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

Introduction
- Individuals who develop chronic wounds often have a comorbid condition (eg, diabetes or hypertension) that affects wound healing.
- An individual with diabetes has a 19.3% lifetime risk of developing a diabetic foot ulcer (DFU), which has a negative impact on their quality of life.
- Chronic DFUs are susceptible to infection, which increases risk of amputation.
- 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 (OMC), 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 (NCT05131292).
- Here, we present outcomes of 4 patients with chronic DFUs who participated in this study.

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.

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.

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.

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
- An 87-year-old male patient with a history of hypertension and an HgbA1c of 6.8 presented with a left plantar first metatarsal phalangeal joint DFU that measured 1.31 cm × 1.27 cm × 0.12 cm (Figure 2A).
- Previous treatment was silver alginate.
- At TV1, the patient received mechanical debridement for his DFU.
- At TV2, the patient received combination therapy and sharp debridement for his DFU.
- At TV5, his DFU measured 0.24 cm × 0.33 cm.
- The patient was noncompliant with SOC.
- At TV10, the patient received combination therapy for his DFU and sharp debridement of the periwound callus.
- At TV11, his DFU was healed (Figure 4B).
- During the study, the patient was compliant with SOC offloading.

Patient 2
- A 7-year-old male patient with a history of hypertension and an HgbA1c of 8.6 (noncompliant with diabetes treatment) presented with a left medial malleolar DFU of 1–3 month duration that measured 1.75 cm × 0.41 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, the patient received combination therapy, mechanical debridement, foam dressings, and compression.
- At TV11, the patient's DFU was improving and measured 0.63 cm × 1.37 cm × 0.2 cm.
- In addition to combination therapy, he received mechanical debridement at TV1 and sharp debridement at TV1 for his DFU.
- The patient's wound continued to improve, and at TV10, it measured 0.58 cm × 0.27 cm × 0.2 cm (Figure 2B).
- During the study, the patient was noncompliant with SOC offloading.

Patient 3
- A 57-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 × 1.50 cm × 0.32 cm (Figure 5A).
- At SV1, the patient received sharp debridement for his DFU.
- At TV2, he received combination therapy and sharp debridement of his DFU.
- At TV5, the area of the wound decreased from 1.84 cm to 1.08 cm and was improving, but the depth increased from 0.32 cm to 0.37 cm.
- After TV5, the patient was lost to the trial and received no further treatment.

Patient 4
- A 57-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 × 1.50 cm × 0.32 cm (Figure 5A).
- At SV1, the patient received sharp debridement for his DFU.
- At TV2, he received combination therapy and sharp debridement of his DFU.
- At TV5, the area of the wound decreased from 1.84 cm to 1.08 cm and was improving, but the depth increased from 0.32 cm to 0.37 cm.
- After TV5, the patient was lost to the trial and received no further treatment.

DISCLOSURES
The study was sponsored by Omeza, LLC (Sarasota, FL). Medical editing and editorial assistance were provided by Scientific Information Services, LLC (Princeton, NJ, USA), and were funded by Omeza, LLC.

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REFERENCES

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