Evaluation of a Human Amniotic Membrane Allograft (AMNIOEXCEL®) for Treating Challenging Diabetic Lower Extremity Ulcers

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Introduction:

Lower extremity ulcers are a serious and significant complication for diabetic patients, leading to a drain on the overall cost of healthcare\textsuperscript{1,2}. The development of a better treatment strategy for these patients is critical to ensure the best outcomes, reduce or prevent amputations, and to minimize the burden on healthcare costs.

The use of human amniotic membrane to treat a variety of wounds dates back nearly a century\textsuperscript{3} but was limited in its use because of safety challenges and concerns with disease transmission. However, over the last several years, processes have been developed to clean and sterilize human amniotic membrane tissue yielding a room temperature-stable, safe tissue.\textsuperscript{4}

The natural human amniotic membrane is an attractive option for treating complex, chronic wounds because of its non-immunogenic\textsuperscript{5}, anti-inflammatory\textsuperscript{6} and anti-bacterial\textsuperscript{7} properties. The tissue also provides a matrix for cellular migration and proliferation and a number of essential growth factors and cytokines.\textsuperscript{8}

\textbf{AMNIOEXCEL\textsuperscript{®}} is a human amniotic membrane, donated from consenting women and retrieved at the time of child birth. This tissue is procured during cesarean section and the processing technology utilized maintains the extracellular matrix components and growth factors essential in the wound healing process. This paper provides an early look at the use of \textbf{AMNIOEXCEL\textsuperscript{®}} in complex, diabetic foot ulcers (DFUs).

Methods:

\textbf{AMNIOEXCEL\textsuperscript{®}} is available in a variety of sizes, provided dehydrated and stored at room temperature. Three patients were treated with a total of five wounds from February 2014 to April 2014. All wounds were prepared with sharp debridement to ready the wound bed for placement of the membrane. The \textbf{AMNIOEXCEL\textsuperscript{®}} was carefully removed from the sterile package with forceps and trimmed to size, if necessary, to overlap the wound margins by approximately 1mm. Once the membrane was placed into the wound, a moistened cotton swab was used to remove any air bubbles and ensure intimate contact with the wound bed. A non-adherent dressing was used to cover the membrane and was secured in place with retention tape. The wound was covered by a foam dressing which was used as a bolster to secure the membrane. All wounds were off-loaded.
Patient 1
Wound 1

Patient Information:
36 year old female patient with poorly controlled Type I diabetes and a history of neuropathy and chronic ulcerations. Patient had significant bony deformities in the left foot secondary to Charcot arthropathy.

Initial Examination:
Patient presented with a Wagner Grade II full thickness diabetic ulcer on the medial aspect of the left ankle.

Treatment:
Previous treatment consisted of standard wound care including debridement, exudate management and off-loading.

After failing to progress with standard of care, AMNIOEXCEL® human amniotic membrane allograft was used on the wound. At the time of initial placement, week 0, the wound was approximately 5.8 cm². Patient received 3 applications of the amniotic membrane, placed once every two weeks.

Outcome:
Wound improved dramatically and presented rapid progress demonstrated by contraction, granulation and decrease in size including depth. Full wound closure was achieved by week 6.
**Patient 1**

**Wound 2**

**Patient Information:**
36 year old female patient (same as previous).

**Initial Examination:**
Patient presented with a Wagner Grade II full thickness diabetic ulcer on the plantar aspect of the left heel.

**Treatment:**
Previous treatment consisted of standard wound care including debridement, exudate management and off-loading.

After failing to progress with standard of care, **AMNIOEXCEL®** human amniotic membrane allograft was used on the wound. At the time of initial placement (week 0), the wound was approximately 1.0 cm². Patient received 2 applications of the amniotic membrane, one at week 0 and one at week 2.

**Outcome:**
Wound improved dramatically and presented rapid progress demonstrated by contraction, granulation and a decrease in size, including depth, reaching full closure at 3 weeks.
Patient 2
Wound 1

Patient Information:
67 year old female with a history of diabetes, neuropathy, chronic osteomyelitis and Charcot deformity of the left foot.

Initial Examination:
Patient presented with a Wagner Grade II full thickness diabetic ulcer on the lateral aspect of the left ankle.

Treatment:
Previous treatment consisted of standard wound care including debridement, drainage management and off-loading.

After failing to progress with standard of care, **AMNIOEXCEL®** human amniotic membrane allograft was used on the wound. At the time of initial placement (week 0), the wound was approximately 3.6 cm². Patient received 2 applications of the amniotic membrane, placed at week 0 and week 2.

Outcome:
Wound demonstrated contraction and granulation. By week 4, overall wound size and depth had improved dramatically.
Patient 3
Wound 1

Patient Information:
69 year old male with a history of hypertension, diabetes, neuropathy, arterial insufficiency and chronic ulcerations on both feet. Four months prior to treatment with the membrane, patient underwent right lower extremity angioplasty and surgical debridement. One month prior, patient underwent right superficial femoral artery to dorsalis pedis bypass.

Initial Examination:
Patient presented with a Wagner Grade II full thickness diabetic ulcer on the lateral edge of the right foot.

Treatment:
Previous treatment consisted of standard wound care including debridement, exudate management and off-loading. In addition, patient had been treated prior with negative pressure wound therapy (NPWT) and a living bi-layered skin substitute.

After failing to progress with this treatment, AMNIOEXCEL® human amniotic membrane allograft was used on the wound. At the time of initial placement (week 0), the wound was approximately 2.6 cm². Patient received 3 applications of the amniotic membrane, placed once every two weeks.

Outcome:
Wound presented rapid progress demonstrated by contraction, granulation and decrease in size. Wound closure was achieved by week 6.
Patient 3
Wound 2

Patient Information:
69 year old male (same as previous). Four months prior to treatment with the membrane, patient underwent left lower extremity angioplasty.

Initial Examination:
Patient presented with a Wagner Grade II full thickness diabetic ulcer on the lateral edge of the left foot.

Treatment:
Previous treatment consisted of standard wound care including debridement, exudate management and off-loading.

After failing to progress with standard of care, AMNIOEXCEL® human amniotic membrane allograft was used on the wound. At the time of initial placement (week 0), the wound was approximately 3.5 cm². Patient received 3 applications of the amniotic membrane, placed once every two weeks.

Outcome:
Wound presented rapid progress demonstrated by contraction, granulation and decrease in size. Full wound closure was achieved by week 6.
Discussion

Early results with the use of AMNIOEXCEL® human amniotic membrane allograft are encouraging and suggest that incorporating this product into the wound care regimen for complex lower extremity DFUs can be beneficial. Controlled, prospective studies are needed to further analyze this technology however, these cases suggest that AMNIOEXCEL® can be a viable option for treating recalcitrant DFUs.

Barry Rosenblum, DPM serves as a paid consultant for Derma Sciences, Inc.

References