COMPARATIVE EFFECTIVENESS OF A BILAYERED LIVING CELLULAR CONSTRUCT AND A CRYOPRESERVED CADAVERIC SKIN ALLOGRAFT FOR USE IN VENOUS LEG ULCERS

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INTRODUCTION

- Venous leg ulcers (VLUs) represent 60-80% of the chronic wounds that impact nearly 2.5% of the US population[1,2]
- The economic burden of VLU's in the US is estimated at $14.9 billion annually[3]
- A bilayered living cellular construct, BLCC[(a)], is approved by the FDA for the treatment of VLUs and diabetic foot ulcers
- BLCC is a bioengineered living skin substitute that contains living keratinocytes and fibroblasts that produce growth factors and cytokines
- Skin substitutes eliminate the need for a donor site while reducing risk of infection, mortality, and morbidity[4]
- CCSA[(b)] is a cryopreserved cadaveric skin allograft marketed under Section 361 of the Public Health Service (PHS) Act as Human Cells, Tissues, and Cellular and Tissue-based Products (PHS 361; HCT/Ps)
- Electronic medical records for wound care management (WoundExpert®, NetHealth)[(c)] were used to evaluate the effectiveness of BLCC vs CCSA for the treatment of VLUs*
- [(a)] Apligraf®, Organogenesis Inc., Canton, MA
  [(b)] TheraSkin®, Bioventus; Durham, NC
  [(c)] WoundExpert®, Net Health, PA

OBJECTIVE

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

METHODS

Study Population

- Electronic medical records (WoundExpert®, Net Health, PA)[(c)] collected between 2019 and 2022 on 10,220 VLUs were analyzed
- 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 9,563 BLCC- and 657 CCSA-treated VLUs
- Treatment period started with the first use of BLCC or CCSA
- 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, 18, 24, and median time to heal
- Cox Hazard ratio (HR) with 95% confidence interval (CI), and P-value were determined with terms for treatment, baseline wound area, baseline wound duration, baseline wound depth and patient age at first treatment

RESULTS

- Patient baseline demographics, wound, and treatment characteristics were comparable between groups
- BLCC treatment significantly reduced the median time to wound closure by 40%, achieving healing 83 days sooner (210 vs. 127 days; *P*<0.0007) (Figure 1)
- Frequency of wound closure for BLCC (9,563 wounds) was significantly greater than CCSA (657 wounds) at week 8 (23 vs. 19%), 12 (34 vs. 28%), 18 (45 vs. 38%), and 24 (53 vs. 45%); (*P*<0.0001) (Figure 2)
- Treatment with BLCC increased probability of healing by 31% compared to CCSA at each timepoint over the entire study

Figure 1: Median Time to Wound Closure

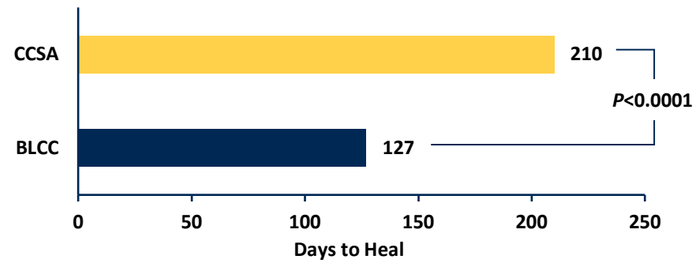
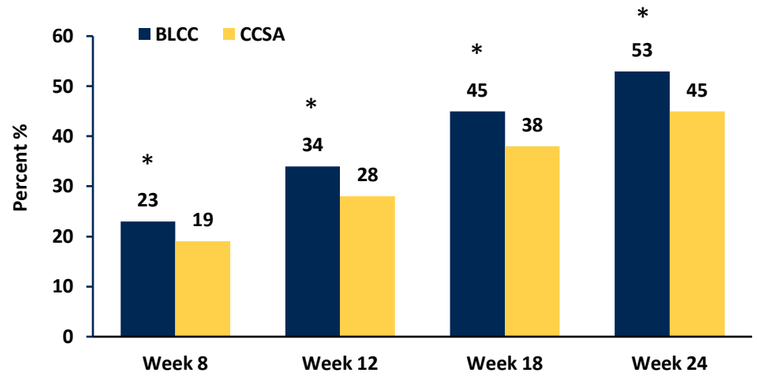


Figure 2: Percentage of Wounds Achieving Closure



*P<0.0001.

CONCLUSIONS

- BLCC significantly improved the probability, frequency, and incidence of healing when compared to CCSA
- Cox adjusted survival data for wound closure showed that BLCC was superior to CCSA at all timepoints including: 8 weeks (23 vs 19%), 12 weeks (34 vs 28%), 18 weeks (45 vs 38%), and 24 weeks (53 vs 45%); *P*<0.0001. HR = 1.31 [95% CI (1.17, 1.49)]; P<0.0001
- BLCC showed a 31% greater probability of wound closure on a weekly basis for the entire 24-week study period compared with CCSA-treated VLUs
- These data may help guide VLU treatment practices. BLCC RWD in VLUs showed consistent results when compared to data from BLCC pivotal RCTs that supported FDA approvals in VLUs and DFUs [5,6]

*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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