Management of Chronic Wounds using Combination Therapy Combined with Standard of Care: Outcomes of 4 Trial Participants with Diabetic Foot Ulcers

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Introduction

- Individuals who develop chronic wounds often have a comorbid condition (eg, diabetes or hypertension) that affects innate healing[1]
- An individual with diabetes has a 19-34% lifetime risk of developing a diabetic foot ulcer (DFU), which has a negative impact of their quality of life[2]
- Chronic DFUs are susceptible to infection, which increases risk of amputation[1,2]
- A novel, proprietary combination therapy (Omeza LLC, Sarasota, FL) has been developed in accordance with the clinical perspective that effective wound care should mimic the effects of wound healing in a healthy body
- The combination therapy is composed of:
  - A wound therapy formulation (OCM™), a drug/device that contains peptides, omega fatty acids, and anabolic metabolites that support synthesis of new tissue
  - A wound preparation formulation
  - A skin protectant formulation
- A real-world evidentiary study assessing efficacy and safety of the combination therapy in patients with chronic wounds of multiple etiologies, including DFUs, is currently being conducted (NCT05921292)
- Here, we present outcomes of 4 patients with chronic DFUs who participated in this study

Objective

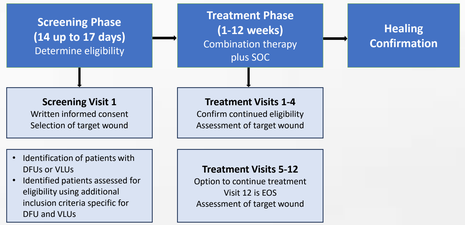
- A primary objective of the study was to evaluate the potential effectiveness of the combination therapy in the management of any type of chronic wound

Methods

Study Design

- The ongoing study is being conducted in 3 phases: screening, treatment, and healing confirmation (**Figure 1**)
- During the treatment phase, patients' chronic wounds were managed with combination therapy in conjunction with standard of care (SOC)
  - SOC included debridement, off-loading, and necessary or approved medications other than those applied to the surface of the ulcer
- At the end of 4 weeks of treatment visits, patients whose wounds were not healed had the option of continuing therapy for up to 8 additional weeks

Figure 1. Design of clinical trial.



Abbreviations: EOS, end of study; DFU, diabetic foot ulcer; SOC, standard of care; VLU, venous leg ulcer.

- Adult (≥21-year-old) patients with any type of chronic wound/ulcer from 2 cm^2 to 100 cm^2 in size were eligible for enrollment
  - Target wounds with clinical signs and symptoms of infection were excluded
- Patients with DFUs were required to have a diagnosis of Type 1 or Type 2 diabetes and a DFU of Wagner grade 1 or 2
- Key endpoints were to evaluate percent area reduction (PAR) in ulcer size at week 4 and time to complete wound closure

Results

Case Series

- The four patients included in this case series were adults with Type 2 diabetes and DFUs of Wagner grade 1 who participated in the clinical trial
- The patients' DFUs were managed with combination therapy and SOC from the first treatment visit (TV) until complete closure of their wound or end of study
- No adverse events related to treatment were reported for the patients included in this case series

Patient 1

- A 52-year-old male patient with a history of hypertension and an HgbA1c of 9.6 presented with a right plantar forefoot DFU of 3–6-month duration that measured 2.75 cm × 2.31 cm (**Figure 2A**)
- Previous treatment was silver alginate and SOC
- The patient reported neuropathic pain in his lower extremities
- At screening visit 1 (SV1), his DFU was managed with sharp debridement
- His wound steadily improved and, at TV5, had decreased in size to 1.26 cm × 1.05 cm × 0.1 cm
- At this time, he received combination therapy, foam, and compression to manage his DFU
- At TV6, the patient's DFU was determined to be healed (**Figure 2B**)

Figure 2. Patient 1: DFU that healed after combination therapy and SOC.

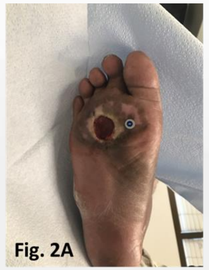


Fig. 2A

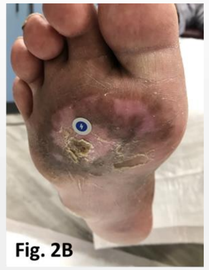


Fig. 2B

Patient 2

- A 47-year-old male patient with a history of hypertension and an HgbA1c of 8.6 (noncompliant with diabetes treatment) presented with a left medial malleolus DFU of 1–3-month duration that measured 7.75 cm × 4.41 cm × 0.29 cm (**Figure 3A**)
- Previous treatment was SOC (offloading)
- At SV1, the patient received mechanical debridement, foam dressing, and compression therapy for his DFU
- At TV1, he received combination therapy, mechanical debridement, foam, and compression
- At TV5, the patient's DFU was improving and measured 6.83 cm × 3.37 cm × 0.2 cm
- In addition to combination therapy, he received mechanical debridement at TV6 and sharp debridement at TV8 for his DFU
- The patient's wound continued to improve, and at TV10, it measured 5.94 cm × 2.07 cm × 0.2 cm (**Figure 3B**)
- During the study, the patient was noncompliant with SOC offloading

Figure 3. Patient 2: DFU that continued to improve after combination therapy and SOC.

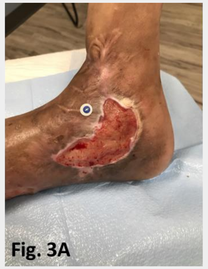


Fig. 3A

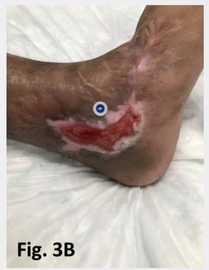


Fig. 3B

Patient 3

- A 67-year-old male patient with a history of atrial fibrillation and hypercholesterolemia and an HgbA1c of 7.1 presented with a left plantar first metatarsal phalangeal joint DFU that measured 1.31 cm × 1.27 cm × 1.59 cm (**Figure 4A**)
- Previous treatment was silver alginate
- At SV1, the patient received sharp debridement for his DFU
- From TV1-9, he received combination therapy and sharp debridement for his DFU
- At TV5, his DFU measured 1.24 cm × 1.33 cm
- The patient wore customized shoes and received a secondary foam dressing for his DFU
- At TV10-11, the patient received combination therapy for his DFU and sharp debridement of the periwound callus
- At TV12, his DFU was healed (**Figure 4B**)
- During the study, the patient was compliant with SOC offloading

Figure 4. Patient 3: DFU that healed after combination therapy and SOC.

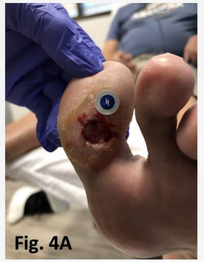


Fig. 4A

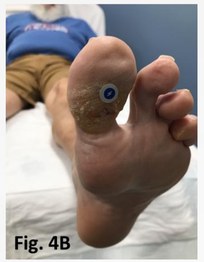


Fig. 4B

Patient 4

- A 53-year-old male patient with a history of hypertension and an HgbA1c of 8.5 presented with a right lateral midfoot DFU that measured 1.89 cm × 1.5 cm × 0.12 cm (**Figure 5A**)
- At SV1, the patient received sharp debridement for his DFU
- At TV1-3, he received combination therapy and sharp debridement of his DFU
- At TV5, the area of the wound had decreased from 1.84 cm^2 to 1.08 cm^2 and was improving, but the depth had increased from 0.17 cm to 0.39 cm (**Figure 5B**)
- After TV5, the patient was lost to the trial and received no further treatment

Figure 5. Patient 4: DFU that was improving after combination therapy and SOC (patient lost to trial).

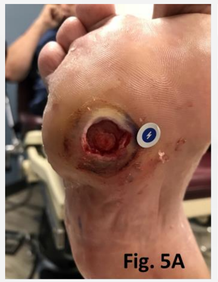


Fig. 5A

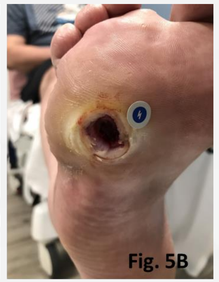


Fig. 5B

Conclusions

- Outcomes of these cases show that 2 of 3 DFUs that were managed with a novel combination therapy and SOC healed by the end of the treatment period; 1 patient was lost to the study
- All 4 patients had comorbid conditions that affect innate healing
- Final study results, which include patients with wounds/ulcers of multiple etiologies, are forthcoming
- Additional clinical trials evaluating the combination therapy for the treatment of DFUs (NCT05417425) and VLUs (NCT05291169) are underway
- Studies assessing the combination therapy in real-world settings are also underway
- Results from those studies will expand and enhance the current evidence supporting the use of the combination therapy in multiple types of chronic or refractory wounds

REFERENCES

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2. Edmonds M, et al. J Clin Orthop Trauma. 2021;17:88.

DISCLOSURES

YD: Research support, Omeza, LLC.
KR-P: Research support, Omeza, LLC.
NR-M: Research support, Omeza, LLC.
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NW: Research support, Omeza, LLC.
JA: Research support, Omeza, LLC.
DB, SJB: Employees, Omeza.

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