MiMedx

VOLUME 1 | EDITION 1

MIMEDX PLACENTAL-BASED ALLOGRAFTS

VASCULAR SURGERY CASEBOOK

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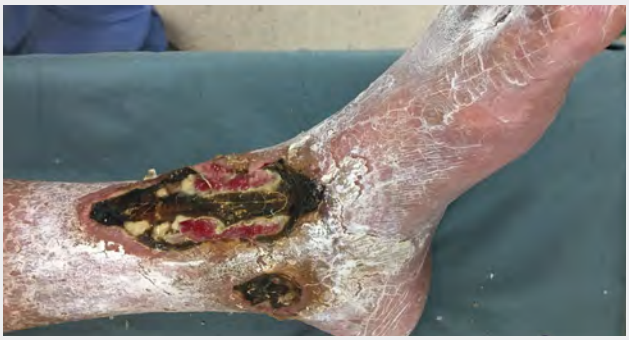
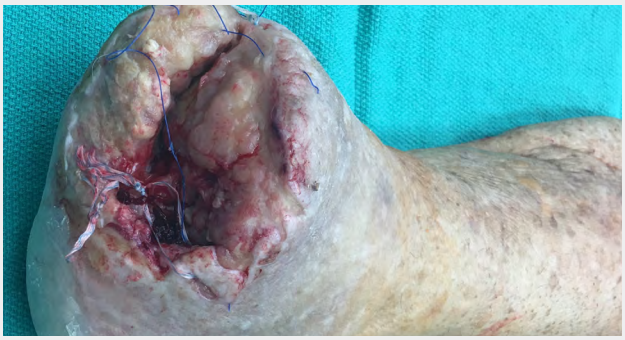
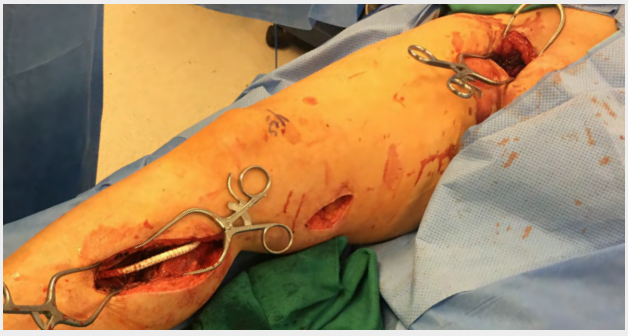


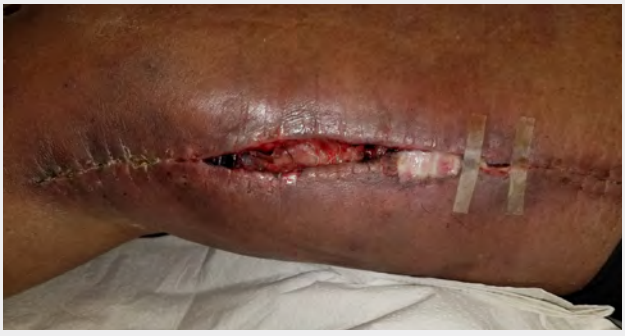
LEFT LOWER EXTREMITY (LLE) WITH AMNIOFIX®, EPIFIX®, AND NPWT



BELOW THE KNEE AMPUTATION (BKA) AFTER PRIOR AMPUTATION DEHISCENCE WITH AMNIOFIX



REVISIONARY FEMORAL POPLITEAL BYPASS SURGERY WITH AMNIOFIX AND AMNIOFIX INJECTABLE



LOWER EXTREMITY BYPASS DEHISCENCE WITH EPIFIX AND NPWT

SB653.003

Left Lower Extremity (LLE) with AmnioFix, EpiFix, and NPWT

Challenge

Challenges in critical limb ischemia extend beyond those limited to the extremity itself. Patients with atherosclerotic risk factors tend to have multi-vessel disease, such as coronary artery disease (CAD) and peripheral artery disease (PAD). Patients with complex wounds, who would otherwise be ideal candidates for lower extremity bypass, often cannot undergo general anesthesia and thus are left with endovascular therapy and advanced wound therapies as their remaining options for limb salvage as an alternative to undergoing primary amputation.

Clinical History

A 62-year-old male presented to the ER with chest pain and chronic left lower extremity wounds that extended from the lower leg onto the forefoot and on the medial malleolus (Figure 1). The patient also had a history of myocardial infarction, hypertension, diabetes, smoking, severe PAD and prior failed endovascular therapy at another institution. The patient was evaluated for the chest pain and was found to have severe CAD. The cardiothoracic surgeons would not intervene surgically because of his underlying LLE necrosis and infection.

Vascular surgery was consulted for a lower extremity bypass, but the patient was found not to be a surgical candidate for general anesthesia due to his severe CAD and other comorbidities. The patient was therefore taken for repeat endovascular therapy including atherectomy of the left superficial femoral artery (SFA), angioplasty, and placement of two SFA stents, which successfully revascularized flow to the foot.

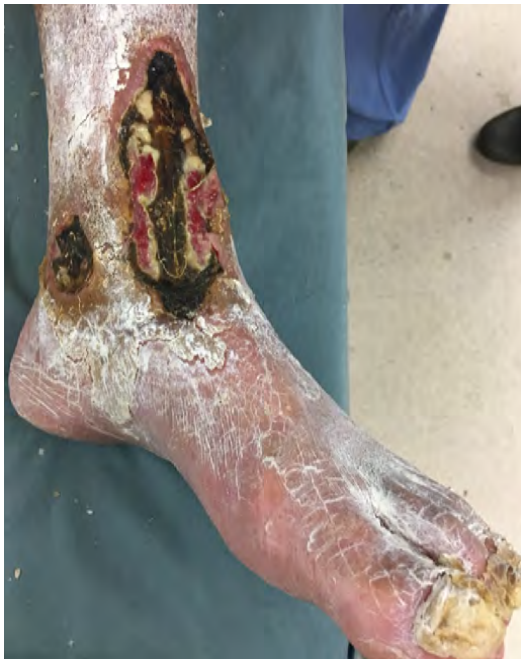


Figure 1: LLE wounds at presentation

Surgical Intervention

The patient was taken to the OR for wound debridement two days later. The wound necrosis involved the subcutaneous tissues and portions of the extensor digitorum longus tendon, but there was no bone exposure. Due to the patient's high risk status and impaired closure status, AmnioFix was applied in conjunction with negative pressure wound therapy (NPWT). AmnioFix is a dehydrated human amnion/chorion membrane allograft. 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 chronic and acute closures. AmnioFix provides a human biocompatible extracellular matrix (ECM) and retains 300+ regulatory proteins.[1-3]

A 6 cm x 16 cm AmnioFix graft was perforated for exudate pass through and cut to fit both the large area wound on the forefoot and the ankle wound. The grafts were covered with a non-adherent gauze dressing. A negative pressure foam dressing was then cut to size, applied over the non-adherent gauze, sealed, and set to the recommended pressure settings (Figures 2-4). Dressings were left in place for five days before the first NPWT dressing change. At day nine, the non-adherent dressing was removed and good early granulation tissue formation was observed. A future skin graft procedure was being considered for wound closure, but this option was ultimately avoided as the wound progressed over the following weeks.

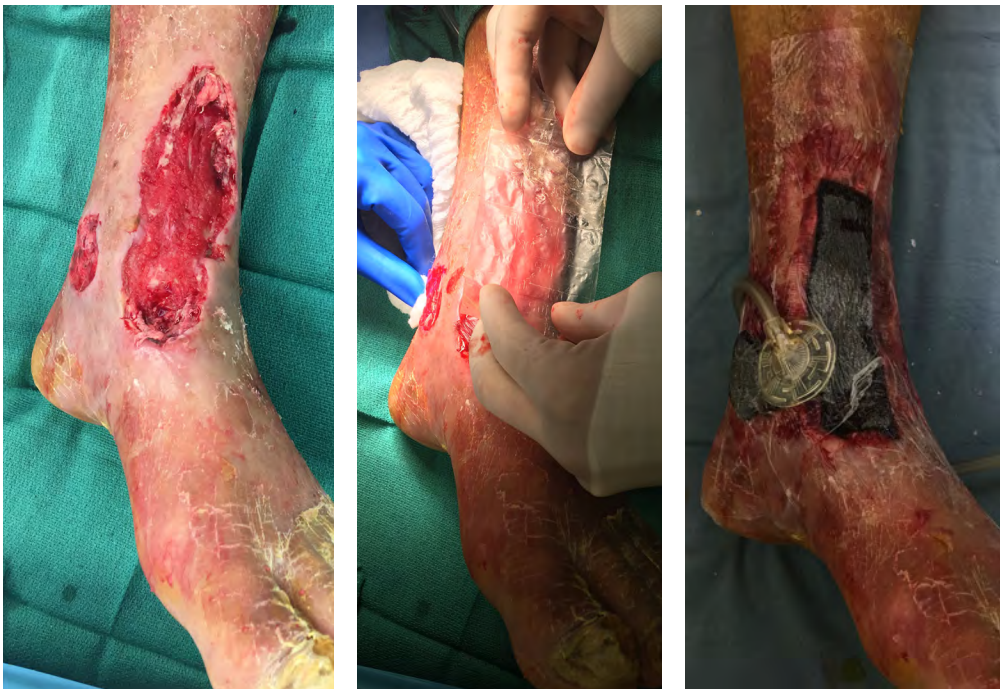


Figure 2-4: AmnioFix used in conjunction with NPWT

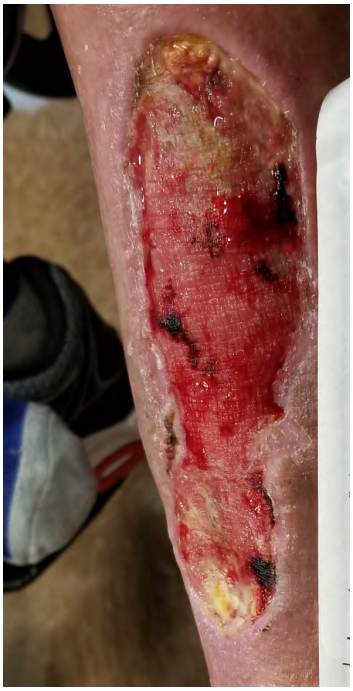


Figure 5: Week 2 S/P 1st EpiFix treatment

✓ **TECHNIQUE TIP:**

Site Preparation: Thorough debridement

Allograft Application: Cut allograft sheet to wound size; some opt to perforate or use the EpiXL Fenestrated allograft

Dressings: Place non-adherent gauze below trimmed NPWT foam dressing; use normal -125 mmHg suction settings; leave non-adherent dressings in place for 5-7 days to keep biologic graft undisturbed, NPWT dressing changes per institutional protocol*

NOTE: *AmnioFix and EpiXL Fenestrated are available for use in the OR and EpiFix is available in the outpatient clinic or office setting.*

Follow-Up

At the two week follow-up, healthy granulation tissue was observed throughout (Figure 5). EpiFix was applied in the office and the allografts were again left in place for five days before normal NPWT dressing changes resumed (Figure 6). EpiFix is a dehydrated human amnion/chorion membrane allograft (Figure 7). EpiFix 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. EpiFix provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[1-3]

Seven weeks after the initial endovascular therapy, surveillance duplex scanning showed recurrent anterior tibial stenosis, which was then successfully treated with atherectomy and angioplasty to again optimize perfusion. A final EpiFix application was done on Week 9 and the wound progression to closure continued with the exception of a dime sized area on the LLE with exposed tendon seen on Week 13 (Figure 8). At that point, NPWT was discontinued and the remaining area was treated with conventional dressings and was fully closed and stable at follow-up one month later (Figure 9).

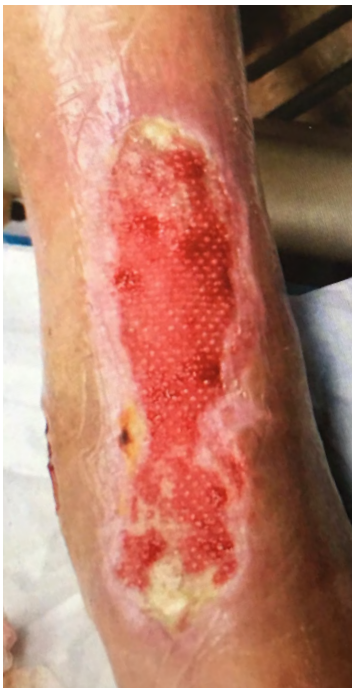


Figure 6: Week 4 S/P 2nd EpiFix treatment

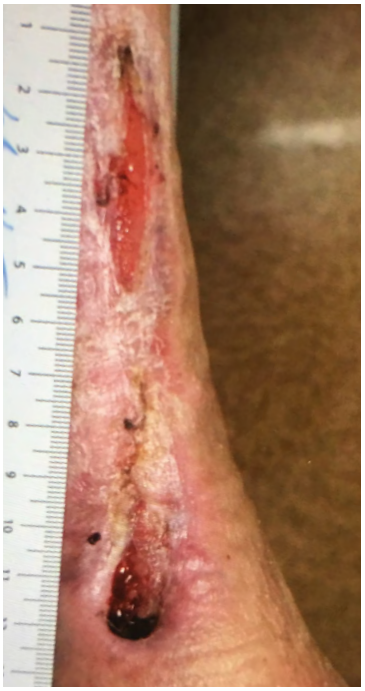


Figure 8: Week 13 S/P 3rd EpiFix treatment

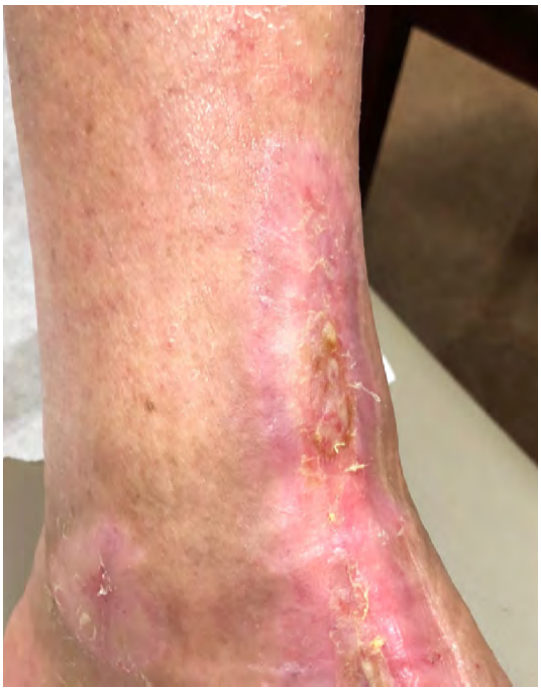


Figure 9: Week 17 wound completely closed

Figure 7: EpiFix

Conclusion

This case demonstrates an appropriate use of advanced therapies to gain additional treatment options for a very high-risk patient that was not a surgical candidate, but would have otherwise benefited from a bypass procedure. AmnioFix and EpiFix, in conjunction with successful endovascular therapy and NPWT, ultimately helped avoid a likely below the knee amputation or skin grafting procedure to close the wounds. Overall, the time to wound closure in this patient was impressive given the extensive nature of his wounds.

***NOTE-** No studies have been conducted to determine optimal MiMedx allograft usage in conjunction with NPWT. Description based on author's personal experience with both products.*

Below the Knee Amputation (BKA) after Prior Amputation Dehiscence with AmnioFix

Challenge

Despite advances in vascular surgery, endovascular therapy, and wound management, closure of diseased limbs remains challenging. The primary goal of limb salvage is to restore and maintain ambulation. However, closure challenges can further complicate the clinician's efforts. Challenges to wound closure in this setting include non-compliance, PAD, hygiene, smoking, multiple comorbidities, etc. Reported closure rates for transmetatarsal amputations (TMA) range from 40-70%[4], while reoperation rates range from 8 to 63%, with approximately one-third resulting in a major amputation.[5] Once other more conservative limb salvage options have been exhausted, BKA can still offer the patient a relatively functional limb for use with prosthetic to ambulate.

Clinical History

The patient is a 56-year-old female with a history of severe peripheral artery disease, uncontrolled diabetes, end stage renal disease on dialysis, coronary artery disease with a prior percutaneous coronary intervention, and diabetic foot ulcers that led to a TMA by podiatry. She did not have the appropriate arterial revascularization at the time and the TMA site dehisced due to pressure from walking and the impaired closure from severe comorbidities. The wound worsened with necrosis and infection, to the point where re-approximation of the tissue was no longer possible (Figure 1).

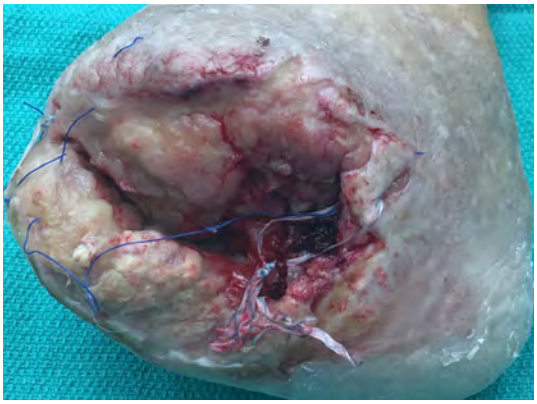


Figure 1: Non-healing dehiscence after TMA

The patient was referred to vascular surgery for her lower limb peripheral arterial disease. Atherectomy and angioplasty were performed to address her superficial femoral artery stenosis and anterior tibial artery stenosis, which successfully improved perfusion to the foot with three vessel run off. The wound would still not heal after one month with multiple debridements and treatments by podiatry. The patient was referred back to vascular surgery and scheduled for a BKA.

Figure 2: AmnioFix

Surgical Intervention

A standard BKA was performed. Based on the patient's history of an inability to close wounds in the setting of adequate perfusion, AmnioFix was used. AmnioFix is a dehydrated human amnion/chorion membrane allograft (Figure 2). 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 chronic and acute closures. AmnioFix provides a human biocompatible extracellular matrix and retains 300+ regulatory proteins.[1-3]

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A 6 cm by 16 cm AmnioFix allograft was cut into several pieces and placed into the surgical site. One portion of the allograft was placed on the muscular bed, where the AmnioFix allograft wound be positioned between muscle and bone after the subcutaneous tissue was closed (Figure 3). The other portions were placed in the subcutaneous space before dermal closure to enhance closure in this high risk suture line (Figures 4-6).**

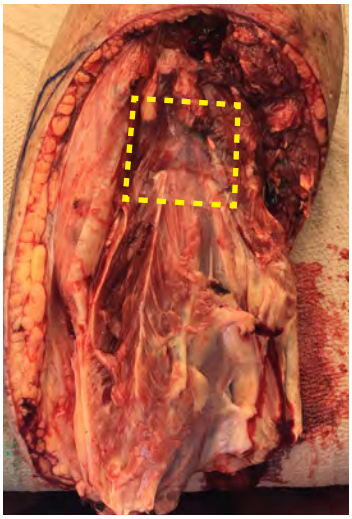

Figure 3: AmnioFix placed on muscular bed

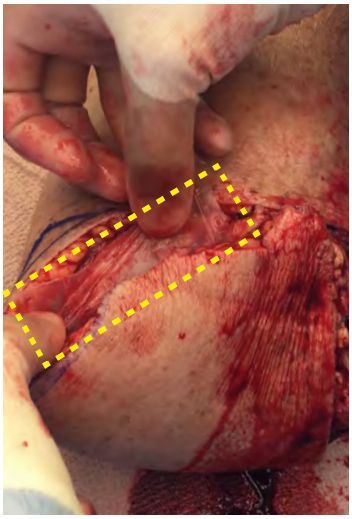

Figure 4: AmnioFix in subcutaneous tissue before closure

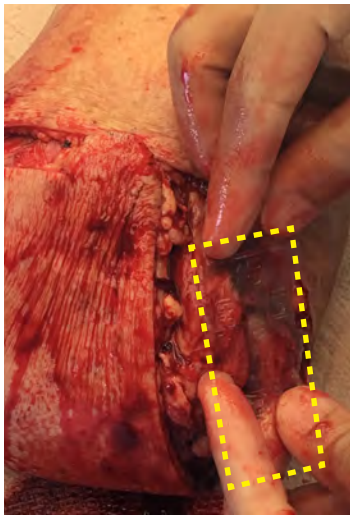

Figure 5: AmnioFix in subcutaneous tissue before closure

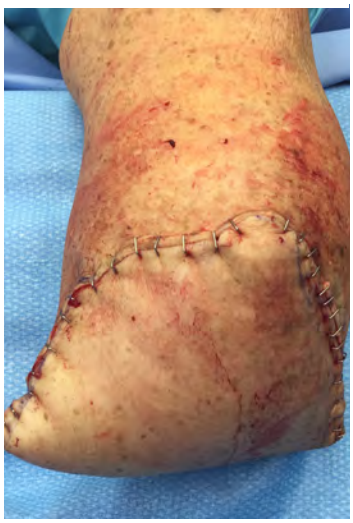

Figure 6: Flap closure

Follow-Up

The patient fell onto her stump in the hospital five days post-operatively. Despite the fall and resultant mild dehiscence, there was no swelling and the stump remained intact (Figure 7). This type of injury could have resulted in amputation failure. After thirty days, the BKA incision was fully closed. The patient was again seen eleven weeks post-op and the amputation remained stable (Figure 8).

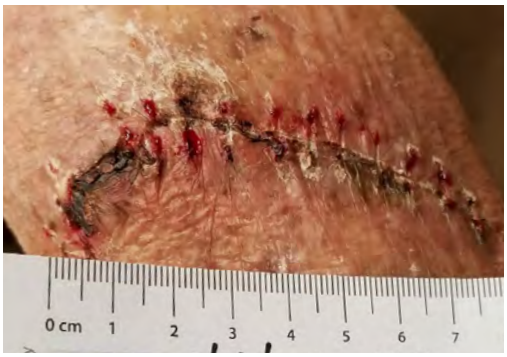

Figure 7: S/P fall onto stump on Day 5

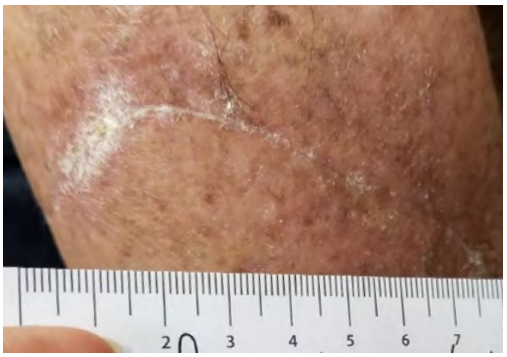

Figure 8: Wound fully closed

Conclusion

High-risk patients, even in the setting of the adequate perfusion, can encounter postoperative wound complications. In this case, despite the early signs of dehiscence, the amputation wound site closed with the use of AmnioFix in a very challenging patient with a history of non-healing.

***NOTE** -Alternatively, pending surgeon's preference, product availability, and/or area coverage goals, AmnioFix Injectable or AmnioFill® may also be used in a similar manner.*

Revisionary Femoral Popliteal Bypass Surgery with AmnioFix and AmnioFix Injectable

Challenge

In an analysis of patients that were readmitted within thirty days of lower extremity bypass (LEB) surgery, the data suggests that the most common post-discharge complications included wound complications (56%), multiple complications (22%), and graft failure (5%).[6] Patients with prior LEB and saphenous vein harvest may present additional challenges when revision surgery is required. These also include failure of wound closure, as prior incisions have compromised local vasculature, seromas, wound infections, and even graft infections.

Clinical History

A 67-year-old male presented with right lower extremity rest pain and was noted to have had a significant vascular history including multilevel occlusive disease and a prior failed lower extremity bypass. Upon examination, the patient was found to have a 2+ femoral pulse and diminished popliteal and pedal pulses. The patient had ischemic rest pain, but no tissue loss. He had a prior femoral to popliteal artery bypass with a non-reversed greater saphenous vein graft that was chronically occluded. Patient comorbidities included the typical atherosclerotic risk factors such as hypertension, nicotine dependence, CAD, diabetes mellitus, and hyperlipidemia.

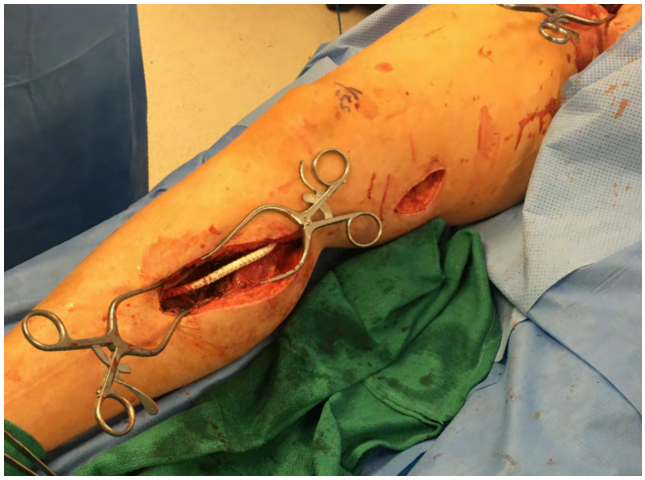

Figure 1: Revisionary femoral bypass surgery

Surgical Intervention

The patient underwent a right femoral to posterior tibial artery bypass using a 6 mm ePTFE graft (Figure 1). The femoral incision was severely scarred from the prior surgery. The posterior tibial artery was diseased, but otherwise was optimal for bypass creation. Due to the patient comorbidities and scar tissue from the prior procedure, which can alter superficial perfusion, both AmnioFix sheet and AmnioFix Injectable allografts were used to help support wound closure at the surgical sites. AmnioFixis a dehydrated human amnion/chorion membrane allograft in sheet and micronized/injectable configurations (Figure 2). 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 for acute and chronic closures. AmnioFix provides a human biocompatible ECM and retains 300+ regulatory proteins.[1-3]

Figure 2: AmnioFix sheet and AmnioFix Injectable

Once the bypass graft was sewn onto the artery, a 2 cm by 12 cm AmnioFix sheet was cut in half and a 2 cm by 6 cm AmnioFix was placed over each ePTFE graft at both the proximal and distal anastomoses (Figures 3,4). A drain was brought out through a separate stab incision. The incisions were then closed in a multi-layer fashion and 160 mg of AmnioFix Injectable was spread over the closures in the subcutaneous space, prior to skin closure (Figures 5-7).

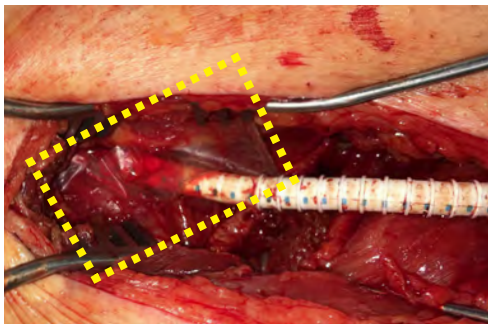

Figure 3: AmnioFix placed in LE anastomosis

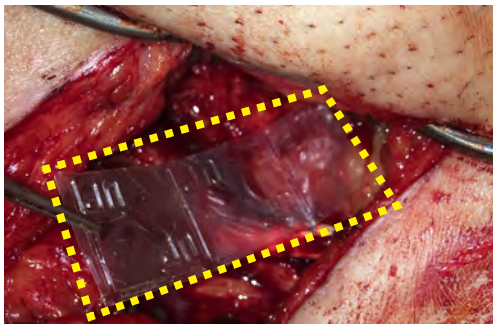

Figure 4: AmnioFix placed in groin anastomosis

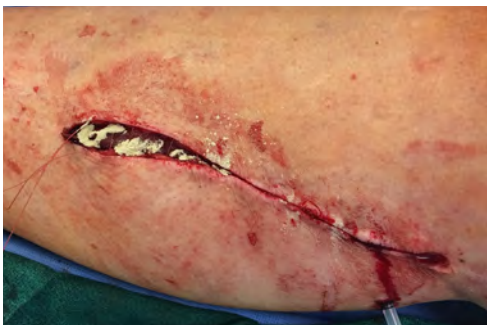

Figure 5: AmnioFix Injectable in subcutaneous tissue before LE closure

Figure 6: AmnioFix Injectable in subcutaneous tissue before groin closure

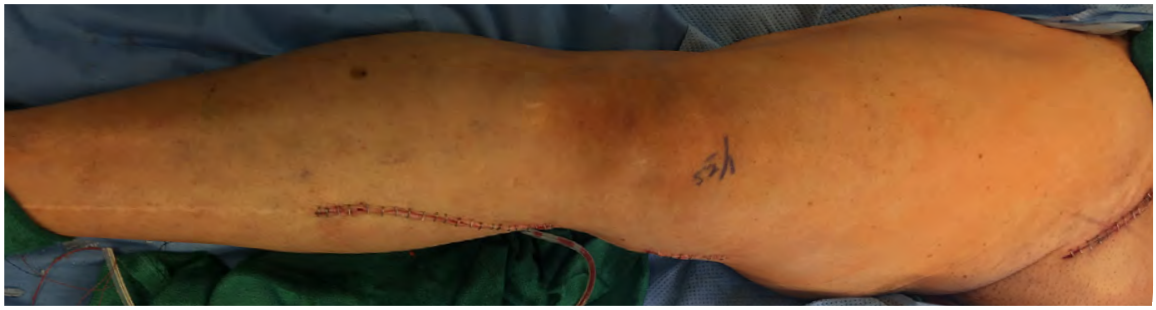

Figure 7: Final closure

Follow-Up

The patient proceeded to wound closure without complications postoperatively. At Week 4 follow-up, the patient's bypass was found to be patent by duplex ultrasonography. The incisions were fully closed, and no lymphoceles or seromas were observed.

Conclusion

Postoperative surgical site complications such as infection, lymphoceles, or seromas in the presence of a prosthetic graft can lead to wound dehiscence, soft tissue infection, and even graft infection. In this case, the use of AmnioFix and AmnioFix Injectable allografts supported wound closure at the surgical sites.

Lower Extremity Bypass Dehiscence with EpiFix and NPWT

Challenge

Data suggests that wound complications following lower extremity bypass surgery are observed in >11% of cases. Notably, wound complications are one of the most common reasons for hospital readmission within 30 days.[6] Wound dehiscence in lower extremity bypass patients commonly occurs secondary to an underlying seroma, hematoma, or tissue flap created during saphenous vein harvest. These wounds can be challenging to close as they often extend along the entire limb. Furthermore, closing these wounds in an expedited fashion helps preserve graft integrity and patency, thus avoiding potential graft infection and or occlusion.

Clinical History

A 78-year-old male presented with a right first toe necrosis and underwent endovascular therapy for known superficial femoral artery (SFA) occlusion. The patient had multiple comorbidities including diabetes, hypertension, hyperlipidemia, peripheral arterial disease, and prior smoking. The initial revascularization was successful, but on follow-up, duplex surveillance showed recurrent occlusion. He subsequently underwent a right femoral to above the knee popliteal bypass with a greater saphenous vein graft. Intraoperatively, a drain was placed along the harvest site. The drain was removed on post-op day four. At that time, the incision was intact with no fluid collection observed. Unlike our current practice when treating high-risk patients, no AmnioFix allografts were placed in the surgical site at the time of the bypass procedure.

During his post-operative hospitalization, his venous bypass was found to be occluded secondary to outflow disease. The patient underwent endovascular therapy with successful revascularization of his native right SFA. A stent graft was placed and good two-vessel runoff to his right foot was noted.

Two weeks later the patient came to the office for staple removal. The incisions had closed, but he had a small seroma at the right medial thigh incision site, which dehisced the next day (Figure 1). The wound was treated initially with wet to dry dressings for four weeks, but did not significantly reduce in size. At this point due to the slow closure progression advanced wound therapy was warranted. The physician felt that the patient met the medical necessity criteria for advanced wound therapy and EpiFix was investigated as an option for in-office treatments. All prior standard of care (SOC) treatments and wound progression were fully documented, an insurance authorization request was submitted, and EpiFix was approved for treatments.^ EpiFix is a dehydrated human amnion/chorion membrane allograft (Figure 2). EpiFix 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. EpiFix provides a biocompatible human extracellular matrix and retains 300+ regulatory proteins.[1-3]

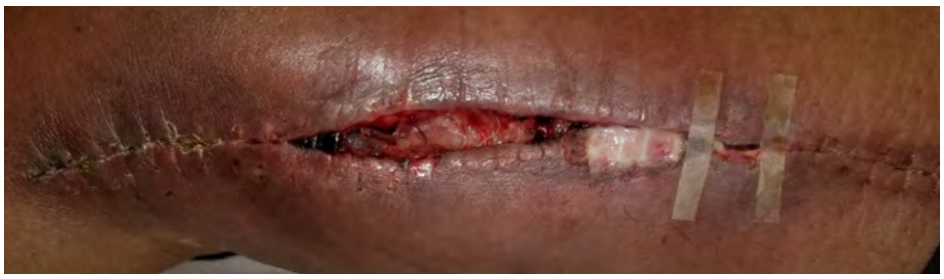

Figure 1: Dehiscence and seroma at the right medial thigh incision site

Figure 2: EpiFix

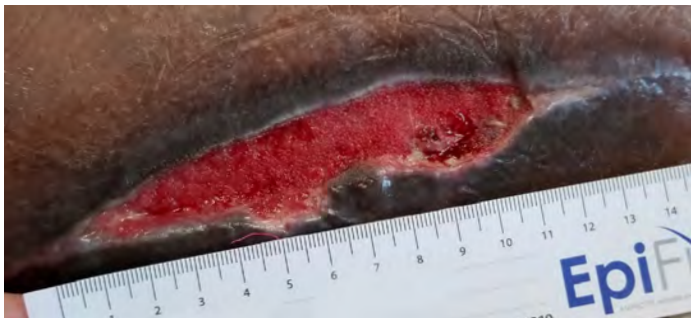

Figure 3: S/P four weeks of SOC dressings, prior to EpiFix application

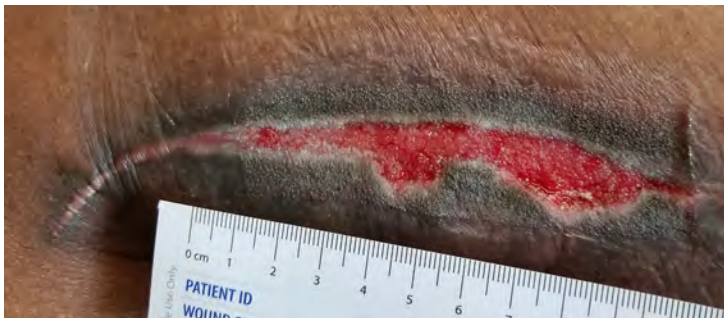

Figure 4: Week 2, S/P two EpiFix + NPWT treatments

A small area was debrided around a thrombosed vein, which was excised. A 4 cm x 4.5 cm EpiFix Mesh allograft was cut into two pieces, placed to fit onto the wound, and dressed with a non-adherent dressing and negative pressure wound therapy (NPWT). The NPWT dressing was left in place for five days in order to leave the EpiFix undisturbed, and the process was repeated again the following week (Figure 3,4). Weekly applications of EpiFix covered with non-adherent and conventional dressings were done in the office setting thereafter. The wound was closed after six weeks of EpiFix application (Figures 5,6).

Figure 5: Week 4, S/P four EpiFix treatments

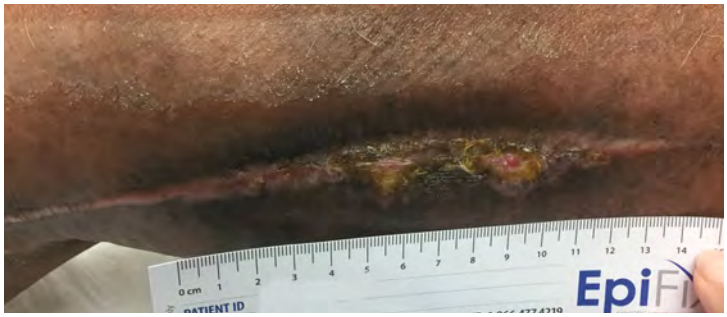

Figure 6: Week 6, S/P six EpiFix treatments

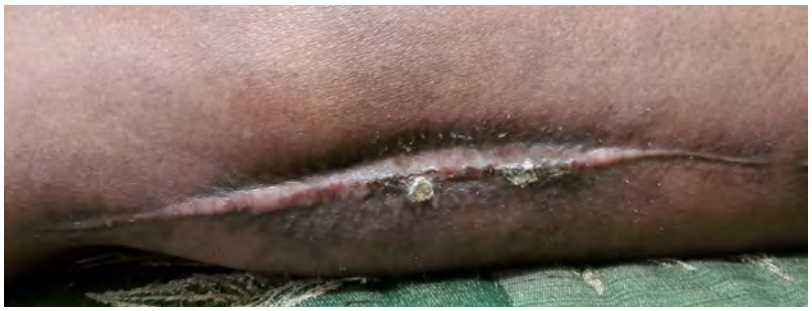

Figure 7: Week 10, wound fully closed and stable

Follow-Up

The patient returned for another follow-up four weeks later and the wound remained fully closed and stable (Figure 7). Lastly, the original complication with the right first toe nearly resolved with only a small scab and an amputation being avoided.

Conclusion

Saphenous vein harvest site breakdown is common among patients with peripheral arterial disease and patients with morbid obesity. In this case, weekly EpiFix applications during in-office visits supported wound closure that was not seen with SOC.

*^**NOTE-** Insurance reimbursement varies by payer, geography, and patient-specific factors. Your local Account Executive or Field Reimbursement Manager can help explain the Insurance Verification Process, as well as resources available to customers.*

To find out more about MiMedx® products:

Please Call: 866.477.4219 **Email: customerservice@mimedx.com**

REFERENCE 1. Koob, et al. J Biomed Mater Res B Appl Biomater. 2014 Aug;102(6):1353-62. **2.** Lei, et al. Adv Wound Care. 2017 Feb 1;6(2):43-53. **3.** MM-RD-00086, Proteome Characterization of Purion Processed Dehydrated Human Amnion Chorion Membrane (dHACM) and Purion Plus Processed Dehydrated Human Umbilical Cord (dHUC) Allografts. **4.** Ammendola, et al. Int Wound J. 2007; 14(1):9-15. **5.** Thorud, et al. J Foot Ankle Surg. 2016; 55(5):1007-1012. **6.** Zhang, et al. J Vasc Surg. 2014; 59(5):1331 – 1339.

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