WOUND CARE, INFECTION, AND BIOFILM

Wound Management Challenges

Effective wound management is a staggering global problem. Treatment of acute and chronic wounds is very costly, both economically and in terms of human suffering.

- Up to 2% of the population in developed countries suffer from chronic wounds.[1]
- 6.7 million Americans, and 20 million people worldwide, are treated every year for chronic wounds.[2-3] In the U.S., this amounts to an annual cost of $50-$80 billion.[2]
- Over 78% of these non-healing and infected wounds involve bacterial biofilm.[4]
- The estimated cost of treating biofilm infections in the U.S. is $94 billion per year.[5]

To date, the standard for advanced wound care in management of acute and chronic wounds has been silver dressings, but clinicians are beginning to seek alternatives for several reasons, including:

- High-volume silver ion release is widely recognized as cytotoxic.
- Because of cytotoxicity concerns, silver dressings are typically not suitable for use with skin grafts and skin substitutes.
- There is growing concern about bacteria becoming resistant to silver.
- Silver ions alone are generally not suitable for the treatment of biofilm, without chemical additives.

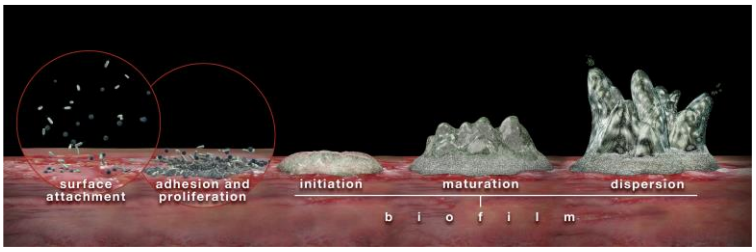
What is Biofilm?

Biofilm is a protective shield that bacteria form to protect themselves from antibiotics and the immune system. Biofilm is increasingly recognized as a prime culprit in wound infection and inhibited healing. It can lock wounds in a chronic inflammatory state, which prevents healing and is notoriously difficult to treat.

How Does it Form?

Bacteria communicate through electrochemical signaling called quorum sensing. When messaging between bacteria grows strong enough, they begin to behave as a coordinated aggregate and signal each other to secrete an extracellular polymeric substance, or EPS, which creates a biofilm shield around the bacteria.[6]

Biofilm Lifecycle



Challenges of Biofilm

As the biofilm structure grows and matures through the stages of its lifecycle, it disrupts normal wound healing and locks the wound in a chronic inflammatory state.[6,10] Biofilm resists attack by the immune system and by antimicrobial agents, including silver.[7-8] Bacteria in biofilm form can become up to 1,000x more resistant to antibiotics when compared to planktonic (non-biofilm) counterparts.[9] Biofilm cannot be visually detected, making removal by debridement (removal of damaged tissue or debris) difficult.[6] Even after aggressive debridement, biofilm can reform in as little as 24 hours.[10] Thus, biofilms pose a rapidly escalating threat to human health.[11]

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In the fight against biofilms and antibiotic resistance, current wound care practices and infection control strategies are no longer adequate. A recent report from the World Health Organization (WHO) deemed antibiotic resistance a significant global health threat, causing 700,000 deaths a year – a figure that is expected to explode to 10 million a year by 2050 if no action is taken.[12]

Using Electrical Interactions to Prevent and Disrupt Biofilm

Electricity works against biofilm. Because bacteria use electrostatic and electrochemical interactions to adhere to a surface and communicate with each other to multiply and create biofilm, using a wound dressing with similar bioelectric properties can disrupt those lines of communication. The therapeutic electric field generated by Vomaris's bioelectric V.Dox™ Technology can short-circuit bacteria's electrical signaling, thereby disrupting their ability to quorum sense and carry out the inter-bacterial communications necessary for biofilm formation. V.Dox Technology has been shown to kill bacteria in biofilm form both *in vitro*[13] and *in vivo*[14]:

Vomaris Bioelectric Technology

Procellera™ Antimicrobial Wound Dressing powered by V.Dox™ Technology

Vomaris's family of Antimicrobial Wound Dressings, powered by V.Dox Technology, is disrupting the advanced wound care market by providing a non-antibiotic solution to the growing wound biofilm and antimicrobial resistance problem. Because electroceutical therapy is not subject to the same metabolic pathways bacteria use to develop drug resistance, it has the potential to circumvent drug resistance.[15] This bioelectric technology platform powers the only antimicrobial wound dressing that is inspired by the body's natural electrical healing process. It employs embedded microcell batteries that generate electricity designed to mimic the skin's own internal electrical energy, which is essential for cell migration and wound healing.

Using Electrical Interactions to Prevent and Disrupt Biofilm

Bioelectric V.Dox Technology has been shown to:

- Kill a broad-spectrum of harmful pathogens, including multi-drug resistant and biofilm-forming bacteria[13]
- Exert a robust electricity-induced antimicrobial impact[13]
- Prevent and disrupt biofilm infection[13-14]
- Accelerate cell migration and re-epithelialization[16]

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