

# Medical Food Doubles the Healing Rate for Diabetic Foot Ulcer: A Case Series

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## Introduction

- Approximately 38 million individuals in the United States have diabetes; of these, 19–34% will develop diabetic foot ulcers (DFUs), and 65% will experience recurrence within 5 years (1), thus creating a \$28 billion economic burden for treating DFUs annually (2).
- Prompt healing of diabetic foot ulcers (DFUs) is critical to reducing morbidity and mortality (1).
- Adjunctive therapies are increasingly evaluated for their potential to accelerate healing compared to literature referenced 12-week healing time (3).
- One such approach involves prescription-only medical food product composed of bioactive pyridoxal 5'-phosphate (P5P; 35 mg), L-methylfolate (LMF; 3 mg), and methylcobalamin (MC; 2 mg) (4) that previously clinically demonstrated to repair endovascular and neurovascular layers by stimulating nitric oxide production for vasodilation, to prevent glycation end products from damaging neurovascular structures, and to

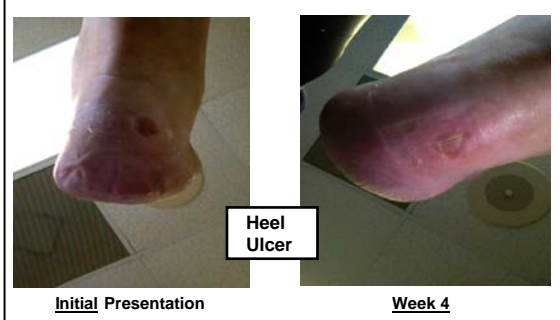
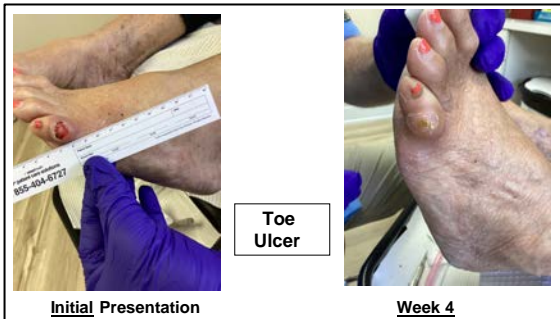
## Study Objectives

- To assess the efficacy and healing speed of the medical food product composed of L-methylfolate calcium 3 mg, methylcobalamin 2 mg, and pyridoxal-5'-phosphate 35mg (LMF-MC-P5P) as adjunctive therapy in managing DFUs (4).
- The primary endpoint was to assess the speed of healing of DFUs in patients who were on SOC with an adjunctive medical food product compared to the literature referenced 12-week healing rate.
- Secondary endpoints included evaluation of patients' skin appearance, natural hydration and oil production, and proprioception of their lower extremities.

## References

1) 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. 2) Nancy Collins, PhD, RDN, LD, NWCC, FAND Medicare Spending on Wound Care: The First Comprehensive study WCEI.Net October 2017. 3) Sheehan P, Jones P, Caselli A, Giurini JM, Veves A. Percent change in wound area of diabetic foot ulcers over a 4-week period is a robust predictor of complete healing in a 12-week prospective trial. *Diabetes Care*. 2003 Jun;26(6):1879-82. 4) METANX. Package insert. Shreveport, LA: AlfaisigmaUSA, Inc.; 2024

## Results



- All patients received the same SOC plus the prescribed medical food formulation.
- All five patients achieved complete wound closure within 6 weeks.
  - Three ulcers healed by week 4, and the remaining two by week 6.
  - These healing times contrast with the previously recommended 12-week closure period for similar DFUs managed with SOC alone (3).
  - This represents a 50–60% reduction in healing time.
- All patients report improvement in their neuropathic symptoms and proprioception to their lower extremities.
- Skin was no longer xerotic and fissured and patients had improvement in natural hydration and oil production
- Notably, no patients experienced re-ulceration over a follow-up period ranging from 6 to 20 months.
- No adverse events were reported.

## Conclusions

- This was a small retrospective cohort case study
- The addition of a prescription medical food containing pyridoxal 5'-phosphate (35 mg), L-methylfolate (3 mg), and methylcobalamin (2 mg) (4) was associated with accelerated DFU healing when combined with SOC.
- The observed faster healing times, 4-6 weeks vs. literature referenced 12 weeks reduces the risk of infection, potential for osteomyelitis, and possible amputation.
- Re-ulceration was not evident up to 20 months during follow ups suggesting sustained efficacy.
- Additional analyses and a larger patient cohort would be needed to

## Methods

- A retrospective chart review was conducted on five patients with Wagner grade 2 diabetic foot ulcers measuring  $\geq 1$  cm in diameter.
- Patient's 5<sup>th</sup> toe ulcer from pressure in an 80 y/o female c type 2 DM and DPN. 77 y/o female type 2 DM c DPN sustained ulcer to the posterior heel from shoe gear and pressure.
- All patients received SOC: the wounds were debrided, decolonized, maintained for moisture balance and offloaded.
- Patients were evaluated weekly, underwent serial debridement as needed, and received localized wound care.
- Each patient was also prescribed the aforementioned medical food formulation for the treatment of diabetic peripheral neuropathy.