

EpiFix™ – Human Amniotic Membrane Allograft for Treatment in Diabetic Wound Care Management

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Introduction





Human amniotic membrane comprises the innermost layer of the placenta and lines the amniotic cavity. The amnion is composed of a single layer of epithelial cells, a basement membrane and an avascular connective tissue matrix. Eligible amnion donors are living mothers that have delivered a live birth through elective cesarean section. All tissues are recovered under full informed consent. Amnion tissue is prepared using a process that maintains graft structural integrity or tissue matrix allowing for the membrane's type IV, V and VI collagens to be delivered to the wound site. This makes amnion an important source of scaffolding material and stem cells that will easily integrate with host tissue to provide for cellular growth and differentiation. Amniotic membrane allografts have been used for a wide variety of clinical applications ranging from ophthalmology to soft tissue reconstructive procedures including burn and wound care management and chronic extremity ulcerations resulting from diabetes. Amnion has biological properties important for wound healing including anti-inflammatory, anti-microbial, anti-fibrosis, anti-scarring and low immunogenicity. The availability, cost, effectiveness, stability and ease of use provide additional benefits as a viable surgical option for the wound care physician.

Materials and Methods

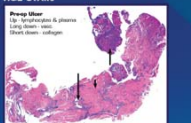
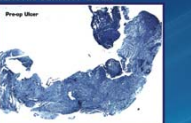
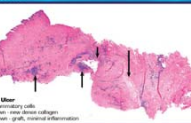
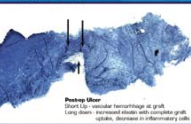
Our patients' initial visits involved a comprehensive review of past medical history and examination of lower extremity circulation to determine necessary wound healing support. A treatment plan was developed to include the following: perform subcutaneous debridement, amniotic membrane graft application (Surgical Biologics, Kennesaw, Georgia)*, wound off-loading and weekly follow-up visits for assessment of wound healing. Patients received standard wound prep cleansing and scrub of the ulcerated area. The wounds were debrided to the subcutaneous tissue, resulting in a bleeding wound bed which would facilitate graft uptake. After irrigation and hemostasis, a 4cm x 4cm non-hydrated amniotic membrane graft was cut to size and applied. The graft was placed onto the site dry and hydrated on the wound. The material did not require additional fixation. A Mepitel dressing was fixed over the graft. Patients were given post treatment instruction to leave the dressing intact and to off-load the wound during ambulation.

* Surgical Biologics is a MiMedx Group Company, www.mimedx.com

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<p>PATIENT (A) PRESENTATION PRE-TREATMENT</p>  <ul style="list-style-type: none"> • 55 year-old insulin dependent diabetic male s/p I&D secondary to right foot necrotizing fasciitis. Neuropathic ulceration of submetatarsal right foot. • Grade II full thickness right submetatarsal wound present for 2 months. Wound size was 4.0x0.6x0.8cm on initial presentation. • Past Medical History: IDDM, Hypertension • Objective findings: No signs of infection, pain or drainage. Strong palpable pulses. Charcot foot presentation. • Previous treatment included hospitalization, I&D x 3, off-loading, HDD x 2, topical abx. 	<p>PATIENT (B) PRESENTATION PRE-TREATMENT</p>  <ul style="list-style-type: none"> • 74 year-old non-insulin dependent diabetic male with non-healing neuropathic ulcer of right great toe. Avid gaffer self treating callus. • Grade II full thickness right hallux wound present for 4 months. Wound size was 0.7x0.6x 0.2cm on initial presentation. • Past Medical History: MDDM, Hypertension, Hyperlipidemia • Objective findings: No sign of infection, pain or drainage. Strong palpable pulses. Epicritic gross sensation of lower extremity was diminished to absent. • Previous treatment included OTC topical medication and oral antibiotics.
<p>PATIENT (A) POST-TREATMENT</p>  <ul style="list-style-type: none"> • Status post 1 week application there is clinical evidence of decreased wound depth, no infection and 100% graft uptake. • With continued use of intravenous antibiotics and proper off-loading, the ulcer closed in 7 weeks reducing the chance of recurring necrotizing fasciitis. 	<p>PATIENT (B) POST-TREATMENT</p>  <ul style="list-style-type: none"> • Status post application at 1 week shows full graft uptake with increase in granulation tissue and decreased wound margin. • The ulcer has resolved 1 month post application with minimal scarring and patient will return to appropriate diabetic shoe gear.

Histology Analysis

<p>PATIENT (B) PRE-TREATMENT</p>	
<p>H&E STAIN</p>  <p>Preop Ulcer Ep: hyperkeratotic & fissured Long Ulcer: ulcer Thick Ulcer: collagen</p>	<p>ELASTIN VERHOFF STAIN</p>  <p>Preop Ulcer</p>
<p>PATIENT (B) POST-TREATMENT</p>	
<p>H&E STAIN</p>  <p>Postop Ulcer Ep: inflammatory cells Long Ulcer: dense collagen Thick Ulcer: graft, minimal inflammation</p>	<p>ELASTIN VERHOFF STAIN</p>  <p>Postop Ulcer Long Ulcer: vascular fibroplasia at graft Thick Ulcer: increased dense collagen, inflammatory cells, decreased inflammatory cells</p>

Results

A total of 10 patients (n=10) were treated with amniotic membrane graft for wound management of neuropathic diabetic ulcers. Eight of ten patients completed the study and exhibited rapid healing within the first 4 weeks of treatment application. Two patients were lost due to non-compliance. Pretreatment wound measurements were taken on all patients with wound volume averages measurements of 3.47cm for the treatment group. Patients received one graft application during the treatment period. Patients were seen weekly to assess wound margins, all patients showed no evidence of infection; drainage or adverse events during the 6-week post-treatment follow up visits. At the 1 follow up visits, all patients showed 100% graft uptake with no evidence of membrane sloughing. At week 4, mean wound closure volumes were calculated at 1.85cm, which results in an overall 46.86% closure rate for 1 treatment application.

Conclusions

Since amnion falls in the category of advanced biologic tissue, a fair clinical comparison can be made with graft products on the market today. The summary of results and findings on this initial study are as follows:

- The inherent ease of application and storage unique to the amniotic membrane graft differentiates it from similar products
- Ninety percent of wounds treated exhibited 100% uptake of the amniotic membrane graft without rejection after 1 week
- An average of 50 percent reduction of wound volume and size was proven by weekly measurements
- Clinical pain, signs of infection, and drainage post application was noticeably less among amniotic membrane graft patients
- Postoperative course and maintenance required by patients is simple and direct, which allows for better compliance

For further information

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