Comparative Effectiveness of a Bilayered Living Cellular Construct and a Cryopreserved Cadaveric Skin Allograft for use in Pressure Injuries

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INTRODUCTION

- Pressure injuries (PRIs) can develop in patients due to immobility and are at risk for infection, pain, disability and longer hospital stay.[1,2]
- PRIs can develop in patients with underlying comorbidities that decrease tissue perfusion, causing a delay in wound healing.[3]
- A single PRI carries a cost of patient care as high as $151,700 and over 60,000 US individuals die due to PRIs annually.[4,5]
- 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.[6]
- 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 PRIs.*

[(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 PRIs.

METHODS

Study Population

- An analysis was conducted on 969 PRIs treated with BLCC or CCSA between 2020 and 2022.
- PRIs over anatomical locations (sacrum, coccyx, greater trochanter, ischial tuberosity, calcaneus, and lateral malleolus) and Stages II–IV with surface areas between 1-20 cm^2 were included.
- Patients with no baseline wound measurements or follow-up visits were excluded.

Statistical Analyses

- Analyses were performed on 969 PRIs: 735 BLCC-treated and 234 CCSA-treated.
- 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 PRIs 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 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 59.1%, (20.3 months CCSA; vs. 8.3 months, BLCC); p=0.0002 (Figure 1).
- Frequency of wound closure for BLCC (735 wounds) was significantly greater than CCSA (234 wounds) at week 8 (19 vs. 12%), 12 (28 vs. 18%), 24 (44 vs. 30%), and 36 (51 vs. 36%); p=0.0003 (Figure 2).
- Cox Hazard Ratio was computed as HR = 1.66 [95% CI (1.26, 2.19)]; p=0.0003.

Figure 1: Median Time to Wound Closure

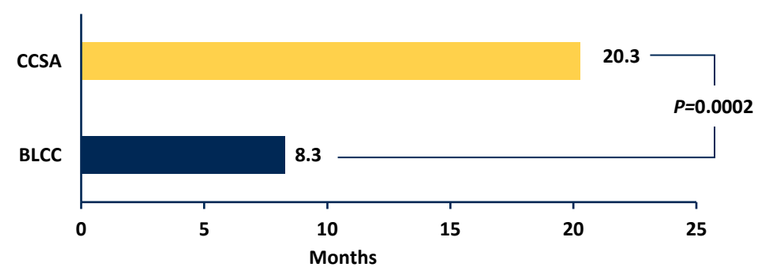
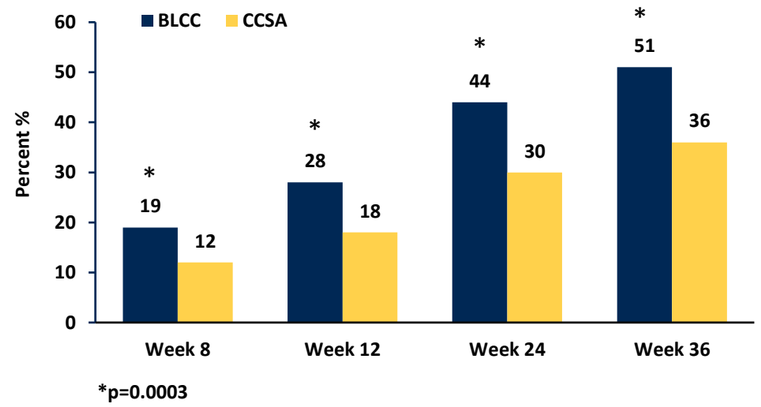


Figure 2: Percentage of Wounds Achieving Closure



*p=0.0003

CONCLUSIONS

- BLCC significantly improved the probability, frequency, and incidence of healing when compared to CCSA.
- Treating PRIs with BLCC resulted in a 66% greater probability of healing compared to CCSA at every timepoint over 36 weeks.
- This difference between groups in median time to wound closure demonstrated a 59.1% reduction with the use of BLCC; p=0.0002.
- BLCC RWD in PRIs showed consistent results when compared to data from pivotal RCTs that supported FDA approvals in VLUs and DFUs.[7,8]

*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

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

ORGANOGENESIS

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