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 29cm² 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.

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.







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

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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