# EARLY OUTCOMES FROM THE RENEW MODIFIED PLATFORM TRIAL OF CELLULAR, ACELLULAR, AND MATRIX-LIKE PRODUCT INTERVENTIONS FOR DIABETIC FOOT ULCERS

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## INTRODUCTION

- Diabetic foot ulcers (DFUs) represent a major source of morbidity, cost, and impaired quality of life.
- Standard of care (SOC) for DFUs include sharp debridement, offloading, reducing bacterial load and maintaining moisture balance .
- Advanced wound management incorporates cellular, acellular, and matrix-like products (CAMPs) - a broad category of biomaterials, synthetic materials, and biosynthetic matrices that support the repair and/or regeneration of injured tissues through various mechanisms of action.

## METHODS

- RCT (clinicaltrials.gov NCT07086443) conducted across 10 SerenaGroup, Inc & affiliated sites in the United States.
- 63 eligible subjects w/ nonhealing DFUs Sep 2025 start, enrolled in amnion, intermediate layer, and chorion (AIC) + SOC arm (**Table 1**).
- Bayesian statistical analysis performed to compare wound closure rate of AIC + SOC arm to synthetic control (SC) arm derived from meta-analysis study.
- Wounds are measured weekly with digital photographic planimetry and physical examination.

**Table 1:** Key Inclusion and Exclusion Criteria

| INCLUSION CRITERIA | EXCLUSION CRITERIA |
|---|---|
| • At least 18 years of age<br>• Diagnosis of type 1 or 2 Diabetes mellitus<br>• Surface area between 1.0cm$^2$ and 15.0cm$^2$<br>• Present between 4 and 52 weeks, treated with SOC<br>• Must be Wagner grade 1 or 2<br>• Has adequate perfusion | • Life expectancy <6 months<br>• Ulcer has infection, cellulitis, or osteomyelitis<br>• Use of immunosuppressants, cytotoxic chemotherapy, or topical steroids<br>• Known allergy/sensitivity to PBS, IPA, processing solutions, reagents, or latex.<br>• Partial amputation that impedes proper offloading<br>• Surface area has reduced in size by >20% in 2 weeks prior to SV or by >25% from SV to TV-1<br>• Previously treated with HBOT or CAMP |

**Table 2:** Endpoints

| PRIMARY ENDPOINT | SECONDARY ENDPOINT |
|---|---|
| • The percentage of target ulcers achieving complete wound closure in 12 weeks. | • Percentage wound area reduction from TV-1 to TV-13 |

## RESULTS

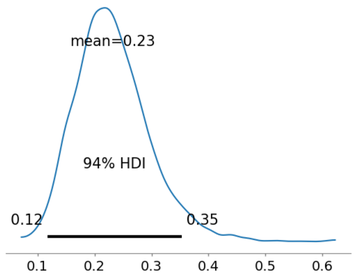


**Figure 1:** G-COMP SC Wound Closure

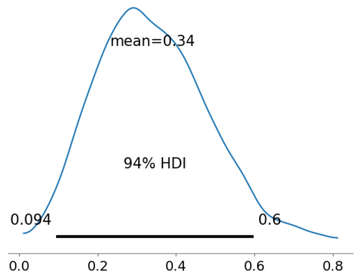


**Figure 2:** G-COMP AIC + SOC Wound Closure

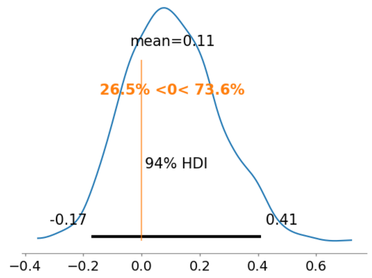


**Figure 3:** G-COMP Absolute Difference

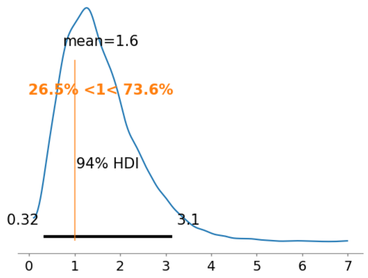


**Figure 4:** G-COMP Risk Ratio

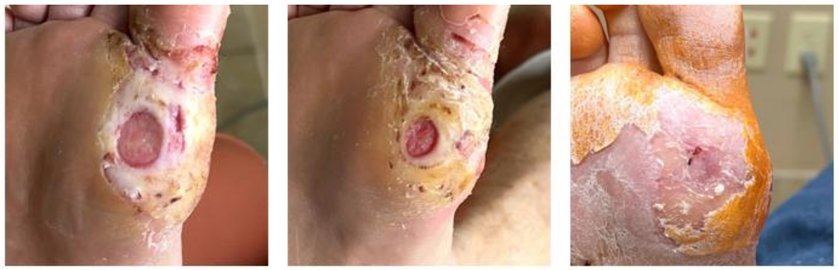

**Figure 5:** Digital Images from SV-1, TV-1, and HCV (Left to Right), AIC + SOC Treatment Arm

Standardized marginal effects (G-COMP) at week 12 were calculated using the posterior for the primary endpoint. The estimated probability of complete wound closure under SC was 23% (12%–35%), compared with 34% (9%–60%) under the treatment arm. This corresponds to a posterior absolute difference of 11% (-17%–41%) and a risk ratio of 1.6 (0.32–3.1) in favor of AIC.

## CONCLUSIONS

- **For this interim analyses, wounds managed with AIC products trended toward superiority over those managed with SOC.**
- **These results confirm that the trial design is viable. Enrollment will continue until target for statistical power (at α = 0.05) is achieved.**

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