

# Stimulation of Perfusion and Healing Using Microvascular Tissue in a Series of Refractory Complex Diabetic Wound Cases



Jonathan Arnold, MD, CWS-P, ABPM-UHM <sup>1</sup>

<sup>1</sup>Medical Director, The Healing Center at Mercy Medical Center, Cedar Rapids, IA

## Background

The microvasculature serves as the foundation for granulation and remodeling during wound healing. Repair of damaged microvascular structure and restoration of adequate blood flow to provide oxygen and nutrients to the site is essential to promote healing and then minimize tissue breakdown in a newly epithelialized wound. Advanced age, diabetes, and radiation are among the reasons the healing process can be further compromised, leading to poor tissue quality and lack of healing.

Processed MicroVascular Tissue (PMVT\*) is a sterile, off-the-shelf human structural microvascular tissue allograft consisting of microvessel extracellular matrix intended to repair deficient microvascular tissue, improve blood flow, and support the healing of full-thickness wounds. PMVT is packaged as a 19.5mm lyophilized disk in a sealed glass vial for single-patient use, and can be topically applied in a dry form to the surface of the wound or injected locally after reconstitution with USP sterile water at the edges of the wound.



## Methods

Here we report on real-world clinical experiences with PMVT in three challenging nonhealing wounds. All patients received weekly or semi-weekly topical PMVT treatment until wound sites demonstrated active healing with evidence of good micro-circulation and progressing re-epithelialization. In all cases, PMVT was covered with a nonadherent dressing and left untouched between visits. Patients were directed not to change the wound dressing, to comply with standard care guidance appropriate for each of their wounds, and to return weekly for assessment of the wound and (if needed) reapplication of the PMVT product. Wound size was measured using a ruler at each visit. Closure criteria were 100% epithelialization with no maceration, exudate, or signs of infection.

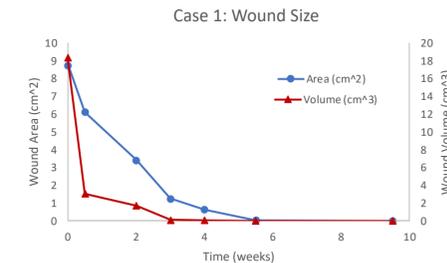
\*mVASC®, MicroVascular Tissues, Inc.

ML-1060-02 Rev. 1, Mar. 2023

## Clinical Cases

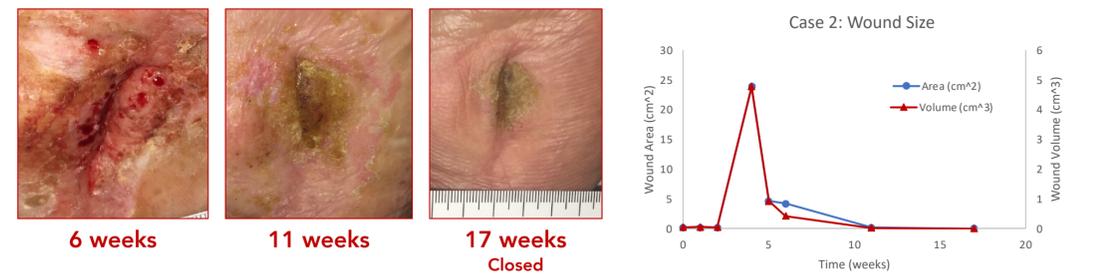
### Case 1: 57 y/o M, Metatarsal DFU:

The patient, a 57-year-old male with poorly controlled Type 2 Diabetes who had a prior right foot transmetatarsal amputation, presented with a DFU on his 5<sup>th</sup> metatarsal at the TMA site. Following 6 months of unsuccessful treatment with standard dressings, collagen, offloading, hyperbaric oxygen, and IV antibiotics, he presented with a refractory wound 7 cm<sup>2</sup> in area and 2 cm deep, with exposed bone and chronic osteomyelitis. He was treated with weekly applications of topical PMVT along with additional IV antibiotics. After just one treatment of PMVT, over 80% of the wound volume had been filled in with new tissue. After 6 applications, the restored vascularity of the healing tissue was clinically evident, and PMVT treatment discontinued. The ulcer went on to fully close in 4 additional weeks with standard care, and has remained healed 9 months following closure.



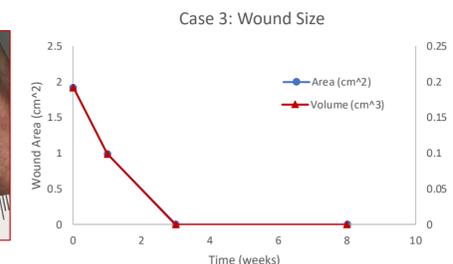
### Case 2: 65 y/o M, Charcot DFU:

The patient is a 65-year-old male who presented with a poorly granulated 1cm<sup>2</sup> left plantar Charcot DFU. The wound had been open for more than one year despite standard care including serial debridement, NPWT, and total contact casting. The lesion extended 0.4cm deep to devitalized bone, and the patient was being treated concurrently for chronic osteomyelitis upon presentation and initiation of PMVT treatment. Between 2 and 4 weeks, offloading noncompliance led to re-emergence of infection, requiring significant debridement and initiation of antibiotics. Following this, the wound area was now 24 cm<sup>2</sup>. Despite this setback, after 3 additional PMVT applications, the wound had become 99% epithelialized, and PMVT treatment discontinued. The ulcer went on to fully close in 6 additional weeks with standard care, and has remained healed 6 months to date following closure.



### Case 3: 76 y/o M, Mohs Defect:

Patient 3, a 76-year-old hypertensive male with Type 2 Diabetes and peripheral vascular disease, presented with a 2cm<sup>2</sup> area Mohs defect on his left hand that had been open for more than 4 weeks. A single topical application of one PMVT disk was made, and covered with a nonadherent dressing. The defect was nearly 50% closed in one week, and by 3 weeks after the PMVT treatment the wound was fully healed. 6 months after closure, the wound has remained closed.



## Discussion

Reversing the stalled wound pattern, restoring blood flow, and changing the trajectory of healing towards wound resolution have been previously reported as hallmarks of PMVT treatment.<sup>1-3</sup> PMVT has previously demonstrated increased healing and wound perfusion in a 100-subject randomized controlled trial on chronic neuropathic Wagner 1 and 2 DFUs.<sup>4</sup> PMVT's microvascular extracellular matrix composition drives host cell attachment and supports angiogenesis, important modes of action in the treatment of wounds with deficient microvascular tissue.

## Conclusions

Improvement of perfusion in these three refractory wounds are indicative of PMVT's ability to support the repair and reconstruction of microvascular tissue, which in turn drove complete wound healing.

### References:

- 1) Arnold JF, et al. SAWC Fall 2021.
- 2) Dobke M, et al. SAWC Spring 2019, CS-018.
- 3) Dobke M, et al. Regen Med. 2020;15(2):1313-28.
- 4) Gould LJ, et al. Int Wound J. 2022;19(4):811-25.

PMVT is marketed in accordance with FDA HCT/P regulations, and is restricted to homologous use for supporting the repair of damaged microvascular tissues.