ARTICLE IN REVIEW:

Dermacell AWM® in the Treatment of Large Diabetic Foot Ulcers with Exposed Tendon and Bone

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TITLE: A Prospective, Multicenter, Single-Arm Clinical Trial for Treatment of Complex Diabetic Foot Ulcers with Deep Exposure Using Acellular Dermal Matrix

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STUDY DESIGN: Prospective, single arm, multicenter open-label trial. Two study sites in 2 states (one urban and one rural). 47 patients

RESULTS: This study included 47 diabetic patients suffering from non-healing ulcers lasting 4 months on average. Mean ulcer size was 29cm^2 with 96% of patients having exposed bone. All patients achieved 100% granulation at a mean of 4 weeks. An average of 1.2 applications of Dermacell AWM were used. At 16 weeks, the average reduction of wound area was 80.3%. No complications were associated with use of Dermacell AWM. This study demonstrates how effective just one application of Dermacell AWM is at healing large complex DFUs with exposed bone.

100% granulation:

With 1.2 applications of Dermacell AWM, all 47 patients achieved 100% granulation by 4 weeks.

80% average wound size reduction:

By 16 weeks, the average wound size had reduced by 80%. Given more time, more of these large and complex DFUs may have completely healed.

Reduced amputation rate:

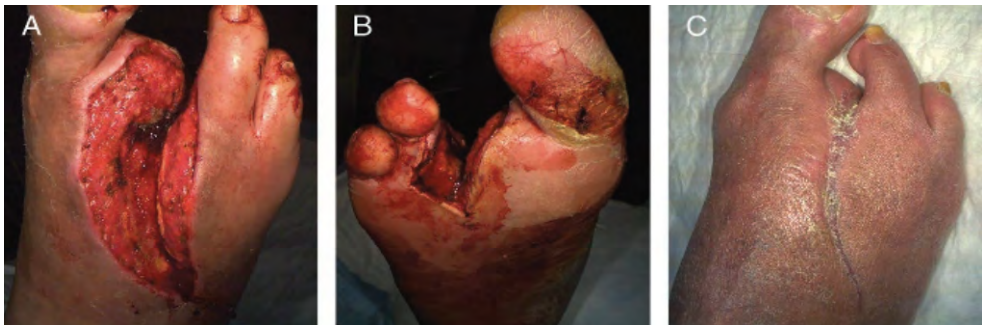
The rates of amputation in this study for noninfected and infected ulcers were 1.2% and 11.1%, respectively, substantially lower than the reported rates available of 6.5% to 18.3%.[1,2]

Faster healing than competitors:

In a comparative study, Grafix CORE® took twice as long and 6 times as many applications to achieve 100% granulation compared to one application of Dermacell AWM, emphasizing the efficacy and cost-effectiveness of Dermacell AWM.[2]

Healing progression of a **large** diabetic foot ulcer with exposed bone after a **single application** of Dermacell AWM

A and B, single diabetic foot ulcer with exposed bone. C, Ulcer 16 weeks after a single application of Dermacell AWM.



References:

1. Armstrong DG, Lavery LA, Harkless LB. Validation of a diabetic wound classification system. The contribution of depth, infection, and ischemia to risk of amputation. Diabetes Care. 1998 May;21(5):855-9.
2. Frykberg RG, Gibbons GW, Walters JL, Wukich DK, Milstein FC. A prospective, multicenter, open-label, single-arm clinical trial for treatment of chronic complex diabetic foot wounds with exposed tendon and/or bone: positive clinical outcomes of viable cryopreserved human placental membrane. Int Wound J. 2017 Jun;14(3):569-577.

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