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ABSTRACT

Evaluation of dual layer amnion patch on the healing rate of chronic diabetic foot ulcers: an interim analysis of the Med-Maxx SG trial

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Abstract

Background: Diabetes often results in persistent and expensive complications, including diabetic foot ulcers (DFUs), which result in substantial morbidity and mortality. Despite compliance with standard of care (SOC) protocols, healing remains inadequate, emphasizing the need for novel and economically sustainable therapies.

Methods: This interim analysis of a multi-center, open label, randomized controlled trial evaluated the efficacy of dual layer amnion patch (DLAP; Amnio-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. Fi-nal 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: Probability of wound closure at week 12 was 4% (94% credible interval: 0.004%-12%) under SOC and 35% (94% CI: 17%-54%) under DLAP, corresponding to an absolute improvement of 31% (94% CI: 12%-48%) and a risk ratio of 41 (94% CI: 1.2 to 115). This indicates a 99.9% posterior probability that DLAP improves wound closure compared with SOC. At week 12, mean PAR was 75% (94% credible interval: 50%-95%) for SOC only, and 73% (94% CI: 47%-95%) for DLAP. The absolute difference in PAR is 2.4% (94% CI: −35%-39%).

Conclusion: DFUs treated with DLAP were more likely to reach full closure by week 12. Remaining open wounds were more resistant to shrinkage, resulting in lower mean PAR among non-closers; SOC patients were more frequently "partially healed", showing large proportional area reductions without closure. Closure and PAR results are consistent and complementary: DLAP increases the probability of full closure, while SOC patients frequently remain partially closed with continued wound area reduction.

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