Peptide Biomimetic Matrix Rescues High-Risk Diabetic Foot Ulcers from Amputation

Manooj Prasad, DPM[1]
Affiliation: [1]RWJ Barnabas Health, Garden State Foot & Ankle, New Jersey, USA

Introduction

As the leading cause of non-traumatic lower extremity amputations, diabetic foot ulcers (DFUs) have an associated 5-year mortality rate of 50-70%. DFUs are also highly prone to infection, which significantly increases morbidity and raises the rate of lower extremity amputations up to 90%.

This case series evaluates the performance of a novel, **self-assembling peptide-based biomimetic matrix* (BMM*)** in complex Wagner 2-4 DFUs. BMM is deployed in a prefilled syringe with an optional applicator tip for access to hard-to-reach areas. The peptide self-assembles into a 3D scaffold that resembles the extracellular matrix of the native dermis to support tissue regrowth while serving as a barrier to protect against bacteria.

Methods

Three patients with multiple serious comorbidities (including cerebral vascular accident, coronary artery disease, deep venous thrombosis, Charcot deformity, history of amputation, infection/gangrene) presenting with **complex, hard-to-heal diabetic foot ulcers** (4 wounds total), at **risk for below-the-knee amputation**, were selected to receive BMM. All wounds were extensive and full-thickness, involving exposed structures / infection / gangrene (Wagner 2-4).

Wounds were extensively debrided to remove devitalized tissue (including biofilm, exudate, necrotic tissue, fibrin, and slough) prior to BMM application, following the manufacturer's instructions. Wound characteristics were assessed at baseline and during follow-up visits.

Table 1. *Patient medical history and wound characteristics*

Patient#-Wound#	Medical History	Wound type & complexity	Wound location	Wound age	Previous interventions
1-01	Diabetes, cerebral vascular accident, and Difficulty Walking. History of Coronary Stent Replacement	DFU Wagner Grade 3 with Exposed Bone, Deep Undermining & Underlying Osteomyelitis	Right plantar heel	unknown	unknown
2-01	Diabetes, Peripheral Artery Disease, Deep Venous Thrombosis. Hx of Gangrene Right 5th Toe, Multiple Diabetic Foot Ulcers, Psoriasis, MSSA Infection. Surgical Hx of Lower Extremity Revascularization, Angioplasty, Toe Amputations, Vein Ablation Left leg.	DFU Wagner Grade 4 post-amputation complication	Right foot, 5th toe and 5th metatarsal resection site	4 months	Amniotic graft
2-02	Diabetes, Peripheral Artery Disease, Deep Venous Thrombosis. Hx of Gangrene Right 5th Toe, Multiple Diabetic Foot Ulcers, Psoriasis, MSSA Infection. Surgical Hx of Lower Extremity Revascularization, Angioplasty, Toe Amputations, Vein Ablation Left leg.	DFU Wagner Grade 2	Left plantar foot	0 weeks (newly developed ulcer)	No previous treatment
3-01	Diabetes Mellitus, Peripheral Artery Disease, Anemia, Chronic Renal Failure, End-Stage Renal Disease, Osteomyelitis (Right Heel), Diabetic Neuropathy. Multiple toe amputations, History of Gangrene and Ray Resection, Partial Calcanectomy of Right Heel, below-knee amputation (left).	DFU Wagner Grade 3 with Charcot Foot Deformity high risk of BKA right leg	Right plantar heel	2.5 years	Hyperbaric oxygen therapy, revascularized

Results

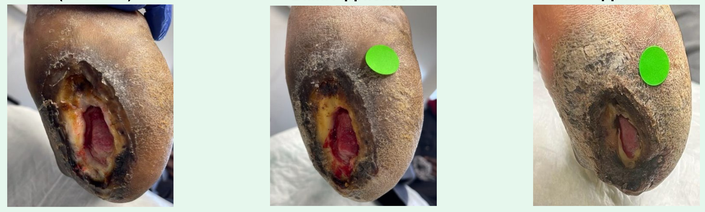
All patients tolerated BMM applications well and responded positively to the treatment. Despite the failure of previous interventions and risk for below-the-knee amputation, all cases showed **rapid wound healing progression** with **coverage of originally exposed structures**.

Complete coverage was observed in 3/4 wounds, and 1 wound achieved partial coverage. In all cases, a **substantial reduction in wound depth** was observed with **the formation of healthy granulation tissue after a single BMM application. Percent area reduction (PAR) greater than 50% was achieved by 2 weeks**, with complete closure confirmed in 2 cases within 14 weeks. An improvement in exudate and in peri-wound skin appearance was also noted. No product-related adverse events were observed.

Figure 1. *Representative images of wounds before and after BMM treatments*

Wound 1-01: DFU Wagner Grade 3 with Exposed Bone and Deep Undermining

Before BMM (Baseline) | 1 week after one BMM Application | 7 weeks after four BMM Applications



- ✓ Drastic reduction in depth and undermining after a single BMM application
- ✓ 57% wound area reduction after two BMM applications (2 weeks)
- ✓ Complete coverage of the exposed bone; partial coverage of exposed tissues

Wound 2-01: Deep DFU with Post-Amputation Complication

Before BMM (Baseline) | 1 week after one BMM Application | Follow-up visit after 14 weeks

- ✓ Rapid and substantial depth and area reduction after the first BMM application
- ✓ Complete wound closure by 14 weeks
- ✓ Improvement in peri-wound skin appearance

Wound 2-02: DFU Wagner Grade 2

Before BMM (Baseline) | 2 weeks after two BMM applications | 3 weeks after three BMM applications

- ✓ Rapid wound depth reduction & robust healthy granulation tissue
- ✓ 53% wound area reduction by 2 weeks
- ✓ Improvement in peri-wound skin appearance

Conclusions

This small case series suggests BMM as an advanced treatment modality for the management of complex, high-risk diabetic foot ulcers. BMM was easy to apply and conformed to the wounds, resulting in rapid tissue regrowth over the exposed structures, substantial PAR, and overall wound improvement, lowering the risk of limb loss. Larger clinical studies are required to confirm these findings.

References:

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McDermott K, Fang M, Boulton AJM, Selvin E, Hicks CW. Etiology, Epidemiology, and Disparities in the Burden of Diabetic Foot Ulcers. Diabetes Care. 2023 Jan 1;46(1):209-221. PMID: 36548709; PMCID: PMC9797649.

BMM**: **G4Derm® Plus, Gel4Med Inc.

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