

Use of a new acellular dermal matrix* for treatment of non-healing wounds in the lower extremities of the diabetic patient

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Introduction

Many diabetics develop lower extremity ulcers that do not heal. Without medical treatment, chronic wounds can further deteriorate resulting in infection, discomfort, and pain. If the infection spreads to nearby bone, surgery may be required to remove part of the bone, or to amputate the foot and possibly part of the leg. Recently, it has become more common to treat these wounds using human acellular dermal matrices.^{1,3} Theoretically, decellularization removes potentially immunogenic material and provides a clean scaffold for host cellular and vascular in-growth. A new process has been developed yielding a human acellular dermal matrix cleaned of ≥97% DNA and cellular constituents. It is hypothesized that this process will yield an equivalent or superior material for chronic wound treatment than currently available matrices. The resultant material, an acellular dermal matrix, here referred to as D-ADM* (Figure 1), is provided at room temperature, hydrated, sterile, and ready to use. Thus, in this study, D-ADM (human skin treated with this new processing technology) was used to treat chronic wounds in the lower extremity of the diabetic patient and the progress of wound healing was assessed.

*DermACELL® LifeNet Health, Virginia Beach, VA

Figure 1. D-ADM



Materials and Methods

In this evaluation, 15 consecutive patients meeting inclusion and exclusion criteria were treated with D-ADM. Patients were included if their wounds had persisted for at least 6 weeks (wound duration in the study ranging from 2 months to 5 years with an average of 2 years), showed signs of adequate local blood circulation, and were ≥1 cm² and <1 cm deep. Other inclusionary criteria included presence of full thickness wounds to the foot or ankle secondary to either insulin dependent or non-insulin dependent diabetes mellitus; recent HgA1C <12; and ability to comply with off-loading and dressing change requirements. Exclusionary criteria included patient classification as minors, prisoners, and pregnant women; evidence of clinical infection (unless being treated at the time of application); necrotizing fasciitis, deep abscesses in the soft tissue, gas gangrene; need for any additional concomitant dressing materials other than the ones approved for this study; and has undergone treatment with a living skin equivalent within the last 4 weeks prior to initiation of D-ADM treatment.

Wounds were thoroughly debrided with a sharp blade. The D-ADM [prepared using a combination of non-denaturing anionic detergent (N-Lauroyl sarcosinate, NLS), recombinant endonuclease (Benzonase®), and antibiotics (Polymixin B, Vancomycin, and Lincomycin) and terminally sterilized with a low dosage of gamma irradiation at low temperatures to a Sterility Assurance Level of 10⁻⁶] was trimmed accordingly, applied to the wound, and secured by suture, Steri-strip, or non-adherent dressing. Treated wounds were typically covered with non-adherent dressing, moist gauze, and a light compression bandage. Patients were clinically evaluated at each visit, on a weekly basis, for up to 12 weeks, based on healing. Dressings were left in place for a minimum 5 days and a maximum of 7 days, and were changed by the clinician at follow-up. Single applications of D-ADM were employed except for 3 cases where a second D-ADM was applied due to either non-compliance or clinician preference.

Results

As shown in Table 1 complete wound closure was observed in 6 of the 13 patients currently completed with the study, for a 46% closure rate. Substantial wound healing (95% closure or greater) was noted in 9 of 13 patients for a rate of 69%. Among these patients there was an average duration to closure of 10 weeks and integration of the D-ADM with surrounding tissue.

Results at 12 Weeks

	# of Patients (out of 13)	Wound Closure Rate
Complete Wound Closure	6	46%
Wound Healing**	9	69%

Table 1. Wound Closure and Wound Healing Data

**Wound healing defined as 95% or greater wound closure

Summary

Here we describe a study using D-ADM to treat non-healing diabetic foot ulcers and observations of wound healing throughout a 12-week period post-D-ADM application. These results compare very favorably with other methods of advanced wound care.

References

- Winters, C., Brigido, S., Liden, B., Simmons, M., Hartman, J., Wright, M. 2008. A Multicenter Study Involving the Use of a Human Acellular Dermal Regenerative Tissue Matrix for the Treatment of Diabetic Lower Extremity Wounds. *Advances In Skin and Wound Care*, 21(8), 375-381
- Randall, K., Booth, B., Miller, A., Russell, C., Laughlin, R. 2008. Use of an Acellular Regenerative Tissue Matrix in Combination with Vacuum-assisted Closure Therapy for Treatment of a Diabetic Foot Wound. *The Journal of Foot and Ankle Surgery*, 47(5), 430-433.
- Brigido SA, Boc SF, Lopez RC. Effective management of major lower extremity wounds using an acellular regenerative tissue matrix: A pilot study. *Orthopedics* 2004; 27:15145-s149.

Presentation of two cases of successful wound treatment with D-ADM

Patient 9: A 47 y.o. female presented with a Wagner Grade 2 non-healing diabetic ulcer on the plantar first medial head (Figure 2a). The patient reported existence of the ulcer for at least 1.5 years prior, which was non-responsive to conventional treatment. Following sharp edge debridement at Week 0, D-ADM was applied (Figure 2b) and secured with sutures and covered with a non-adherent dressing (Adaptic by Johnson & Johnson), moist gauze (Kerlix by Covidien), followed by a secure wrapping with the compression bandage (Coban by 3M). The patient went on to a successful outcome with a single application of D-ADM as noted by the substantial healing at week 12 (Figure 2c).



Figure 2a. Initial Wound Presentation



Figure 2b. One Week Post-Operative



Figure 2c. Twelve Weeks Post-Operative

Patient 12: A 50 y.o. female presented with Wagner Grade 2 non-healing wounds secondary to diabetes. The wounds (Figure 3a) had existed for at least 2 years prior to treatment. Following sharp edge debridement, D-ADM was applied (Figure 3b) and secured with sutures and covered with a non-adherent dressing (Adaptic by Johnson & Johnson), moist gauze (Kerlix by Covidien), followed by a secure wrapping with the compression bandage (Coban by 3M). At 3 weeks post application, the wounds had substantially healed (Figure 3c). By week 9, the two wounds exhibited 95-100% wound closure and healing with a single application of D-ADM.



Figure 3a. Before D-ADM Application



Figure 3b. After D-ADM Application



Figure 3c. 3 Weeks Post-D-ADM Application