

ARTICLE IN REVIEW:

A randomized clinical trial of DermACELL AWM® in the treatment of diabetic foot ulcers

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TITLE: A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator.

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STUDY DESIGN: Multicenter, randomized, controlled, open-label trial. Thirteen study sites in 9 states.

RESULTS: This study included 168 diabetic patients suffering from non-healing diabetic foot ulcers (DFUs) for 10 months on average. Patients were treated with Dermacell AWM, GraftJacket®, or conventional care. The average ulcer size was 3.6 cm² with 60% of ulcers being on the plantar foot. At all time-points, wounds treated with one application of Dermacell AWM demonstrated significantly greater healing than conventional treatment. GraftJacket did not significantly improve healing over conventional care. Four weeks after study completion, 100% of wounds healed with Dermacell AWM remained healed. The results of this study show that Dermacell AWM has better healing rates than conventional care for treating DFUs.

65% of DFUs healed in 12 weeks:

By 12 weeks, 65% of ulcers treated with one application of Dermacell AWM were healed compared to 41% with conventional care.

89% healed by 24 weeks:

The number of healed wounds increased to 89% at 24 weeks compared to 67% with conventional care.

100% of patients remained healed:

Four weeks after the termination of the study, 100% of wounds treated with one application of Dermacell AWM remained healed compared to 87% of wounds treated with conventional care.

Complete healing of a DFU



Week 0



Week 2



Week 11

68-20-202.00

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