



Real-World Outcomes of Fetal Bovine Dermis in Diabetic Foot Ulcer Management

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INTRODUCTION

- Diabetic foot ulcers (DFUs) are complex chronic wounds characterized by impaired vascularity, delayed closure, and a high risk of infection
- Advanced biologic scaffolds such as fetal bovine dermis (FBD) provide structural support and promote tissue regeneration in challenging wound environments.¹⁻⁷
- A prior randomized controlled trial (RCT) demonstrated significantly higher 12-week closure rates for FBD compared to standard of care (59.5% vs 35.4%), establishing its clinical benefit under controlled conditions.⁸
- Understanding whether outcomes observed in controlled trials translate to everyday clinical practice is essential for assessing the broader clinical utility of FBD.

OBJECTIVE

To assess real-world effectiveness and safety performance of a FBD scaffold (Fig. 1) in the management of DFUs.

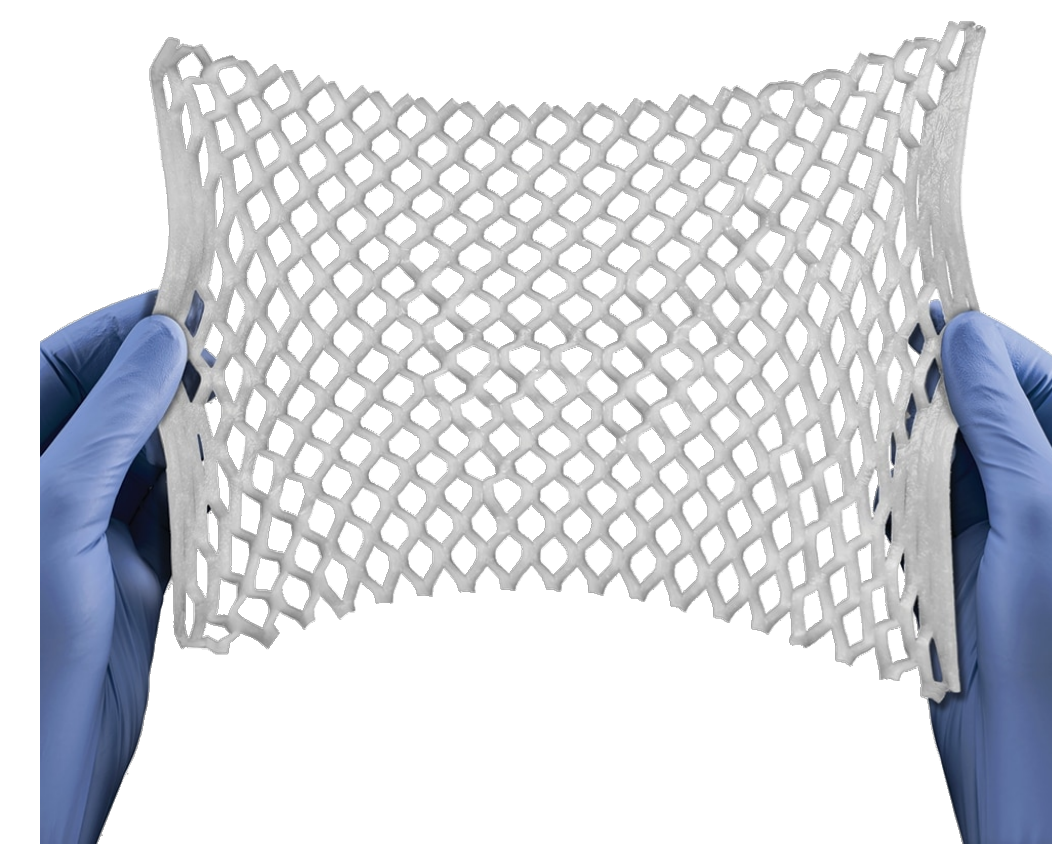


Figure 1. PriMatrix Dermal Scaffold (Integra LifeSciences, Plainsboro, NJ)

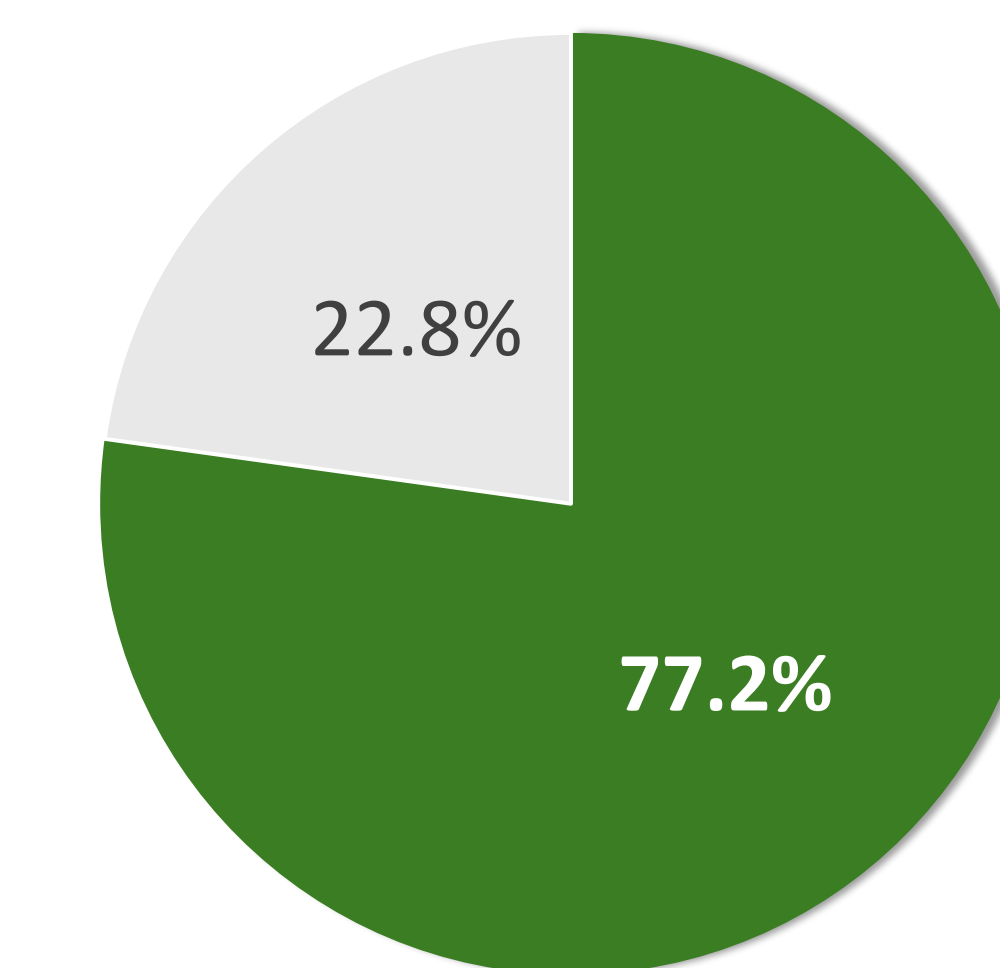
RESULTS

A total of 123 real-world complex wound cases were included:

- 61.1% male (75/123)
- 30.0% ≥ 70 years, 7.3% <30 years
- Submitted by 95 clinicians

Figure 2. Wound closure status at 12 weeks.

Complete Closure
■ Yes ■ No



The majority of DFU wounds closed by week 12

Low complication rates were observed with no device-related adverse events reported

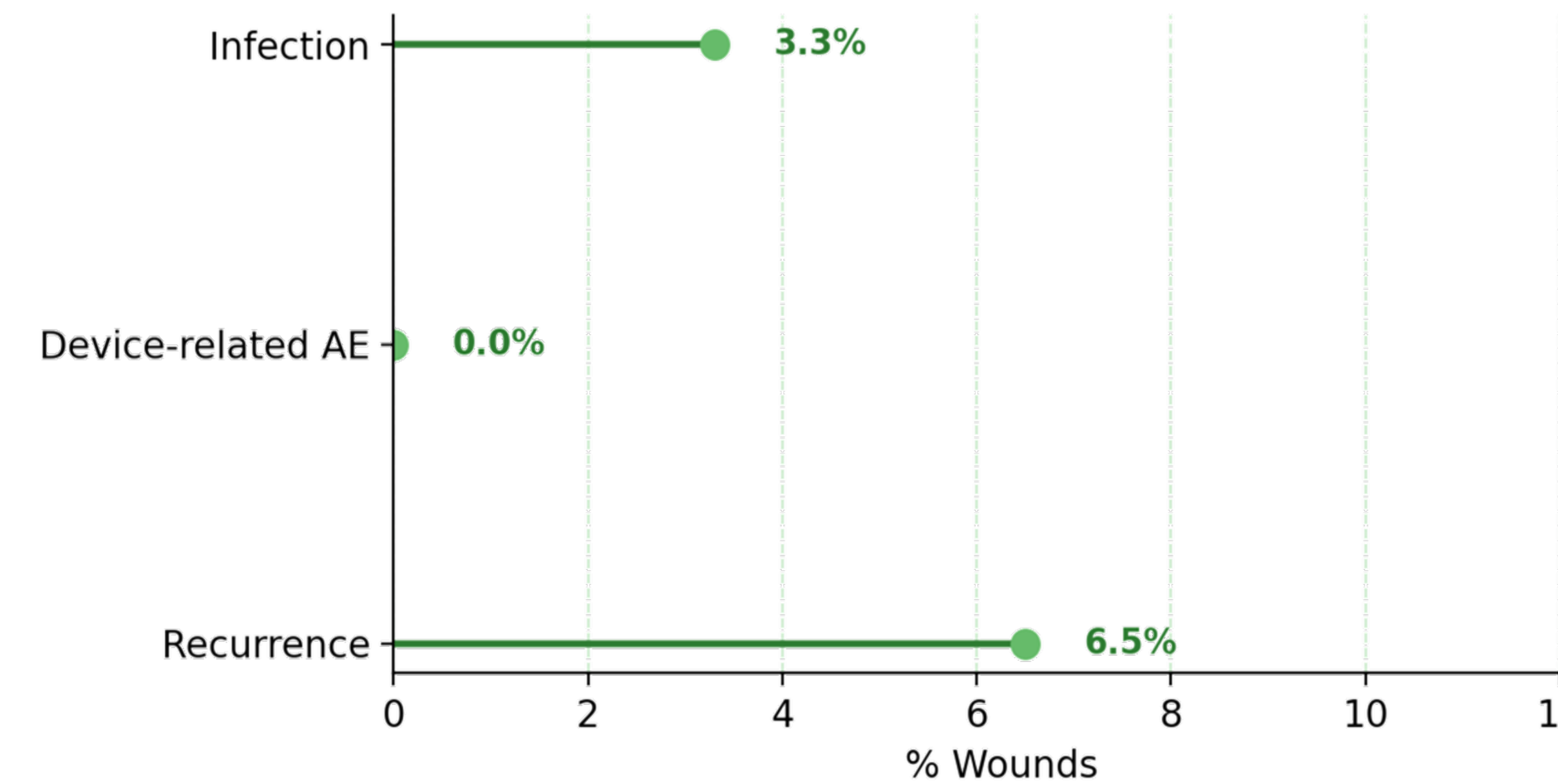


Figure 3. Reported safety events across DFU cases.

DFU progressed to closure over time, with most closing within 9-12 week

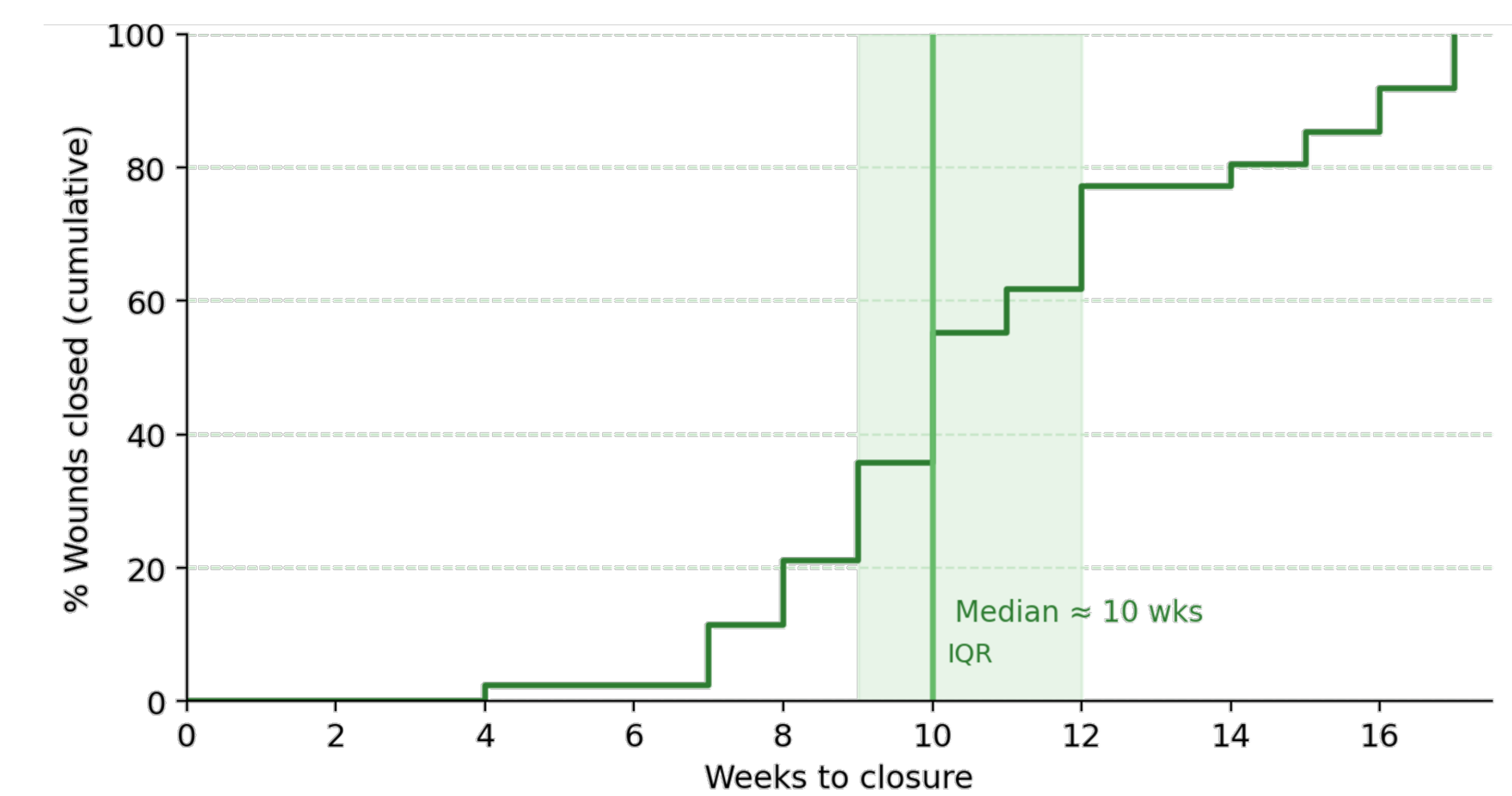


Figure 4. Cumulative time-to-closure curve with median and interquartile range.

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 could enter up to 20 cases.
- Structured forms were used to capture:
 - 12-week closure status
 - Time to closure
 - Adverse events
- Analysis focused exclusively on DFU cases and was descriptive in nature.
- The study was exempt from IRB/consent requirements due to its retrospective, anonymized design.

DISCUSSION

- The results demonstrated favorable performance of FBD in DFU management.
- Outcomes align with the clinical benefits previously demonstrated in the RCT, supporting FBD's real-world effectiveness extended beyond controlled study settings.
- Low infection incidence and recurrence supplied evidence on durable closure in typical DFU care environments.
- Although limited by retrospective design and variable follow-up, broad clinician participation support the relevance of these real-world findings.

CONCLUSION

- FBD use in DFUs was associated with favorable real-world results, low safety events and recurrence, aligning with prior RCT evidence.
- Findings support FBD as a practical option for DFU management, with additional prospective studies warranted to further confirm the findings.

References:

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