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ABSTRACT

Evaluation of amnion chorion amnion placental allograft in the management of nonhealing diabetic foot ulcers and venous leg ulcers: a preliminary case series of the TIGERCAMP clinical trial

Thomas Serena[1] MD | **Siobhan McGurk**[1] | **Brianna Tramelli**[1] | **Emily King**[1] MS | **Dereck Shi**[1] MS | **Gregory Bohn**[1] MD | **Henry Ohse**[1]

[1]SerenaGroup, Inc., Cambridge, MA

Correspondence: Brianna Tramelli (btramelli@serenagroups.com)

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Abstract

Background: Diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) are chronic wounds that often demonstrate delayed closure and limited response to standard-of-care (SOC) procedures. Their persistence impacts quality of life and leads to elevated morbidity, mortality, and healthcare expenditures. The limited effectiveness of current management approaches highlights the need for additional, innovative, and cost-effective strategies.

Methods: This case series of 2 patients with VLU and 1 patient with a DFU were evaluated at 3 sites between May 2025 and August 2025. Eligible subjects had target ulcers between >1.0 cm2 and 20.0 cm2 at enrollment that had not closed after 4 weeks of SOC. Subjects received a topical application of the amnion chorion amnion placental allograft (ACA; ACAPatch™, Tiger Wound Care Medical, LLC, Conshohocken, PA, USA) in addition to SOC for up to 12 weeks or until com-plete (100%) wound closure. Wounds were measured by digital imaging at baseline and each weekly visit. Safety and tolerability were monitored throughout.

Results: All patients were female, age ranged from 59 - 82 years, with baseline wounds 7.0, 9.4, and 2.3 cm² (mean 6.2; SD 2.9). Cumulative PAR milestones (≥50/≥75/≥90) were achieved by Weeks 1/2/4, 4/6/8, and 1/3/8, respectively, with complete closure at Weeks 5, 9, and 12; closures were confirmed at a subsequent closure confirmation visit. Progressive granulation and epithelialization were observed in all cases. No product-related adverse events were reported.

Conclusion: Preliminary findings indicate ACApatch™ may aid SOC in advancing wound clo-sure rates in chronic DFUs and VLUs unresponsive to SOC alone. Results support continued evaluation in controlled studies to confirm efficacy and cost-effectiveness.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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