REAL WORLD DATA ANALYSES OF A BILAYERED LIVING CELLULAR CONSTRUCT AND A FETAL BOVINE COLLAGEN DRESSING FOR USE IN PRESSURE INJURIES

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INTRODUCTION

- Pressure injuries (PRIs) raise the risk for infection, pain and disability and longer hospital stay, amounting to increased morbidity and mortality[1,2]
- Pressure ulcers occur in up to 23% of patients in long-term care and rehabilitation facilities and at an incidence of 10-41% in ICU patients[3]
- The US national cost of hospital-acquired PRIs may exceed $26.8 billion[4]
- A bilayered living cellular construct (BLCC)[(a)], bioengineered with living keratinocytes and fibroblasts, is FDA approved for the treatment of venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs)[5,6]
- FBCD[(b)] is an acellular dermal matrix derived from fetal bovine dermis marketed under Section 510(k) of the Food, Drug, and Cosmetic (FD&C) Act
- 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)]PriMatrix®, Integra Life Sciences, Princeton, 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 PRIs.

METHODS

Study Population

- An analysis was conducted on PRIs treated with BLCC or FBCD between 2018 and 2022 on 1,353 PRIs
- 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 1,353 PRIs: 1,048 BLCC-treated and 305 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 PRIs 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 36%, achieving healing 58 days sooner (161 vs. 103 days; *P*<0.0007) (**Figure 1**)
- Frequency of wound closure for BLCC (1,048 wounds) was significantly greater than FBCD (305 wounds) at week 8 (29 vs. 17%), 12 (42 vs. 27%), 18 (56 vs. 39%), and 24 (64 vs. 45%); (*P*<0.0001) (**Figure 2**)
- Treatment with BLCC increased probability of healing by 65% compared to FBCD throughout the period of observation

Figure 1: Median Time to Wound Closure

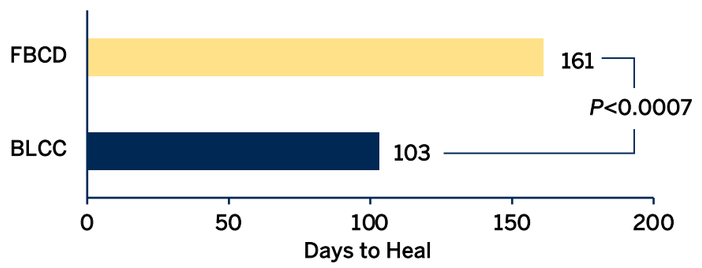
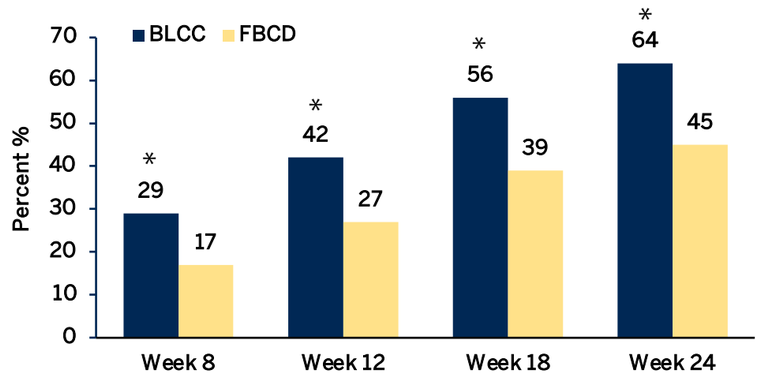


Figure 2: Percentage of Wounds Achieving Closure



*P<0.0001.

CONCLUSIONS

- BLCC significantly improved the probability, frequency, and incidence of healing when compared to FBCD
- Cox adjusted survival data for wound closure showed that BLCC was superior to FBCD at all timepoints including: 8 weeks (29 vs 17%), 12 weeks (42 vs 27%), 18 weeks (56 vs 39%), and 24 weeks (64 vs 45%); *P*<0.0001
- BLCC showed a 65% greater probability of wound closure on a weekly basis for the entire 24-week study period compared with FBCD-treated PRIs: HR = 1.65 [95% CI (1.37, 1.99)]; *P*<0.0001
- These data may help guide PRI treatment practices. BLCC RWD in PRIs showed consistent results when compared to data from pivotal RCTs that supported FDA approvals in VLUs and DFUs[7,8]

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DISCLOSURES

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

*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.

ORGANOGENESIS

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