

Retrospective Real World Comparative Effectiveness of Ovine Forestomach Matrix and Collagen/Oxidized Regenerated Cellulose in the Management of Venous Leg Ulcers: An Interim Analysis

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INTRODUCTION

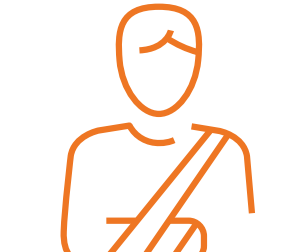
Deciphering the relative efficacy of various treatment modalities for venous leg ulcers (VLUs) has proven to be challenging. Retrospective real-world evidence (RWE) studies have emerged as an innovative method to evaluate treatment efficacy in challenging cohorts that otherwise might be excluded in strictly designed randomized controlled trials. This retrospective pragmatic RWE study compared the healing outcomes of venous leg 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 (CPH) analysis. Sub-group analysis was conducted based on the number of WCC applications.




223
Wound care centers (WCC)




25,762
Patients

•Exclude VLU managed with both products
•Exclude wounds under palliative care
•Exclude wounds under active care
•Exclude wounds with no baseline, or no follow-up
•Exclude patients without documented compression therapy
•Exclude anatomic locations other than "leg"
•**Include only VLU (CEAP 6)**
•**Include VLU ≥2 applications**
•**Include VLU treated since 2014**

OFM




470
VLU




312
Patients

Collagen/ORC

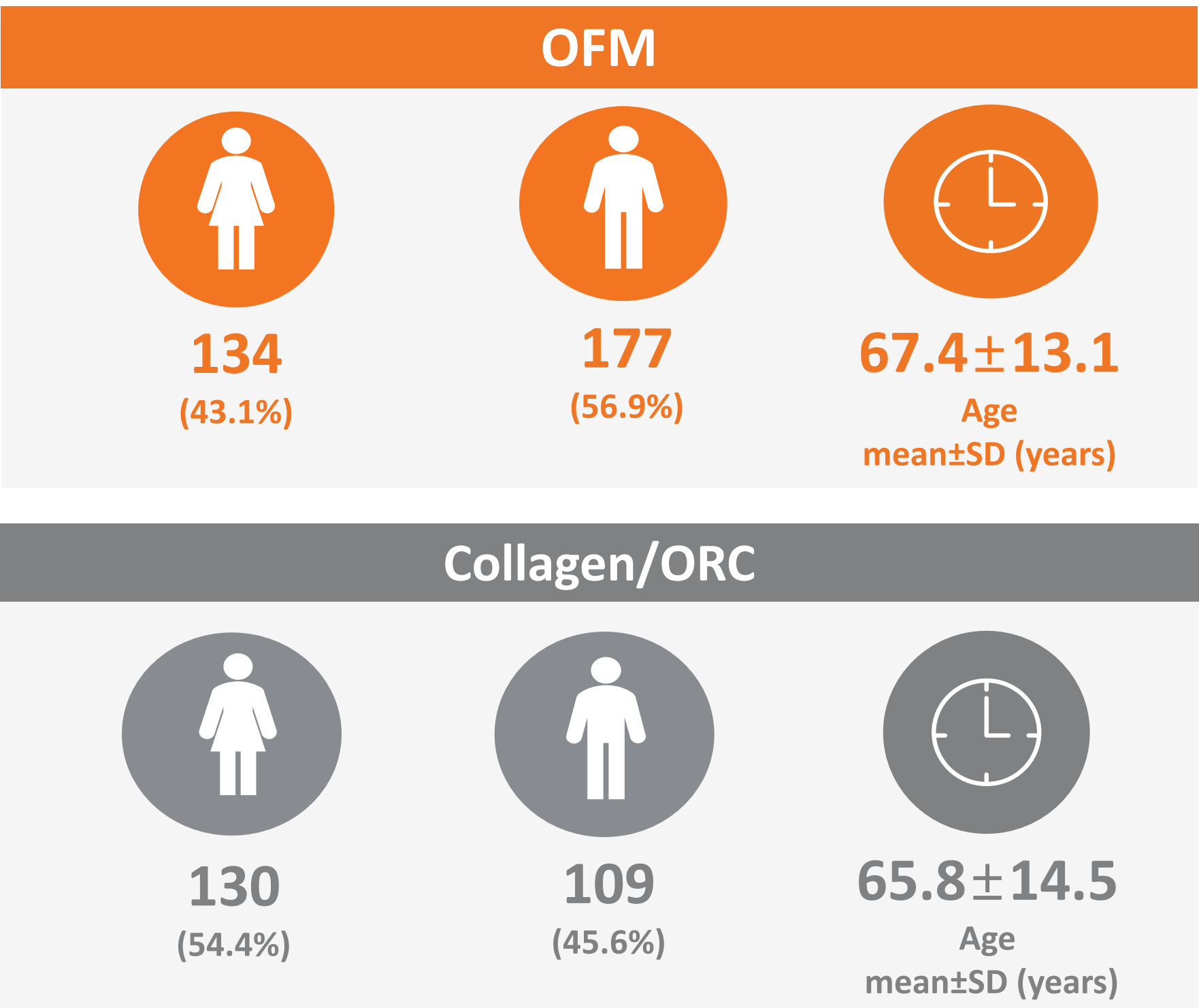


360
VLU

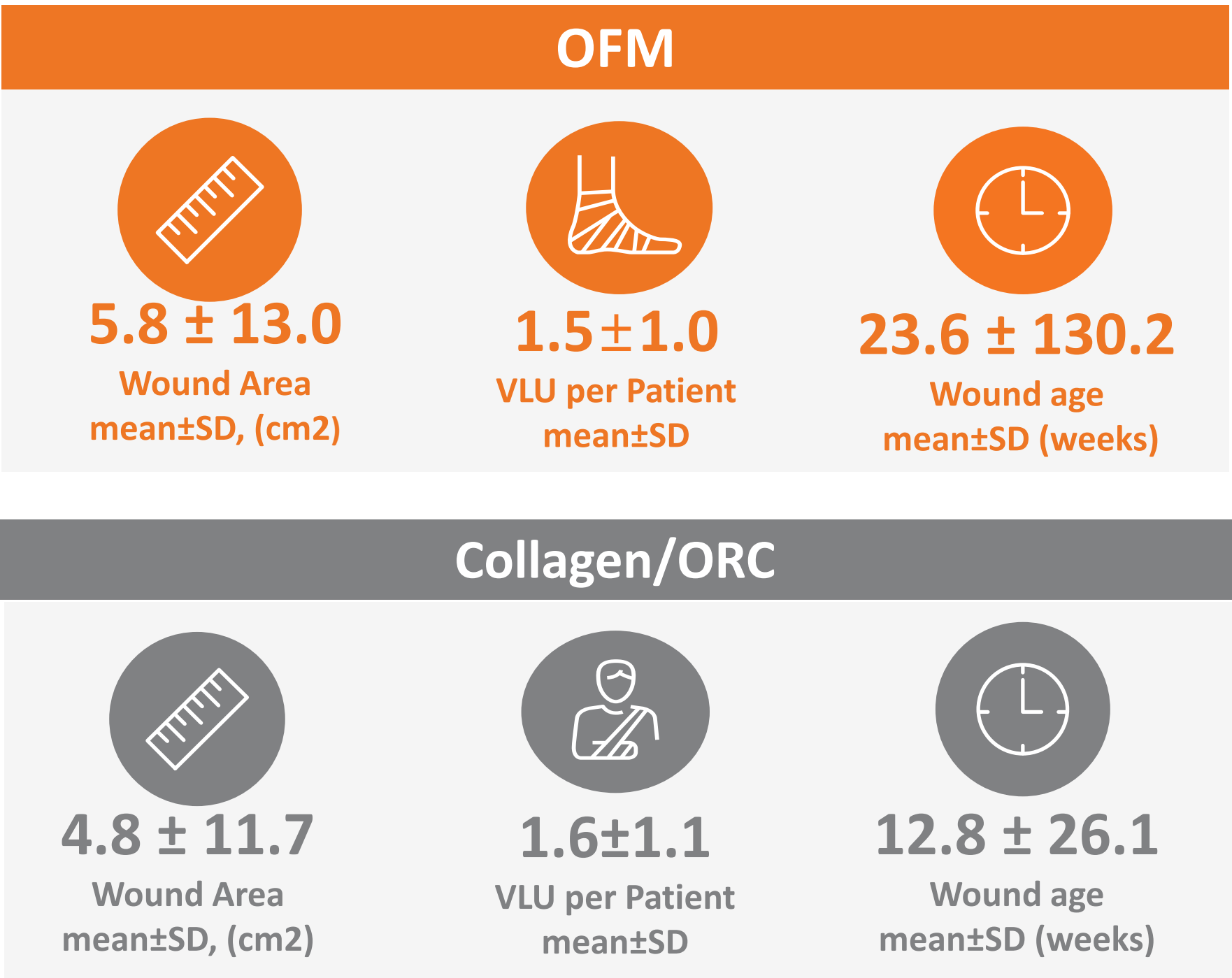


239
Patients

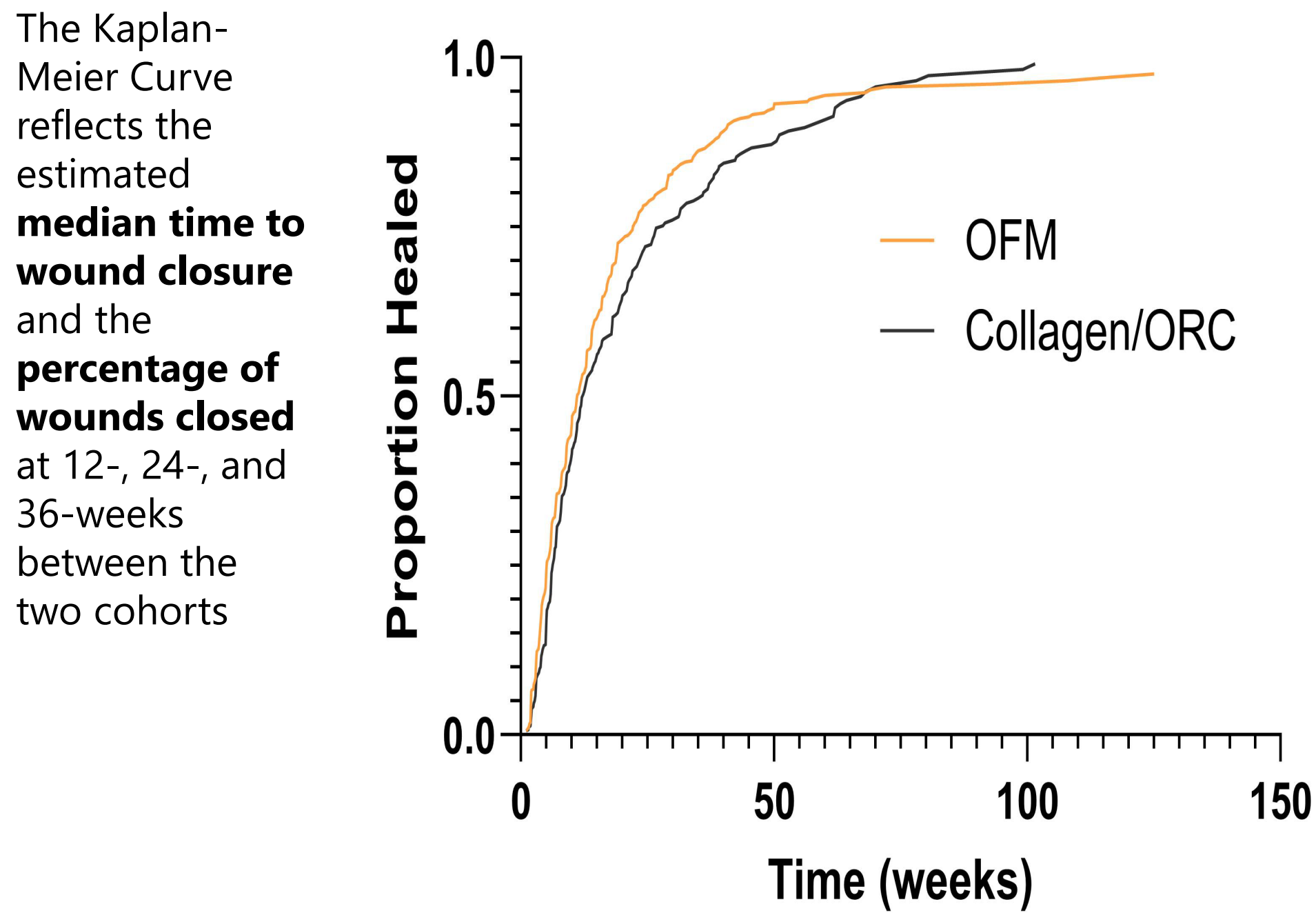
RESULTS – PATIENT DEMOGRAPHICS



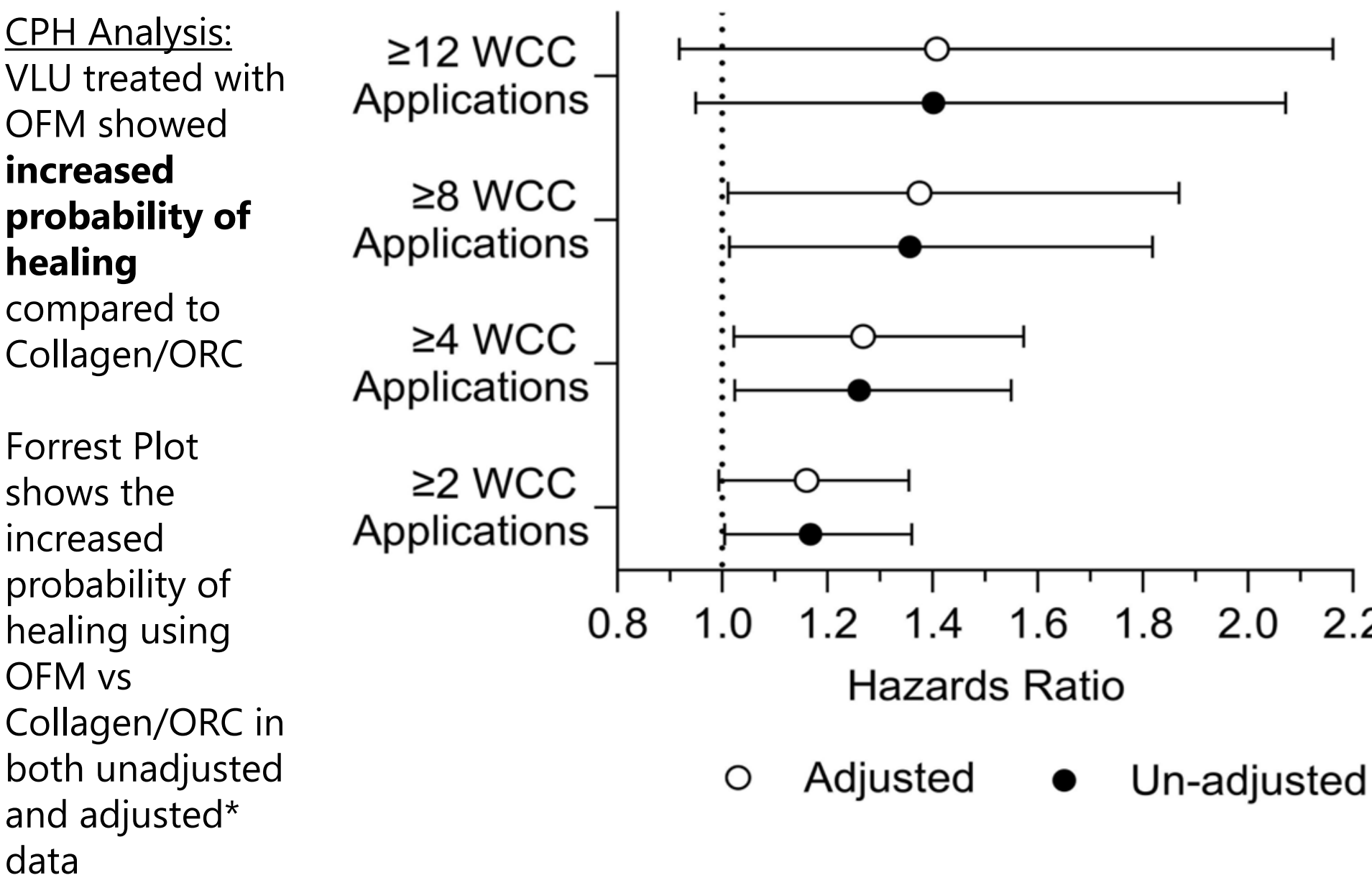
RESULTS - BASELINE WOUND CHARACTERISTICS



RESULTS – KAPLAN-MEIER SURVIVAL ANALYSIS

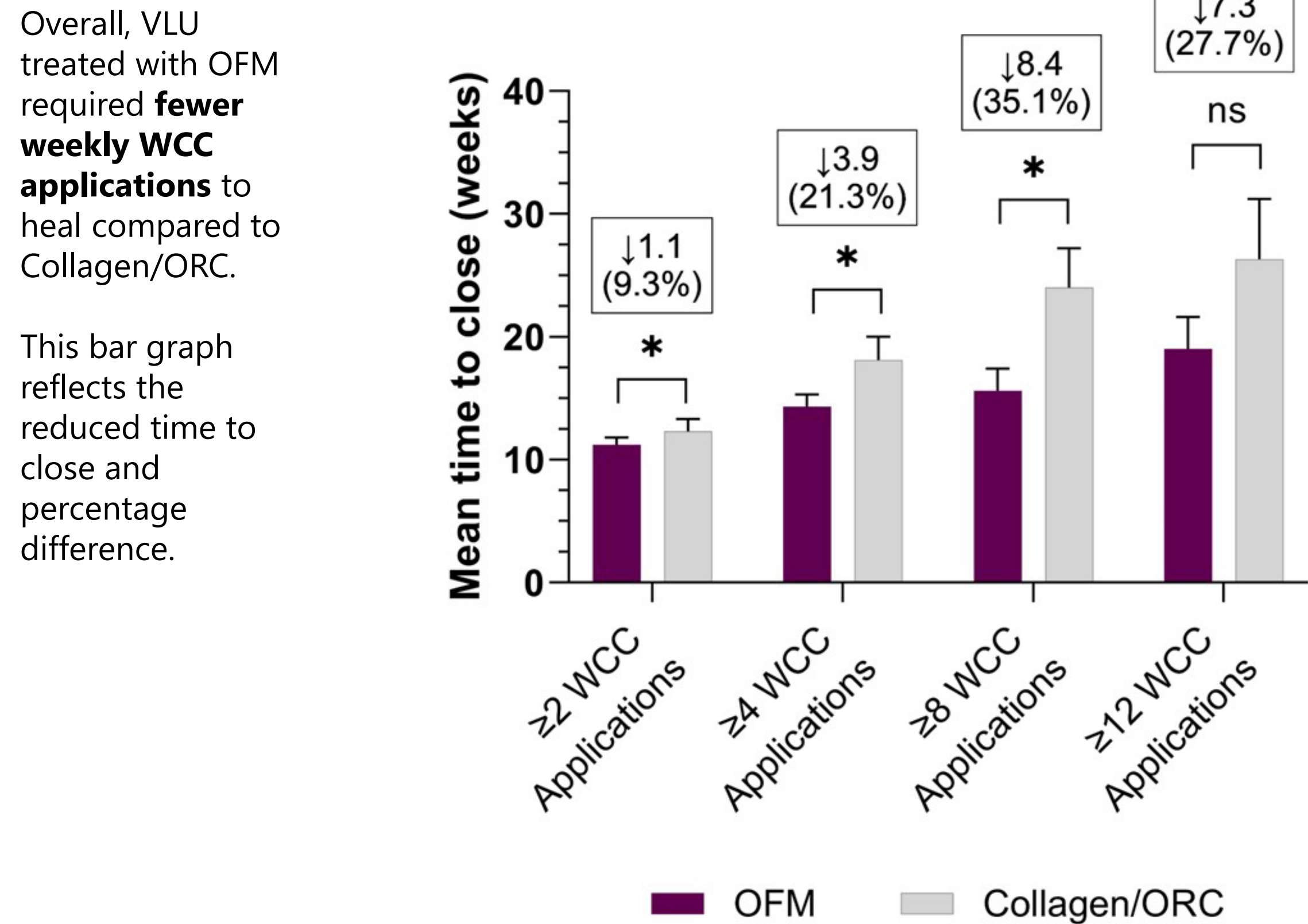


RESULTS – CPH ANALYSIS:PROBABILITY OF CLOSURE



*Adjusted data accounting for patient age, gender, initial wound size, and wound duration.

RESULTS - AVERAGE REDUCTION IN TIME TO CLOSE (WEEKS)



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 VLUs relative to wounds managed with collagen/ORC.
- This study further substantiates the growing body of evidence¹ to support the use of OFM as a first line intervention to improve wound closure rates.



830
Total VLUs evaluated



Up to 8.4 weeks
Faster closure with OFM vs collagen/ORC



Up to ~40%
Increased probability of healing, with OFM vs collagen/ORC

REFERENCES:¹ 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/wj.13670. Funding for the study was provided by Aroa Biosurgery Limited. * =Endoform™ Natural. ^ =Promogran™ (KCI/3M™).