

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

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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.

449
Wound care centers (WCC)

25,762
Patients

➔

OFM

1,150
DFU

807
Patients

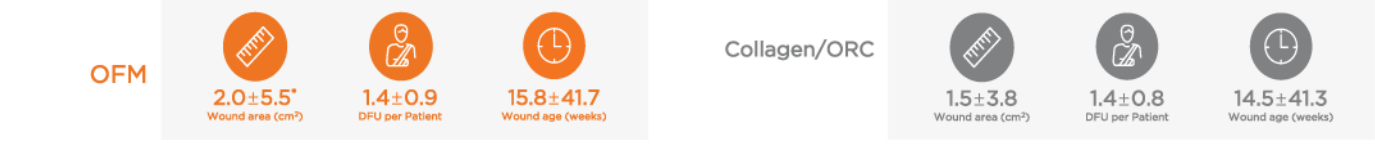
Collagen/ORC

1,072
DFU

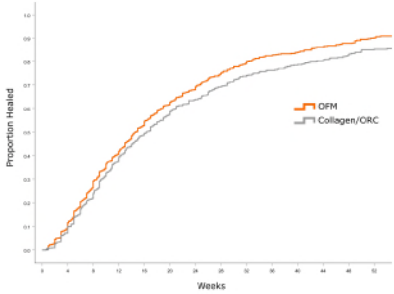
783
Patients

- Exclude DFU managed with both products
- Exclude wounds under palliative care
- Exclude wounds under active care
- Exclude wounds with no baseline, or no follow-up
- Include DFU ≤ 2 applications
- Include DFU treated since 2014
- Include initial size > 150 cm²
- Include only DFU
- Include locations 'forefoot', 'foot' and 'rear foot'

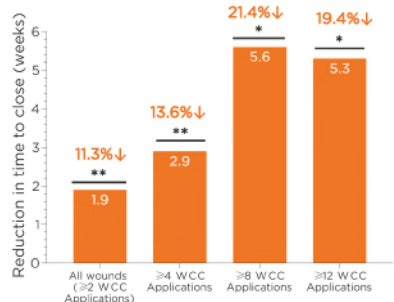
RESULTS - BASELINE WOUND CHARACTERISTICS



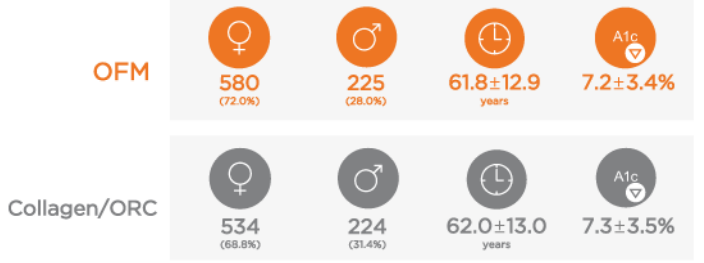
RESULTS - KAPLAN-MEIR SURVIVAL ANALYSIS



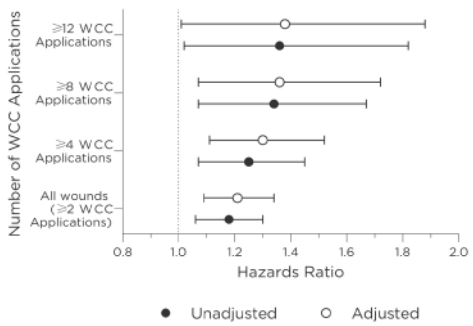
RESULTS - AVERAGE REDUCTION IN TIME TO CLOSE (WEEKS)



RESULTS - PATIENT DEMOGRAPHICS



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 Endoform as a first line intervention to improve wound closure rates.

2,222
Total DFUs evaluated

Up to 5.6 weeks
Faster closure with OFM vs collagen/ORC

Up to 38%
Increased probability of healing, with OFM vs collagen/ORC

REFERENCES AND DISCLOSURES: 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/iwj.13670. Funding for the study was provided by Aro Biosurgery Limited. * = Endoform™ Natural. ^ = Promogran (KCI/3M).