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ABSTRACT

Evaluation of acellular human dermis graft on the healing rate of chronic diabetic foot ulcers: an interim analysis of the Derm-Maxx trial

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Abstract

Background: Diabetic foot ulcers (DFUs) remain a chronic and costly complication of diabetes, associated with morbidity and mortality. Healing outcomes are often suboptimal, despite compliance with standard of care (SOC) protocols, highlighting the need for innovative and cost-effective therapeutic approaches.

Methods: This interim analysis of a multi-center, open label, randomized controlled trial evaluated the efficacy of acellular human dermis graft (AHDG; Derm-Maxx™, Royal Wound-X, Hackensack, NJ 07601, USA) on chronic DFU closure. Primary endpoints were complete closure at 12-weeks and percentage area reduction (PAR). Interim data were reviewed for this analysis. Final database lock and quality control checks were pending. Uncertainty was propagated using a Bayesian approach to provide credible estimates despite the provisional data status.

Results: The probability of wound closure at week 12 was 19% (94% credible interval: 6.3%-32%) with SOC, and 45% (94% CI: 33%-57%) with AHDG, representing an absolute improvement of 27% (94% CI: 13%-41%) and a risk ratio of 2.8 (94% CI: 1.2 to 4.9). This indicates a 99.9% posterior probability that AHDG improves closure compared with SOC. At week 12, mean PAR was 85% (94% credible interval: 72%-97%) for SOC only wounds versus 66% (94% CI: 38%-91%) for wounds in the AHDG arm. The absolute difference in PAR is 19% (94% CI: 12%-49%).

Conclusion: Wounds in the AHDG arm were more likely to achieve complete closure by week 12. Remaining open wounds exhibited slower closure, resulting in lower mean PAR among non-closers. Additionally, wounds in the SOC group more frequently remained "partially closed," with continued but incomplete area reduction. Closure and PAR outcomes are consistent and complementary, indicating that AHDG enhances the likelihood of complete wound closure in comparison to SOC only.

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