

■ ABSTRACT

# Evaluation of single layer amniotic membrane in the management of nonhealing diabetic foot ulcers: an interim analysis of CAMPX

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## Abstract

**Background:** Diabetic foot ulcers (DFUs) represent a chronic and debilitating complication of diabetes, contributing substantially to patient morbidity, mortality, and economic burden. Despite advances in clinical management, outcomes with the current standard of care (SOC) remain suboptimal, with many ulcers failing to achieve complete closure. These limitations reinforce the need for innovative, cost-effective solutions that promote wound closure.

**Methods:** This randomized controlled multicenter clinical trial evaluated the efficacy of single layer amniotic membrane (SLAM) plus SOC versus SOC alone in achieving complete closure of nonhealing DFUs over 12 weeks. The primary endpoint was complete wound closure, defined as 100% re-epithelialization without drainage for two consecutive weeks, confirmed by blinded independent review.

**Results:** In Intent-To-Treat (ITT), the SLAM + SOC arm achieved a 13.1% closure rate versus 8.8% with SOC alone, with findings consistent in the Per-Protocol (PP) population. Additionally, the percent area reduction (PAR) from TV-1 to TV-13 measured weekly with digital photographic planimetry and physical examination were analyzed. For ITT, SLAM + SOC outperformed SOC on both average and median wound-area reduction.

**Conclusion:** The interim analysis demonstrated that wounds managed with SLAM products trended toward superiority over those managed with SOC.

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