

ARTICLE IN REVIEW:

Greater healing using DermACELL AWM[®] versus conventional care to treat venous leg ulcers using one application

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TITLE: A randomized clinical trial comparing a human acellular dermal matrix versus conventional care for the treatment of venous leg ulcers.

AUTHOR: Cazzell S.

Study Design: Pilot study (exploratory arm from a multicenter, randomized, controlled, open-label trial). Twenty-eight patients across 3 study sites in 2 states.

RESULTS: This study included 28 patients suffering from non-healing venous leg ulcers (VLUs) lasting 22 months on average. VLUs were treated with Dermacell AWM, or conventional treatment. The mean ulcer size was $\geq 7\text{cm}^2$. After one application of Dermacell AWM, 44% of patients were healed by 24 weeks. The average wound reduction using Dermacell AWM was 60% compared to 8.1% using conventional care. At the 3-month follow-up appointment, 75% of ulcers that were completely healed by 4 weeks remained healed. Treatment of VLUs with Dermacell AWM resulted in faster, greater, and more persistent healing than conventional treatment.

44% of VLUs healed:

By 24 weeks, 44% of ulcers treated with one application of Dermacell AWM were healed, a rate higher than conventional treatment (33%).

60% average wound size reduction:

The average reduction of wound size at 24 weeks was 60% in ulcers treated with Dermacell AWM. Conventional treatment resulted in only 8.1% reduction.

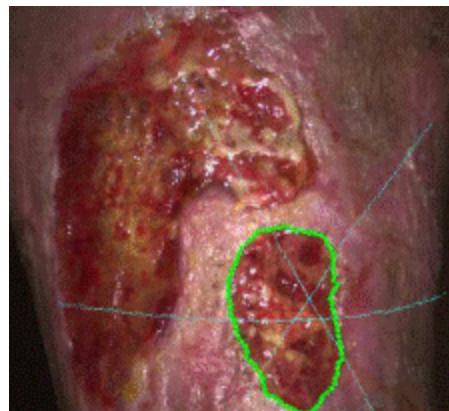
75% of patients remained healed:

At 1 month post-termination visit, 100% of healed wounds remained closed compared to 67% for conventional care. At 3 months post-termination, 75% of these wounds remained healed compared to 33.3% for conventional care.

Healing progression of venous leg ulcers after treatment with Dermacell AWM



6.6cm² preoperative venous leg ulcer after debridement



Early incorporation at 1 week post-treatment



Complete healing 11 weeks after one application of Dermacell AWM

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