Real World Data Comparative Effectiveness Study of a Bilayered Living Cellular Construct and a Dehydrated Amnion Chorion Membrane for the Treatment of Pressure Injuries

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INTRODUCTION

- Pressure injuries (PRIs) place patients at risk for infection, pain, disability, and prolonged hospital stays, contributing to increased morbidity and mortality.[1,2]
- The cost of caring for a single PRI can reach as high as $151,700, and over 60,000 US individuals die due to PRIs each year.[3,4]
- 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.[5]
- 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)[(c)] were used to evaluate the effectiveness of BLCC vs dHACM for the treatment of PRIs*

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

OBJECTIVE

Using deidentified patient data from a wound specific electronic medical record we compared the effectiveness of BLCC to dHACM for the treatment of Pressure Injuries/Pressure Ulcers(PRIs) in a retrospective comparative effectiveness study.

METHODS

Study Population

- An analysis was conducted on 1051 PRIs treated with BLCC or dHCAM between 2021 and 2023 a 270 US wound care facilities.
- PRIs over anatomical locations (sacrum, coccyx, greater trochanter, ischial tuberosity, calcaneus, and lateral malleolus) and Stages II–IV with surface areas between 1-200 cm^2 were included.
- Patients with no baseline wound measurements or follow-up visits were excluded.

Statistical Analyses

- Analyses were performed on 1051 PRIs: 735 BLCC-treated and 316 dHCAM-treated.
- Treatment period started with the first use of BLCC or dHCAM.
- 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.

RESULTS

- Patient baseline demographics, wound, and treatment characteristics were comparable between groups.
- BLCC treatment significantly reduced the median time to wound closure by 41%, achieving healing 11.4 weeks sooner (16.6 vs. 28.0 weeks), p=0.008. (Figure 1).
- Cox derived estimates of wound closure for BLCC compared to dHACM were significantly greater by week 8 (32% vs. 25%), 12 (42% vs. 34%), 24 (58% vs. 49%), and 36 (67% vs. 57%); p=0.008 (Figure 2).
- Cox regression analysis showed that treatment with BLCC increased the probability of healing by 32% compared with dHACM. Hazard Ratio=1.32 [95% CI (1.07,1.62)]; p=0.008.

Figure 1: Median Time to Wound Closure

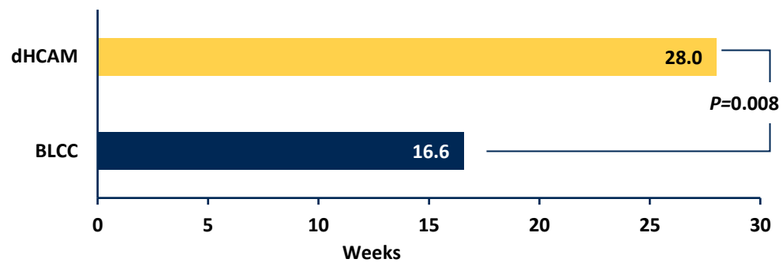
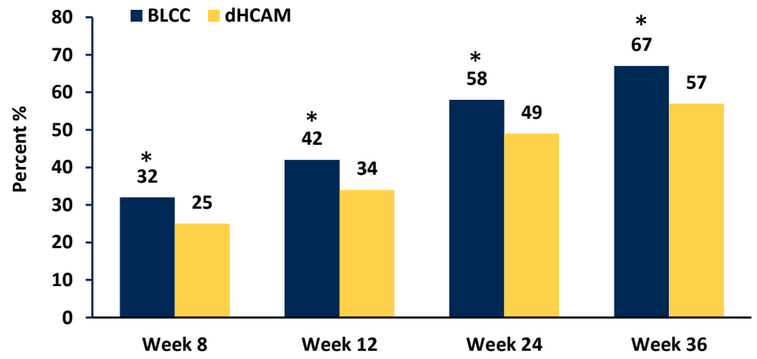


Figure 2: Percentage of Wounds Achieving Closure



*p=0.008

CONCLUSIONS

- These real-world data demonstrate that the frequency, time, and probability of wound closure for BLCC-treated PRIs was significantly improved when compared to dHACM-treated PRIs.
- Data from real world comparative effectiveness assessments can guide clinicians to limit overuse of less effective therapies and underuse of more effective therapies.
- The PRI RWD results using BLCC are comparable to pivotal RCT results that supported FDA approvals of BLCC for the treatment of VLUs and DFUs.[6,7]

*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.

REFERENCES

1. Li Z, Lin F, Thalib L, Chaboyer W. Global prevalence and incidence of pressure injuries in hospitalised adult patients: A systematic review and meta-analysis. *Int J Nursi Studies* 2020;105:103546.
2. Chung M-L, Widdel M, Kirchhoff J, et al. Risk factors for pressure injuries in adult patients: a narrative synthesis. *Int J Environ Res Public Health*. 2022;19(2):761.
3. Internet Citation: 1. Are we ready for this change?. Content last reviewed October 2014. Agency for Healthcare Research and Quality, Rockville, MD.https://www.ahrq.gov/patient-safety/settings/hospital/resource/pressureulcer/tool/pu1.html
4. Mervis JS, Phillips TJ. Pressure ulcers: Pathophysiology, epidemiology, risk factors, and presentation. Journal of the American Academy of Dermatology. 2019;81(4):881-890.
5. Apligraf [package insert]. Canton, MA: Organogenesis Inc.; 2017.
6. Falanga V, Sabolinski M. A bilayered living skin construct (APLIGRAF) accelerates complete closure of hard-to-heal venous ulcers. *Wound Repair Regen*. 1999;7(4):201-207.
7. Falanga V, Margolis D, Alvarez O, et al. Rapid healing of venous ulcers and lack of clinical rejection with an allogeneic cultured human skin equivalent. Human Skin Equivalent Investigators Group. *Arch Dermatol*. 1998:34(3):293-300.

Disclosures

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

ORGANOGENESIS

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