Reducing Biofilm in the Wound Bed of Deep Dermal Wounds Using a Novel Non-Biologic Topical Liquid Agent

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Introduction

Chronic wounds account for significant patient morbidity and has a major economic impact on the cost of healthcare. There are many causes for wounds to stall in the inflammatory phase, the development of biofilm plays a significant role in this process. Clinicians have increasingly adopted the widespread use of topical agents to manage chronic wound infection, despite limited data on their effectiveness *in vivo*.

Innovative Technology

This study sought to evaluate the evidence of a novel topical, non-biologic technology employed to treat the biofilms of chronic wounds. Regenerative Debridement Technology (RDT*) is a topical liquid agent tissue during standard mechanical debridement procedures. It removes necrotic tissue and destroys biofilm upon contact. This chemical process works on a unique non-biologic platform; mechanical, cellular, and molecular.

A Handheld Flourescence Imaging Device** can instantly detect wound bed elevated bacterial loads. This device emits a precise wavelength of safe violet light, which interacts with the wound tissue and bacteria causing the wound bed to emit flourescence. This flourescence signal is related to the components of the wound, including the presence of elevated bacterial loads. Certain bacteria species are well established in the literature to produce prophyrins and pyoverdines that emit red flourescence. Bacterial loads more than 10^4 CFU/g typically correspind to those with moderate to heavy growth on a semi-quantitative scale.

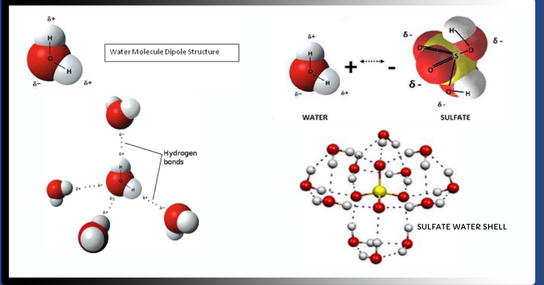
RDT, EPIEN Medical, Inc. St. Paul, MN
**MolecuLight Corp, Pittsburg, PA

Regenerative Debridement Technology(RDT*): Science and Mechanism of Action

RDT* can be characterized by its functionality as clinical tool that is designed to perform controlled, intense, instantaneous water extraction from the top layer of necrotized tissue on a lesion surface. The term "desiccation shock" is used to describe the effect that contact of the RDT* product has on the tissue surface, i.e., contact delivers a very brief, focal, intense water extraction from the superficial wound bed. This therapeutic liquid used to instantaneously convert necrotized tissues, microbial biofilm and other proinflammatory pathogenic substances on the surface of a wound bed into harmless devitalized tissue coagulum. Therefore, treatment of the wound bed with RDT* is intended to significantly mitigate biofilm on and in the wound bed.

RDT* products are formulated as concentrated aqueous solutions of aromatic sulfonic acids and sulfuric acid. These act as potent desiccants when they are prepared in a sufficiently concentrated form. The intensity and capacity of the desiccation activity of the solution can be carefully controlled by adjusting the concentration of the constituents during formulation.

The sulfate groups of the formulation strongly attract water molecules and form a "sulfate water shell". This is favored thermodynamically and the electrostatic attractive forces of the concentrated sulfates in RDT* extract water from the wound surface that instantaneously forms the coagulum that harbors the necrotic tissue, biofilms, and post inflammatory markers that delay wound healing. Therefore, this novel debridement method is truly a cellular and molecular method of extraction.

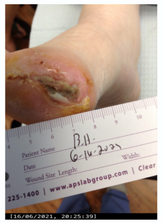


Case 1

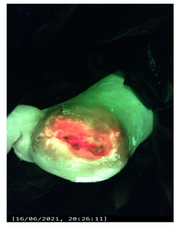
Initial Evaluation
- 77-year-old, female with diabetes presents to the clinic for a post-operative assessment.
- Presented with a non-healing surgical wound resulting from a great toe amputation, status post, 3-weeks.
- She had poor vascularity, normal blood sugar levels, and there were no signs or symptoms of infection (no malador, purulent drainage, or cellulitis).

Clinical Assessment and Pathway
- Fluorescence imaging (MolecuLight *i:X*) reveals bright and blush fluorescence in the wound bed and periwound, respectively, indicating pathogenic bacterial burden at levels > 10^4 CFU/g.
- A sample from the bright red fluorescence was cultured and was positive for Corynebacterium, Enterococcus, and Peptostreptococcus.
- The wound was treated with antimicrobial dressings (AQUACEL Ag Advantage, ConvaTec, Inc.).
- The patient returned two weeks later for treatment and a novel molecular debridement technology was used for adjunctive wound bed preparation (EPIEN Medical, Inc. St. Paul, MN)
- The Regenerative Debridement Technology application was used for 30 seconds and rinsed with saline. A pre and post MolecuLight image was captured to evaluate the bioburden in the wound bed.

Pre-Regenerative Debridement Technology Application

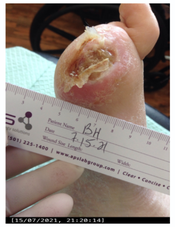


Pre-treatment with Regenerative Debridement Technology

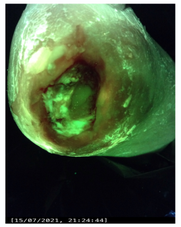


MolecuLight image prior to treatment. Wound bed with > 10^4 CFU/g.

Post Regenerative Debridement Technology Application



Post Regenerative Debridement Technology treatment.



Post treatment MolecuLight image. No signs of bioburden.

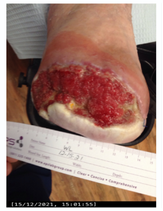
Results
The initial wound bed was heavily impacted with bioburden with evidence of > 10^4 CFU/g prior to the application of Regenerative Debridement Technology. After one 30 second application of Regenerative Debridement Technology, the MolecuLight image revealed a wound bed that had been cleared of bioburden. Standard of care dressings with AQUACEL Ag Advantage continued. The patient went on to heal uneventfully.

Case 2

Initial Evaluation
- Patient is a 62-year-old Caucasian male s/p TMA with TAL.
- PMH: type 2 diabetes mellitus, HTN, heart disease, peripheral neuropathy.
- Pulses palpable, edema, decrease sensation.
- Complications consistent with hematoma and subsequent abscess.
- Amputation sight was left open, IV antibiotics and NPWT regiment. NWB with wheelchair.
- Ulceration measures approximately 11 cm X 5.5 cm x 0.5 cm, red granular base with no fibrous tissue. Postive serous drainage.

Clinical Pathway
- MolecuLight fluorescence wound imaging performed after debridement showing red hue indicating bacterial load > 10^4 CFU/g.
- Regenerative Debridement Technology applied for 45 seconds, rinsed with sterile saline.
- MolecuLight fluorescence wound imaging revealing no major red hue and minimal cyan fluorescence at certain area of ulceration. Continue NPWT.
- 8 days later, a second application of Regenerative Debridement Technology for 45 seconds followed by sterile saline rinse.
- MolecuLight fluorescence wound imaging revealing no signs of infection in the wound bed. Continue NPWT.
- Patient was prepared for wound covering application in the operating room and successfully healed.

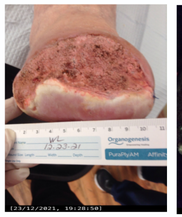
Pre-Regenerative Debridement Technology Application



Pre-treatment with Regenerative Debridement Technology

MolecuLight image prior to treatment. Wound bed with > 10^4 CFU/g.

Post Regenerative Debridement Technology Application



Post Regenerative Debridement Technology treatment.

Post treatment MolecuLight image. No signs of bioburden.

Results
The initial wound bed was heavily impacted with bioburden with evidence of > 10^4 CFU/g prior to the application of Regenerative Debridement Technology. A second application was accomplished as clinically indicated and the final fluorescence image indicated removal of bioburden. The NPWT continued until the patient had the wound covered and successfully healed.