Retrospective Case Series Evaluating the Effects of a Novel Thermoreversible Antimicrobial Gel on Bacterial Loads on Diabetic Foot Ulcerations as Measured by Bacterial Fluorescence Imaging

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INTRODUCTION

The presence of bioburden and biofilm is commonly associated with non-healing chronic wounds[1]. Bioburden refers to the population of microorganisms present on or within a wound. These microorganisms can include bacteria, fungi, viruses, and other pathogens. Biofilms, on the other hand, are complex communities of microorganisms embedded within a protective matrix of extracellular polymeric substances that they produce[1]. This protective matrix provides a shield against the body's immune response and antimicrobial treatments, allowing bacteria to persist and exacerbate inflammation[1]. Disruption of biofilms is challenging and may require specialized interventions to effectively eradicate bacterial colonies.

Effective management of bacterial colonization and infection is crucial for promoting timely wound closure and reducing the risk of complications in chronic wounds. This may involve strategies such as debridement, antimicrobial therapy, and optimization of wound dressings. With the aid of real time bacterial fluorescence imaging, we have evaluated the effects of a novel thermoreversible antimicrobial gel on bacterial loads in difficult-to-heal diabetic foot ulcerations.

METHODS

In a retrospective study involving five patients with chronic diabetic foot ulcerations, all individuals exhibited high bacterial loads as assessed by the MolecuLight bacterial fluorescence imaging machine. Throughout the four-week treatment period, the ulcers were debrided at each office visit, and a novel antimicrobial wound gel was applied. The treatment protocol consisted of daily applications of an antimicrobial wound gel, daily dry dressing changes and offloading using a cam walker as part of standard care unless otherwise specified. Utilizing the MolecuLight device, bacterial loads were evaluated prior to the initiation of treatment and at each application subsequent visit.

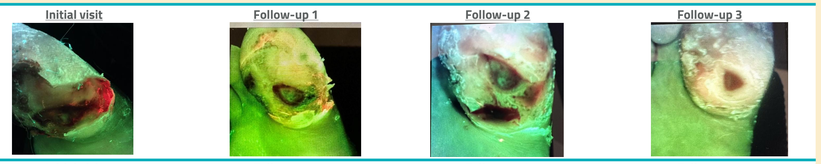
RESULTS

Bacterial load, as assessed by MolecuLight device, consistently decreased during treatment and dropped below detection limits by or before the fourth week for all five patients. Four patients also experienced a decrease in wound size by time the treatment period was completed.

CASES

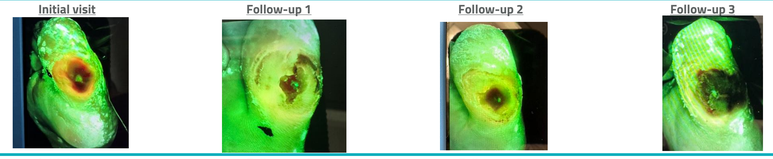
Case 1: 66/F

- DM, GERD, Neuropathy
- Wound age: 2 months
- Prior treatment: triple antibiotic ointment and adhesive bandage



Case 2: 41/F

- DM, HTN, neuropathy, thyroid disease
- Wound age: 4 weeks
- Prior treatment: triple antibiotic ointment
- Patient not utilizing CAM walker between Follow-up 2 and 3

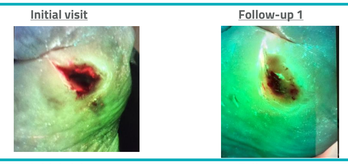


Case 3: 56/F

- GERD, DM, HTN, neuropathy, thyroid disease, concussion with mild memory loss
- Wound age: 1 month
- Prior treatment: betadine with alginate dressing

Case 4: 46/F

- DM, HTN, neuropathy
- Wound age: 1 week
- Prior treatment: mupirocin



Case 5: 52/M

- DM, neuropathy, HTN, anxiety
- Wound age:: 2 months
- Prior treatment: CAM walker and silver alginate dressing

CLINICAL SIGNIFICANCE

Presence of high bio burden levels and wounds has been proven to delay wound healing and have a significant negative effect on wound healing rates[2]. High bacterial burden in wounds is known to hinder healing, making its reduction crucial. In this series of patients, the addition of a novel thermoreversible antimicrobial gel to standard of care lead to observable reductions in the level of bacteria loads in chronic diabetic wounds.

The gel contains a pluronic surfactant that gives it its' thermoreversible properties. This refers to its' liquid state at room temperature and thickened state as it warms up to body temperature. The broad-spectrum antimicrobial agent in this gel is polyhexamethylene biguanide (PHMB) which kills bacteria, fungi, parasites and certain viruses[3]. PHMB's mechanism of action involves disrupting microbial cell membranes, leading to cell lysis and death. This mechanism is less prone to resistance development because unlike antibiotics that often target specific bacterial structures or enzymes, PHMB acts by disrupting the integrity of microbial cell membranes. Both active ingredients discussed coupled with the outcomes of this study indicate the potential of utilizing this novel thermoreversible antimicrobial gel for the treatment of chronic wounds. Use concurrently with standard of care or with advanced modalities such as skin substitutes, this gel may be used to decrease bioburden.

REFERENCES

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3. Rippon, M. wt al (2023). *Journal of wound care,* 32(1), 5–20.