

Assessing Treatment Efficiency in Diabetic Foot Ulcers: Retention-Processed Amnion/Chorion Membranes Versus SOC: A Retrospective Analysis

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Key words : Diabetic foot ulcers, DFU, placental membrane, retrospective, amnion chorion, AC

Introduction: Diabetic foot ulcers are a severe complication for diabetic patients, significantly impacting patient quality of life and healthcare systems efficiency. These ulcers often lead to hospitalization and amputation. Traditional Standard of Care treatments are inadequate for many patients, necessitating the use of advanced wound care products, such as human placental membranes. This study conducts a retrospective analysis to compare the effectiveness of a human placental amnion/chorion membrane product using retention-based processing (RE-AC) and Standard of Care (SOC) in managing chronic diabetic foot ulcers (DFUs).

Materials/Methods: The study collected retrospective observational data from electronic health records (EHRs) of patients treated with RE-AC at three outpatient wound care centers. Additionally, synthetic control SOC patients were matched from a wound registry using Coarsened Exact Matching (CEM). Patients were categorized into two cohorts based on whether they received RE-AC or SOC. Key metrics included wound size progression and wound closure. The analysis employed Bayesian regression and Hurdle Gamma Analysis of Variance (ANCOVA) models.

Results:

Results indicated that RE-AC achieved approximately 10% higher expected wound closure rate compared to SOC at 12 weeks. Further, for wounds that did not close, RE-AC resulted in approximately 60% expected Percent Area Reduction (xPAR), whereas SOC wounds stalled or grew larger.

Discussion/Conclusions: The findings suggest that R-AC is superior to SOC for wound closure and expected Percent Area Reduction. This preeminence likely leads to reduced treatment costs, optimized resource utilization and improved outcomes in the DFU patient population; ultimately resulting in improved patient care.

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* Patent pending

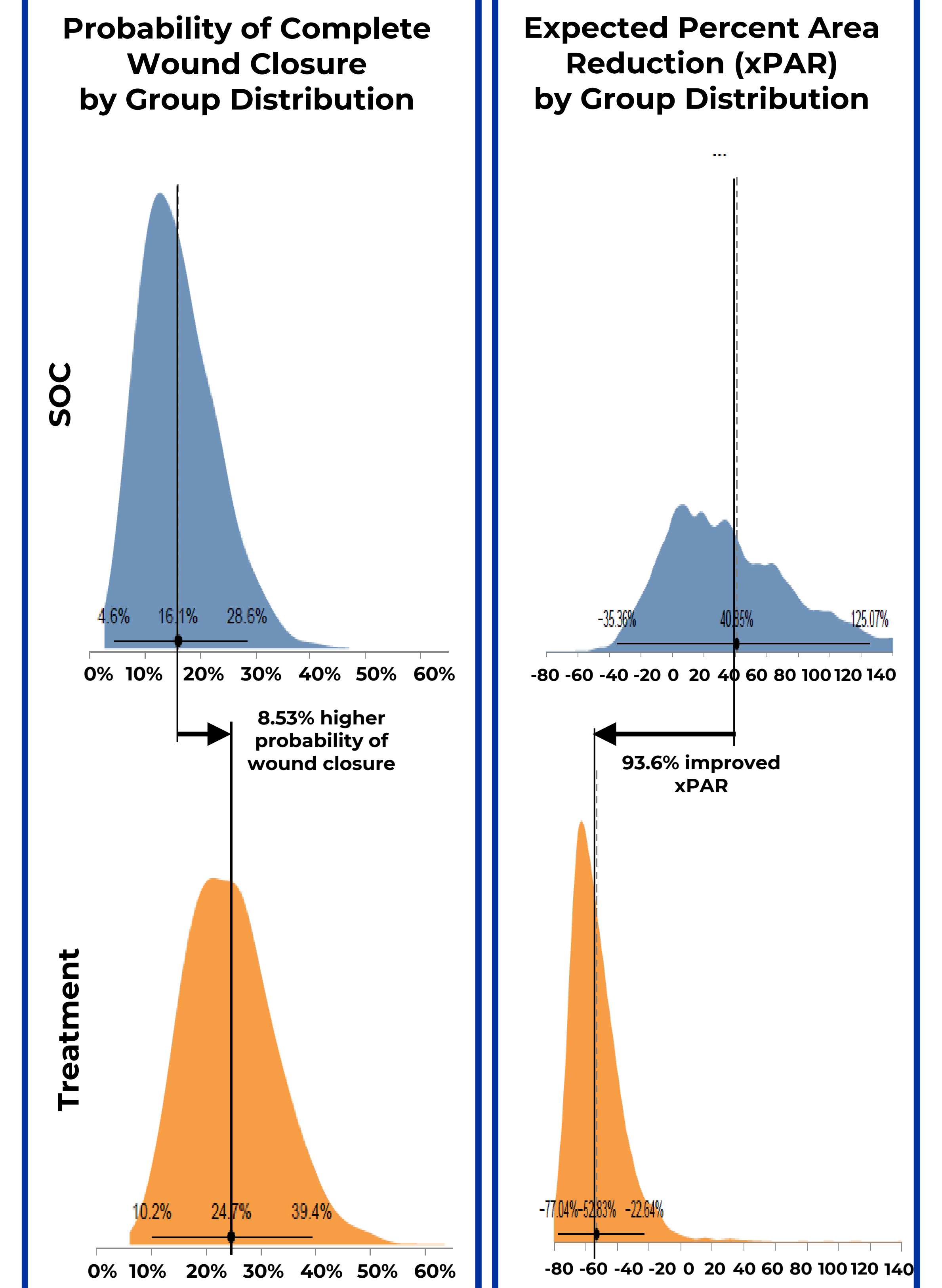
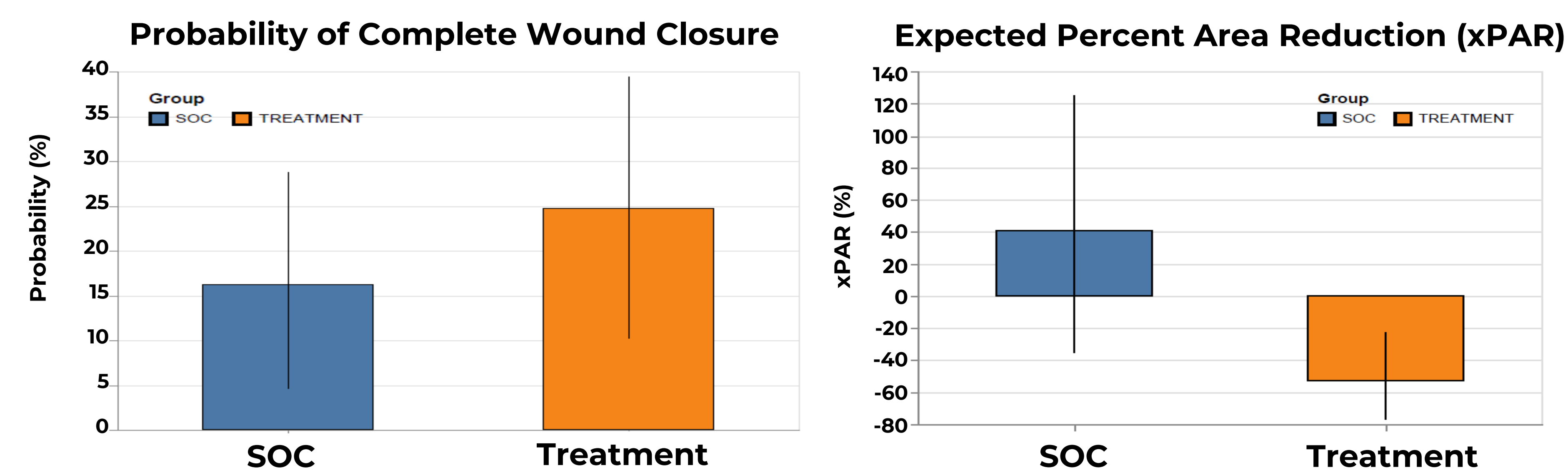
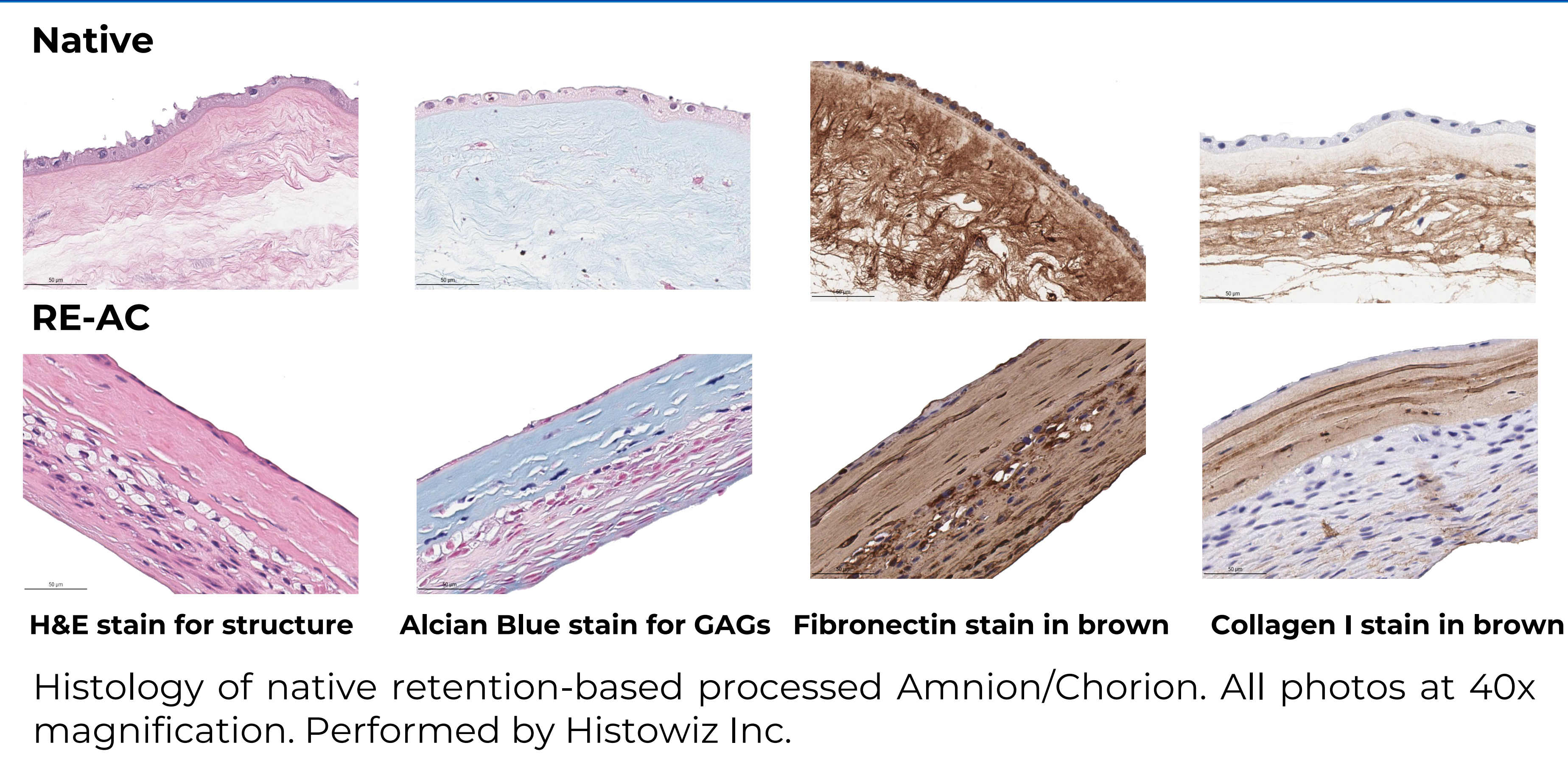
Abstract

Diabetic foot ulcers are a severe complication for diabetic patients, significantly impacting patient quality of life and healthcare systems efficiency. These ulcers often lead to hospitalization and amputation. Traditional Standard of Care treatments are inadequate for many patients, necessitating the use of advanced wound care products, such as human placental membranes. This study conducts a retrospective analysis to compare the effectiveness of a human placental amnion/chorion membrane product using retention-based processing (RE-AC) and Standard of Care (SOC) in the treatment modality for chronic diabetic foot ulcers (DFUs).

Methods/Statistical Analysis

The study collected retrospective observational data from electronic health records (EHRs) of patients treated with retention based processed Amnion/Chorion* (RE-AC) as a wound covering at three outpatient wound care centers. Additionally, synthetic control SOC patients were matched from a wound registry using Coarsened Exact Matching (CEM). Patients were categorized into two cohorts based on whether they received RE-AC or SOC. Key metrics included wound size progression and wound closure. The analysis employed Bayesian regression and Hurdle Gamma Analysis of Variance (ANCOVA) models. These methods allow for the highest statistical power for analyses that are focused on change from baseline and increases statistical power and precision. They are a more robust approach and offer the opportunity to control potential confounding variables, thereby enhancing the precision of our findings

Native AC Versus Retention Processed AC



Submitted for publication

Results/Conclusions

Results indicated that the use of RE-AC as a covering achieved almost a 10% higher expected wound closure rate compared to SOC at 12 weeks (8.53% (credible interval: 5.60% - 10.7%). Further, for wounds that did not close, RE-AC resulted in a 93.6% (credible interval: 147.7% - 41.6) improvement in expected Percent Area Reduction (xPAR) over the SOC group at 12 weeks. We noted that on average, SOC wounds stalled or grew larger. In terms of a risk ratio comparing the study group with SOC, we found a 52% benefit in the RE-AC group (RR= 1.52). The findings suggest that R-AC is superior to SOC when used as a covering for wound treatment and resulted in an expected Percent Area Reduction by 12 weeks. This benefit likely leads to reduced treatment costs, optimized resource utilization and improved outcomes in the DFU patient population; ultimately resulting in improved patient care.



Our membranes are intended for homologous use as a barrier membrane or protection over acute and/or chronic wounds.

