

Real-World Outcomes Using Fetal Bovine Dermis for Complex Wounds

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INTRODUCTION

- Complex wounds featuring tunneling, undermining, or persistent drainage present significant management challenges
- Their irregular geometry and limited tissue interface often diminish the effectiveness of standard wound care approaches and are commonly associated with delayed closure and increased infection risk.¹⁻³
- Biologic scaffolds, including fetal bovine dermis (FBD), may offer therapeutic advantages in these settings.⁴⁻¹⁰
- By conforming to irregular wound beds and supporting tissue integration and regeneration, FBD may help address limitations of traditional treatment approaches in complex wound presentations.

OBJECTIVE

This study evaluated the real-world performance of a marketed FBD device (Fig.1) in wounds characterized by tunneling, undermining, or persistent drainage, using retrospective clinical chart data.

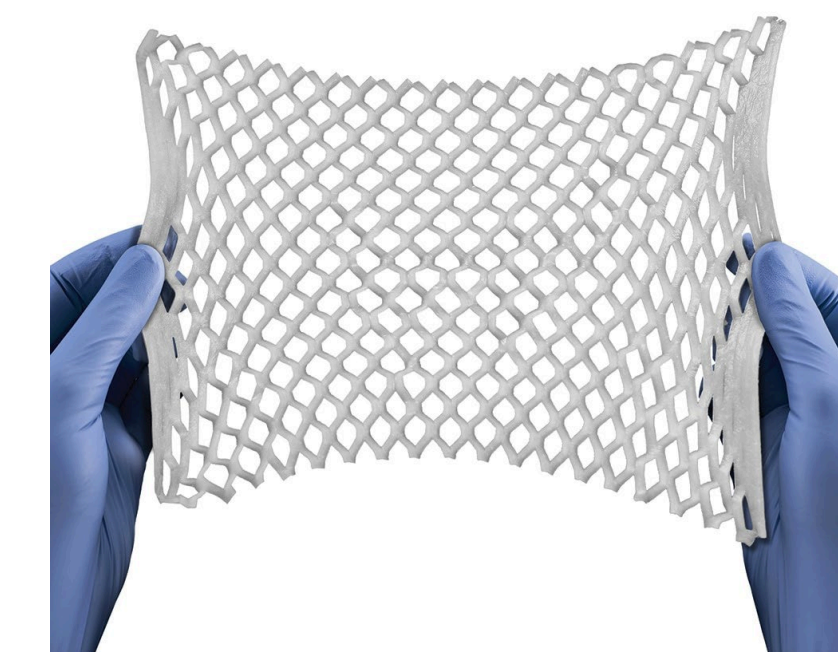
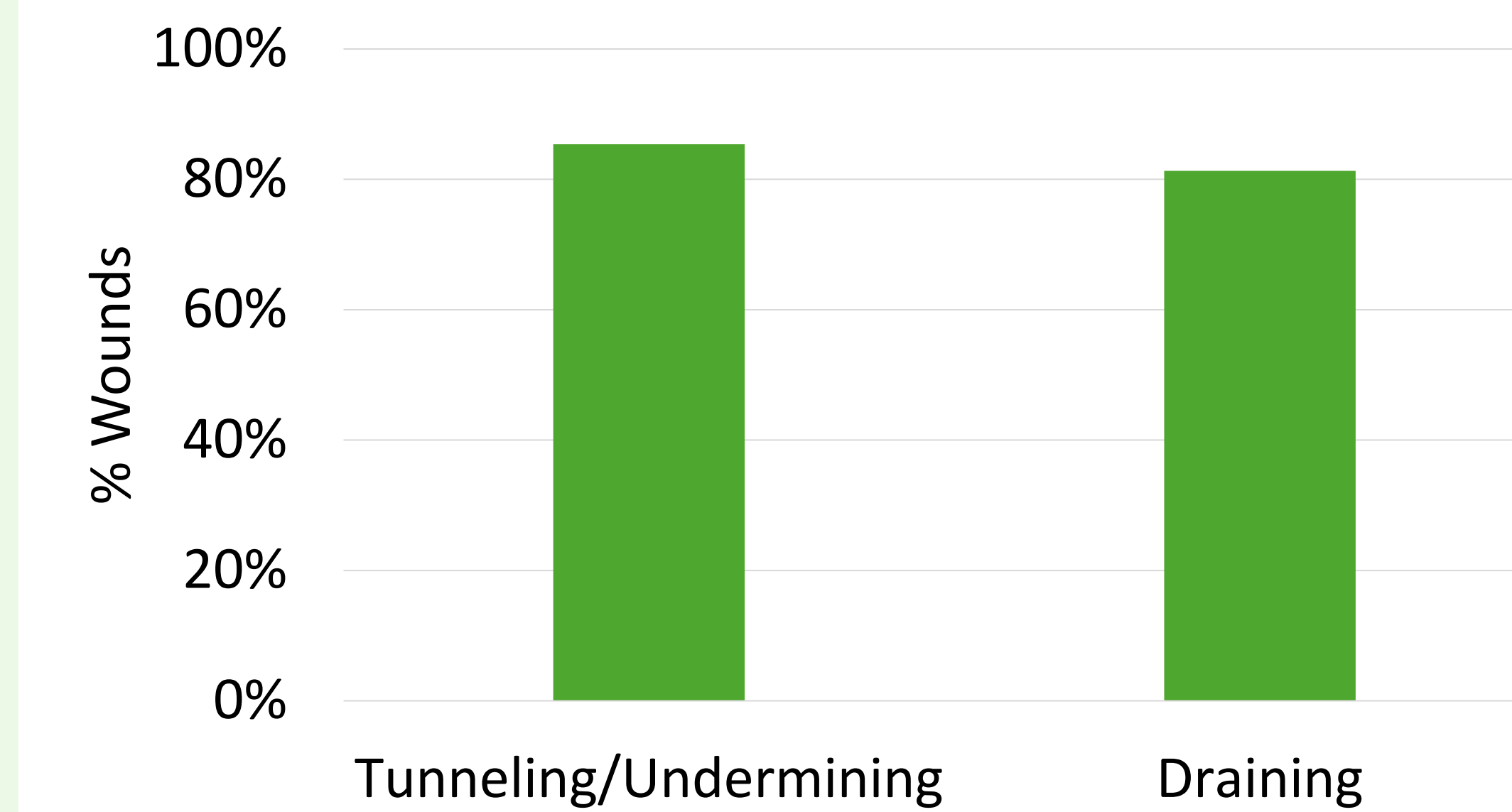


Figure 1. PriMatrix Dermal Scaffold (Integra LifeSciences, Plainsboro, NJ)

RESULTS

A total of 246 real-world complex wound cases were included:

- 123 tunneling/undermining
- 123 draining
- Submitted by 83 and 76 clinicians, respectively

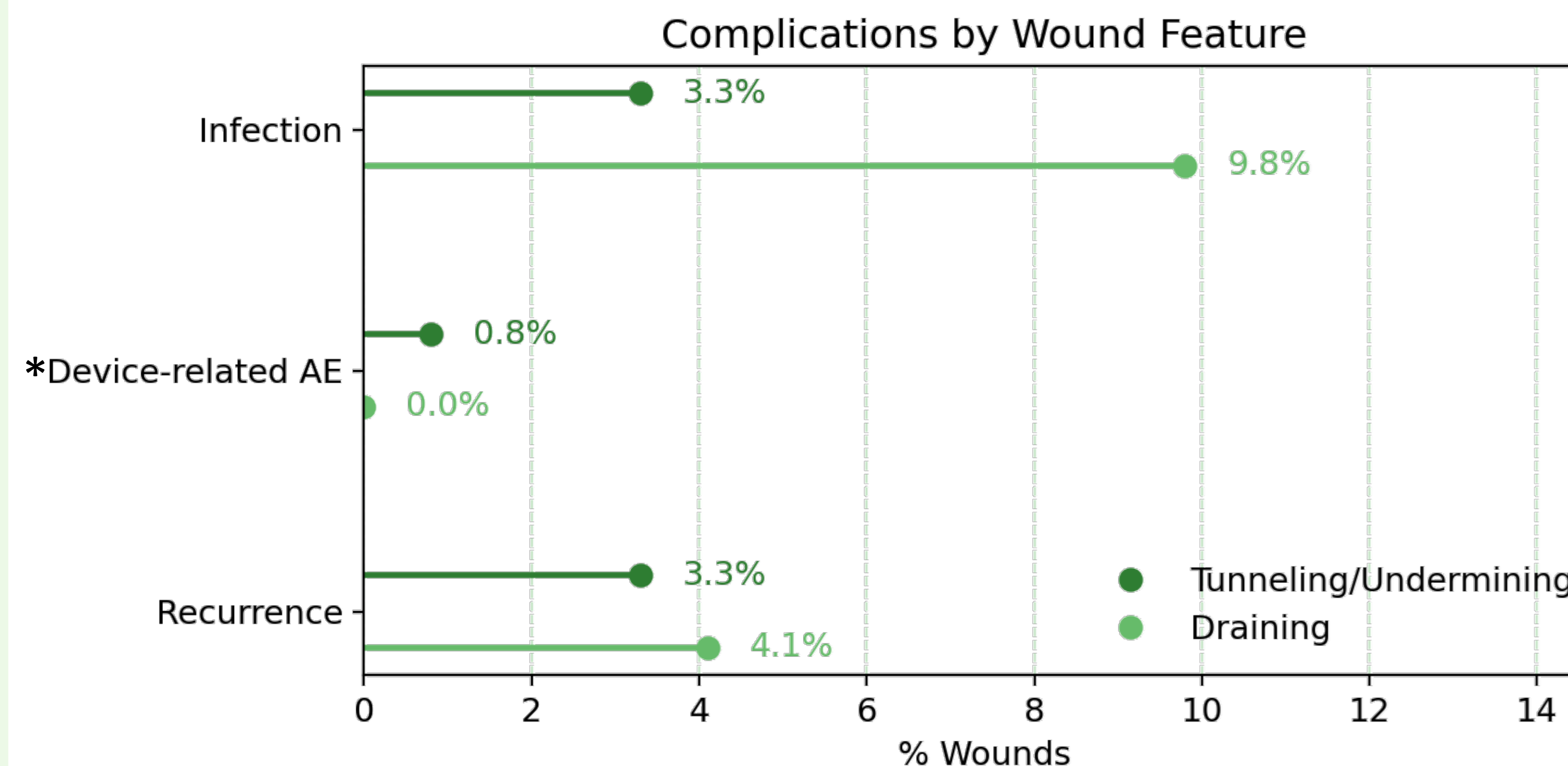


Consistently high rates of wound closure observed across wound features

Figure 2. Proportion of wounds achieving complete closure at 12 weeks.

METHODS

- A retrospective chart review was performed using a HIPAA-compliant digital platform that enabled secure abstraction of real-world clinical data.
- Licensed clinicians from US and EU submitted de-identified cases treated with the FBD device between June 2022 and June 2025. Each contributor was permitted to enter up to 20 cases.
- Cases were included if wounds exhibited tunneling, undermining, or persistent drainage, and all data were captured via structured forms to ensure consistency.
- Outcomes were assessed at 12 weeks, included:
 - Status of wound closure
 - Safety events, including device-related adverse events (AEs), infection-related complications, and recurrence
- Descriptive statistics were performed to summarize the dataset.
- Because the dataset consisted of fully anonymized retrospective information, the study did not require IRB approval or patient consent, consistent with regulatory allowances for secondary use of de-identified data.



- Infection-related complications remained low across wound features
- Device-related adverse events were rare, with none reported in draining wounds
- Wound recurrence was infrequent, all cases occurred within 6 months

Figure 3. Proportion of wounds with safety event occurrences. *Device-related adverse events were only limited to inflammation.

DISCUSSION

- This study showed that an FBD device achieved high closure rates with low complication occurrences across complex wound types studied
- Infection-related complications remained uncommon, though higher in draining wounds, reflecting their greater clinical complexity and bioburden.
- As a retrospective analysis, these findings are subject to limitations, including selection bias, documentation variability, and the absence of a comparator arm. However, the broad clinician participation support the real-world relevance of the findings.

CONCLUSION

- Use of an FBD scaffold in complex wounds with tunneling, undermining, or drainage features was associated with favorable outcomes, low device-related AEs, and minimal recurrence in routine practice.
- These results support FBD as a practical option for anatomically irregular wounds, with prospective studies needed to further confirm these findings.

References:

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