A case series to evaluate Omeza® products in combination therapy for the treatment of lower extremity ulcers of mixed etiologies exhibiting bacterial contamination as determined by a novel violet-light camera system and correlating biomarkers

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OMEZA®
COMPLETE WOUND CARE, DELIVERED SIMPLY

Introduction

Wound healing is optimized by utilizing therapies that control bacterial burden, decrease tissue inflammation, support the extracellular matrix and establish a balanced healing environment. The Omeza® products are formulated to combat the underlying pathophysiologies contributing to wound chronicity. All products contain an anhydrous formulation of Omega-3, 6 and 9 oils designed to deliver nutrients for balanced wound healing.

Objective

This pilot study evaluated the total wound area reduction in subjects treated with the Omeza products and tracked bacterial burden via fluorescence images and PCR cultures throughout the 12-week treatment period.

Methods

This is a single-site, open label, case series. 3 subjects >18 years and having open wounds of the lower extremity were enrolled. All subjects signed the informed consent and successfully completed the screening visit prior to entering the study. Fluorescence and standard wound photographs and measurement were obtained weekly via a fluorescence imaging device. PCR wound cultures were obtained per protocol. Wound debridement was performed per discretion of the investigator followed by application of Omeza products used in combination therapy plus SOC dressings. Patients were seen weekly throughout the course of the study.

Results

- This case series included one diabetic foot ulcer and two venous leg ulcers.
- The mean baseline wound age was 24 weeks with a mean baseline wound size of 8.61 cm2.
- The mean wound area reduction of all wounds combined was 82%.
- The two VLUs healed during the study period.
- The TWAR of the DFU was 53% at 6-weeks when the patient was lost to follow-up due to a geographic relocation.
- Fluorescence imaging showed clearance of pathologic levels of bacterial contamination over the course of the study for all subjects.

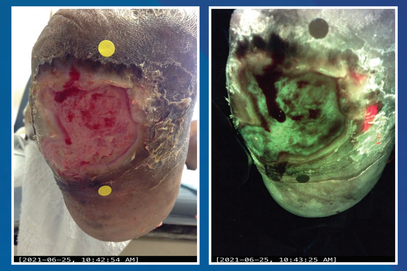
Protocol:

- **Apply Omeza Lidocaine Lavage to periwound, wait 5 minutes**
- **Perform appropriate sharp debridement as indicated**
- **Apply additional Omeza Lidocaine Lavage to periwound**
- **Apply Omeza Collagen Matrix**
- **Apply Omeza Skin Protectant to periwound**
- **Apply absorbent non-adhesive foam dressing**

Conclusion

The use of Omeza products in combination proved to be effective and safe. The wounds included in this study were stalled in the inflammatory stage with no signs of healing. The Omeza products supported wound healing and reduced bacterial loads in this patient cohort.

SUBJECT 1 VISIT 1
POST DEBRIDEMENT



SUBJECT 1 VISIT 6
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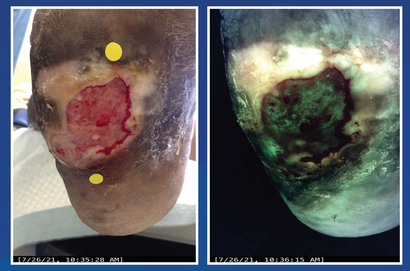

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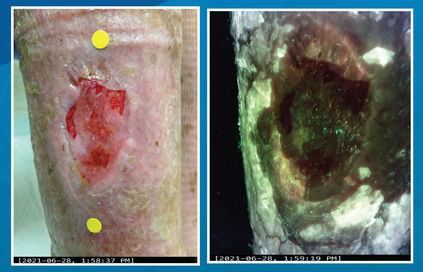

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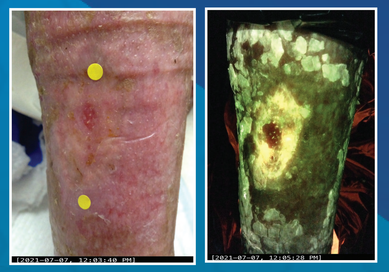

SUBJECT 2 VISIT 3
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SUBJECT 3 VISIT 1
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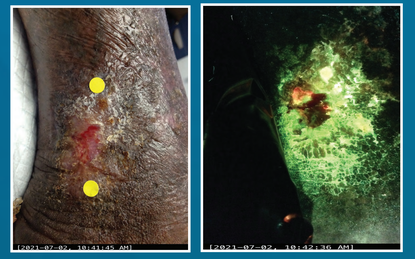

SUBJECT 3 VISIT 2
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SUBJECT 3 VISIT 2
POST DEBRIDEMENT

SUBJECT 3 VISIT 3
HEALED

References:

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