Use of a Purified Reconstituted Bilayer Matrix in the Management of Non-Healing Diabetic Foot Ulcers Improves Patient Outcomes vs Standard of Care – Results of A Prospective Randomized Controlled Multicenter Clinical Trial

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Introduction: Patients with diabetic foot ulcers (DFUs), in particular when unresponsive to standard wound care, face serious risks of severe complications, including infection and amputation. The management of DFUs is associated with increasing social and financial burdens. In a previous series of 10 patients the authors evaluated a unique Purified Reconstituted Bilayer Matrix (PRBM) and found the material to be easy to apply as well as safe and efficacious in the treatment of chronic DFUs¹. PRBM is a porcine derived advanced acellular bilayer scaffold². The lower porous layer is designed for close adaptation to the wound bed and immediate wound fluid uptake due to its sponge-like architecture and hydrophilic properties¹. The chemical composition is intended to modulate matrix metalloproteinase activity and serve as a scaffold for cellular ingrowth and eventual revascularization³. The thin upper compact layer facilitates easy handling and is intended to provide support and protection to the wound site³. Its chemical composition is designed to bind and preserve growth factors and guide re-epithelialization by mimicking the structure of the basement membrane³.

Methods: We conducted a prospective, multi-center, RCT comparing outcomes in patients with DFUs treated weekly for up to 12 weeks with PRBM or Standard of Care (SOC). Major inclusion criteria were DFUs between 1 and 25 cm2 initial area and having no wound ischemia.

Included

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- Data of 40 randomized patients
- 39 patients completed study per the protocol
- I patient was withdrawn due to SAE requiring hospitalization

Analysis

- Correct correlation between wound healing process status of 6 and 12 weeks was determined
- Patient characteristics at baseline between treatment groups were compared using CONSORT criteria
- Calculations were made using PASS13

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References

Objectives: To assess safety and performance of Purified Reconstituted Bilayer Matrix (PRBM) compared to standard of care (SOC) in treating non-healing DFUs.

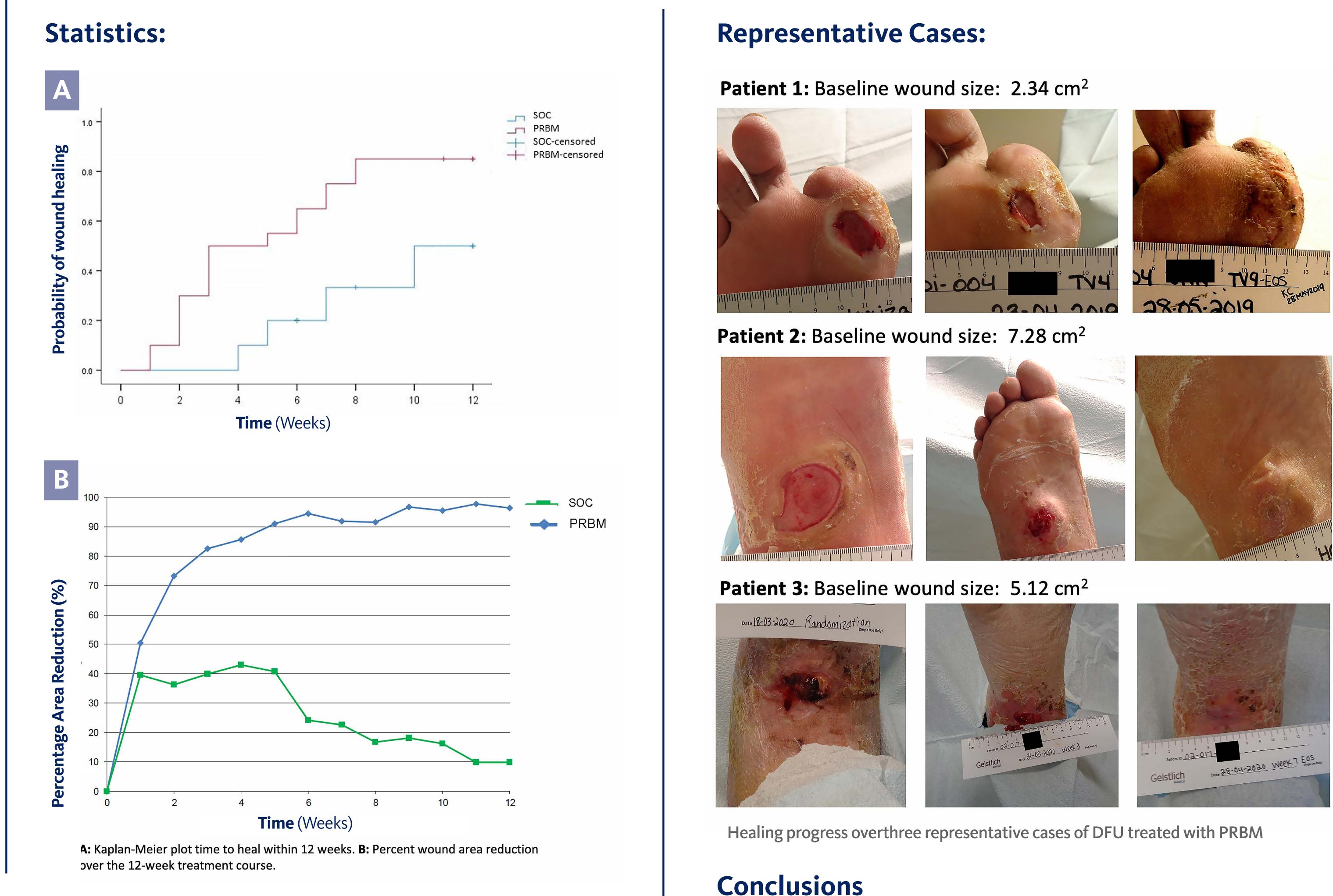
Patient Population:

Variable	PRBM (n=20)	SOC (n=20)	P
Gender M (%)/F (%)	13 (65%)/ 7 (35%)	12 (60%)/ 8 (40%)	0.74
Age (years)	59.3 ± 13.35	66.5 ± 11.26	0.073
BMI (kg/m ²)	33.0 ± 7.68	31.8 ± 7.1 4	0.49
HbA1c (screening)	7.2 ± 1.20	6.9 ± 1.83	0.19
HbA1c (end of study)*	6.7 ± 1.17	6.6 ± 1.71	0.92
Duration of Index DFU (weeks)	12.1 ± 8.21	15.6 ± 12.92	0.74
Baseline Wound Area (cm ²)	2.5 ± 2.16	3.5 ± 2.85	0.21
Baseline Wound Depth (mm)			
<2	15 (75%)	11 (55%)	0.18
≥2	5 (25%)	9 (45%)	
Ulcer Location			
Тое	5 (25%)	2 (10%)	0.34
Forefoot	4 (20%)	7 (35%)	
Midfoot	9 (45%)	6 (30%)	
Heel	1 (5%)	4 (20%)	
Ankle	1 (5%)	1 (5%)	

Patient and wound characteristics. Abbreviations: BMI, body mass index; N/A, not applicable. *Values for 1 PRBM subject and 1 SOC subject missing.

- p=0.00043, PP 94% vs 30% p=0.000075).
- Mean Time to heal at 12 weeks was 36.8 days for PRBM Group and 66.5 days for SOC group (p=0.002).
- During the study, no product related adverse events were observed.

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Results • Wounds treated with PRBM were significantly more likely to heal within 12 weeks than those receiving SOC (ITT—85% vs 30%,

Mean percent area reduction (PAR) at 12 weeks was 96.4 % (SD: 10.34) for PRBM group and 9.8% (SD: 89.25) for SOC group.



PRBM effectively and in a safe manner supports healing rate of chronic DFUs reducing wound healing complications.⁴

Compared to SOC treatment, PRBM increases the odds of healing by 13 times.

Weekly applications were well tolerated without any observed product related adverse events.

^{1.} Armstrong et al. An observational pilot study using a purified reconstituted bilayer matrix to treat non-healing diabetic foot ulcers. Int Wound J. 2020. 17(4):966-973. 2. Instructions for use, Geistlich Derma-Gide[®]. Geistlich Pharma AG, Wolhusen, Switzerland.

^{3.} Armstrong et al. Functional Properties of a Purified Reconstituted Bilayer Matrix Designed to Support Natural Wound Healing Activities. PRS Global Open 2021. 9(5): e3596. 4. Armstrong et al. Use of a purified reconstituted bilayer matrix in the management of chronic diabetic foot ulcers improves patient outcomes vs standard of care: Results of a prospective randomised controlled multi-centre clinical trial. Int Wound J. 2022. doi.org/10.1111/iwj.13715.