

Real World Data Comparative Effectiveness Analysis Comparing a Dehydrated Amnion Chorion Membrane and a Fetal Bovine Collagen Dressing for Use in Diabetic Foot Ulcers

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INTRODUCTION

- Diabetic foot ulcers (DFUs) are a serious complication of diabetes associated with amputation, infection, and death and affects approximately 18.6 million people worldwide and 1.6 million in the United States annually.^{1,2}
- Approximately 50-60% of DFUs become infected, with about 20% of moderate to severe infections leading to lower extremity amputations.²
- A randomized controlled trial supports the use of a dehydrated amnion chorion membrane (dACM)^(a) as a protective barrier for use in DFUs.³
- Real-world data (RWD) were used to conduct a comparative effectiveness research study (CER) of dACM versus a fetal bovine collagen matrix (FBCM)^(b) for the management of diabetic foot ulcers (DFUs).
- dACM is a sterile, dehydrated placental allograft intended for use as a protective barrier in the management of acute and chronic wounds including DFUs.
- FBCM is FDA cleared as a 510(k) Class II device for the management of acute and chronic wounds.
- Electronic medical records for wound care management (WoundExpert®, NetHealth)^(c) were used to evaluate the effectiveness of dACM vs FBCM for the management of DFUs.

^(a) Nushield®, Organogenesis Inc., Canton, MA

^(b) Primatrix®, Integra, Plainsboro NJ

^(c) WoundExpert®, Net Health, PA

METHODS

Study Population

- Electronic medical records (WoundExpert) collected between 2021 and 2023 on 632 DFUs were analyzed.
- DFUs between 1-40 cm² were included.
- Patients with no baseline wound measurements or follow-up visits were excluded.

Statistical Analyses

- Evaluations were performed on 173 dACM- and 459 FBCD treated DFUs.
- Treatment period started with the first use of dACM or FBCD.
- A Kaplan-Meier (K-M) analysis was used to compute median time to healing.
- A Cox analysis that adjusted for variables including ulcer area and duration was used to compute frequency of healing.
- The Hazard Ratio (HR) was calculated to determine the probability of healing.

RESULTS

- Patient populations were well matched for patient demographics, wound characteristics and treatment characteristics.
- The median time to healing was 7.0 weeks for dACM and 16.6 weeks for FBCD; p=0.03 (Figure 1).
- This difference between groups demonstrated a 39.8% reduction in time to healing with the use of dACM; p=0.03.
- The frequency of healing for dACM was significantly greater compared to FBCD at week 8 (40% vs 32%), 12 (52% vs 42%), 24 (68% vs 58%), and 36 (76% vs 66%); p=0.03 (Figure 2).
- The HR=1.34 [95% CI (1.03, 1.76)]; p=0.03. dACM treated DFUs resulted in a 34% greater probability of healing compared to FBCD at every timepoint through 36 weeks.

Figure 1: Median Time to Wound Closure

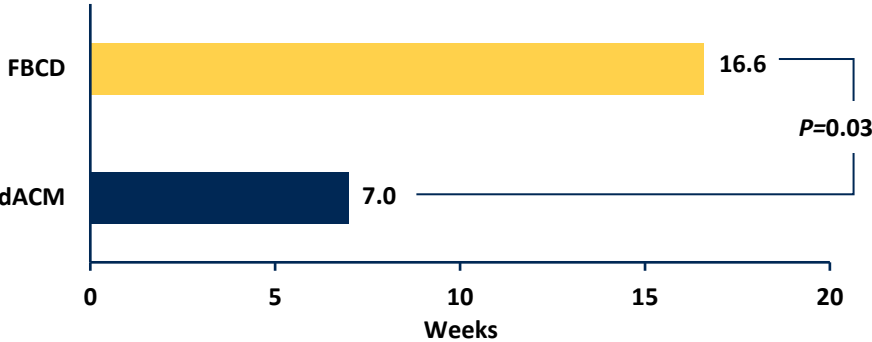
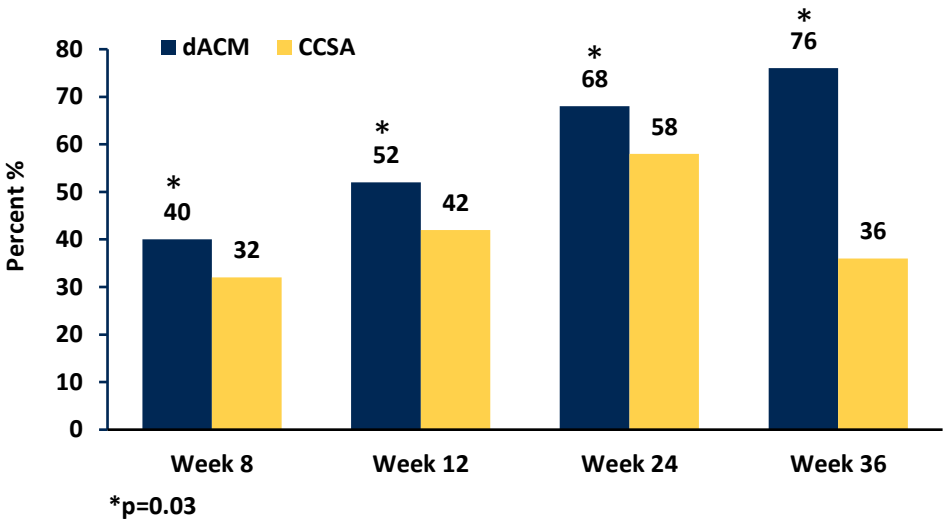


Figure 2: Percentage of Wounds Achieving Closure



CONCLUSIONS

- dACM significantly improved the probability, frequency, and incidence of healing when compared to FBCD.
- RWD analyses demonstrated the frequency of healing was significantly greater for dACM compared to FBCD for DFUs.
- These data may inform patient care and DFU treatment algorithms.
- RWD dACM results showed effectiveness consistent with DFU RCT findings comparing dACM to standard of care (SOC).³

*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.