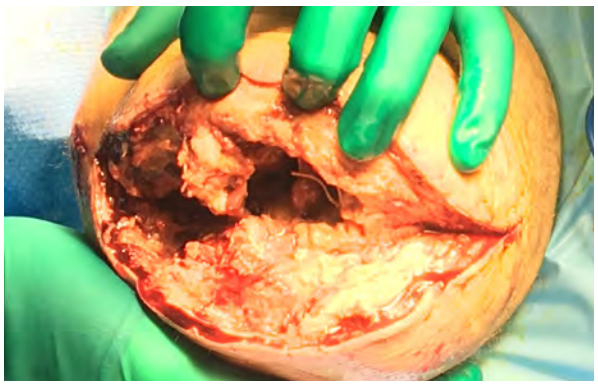

Figure 4: Extensive debridement of recurrent dehiscence of above knee amputation prior to placement of AmnioFix

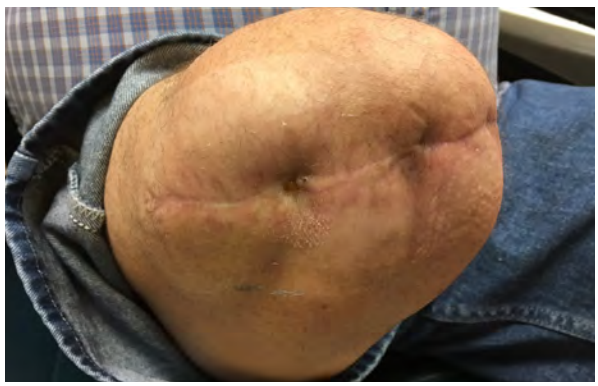

Figure 5: Complete wound closure one month after debridement and wound closure using AmnioFix

Conclusion

The patient began prosthetic fitting and ambulated on his above knee prostheses, his first prosthetic-assisted ambulation since his initial below knee amputation 18 months prior.

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