

■ ABSTRACT

# Evaluation of cellular, acellular, and matrix-like products (CAMPs) in the management of nonhealing diabetic foot ulcers: an interim analysis of the STABLECAMP trial

Thomas E Serena,<sup>1</sup> MD | Brianna Tramelli<sup>1</sup> | Emily King<sup>1</sup> MS | Dereck Shi,<sup>1</sup> MS | Madison Dunn<sup>1</sup> | Manisha Mehta<sup>2</sup> DPM | David Simon,<sup>3</sup> DPM FACFAS | R. Andrew Pavelescu,<sup>4</sup> DPM, FACFAS, FRCPS(Glas)

<sup>1</sup>SerenaGroup Inc., Cambridge, MA, USA; <sup>2</sup>GFC of Southeastern Michigan, Detroit, MI, USA; <sup>3</sup>Mount Sinai Brooklyn Hospital, Brooklyn, NY, USA; <sup>4</sup>The Foot, Ankle, & Vein Specialists, Venice, FL 34293, USA

**Correspondence:** Brianna Tramelli (btramelli@serenagroups.com)

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## Abstract

**Background:** Diabetic foot ulcers (DFUs) are chronic wounds associated with high morbidity, mortality, and economic burden. Current standard of care (SOC) achieves less than optimal healing rates, highlighting the need for novel and cost-effective therapies.

**Methods:** An interim analysis of this multicenter, prospective, randomized controlled modified platform clinical trial evaluated the efficacy of multiple cellular, acellular, and matrix-like products (CAMPs) with SOC versus SOC alone. The primary endpoint was percentage of target ulcers achieving complete wound closure in 12 weeks, defined as 100% re-epithelialization without drainage for two consecutive weeks, confirmed by blinded independent review.

**Results:** In Intent-To-Treat (ITT), the dual layer amnion/chorion membrane allograft (DLACG) with SOC arm achieved a 58.3% closure rate versus 13.3% with SOC alone, a 45% absolute gain that was statistically significant (n=12, 95% CI 15.7% to 68.4%, p=0.001, α=0.05). All other treatment groups were not significant in the ITT population. In Per Protocol (PP), analysis of the four-layer amniotic membrane allograft (FLAG) with SOC arm achieved a 63.6% closure rate versus 23.8% with SOC alone, a 39.8% absolute gain that was statistically significant (n=11, 95% CI 4.5% to 64.8%, p=0.027, α=0.05). All other treatment arms were not significant in PP population. Additionally, the percent area reduction (PAR) from TV-1 to TV-13 measured weekly with digital photographic planimetry, using an imaging device, and physical examination were analyzed. For ITT and PP populations, all treatment arms outperformed SOC on average and median wound-area reduction. For PP, demographic summary statistics were analyzed to determine randomized baseline balance across groups, which was achieved with no statistically significant differences between groups at the time of interim analysis.

**Conclusion:** The interim analysis revealed that the placental membranes products trended toward superiority over SOC. The statistical significance in the ITT population for DLACG suggests that this product is superior to SOC.

**Conflicts of interest:** The authors declare no conflicts of interest. The funders of the STABLE-CAMP study had no role in the design of the study; in the writing of this manuscript, or in the decision to publish the results.

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