Real-World Retrospective Analysis Comparing a Bilayered Living Cellular Construct and a Fetal Bovine Collagen Dressing For Use in Venous Leg Ulcers

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INTRODUCTION

- Venous leg ulcers (VLUs) account for 70%–90% of ulcers found on the lower leg with a prevalence in the US of approximately 600,000.[1]
- VLUs also pose a significant financial burden on the US healthcare system, at an estimated annual cost of $2.5-3.5 billion.[1]
- The high prevalence of venous diseases, specifically venous ulcers, has a significant socioeconomic impact in terms of medical care, days off work and reduced quality of life.[2]
- A bilayered living cellular construct (BLCC)[(a)], bioengineered with living keratinocytes and fibroblasts, is FDA approved for the treatment of venous leg ulcers and diabetic foot ulcers. [3]
- An acellular fetal bovine collagen dressing, FBCD[(b)], has been FDA cleared as a 510(k) Class II device for the management of VLUs and other skin wounds.
- Electronic medical records for wound care management (WoundExpert®, NetHealth)[(c)] were used to evaluate the effectiveness of BLCC vs FBCD for the treatment of VLUs.

[(a)] Apligraf®, Organogenesis Inc., Canton, MA
[(b)] Primatrix; Integra, Plainsboro, NJ
[(c)] WoundExpert®, Net Health, PA

OBJECTIVE

Real-world data (RWD) were used to conduct a comparative effectiveness analysis of BLCC versus FBCD for the treatment of VLUs.

METHODS

Study Population

- An analysis was conducted on VLUs treated with BLCC or FBCD between 2020 and 2022 on 8,355 VLUs.
- Ulcers 1-40 cm^2 were included.
- Patients with no baseline wound measurements or follow-up visits were excluded.

Statistical Analyses

- Analyses were performed on 8,355 VLUs: 8,096 BLCC-treated and 259 FBCD-treated.
- Treatment period started with the first use of BLCC or FBCD.
- Cox Proportional Hazards Regression (Cox) analysis that adjusted for multiple covariates including ulcer area and duration was used to compute the percentage of VLUs with closure at weeks 8, 12, 24, and 36.
- Time to event analysis was performed by the method of Kaplan-Meier (K-M).
- Cox Hazard ratio (HR) with 95% confidence interval (CI), and p-value was computed to determine the probability of achieving healing throughout the study.

RESULTS

- Patient baseline demographics, wound, and treatment characteristics were comparable between groups.
- BLCC treatment significantly reduced the median time to wound closure by 26.5%, (20.0 weeks, FBCD; vs. 14.7 weeks, BLCC); p=0.002 (Figure 1).
- The frequency of healing for BLCC was significantly greater compared to FBCD at week 8 (29% vs 24%), 12 (43% vs 36%), 24 (65% vs 56%), and 36 (75% vs 66%); p=0.004. The HR = 1.28 [95% CI (1.08, 1.52)]; p=0.004 (Figure 2).
- Cox Hazard Ratio was computed as HR = 1.28 [95% CI (1.08, 1.52)]; p=0.004.

Figure 1: Median Time to Wound Closure

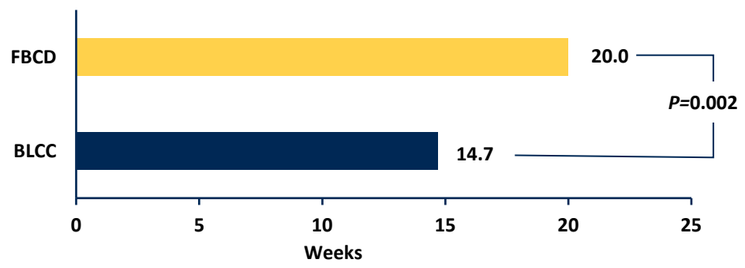
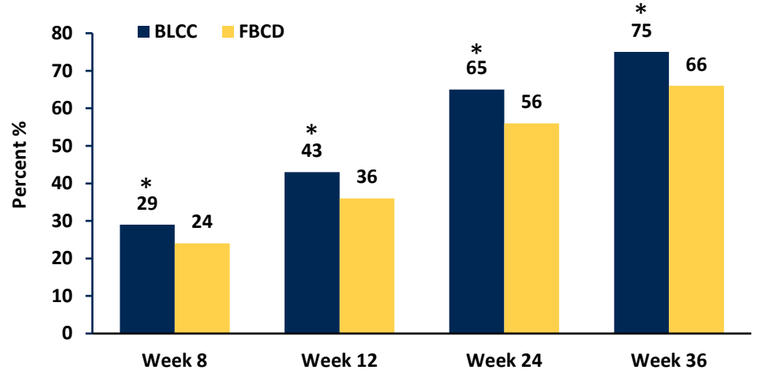


Figure 2: Percentage of Wounds Achieving Closure



*P=0.004

CONCLUSIONS

- RWD analyses demonstrated that BLCC significantly improved healing compared to FBCD for the treatment of VLUs.
- Treating VLUs with BLCC resulted in a 28% greater probability of healing compared to FBCD at every timepoint over 36 weeks.
- This difference between groups in median time to wound closure demonstrated a 26.5% reduction with the use of BLCC; p=0.002.
- These data may help guide decision-making in care of patients with VLUs.
- RWD results in BLCC- treated patients showed effectiveness comparable to pivotal RCT efficacy findings that supported FDA approval of BLCC for the treatment of VLUs [4,5]

*De-identified patient data released to Organogenesis, Inc. was consistent with the terms and conditions of Net Health's participating client contracts and the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Net Health was not involved in any way in the analysis, interpretation, or reporting of the data.

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Disclosures

Oscar Alvarez, PhD and Michael Sabolinski, MD are paid consultants for Organogenesis Inc.

ORGANOGENESIS

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