Publication Brief

A Prospective, Randomized, Controlled Study to Evaluate the Effectiveness of a Fabric-based Wireless Electroceutical Dressing Compared to Standard of Care Treatment Against Acute Trauma and Burn Wound Biofilm Infection

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CONCLUSIONS

- Early treatment with a wireless electroceutical dressing (WED, Procellera™ Antimicrobial Wound Dressing) significantly decreased biofilm severity in all burn wounds
- Incidence of opportunistic pathogens such as *Ralstonia pickettii* and *Serratia marcescens* was significantly lower in WED-treated wounds compared to SoC
- WED may result in a therapy that is superior to silver alone

Background

Infections cause:

60% **of most common complications after burns**

42-65% **of deaths following thermal injuries**

Bacterial biofilm is directly implicated in numerous infections, and it remains a major problem in the management of burns.

Silver-based therapies are among standard care options, but previous pre-clinical studies using a porcine burn biofilm model have shown that once biofilm is established, silver has limited benefit. Further, the concentrations of silver needed to disrupt mature biofilms are potentially toxic.

The authors previously reported on an FDA-cleared and commercially available wireless electroceutical dressing (WED, Procellera™ Antimicrobial Wound Dressing) that generates a weak electric field in a moist wound environment. Their preclinical study demonstrated that WED disrupted biofilm infection and restored skin barrier function.[1]

Study Objective

- Investigate the *in vivo* efficacy of WED compared to the standard of care (SoC) dressing to prevent and disrupt burn biofilm infection
- Hypothesis was that a low electric field (~1V) generated by the moisture-activated WED would reduce biofilm severity and infection load

Study Design And Methods

Prospective, randomized, controlled clinical trial of patients admitted to the **Brooke Army Medical Center (BAMC) and US Army Institute of Surgical Research (USAISR) Burn Center** in San Antonio, TX with dermal burn/traumatic wounds.

38 subjects enrolled

25 complete samples

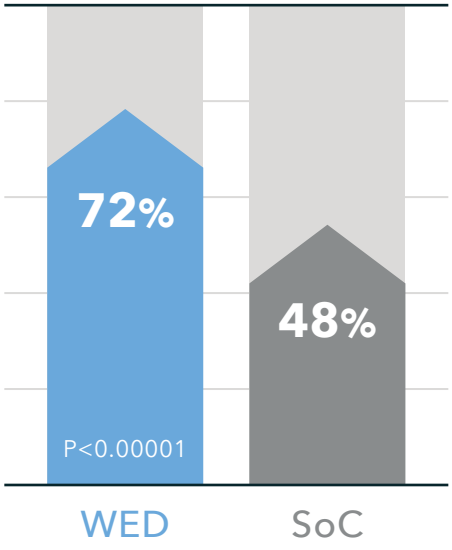
Burn wounds were divided into two parts.
By random selection, one part received **SoC** and the other received **WED.**

SoC included, but was not limited to, silver nylon, silver sulfadiazine (SSD) ointment, and bacitracin.

Biopsies collected on days 0 and 7
for blinded histological, scanning electron microscopic (SEM) examination of biofilm and for blinded quantitative bacteriological analyses.

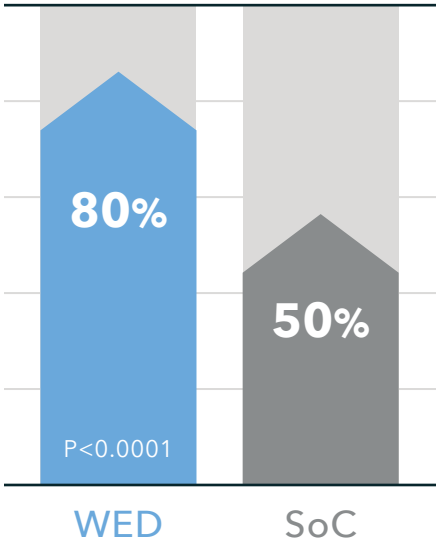
RESULTS

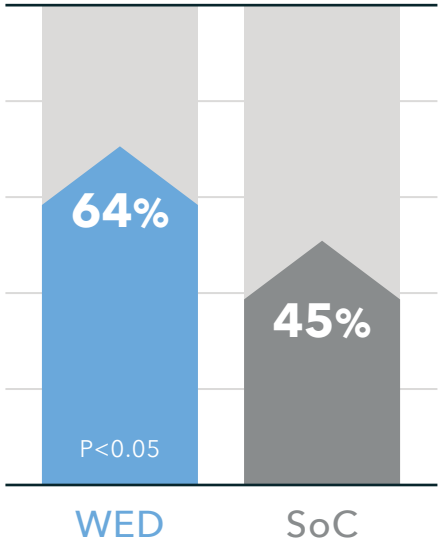
WED significantly decreased biofilm severity in all burn patients



Percent Reduction in Biofilm Severity by Day 7

WED significantly decreased the incidence of specific opportunistic bacterial pathogenic strains in burn patients





Percent Reduction in Incidence of Bacterial Pathogenic Strains by Day 7

1 Barki KG, Das A, Dixith S, Ghatak PD, Mathew-Steiner S, Schwab E, Khanna S, Wozniak DJ, Roy S, Sen CK. Electric Field Based Dressing Disrupts Mixed-Species Bacterial Biofilm Infection and Restores Functional Wound Healing. Ann Surg. 2019 Apr;269(4):756-766.

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