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Introduction

Chronic lower extremity wounds contribute to >\$25 billion in annual US healthcare costs while significantly increasing risk of infection, amputation, morbidity and mortality for millions of patients¹⁻³. Such clinical and economic burden underscores the critical need for improved diagnostic and treatment modalities. This study aimed to evaluate the performance of a **self-assembling peptide biomimetic matrix (BMM)** – designed to support healing via an extracellular matrix-like scaffold for tissue regrowth and antibacterial protection – in chronic lower extremity wounds.

Methods

Patients (n=27) were selected based on severity of comorbidities, wound age (>4 weeks), and failure to respond to previous wound management interventions. Common comorbidities included diabetes, obesity, neuropathy, arterial/vascular diseases, lymphedema, autoimmune disorders, low mobility/difficulty walking, and prior surgeries, including amputations.

A total of thirty (30) chronic lower extremity wounds – including diabetic foot ulcers (DFU), pressure ulcers (PU), venous leg ulcers (VLU), and other non-healing wounds – received the FDA-approved peptide-based BMM* after appropriate wound bed preparation. Out of the 30 wounds, 8 (26.7%) were complicated by exposed tendon/bone or tunneling. Previous failed treatments included SOC, angioplasty/revascularization procedures, advanced skin substitutes, collagen-based matrices, enzymatic debridement, and antimicrobial/antibiofilm products. In a subset of cases (fifteen, 50%), multispectral NIRS, infrared (IR) thermal, and digital imaging were captured using a handheld mobile device**. Wound characteristics and tissue oxygen saturation (StO₂) were assessed at baseline and monitored during the following visits.

Table 1. Patient Demographics and Baseline Wound Characteristics

Characteristics	Values
Subjects	
Total Patients (N); Male/Female (%)	27 (51.9% M / 48.1% F)
Total Wounds (N)	30
Age	
Mean ± SD (years)	69 ± 12
Range (years)	28–97
Wound Duration	
Mean ± SD (weeks)	12 ± 7
Range (weeks)	4–39
Wound Etiology	
Venus Leg Ulcer (VLU), n (%)	14 (46.7%)
Diabetic Foot Ulcer (DFU), n (%)	6 (20.0%)
Pressure Ulcer (PU), n (%)	3 (10.0%)
Other lower extremity wounds (radiation wounds, tunnel wounds, and surgical dehiscence wounds), n (%)	7 (23.3%)

Results

All patients responded positively to BMM treatment, showing **rapid wound healing progression**. Healthy granulation tissue formation was observed after a single application. Wounds involving exposed tendon / bone or tunnels achieved **coverage of the originally exposed structures and tunneling resolution**. **Complete closure was achieved within the study period in 22 cases (73.3%), as early as 2 weeks**. The median time to complete wound closure was 6 weeks and 5 BMM applications.

Key Outcomes

- ❖ **Complete Wound Closure Rate: 73.3% (22/30 wounds fully closed)**
- ❖ **Median Time to Complete Closure: 6 weeks**
- ❖ **Median BMM Applications to Closure: 5 applications**
- ❖ **Product-Related Adverse Events: 0**

Figure 1. Representative images of wounds before and after BMM

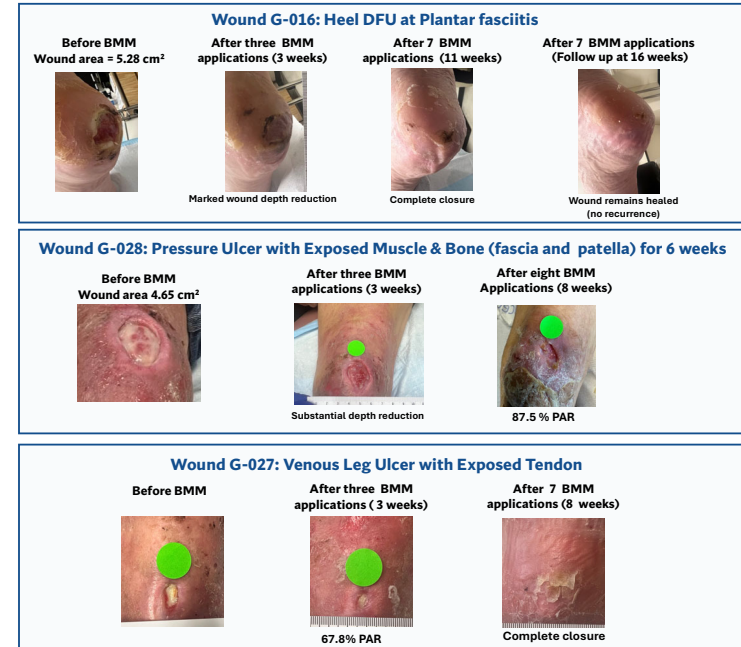
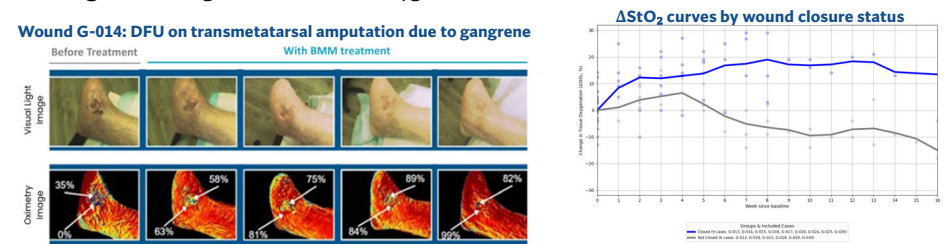


Figure 2. Change in wound tissue oxygenation (ΔStO₂, %) after BMM treatment



In most cases monitored by NIRS, a **rapid and clinically meaningful⁴ increase in tissue oxygenation (ΔStO₂ >11%) was observed after 1-2 BMM applications**. The increase in StO₂ predicted healing, suggesting rapid healthy tissue regrowth and revascularization that resulted in re-epithelialization over time.

Conclusions

This study highlights the safety and efficacy of BMM in treating chronic, refractory lower extremity wounds by fostering an environment that promotes rapid tissue regrowth and revascularization. NIRS imaging provided an objective, non-invasive measure of oxygenation, helpful in predicting ulcer healing trajectory and response to treatment.



References: 1. Nussbaum, S. R. et al. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health 21, 27–32 (2018). 2. Ebot, J. Managing Complex Wounds in Skilled Nursing Facilities (SNFs). Cureus 15, e47581 (2023). 3. Sen CK. Human Wound and Its Burden: Updated 2025 Compendium of Estimates. Adv Wound Care (New Rochelle). 2025 Sep;14(9):429–438. PMID: 40660772. 4. Oropallo A et al. Advancing chronic wound care with near-infrared spectroscopy imaging: clinical applications, measurement parameters, and insights into healing dynamics. Wounds. 2025 Oct;37(10):384–392. PMID: 41270199.

*BMM, G4Derm® Plus, Gel4Med Inc. / ** Mimoso Pro, Mimoso Diagnostics