

Thomas Serena MD¹, Brianna Tramelli BS¹, Zwelithini Tunyiswa BA², and Brittany Bonafide BS¹

INTRODUCTION

- **Diabetic foot ulcers (DFUs)** affect 19–34% of individuals with diabetes and are associated with high morbidity, amputation risk, and **five-year mortality rates of 50–70%**. Despite optimized standard of care (SOC), fewer than 50% of DFUs achieve complete closure within 12 weeks, highlighting the need for adjunctive therapies that promote durable healing.
- **Lyophilized human amnion/chorion membrane (LHACM)** is a tri-layer placental allograft containing regulatory proteins within a biocompatible extracellular matrix that supports the wound healing cascade. This multicenter randomized platform trial evaluated whether adding PURION-processed LHACM to SOC improves 12-week complete closure in chronic, non-healing DFUs.

- **CAMPAIGN** (NCT06600724) is a multicenter, prospective, randomized, controlled platform trial evaluating LHACM products within an adaptive protocol.
- Treatment effects were estimated using a **Bayesian** framework, with interim success defined as a posterior probability ≥ 0.90 .
- **88 participants** were included (SOC n = 28; LHACM n = 60).



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

METHODS

Table 1: Key Inclusion and Exclusion Criteria

INCLUSION CRITERIA	EXCLUSION CRITERIA
<ul style="list-style-type: none"> • At least 18 years of age • Diagnosis of type 1 or 2 Diabetes mellitus • Surface area between 0.7cm² and 20.0cm² • Present minimum 4 weeks, treated with SOC • Must be Wagner grade 1 or 2, including exposed bone, muscle, or tendon • Has adequate perfusion 	<ul style="list-style-type: none"> • Life expectancy <6 months • Ulcer has infection, cellulitis, or osteomyelitis • Use of immunosuppressants, cytotoxic chemotherapy, hydroxyurea, or topical steroids • Known allergy/sensitivity to aminoglycoside antibiotics. • Partial amputation that impedes proper offloading • Surface area has reduced in size by >20% in 2 weeks prior to SV or by >25% from SV to TV-1 • Previously treated with HBOT or CAMP

Table 2: Endpoints

PRIMARY ENDPOINT	SECONDARY ENDPOINT
<ul style="list-style-type: none"> • The percentage of target ulcers achieving complete wound closure in 12 weeks. 	<ul style="list-style-type: none"> • Percentage wound area reduction from TV-1 to TV-13

RESULTS

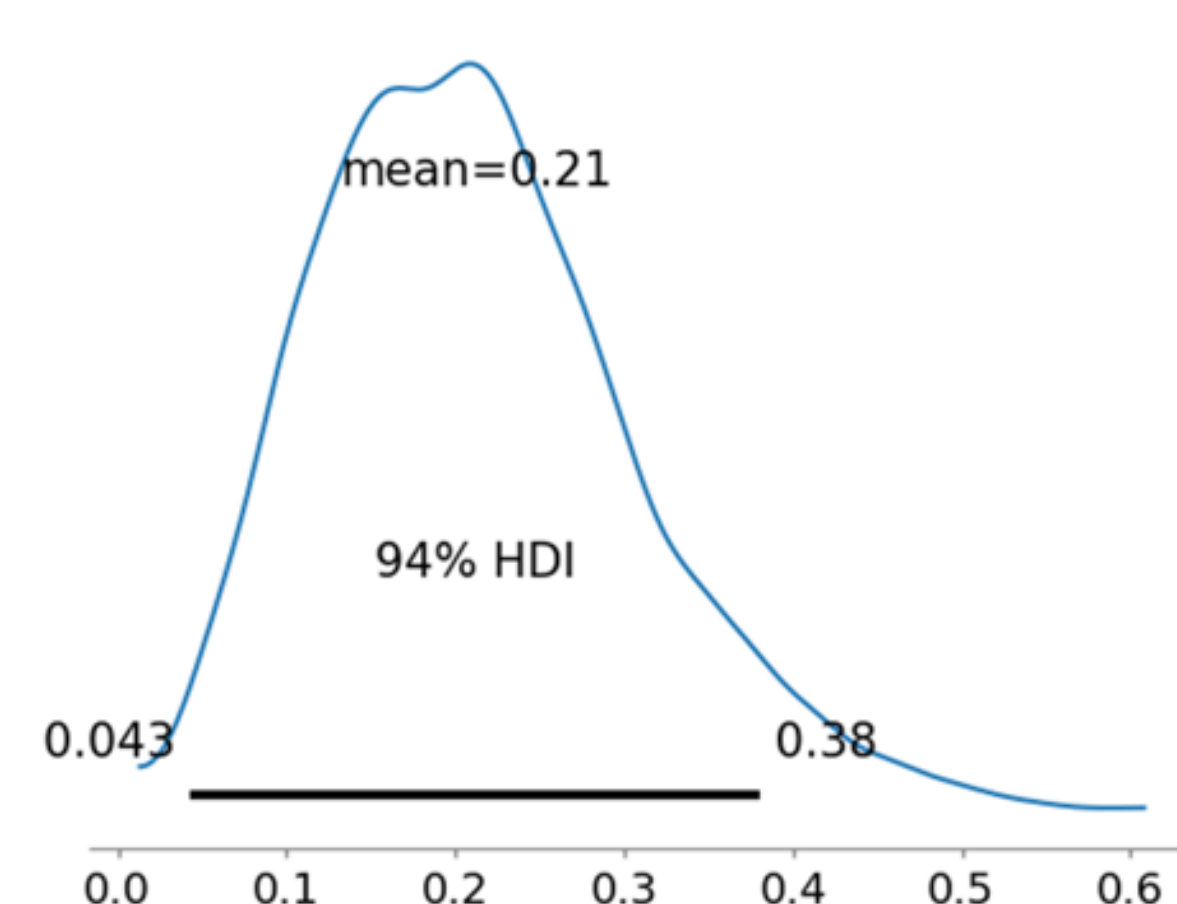


Figure 2: G-AME SOC Wound Closure

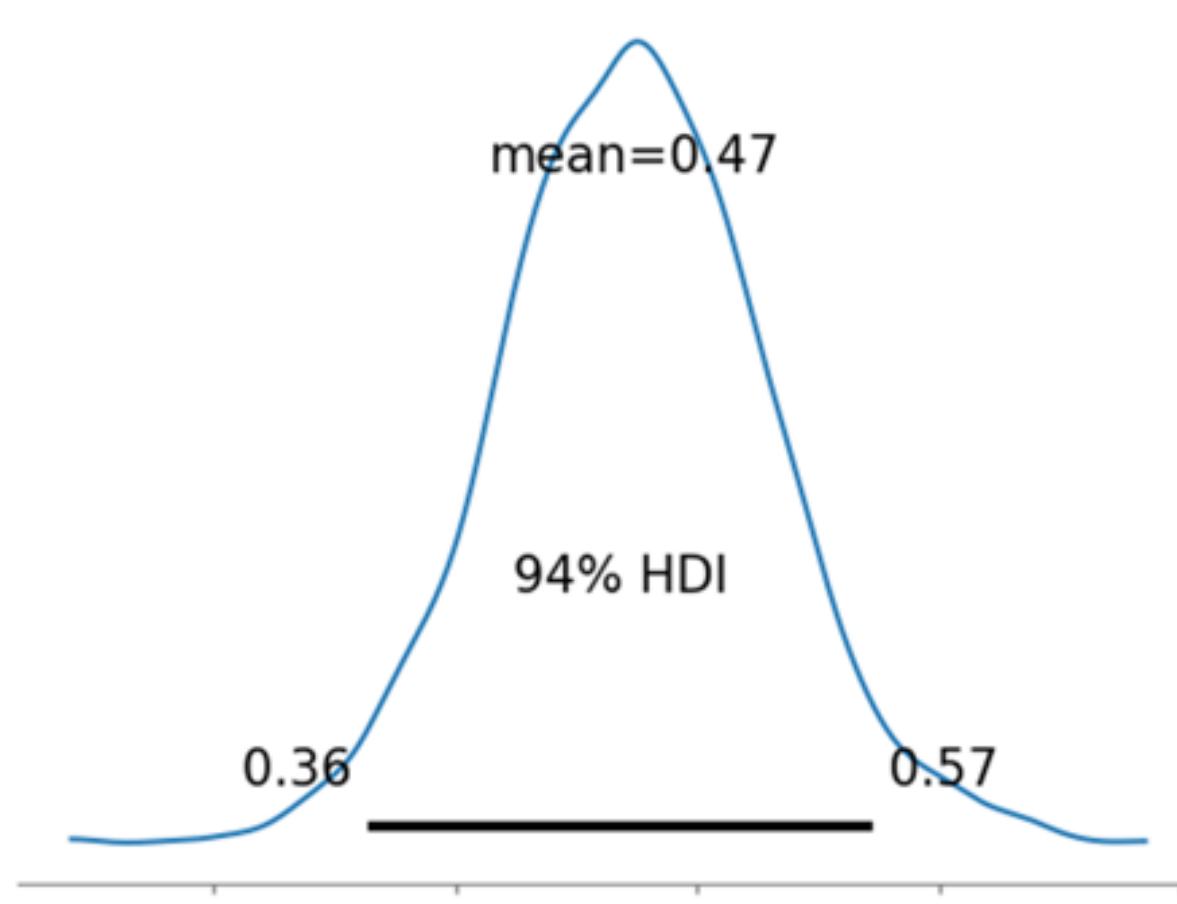


Figure 3: G-AME LHACM + SOC Wound Closure

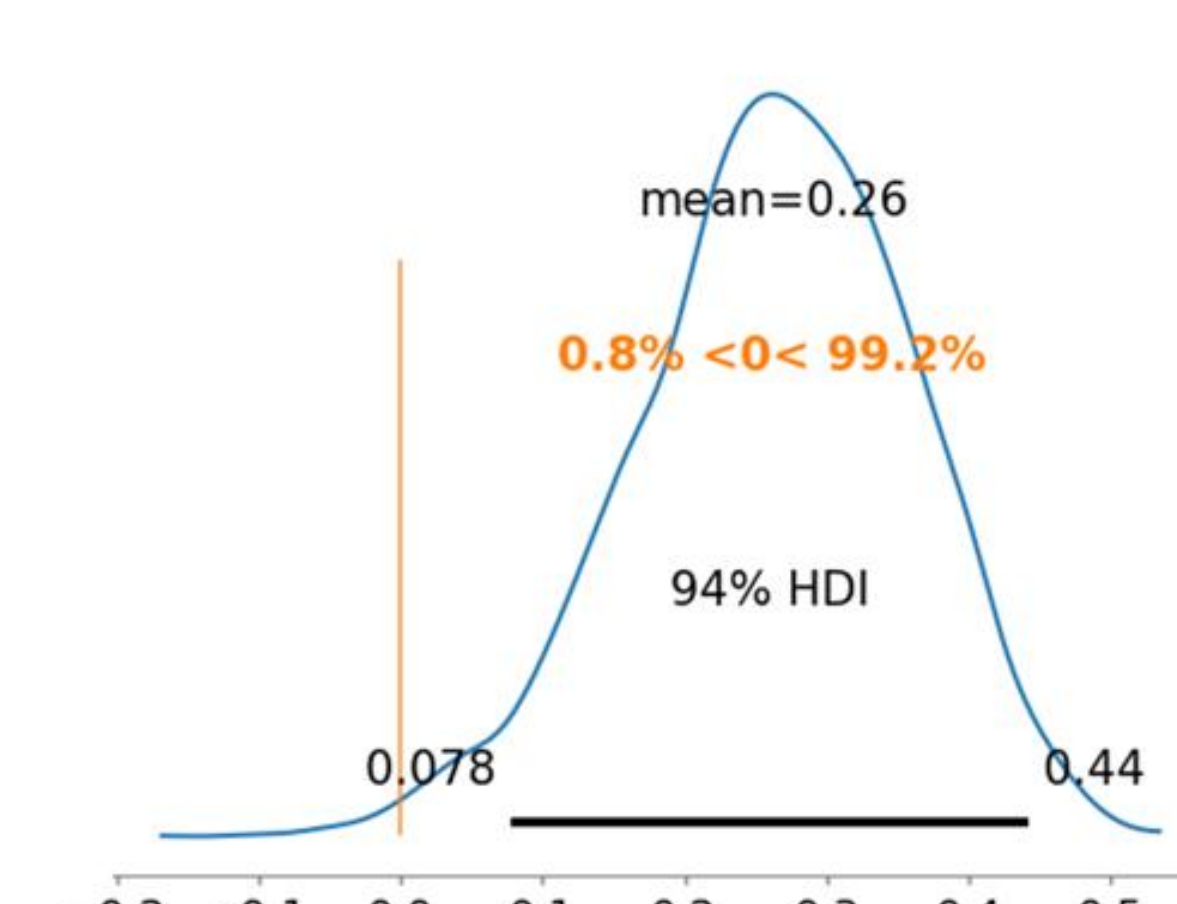


Figure 4: G-AME Absolute Difference

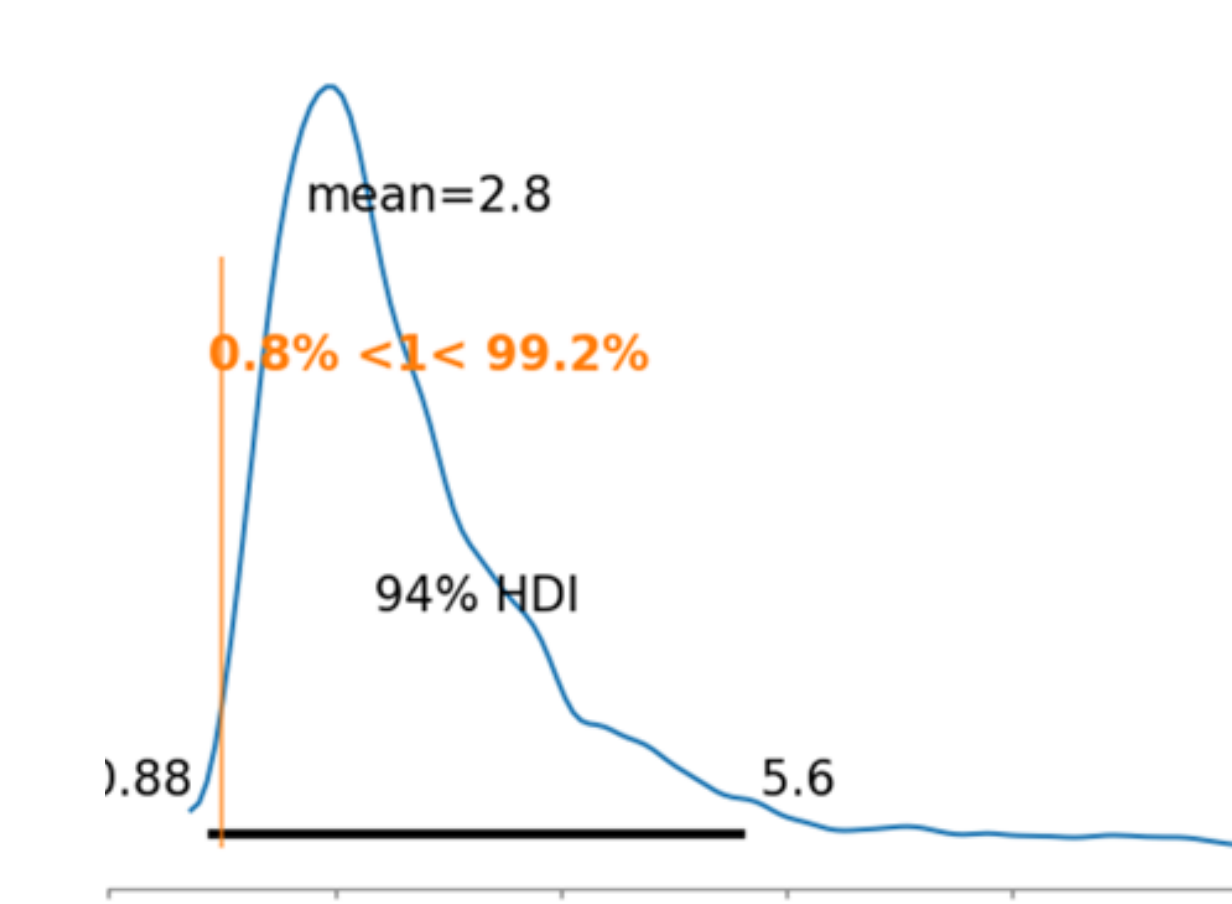


Figure 5: G-AME Risk Ratio

Baseline characteristics were comparable. Group average marginal effects (G-AME) at week 12 were calculated using the posterior for the primary endpoint. The estimated probability of complete wound closure under SOC was 21% (4%–38%), compared with 47% (36%–57%) under the treatment arm. This corresponds to a **posterior absolute difference of 26%** (7%–44%) and a **risk ratio of 2.8** (0.88–5.6) in favor of LHACM (Figures 2-5). Cumulative closure probabilities progressively separated over 12 weeks (Figure 6).

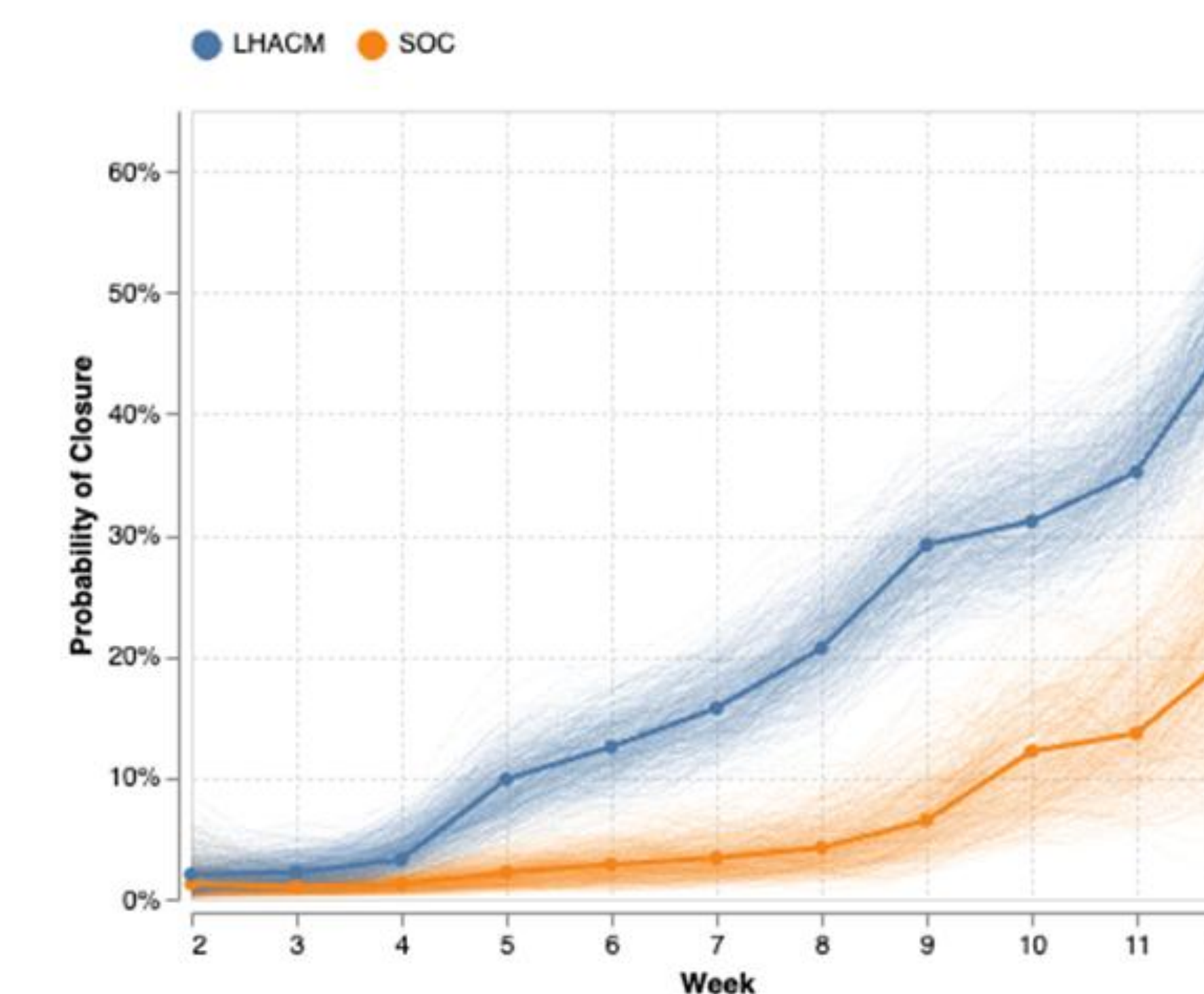


Figure 6: Bayesian Survival Chart

PAR was 92% with SOC and 73% with LHACM, consistent with a greater proportion of SOC-treated ulcers remaining partially open, whereas more LHACM-treated ulcers progressed to complete closure. Adverse event rates were comparable between groups, with no graft-related safety concerns identified.

CONCLUSIONS

In this interim analysis, **PURION-processed LHACM** plus standard of care was associated with a **higher probability of complete diabetic foot ulcer closure** at 12 weeks compared with standard care alone, **exceeding the prespecified success threshold**. Safety outcomes were comparable between groups. These findings provide early evidence of benefit, pending full trial completion.

¹ SerenaGroup, Inc., Cambridge, MA

² Open Wound Research, Puyallup, WA

Funding statement: This study was funded by MIMEDX Group, Inc.