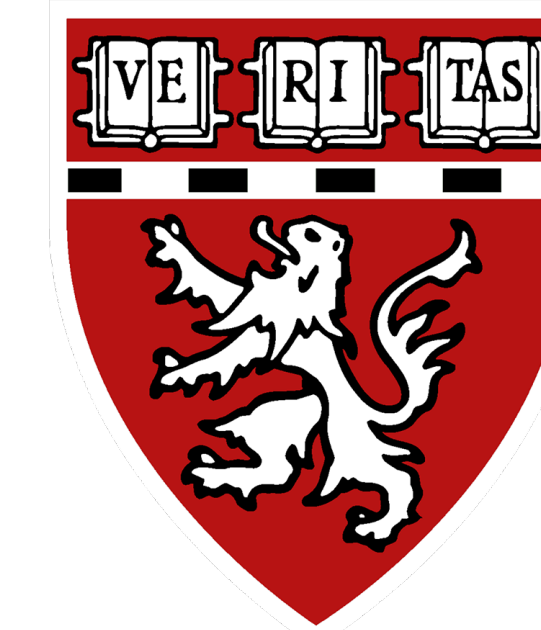


Safety and Efficacy of a Peptide Biomimetic Matrix in Refractory Lower Extremity Wounds



Sara Rose-Sauld¹, Jennifer Skolnik¹, Adam Landsman¹

¹Massachusetts General Hospital Boston, Harvard Medical School, MA, United States



Introduction

Difficult-to-treat lower extremity wounds continue to present a significant clinical and economic burden and remain an important unmet medical need. The purpose of this study was to evaluate the clinical performance of a novel biomimetic matrix (BMM*) in refractory lower extremity wounds. BMM is a **novel, synthetic self-assembling peptide-based Biomimetic Matrix (BMM)** designed to (i) provide antibacterial protection and (ii) support tissue regrowth via a 3D scaffold that resembles the human skin extracellular matrix.

Methods

Twenty subjects were enrolled based on wound chronicity and lack of response to previous treatments, including advanced biological matrices and living cells. Patient comorbidities included diabetes, peripheral vascular disease, neuropathy, Charcot foot, osteomyelitis/infection, history of prior ulcerations, and prior amputations. Twenty difficult-to-treat lower extremity wounds, including diabetic foot ulcers and other non-healing ulcers, received the FDA-approved BMM*. BMM was applied after appropriate wound bed preparation, including debridement, following the manufacturer's instructions. Wound characteristics were assessed at baseline and monitored at subsequent follow-up visits.

Table 1. Patient Demographics and Baseline Wound Characteristics

Characteristics	Values
Total Patients	20
Age	
Mean ± SD (years)	62.8 ± 13.8
Range (years)	37–89
Sex	
Male, n (%)	13 (65%)
Female, n (%)	7 (35%)
Wound Duration	
Mean ± SD (months)	5.9 ± 4.7
Range (months)	1–15 months
Wound Etiology	
Diabetic Foot Ulcer (DFU), n (%)	15 (75%)
Other (Unknown ulcer, Skin Ulcer with undermining and Tunneling), n (%)	5 (25%)
Wagner Grade (DFU only, n = 15)	
Wagner 1, n (%)	9 (60%)
Wagner 2, n (%)	3 (20%)
Wagner 3, n (%)	3 (20%)

Results

Subjects received 1-5 total BMM applications. Despite the failure of previous interventions, in all cases a rapid response towards healing was noted with BMM treatment. A reduction in inflammation followed by formation of healthy granulation tissue was observed as early one week after BMM application. This was followed by maturation of the granulation tissue and progressive re-epithelialization over time. A substantial **depth reduction was observed after a single application**. Wounds presenting with **exposed tendon / bone or tunnels achieved coverage of the originally exposed structures and complete resolution of tunneling**. Within the study period, **complete re-epithelialization was achieved in 17 cases (85%), with 15 ulcers (75%) fully closed by week 12**. The **median time to complete wound closure was 9 weeks [2 BMM applications]**, with some ulcers healing as early as 2 weeks after a single application. Noticeable improvement in odor, drainage, and peri-wound skin integrity was also recorded. No re-infection or adverse events were observed.

Figure 1. Representative images of wounds before and after BMM treatment.

Patient 17: Wagner grade 1 DFU at the midfoot

Before BMM

2 weeks after BMM (single application)

- ✓ 95 percentage area reduction (PAR) within 2 weeks after a single BMM application.
- ✓ Complete wound closure at 4 weeks with 2 BMM applications

Patient 18: Wagner grade 2 DFU at Plantar 3rd intermetatarsal space After Incision and Drainage, probing to tendon

Before BMM

10 weeks after BMM (total 4 applications)

- ✓ 50.2 PAR in 3 weeks after three BMM applications
- ✓ Rapid coverage of exposed tendon
- ✓ Complete closure after 4 BMM applications (week 10)

Patient 9: Wagner grade 3 DFU with exposed flexor tendon/bone

Before BMM

15 weeks (total 4 applications)

- ✓ 93.3 PAR in 8 weeks after a three BMM applications.
- ✓ Rapid coverage of exposed structures
- ✓ Full closure after 4 applications (15 weeks)
- ✓ No signs of infection

Patient 20: Wagner grade 2 DFU at Midfoot foot in a 51-year-old male with diabetes

Before BMM

7 weeks after BMM (single application)

- ✓ 92 PAR in 7 weeks after one BMM application
- ✓ Complete wound closure in 10 weeks with 1 BMM application

Main Outcomes

- ✓ **Complete Wound Closure at 12 weeks** (n, %): **15/20 (75%)**
- ✓ **Time to Complete Closure** (median): **9 weeks**
- ✓ **BMM Applications to Complete Closure** (n): **2 application**
- ✓ **Product-related Adverse Events** (n): **0**

Conclusions

BMM resulted in a rapid healing response of refractory ulcers with early formation of granulation tissue that resulted in re-epithelialization with accelerated wound closure rates. This study demonstrates the safety and efficacy of BMM in treating difficult-to-treat lower extremity wounds by supporting tissue regrowth and re-infection prevention.

References

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*G4Derm® Plus, Gel4Med Inc.

