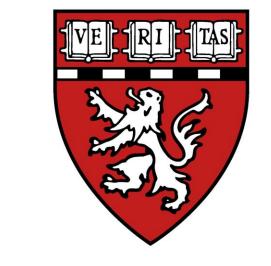
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Clinical Applications of a Novel Biomimetic Matrix in Refractory Diabetic Foot Ulcers (DFUs): A Case Series Analysis



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Introduction

Chronic wounds represent a significant challenge in clinical practice, particularly when both traditional and advanced therapies fail to promote healing¹. **Biomimetic Matrix (BMM)** is a novel, fully synthetic peptide matrix designed to support chronic wound healing by providing a scaffold that resembles the native extracellular matrix (ECM) and offers antibacterial protection.

This case series explores the potential clinical applications of BMM in eight patients with chronic diabetic foot ulcers (DFUs) that failed to respond to standard of care and/or previous treatments with advanced biologics.

Methods

Eight diabetic patients with multiple comorbidities presenting chronic DFUs [Wagner Grade 3 (n=2; 25%), Grade 2 (n=3; 37.5%), and Grade 1 (n=3; 37.5%)] that failed to respond to SOC/advanced therapies (**Table 1.**) were treated with the **FDA-approved BMM (G4Derm Plus, Gel4Med Inc.).**

Table 1. Patients' characteristics at the enrollment, including prior treatments, wound duration, wound location, wound depth, and comorbidities.

	Age	Prior Treatments	Wound Duration (months)	Wound Location	Wagner Classification	Comorbidities
Patient 1	37	A, C, E, HA, LC, O, S, SX, V	39	Heel	2	D, N, OS
Patient 2	37	A, C, HA, LC, O, S, VS	30	Forefoot	1	D, N, OS, PVD
Patient 3	67	E, HA, O	8	Heel	2	D, N
Patient 4	58	A, C, E, HA, LC, LCA, O, S, SX, V	56	Forefoot	1	A, D, N, O, OS
Patient 5	88	C, E, HA, LC, LCA, S, V	3	Ankle	3	D, N, OS, PVD
Patient 6	69	O, S	15	Lateral Foot	1	C, D, N, PVD
Patient 7	70	A, C, E, HA, LC, LCA, O, S	8	Heel	3	D, N, O
Patient 8	84	C, HA, LCA, O, S	13	Mid-arch	2	C, D, N

Prior Treatments: A=Amniotic membrane, C=Collagen-Decellularized, E=Enzymatic Debridement, H=Hyperbaric oxygen, HA=Hypochlorous Acid irrigation, LC=Living cell, LCA=Living cell amniotic, O=Off-loading shoe or boot, S=Silver dressing, SX=Surgery, V=Negative pressure wound therapy, VS=Vascular Surgery. **Comorbidities:** A=Partial Amputation, C=Charcot deformity, D=Diabetes, N=Neuropathy, O=Obesity, OS=Osteomyelitis, PVD=Peripheral Vascular Disease

Results

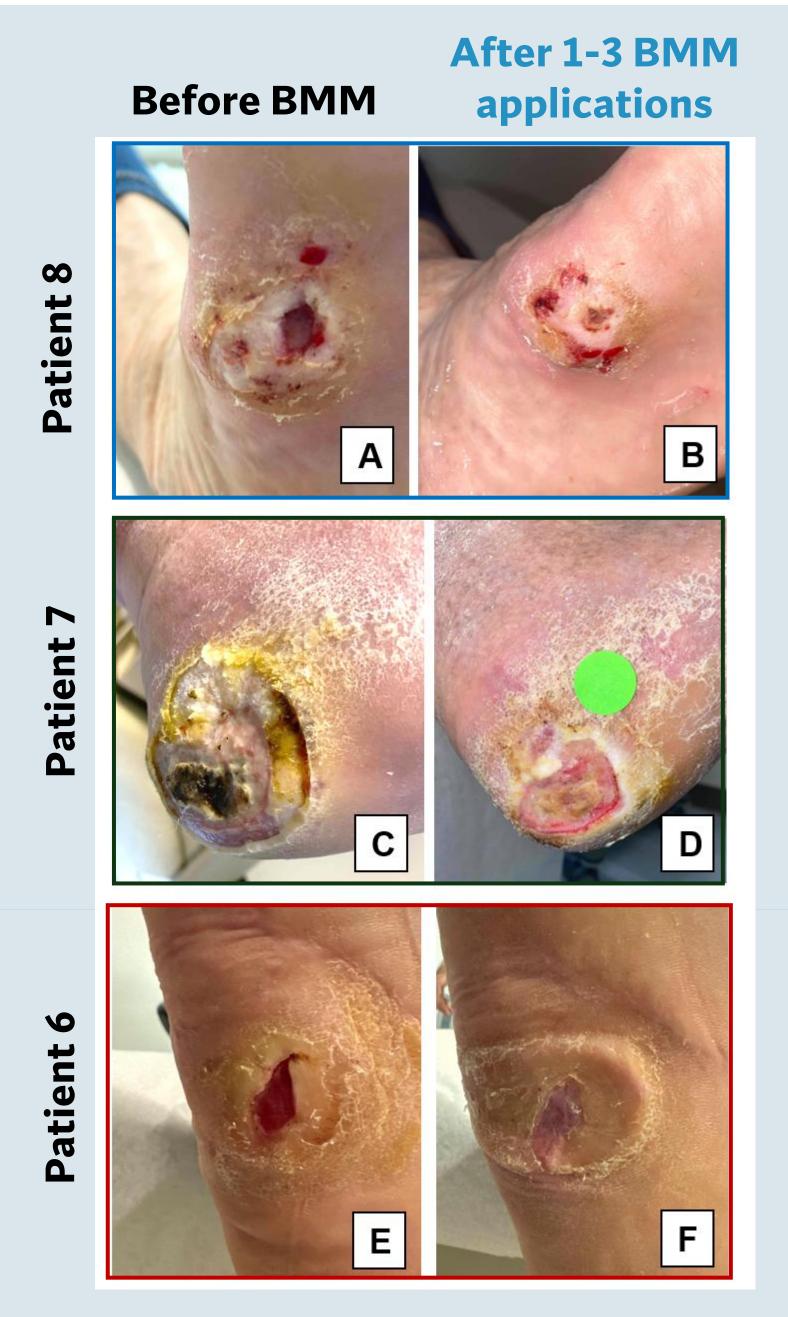
All wounds treated with BMM achieved a substantial percent area reduction (PAR). A mean PAR of 63.6% was achieved in wounds measuring 7.5 cm² on average after six weeks of treatment with one to three BMM applications (Table 2). The treatment length ranged from 5 to 11 weeks, with one patient achieving full wound closure at six weeks following a single application of BMM.

Rapid granulation tissue formation was noted with most wounds showing a noticeable reduction in depth after one or two BMM applications (**Figure 1**). **Odor, drainage, and inflammation were also noticeably improved.** No adverse events were observed.

Table 2. Number of applications, treatment duration, initial and final wound size, and percentages of change in the wound area of patients treated with BMM.

	BMM applications	Follow-up (weeks)	Initial wound size (cm²)	Final wound size (cm²)	Change in wound area (%)
Patient 1	2	7	2.72	2.12	-22.1%
Patient 2	1	6	1.20	0.12	-91.7%
Patient 3	3	5	0.44	0.08	-83.3%
Patient 4	2	5	3.00	1.90	-36.7%
Patient 5	1	11	40.5	18.2	-55.1%
Patient 6	1	6	1.50	0.00	-100.0%
Patient 7	3	5	9.80	5.77	-41.1%
Patient 8	2	6	1.04	0.21	-79.1%
Average	1.875	6.4	7.525	3.55	-63.6%
SD	±0.835	±2.0	±13.652	±6.2322	±28.7%

Figure 1. Representative images of DFUs before and after treatment with BMM. Charcot midfoot ulceration (**Patient 8**) at presentation (**A**) and after 6 weeks with 2 applications of BMM (**B**). Heel ulcer (**Patient 7**) at presentation (**C**) and 5 weeks later, after 3 treatments with BMM (**D**). Midfoot ulcer beneath the 5th metatarsal base (**Patient 6**) at presentation (**E**) and 6 weeks after 1 treatment with BMM (**F**).



Discussion

In this case series, we explored the potential of using BMM based on a novel synthetic peptide technology. Our results show that BMM treatment rapidly induced granulation tissue, substantially reduced the wound area, and improved overall appearance of stalled diabetic lower extremity wounds.

References:

1. Darwin E, Tomic-Canic M. Healing Chronic Wounds: Current Challenges and Potential Solutions. Curr Dermatol Rep. 2018 Dec;7(4):296-302.