REAL-WORLD EVALUATION OF AMNIOTIC GRAFTS IN CHRONIC WOUNDS: PROTOCOL DESIGN AND INTERIM ANALYSIS

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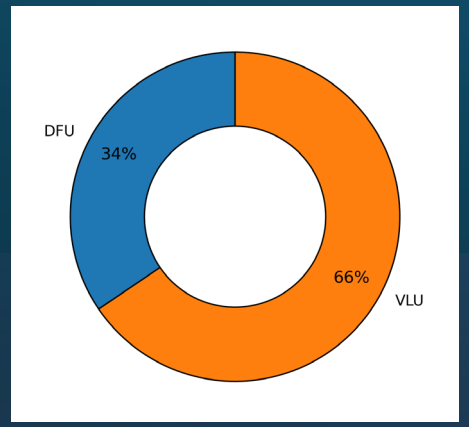
Aim: To evaluate the effectiveness of amniotic tissue grafts as adjuncts to standard care for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) using a pragmatic hybrid platform design.

This real-world evidence (RWE) approach seeks to overcome the limited generalizability of randomized controlled trials by assessing complete wound closure at 12 weeks and percent area reduction in diverse clinical settings.

Methods: Two cohorts (DFU and VLU) were randomized 1:1 to receive one of two amniotic grafts (*IP1 or **IP2) and compared with coarsened matched (CEM) standard-of-care (SOC) control from the United States Wound Registry (USWR).

Weekly follow-up visits occurred up to 12 weeks. At the time of interim analysis, 31 subjects have been enrolled, generating 155 visit records. Feasibility and baseline characteristics were assessed through standardized data cleaning and patient-level aggregation.

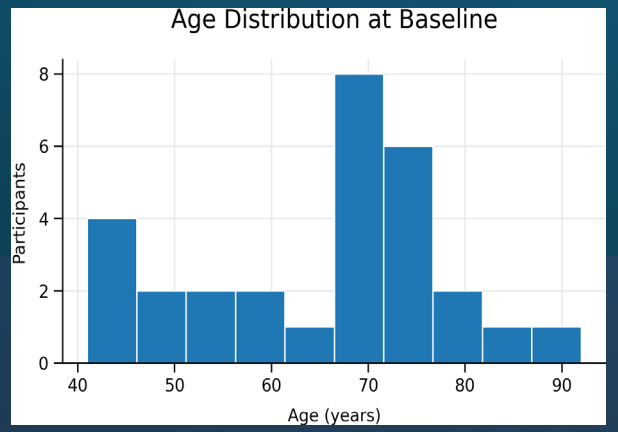


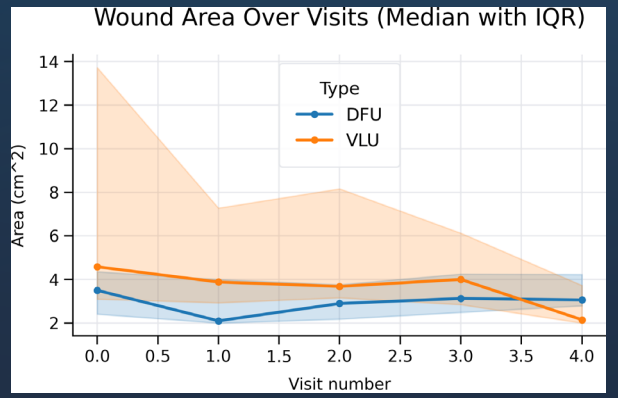
Enrollment Distribution

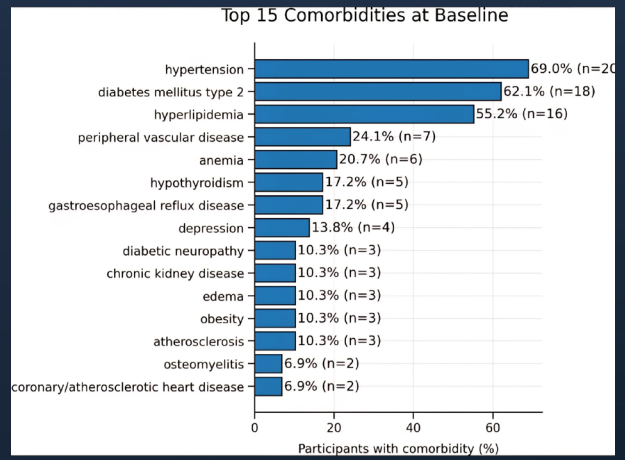
Innovation: This trial uniquely integrates prospective and retrospective data within a hybrid platform framework, enhancing both scientific rigor and real-world applicability.

The use of CEM ensures robust matching of intervention and control groups, while the inclusion of diverse patient populations increases generalizability. The design also leverages the USWR, a CMS-recognized Qualified Clinical Data Registry, to construct a high-fidelity control arm without additional patient burden.

*IP1: BioLab Membrane Wrap Lite
**IP2: BioLab Tri-Membrane Wrap







Results: A total of 31 wounds were included in this interim analysis, with 61% venous leg ulcers (VLU) and 32% diabetic foot ulcers (DFU). Participants had a mean age of 65 years (median 69), and 58% were male. Wheelchair arrival occurred in 35% of visits, and tobacco use (current or former) was reported in 19% of participants.

Patients exhibited a substantial multimorbidity burden, averaging six comorbidities. The most common conditions were hypertension and hyperlipidemia, consistent with chronic disease clustering observed in this population.

Baseline wound areas differed by type, with DFUs showing a median area of 3.5 cm^2 and VLUs 4.6 cm^2, reflecting moderate-sized, chronic wounds at presentation.

Among participants with ≥2 visits, 61.3% demonstrated reduction in wound area, and 22.6% showed increased granulation tissue, indicating early signs of healing across a majority of monitored wounds. Additionally, 13.8% met the threshold of ≥50% wound-area reduction by their last recorded visit.

Conclusions: This real-world hybrid platform trial demonstrates the feasibility of evaluating amniotic tissue grafts in routine clinical practice.

Interim results reveal a high comorbidity burden yet early signals of wound area reduction. By integrating RWE with rigorous methodology, this protocol exemplifies a modern, patient-centered approach to wound care research.