A Real-World Comparative Effectiveness Analysis of a Bilayered Living Cellular Construct and a Dehydrated Human Amnion Chorion Membrane for Use in Pressure Injuries

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Introduction

- Pressure injuries (PRIs) represent a major burden of sickness and reduced quality of life for patients and their caregivers.[1]
- Annual PRI treatment costs in the United States are estimated at $9.1 to $11.6 billion, far greater than prevention cost.[2]
- It is estimated that pressure injuries are the direct cause of death in more than 60,000 patients in the United states each year.[3]
- 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.[4-6]
- dHACM[(b)] is a dehydrated placental membrane 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®) were used to evaluate the effectiveness of BLCC vs dHACM for the treatment of pressure injuries.*

[(a)]Apligraf, Organogenesis Inc., Canton, MA
[(b)]EpiFix®, MiMedx, Marietta, GA
[(c)]WoundExpert®, Net Health, PA

Objective

- Real-world data (RWD) were used to conduct a comparative effectiveness analysis of BLCC versus dHACM for the treatment of pressure injuries (PRIs).

*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.

Methods

Study Population

- Electronic medical records (WoundExpert®, Net Health®) collected between 2017 and 2021 on 1,764 PRIs were analyzed.
- Patients with no baseline wound measurements or follow-up visits were excluded.
- PRIs over anatomical locations including sacrum, coccyx, greater trochanter, ischial tuberosity, calcaneus, and lateral malleolus were included.
- PRIs Stages II–IV with surface areas between 1-20 cm^2 were included.

Statistical Analyses

- Analyses were performed on 1,046 BLCC- and 718 dHACM-treated PRIs.
- Treatment period started with the first use of BLCC or dHACM.
- A Cox analysis that adjusted for variables including ulcer area and duration was used to compute frequency and time to healing.
- The Hazard Ratio (HR) was computed to determine the probability of achieving healing throughout the study.

Summary of Results

- Patient baseline demographics, wound, and treatment characteristics were comparable between groups.
- BLCC treatment significantly reduced the median time to wound closure by 23%, achieving healing 30 days sooner (133 vs. 103 days; p<0.0001). *(Figure 1)*
- Frequency of wound closure for BLCC (1,046 wounds) was significantly greater than dHACM (718 wounds) at week 8 (42 vs. 32%), 18 (56 vs. 44%), 24 (64 vs. 52%), and 30 (69 vs. 57%); (p<0.0001). *(Figure 2)*
- Treatment with BLCC increased probability of healing by 37% compared to dHACM throughout the period of observation; HR = 1.37 [95% CI (1.21, 1.56)]; p<0.0001.

Figure 1. Median Time to Wound Closure

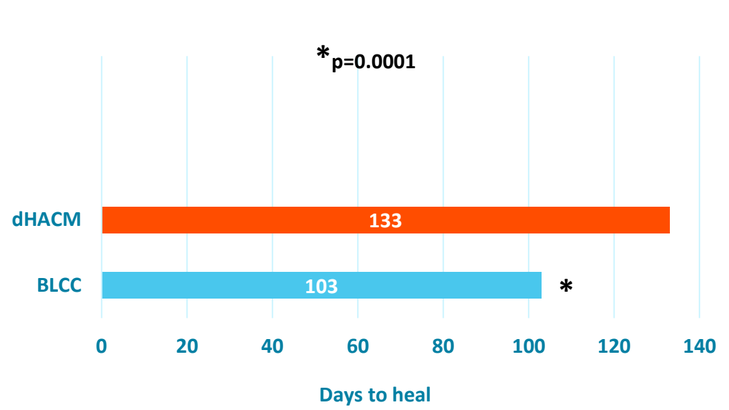
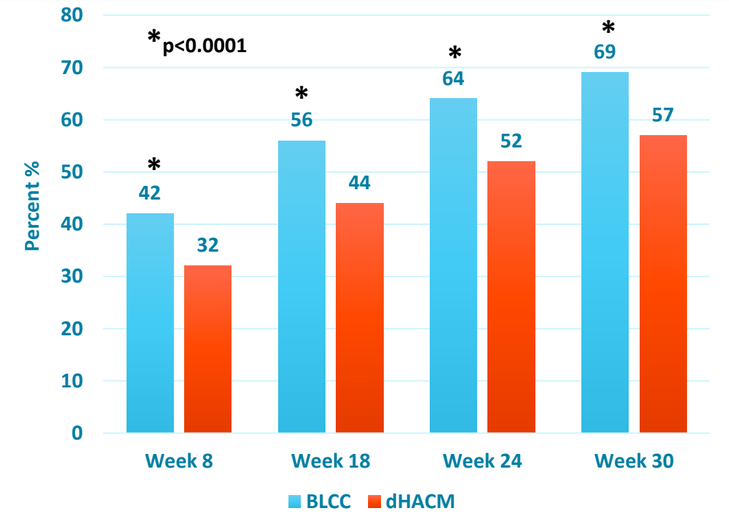


Figure 2. Percentage of Wounds Achieving Wound Closure



Conclusions

- These RWD analyses demonstrated that BLCC significantly improved healing compared to dHACM for the treatment of PRIs.
- BLCC RWD in PRIs showed consistent results when compared to data from pivotal RCTs that supported FDA approvals in VLUs and DFUs [6-8]

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