

Retrospective Real World Comparative Effectiveness of Ovine Forestomach Matrix and Collagen/Oxidized Regenerated Cellulose in the Management of Diabetic Foot Ulcers

¹Brandon A. Bosque, DPM; ²Christopher Frampton, PhD; ³Abigail E. Chaffin, MD; ⁴Gregory A. Bohn, MD; ⁵Kevin Woo, PhD; ⁶Candace DeLeonardis, MBA; ⁷Brian D. Lepow, DPM; ⁸M. Mark Melin, MD; ⁹Tobe Madu, PhD; ¹Shane G. Dowling, MSPAS; ¹Barnaby C. H. May, PhD

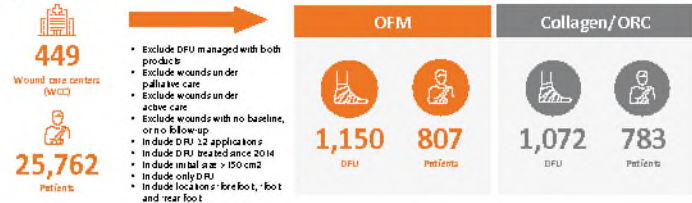
¹Aroa Biosurgery Limited, Airport Oaks, Auckland, New Zealand; ²Department of Psychological Medicine (Christchurch), Otago University, Christchurch, New Zealand; ³Division of Plastic and Reconstructive Surgery, Department of Surgery, Tulane University School of Medicine, New Orleans, Louisiana, USA; ⁴Department of Surgery, Central Michigan University, Tawas City, Michigan, USA; ⁵Queen's School of Nursing, Queen's University, Toronto, Canada; ⁶DSA Health, Tampa, Florida, USA; ⁷Division of Vascular Surgery and Endovascular Therapy, Baylor College of Medicine, Houston, Texas, USA; ⁸M Health Fairview Wound Healing Institute, South Campus, Department of Vascular Surgery, University of Minnesota, Edina, Minnesota, USA; ⁹Tissue Analytics, a Net Health Company, Pittsburgh, Pennsylvania, USA.

INTRODUCTION

Deciphering the relative efficacy of various treatment modalities for diabetic foot ulcers (DFUs) has proven to be challenging. Retrospective real-world data (RWD) studies have emerged as an innovative method to evaluate treatment efficacy in challenging cohorts that otherwise might be excluded in strictly designed randomized controlled trial. This retrospective pragmatic RWD study compared the healing outcomes of diabetic foot ulcers treated with either ovine forestomach matrix (OFM)* or collagen/oxidized regenerated cellulose (ORC)^.

METHODS

Data was extracted from a wound database from 2014 to 2020, representing 449 wound care centers (WCC) across the United States. Data was extracted from a pool of 31,883 wounds and filtered based on the inclusion and exclusion criteria. The median time to wound closure and the percentage of wounds closed at standard time intervals were estimated using the Kaplan-Meier method, and probability of closure by Cox proportional hazards analysis. Sub-group analysis was conducted based on the number of WCC applications.

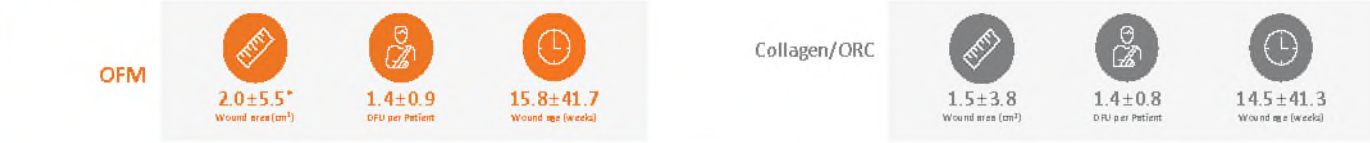


RESULTS – PATIENT DEMOGRAPHICS

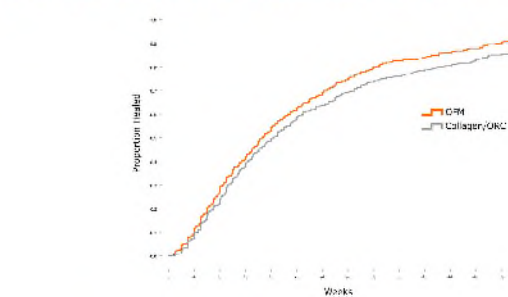


REFERENCES AND DISCLOSURE S: Bosque, B. A., C. Frampton, A. E. Chaffin, G. A. Bohn, K. Woo, C. DeLeonardis, B. D. Lepow, M. M. Melin, T. Madu, S. G. Dowling and B. C. H. May (2021) "Retrospective real-world comparative effectiveness of ovine forestomach matrix and collagen/ORC in the treatment of diabetic foot ulcers." *Int Wound J* 2021; Aug 6; doi:10.1111/ijw.13670 Funding for the study was provided by Aroa Biosurgery Limited. *Endoforn™ Natural ^=Promogran (ICI)3M

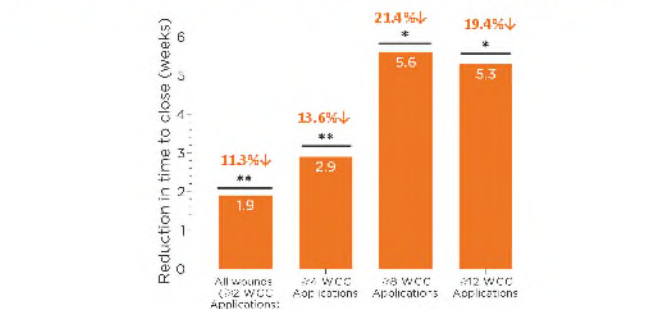
RESULTS - BASELINE WOUND CHARACTERISTICS



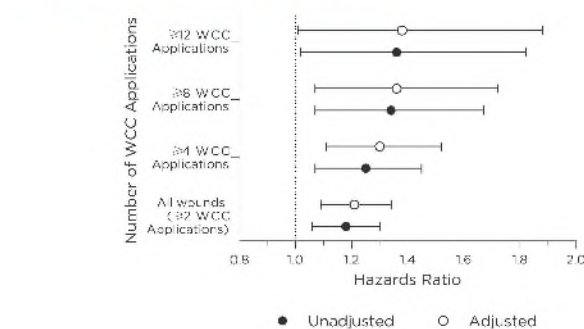
RESULTS – KAPLAN-MEIER SURVIVAL ANALYSIS



RESULTS - AVERAGE REDUCTION IN TIME TO CLOSE (WEEKS)



RESULTS – PROBABILITY OF CLOSURE



CONCLUSION

- First large-scale real-world data analysis demonstrates that the use of OFM reduced the median time to closure, and also increased the probability of closure of DFUs relative to wounds managed with collagen/ORC.
- This study further substantiates the growing body of evidence to support the use of Endoforn as a first line intervention to improve wound closure rates.

