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 to be type IV, V and VII 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 ulcers 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 debried 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 Merpelt 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.

Results

A total of 30 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 3.47xcm 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% graft uptake of the amniotic membrane graft with little 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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