Procellera™
ANTIMICROBIAL WOUND DRESSING
POWERED BY V.DOX™ TECHNOLOGY

Publications Summary

Clinical and Pre-clinical Publications

Study Area
Burn wounds
Design
Prospective, randomized, controlled study

Study Finds Vomaris™ Bioelectric Technology Significantly Decreased Biofilm in Burn Patients

Chan RK, Nuutila K, et al.; *Adv Wound Care (New Rochelle).* 2023 Apr 11. doi: 10.1089/wound.2023.0007. Epub ahead of print.

- Early, short-term treatment with WED 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.

Study Area
Wound biofilm infection
Design
Pre-clinical porcine mechanistic study

Electric Field Based Dressing Disrupts Mixed-Species Bacterial Biofilm Infection and Restores Functional Wound Healing

Barki KG, Das A, Dixith S, et al.; *Ann Surg,* 2017.

- Tested ability of wireless electroceutical device (WED) to manage bacterial biofilm infection in vivo in porcine chronic wound biofilm infection model inoculated with *Pseudomonas aeruginosa* and *Acinetobacter baumannii.*
- WED disrupted existing biofilm infection and prevented biofilm from forming.
- WED repressed genes responsible for quorum sensing, disrupting bacteria's ability to communicate and form biofilm.

Study Area
Diabetic wounds
Design
Prospective case series

Human Acellular Dermal Matrix Paired with Silver-Zinc Coupled Electroceutical Dressing Results in Rapid Healing of Complicated Diabetic Wounds of Mixed Etiology: A Novel Case Series

Cole W; *Wounds.* 2016;28(7):241-247.

- Electroceutical wound dressing used in combination with human acellular dermal matrix in three complex cases (conventional care was unable to close wounds in up to two years).
- All three cases healed fully within six weeks with this alternative treatment.

Study Area
WED in conjunction with NPWT
Design
Randomized controlled clinical trial

A Wireless Electroceutical Dressing Lowers Cost of Negative Pressure Wound Therapy

Ghatak PD, Schlanger R, Ganesh K, et al.; *Adv Wound Care.* 2015;4(5):302-311.

- Thirty (30) chronic wound patients undergoing negative pressure wound therapy (NPWT) were randomized into two arms (control = NPWT standard of care with thrice weekly dressing changes and test = wireless electrical device [WED] + NPWT with twice weekly dressing changes).
- WED + NPWT effectively decreased required dressing change frequency from thrice to twice weekly without any negative impact on wound healing.
- Cost of care with use of WED + NPWT was significantly lower than NPWT alone ($p<0.05$).

Study Area
Acute and chronic wounds
Design
Retrospective dual center review of wound healing outcomes

Demonstration of a Microcurrent-Generating Wound Care Device for Wound Healing within a Rehabilitation Center Patient Population

Whitcomb E, Monroe N, Hope-Higman J, et al.; *J Am Coll Clin Wound Spec.* 2013;4:32-39.

- Evaluated differences in wound healing outcomes when treated with microcurrent-generating wound care device (MCD, n=18) vs. standard of care (SOC, n=20).
- Study population of rehabilitation and long-term care patients with acute and chronic wounds of varied etiology.
- MCD group wounds healed significantly faster (19.78 days) than SOC group (36.25 days) ($p=0.036$)
- 83.3% of MCD group wounds healed monotonically vs. 50% of SOC group ($p=0.018$).

Study Area
Skin graft harvest sites
Design
Prospective single center clinical study

The Use of Bioelectric Dressings in Skin Graft Harvest Sites: A Prospective Case Series

Blount AL, Foster S, Rapp DA, et al.; J *Burn Care Res.* 2012;33(3):354-357.

- Compared acute wound healing after skin grafting (n=13).
- Half of each graft donor site was covered with a standard dressing (control) and half with a bioelectric dressing (test); both were covered with a semi-occlusive dressing.
- One week post-op: significantly greater epithelialization with bioelectric dressing (71.8%) vs. control (46.9%) ($p=0.015$).
- Blinded evaluator rated bioelectric dressing side visually superior in 92.3% of wounds.

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Scientific Publications

Study Area
Anti-fungal properties
Design
In vitro

Ketoconazole Resistant *Candida albicans* is Sensitive to a Wireless Electroceutical Wound Care Dressing

Khona D, Roy S, Ghatak S, et al.; *Bioelectrochemistry*. 2021 Aug 4; 142:107921.

- Tested whether wireless electroceutical dressing (WED, Procellera™) is effective against ketoconazole-resistant yeast *Candida albicans*.
- In vitro model used to test WED, ketoconazole, and the combination of WED + ketoconazole against ketoconazole-resistant *C. albicans*.
- WED significantly affected several critical pathways necessary for *C. albicans* viability. In contrast, silver alone was ineffective.
- Wireless electroceutical dressing (WED) inhibited *Candida albicans* biofilm formation.

Study Area
Anti-biofilm properties
Design
In vitro

Silver-Zinc Redox-Coupled Electroceutical Wound Dressing Disrupts Bacterial Biofilm

Banerjee J, Ghatak PD, Roy S, et al.; *PLoS One*. 2015 Mar 24;10(3):e0119531.

- Tested wireless electroceutical device's (WED) ability to inhibit *Pseudomonas aeruginosa* biofilm.
- WED impaired biofilm formation and significantly impaired extracellular polymeric substance formation compared to two different controls (placebo dressing and silver dressing) ($p<0.05$).
- WED impaired biofilm structures and caused significant cell death compared to controls ($p<0.05$).
- Silver alone was unable to disrupt *Pseudomonas aeruginosa* biofilm.

Study Area
Anti-biofilm properties
Design
In vitro

Antibiofilm Efficacy Evaluation of a Bioelectric Dressing in Mono- and Multi-Species Biofilms

Kim H, Izadjoo MJ; *J Wound Care*. 2015 Feb 24;Suppl2:S10-14.

- Tested a bioelectric dressing's effectiveness against 10 clinical wound pathogens in monospecies and multispecies biofilm settings.
- Bioelectric dressing was effective against monospecies and multispecies biofilm forming bacteria; demonstrated 100- to 1000-fold reductions in bacterial numbers compared to three controls.

Study Area
Re-epithelialization
Design
In vitro

Improvement of Human Keratinocyte Migration by a Redox Active Bioelectric Dressing

Banerjee J, Ghatak PD, Roy S, et al.; *PLoS ONE*. 2014 Mar 3;9(3):e89239.

- Human keratinocytes exposed to bioelectric dressing (BED) demonstrated significantly accelerated cell migration. This effect was not observed with three controls (placebo, silver alone, zinc alone).
- Cells exposed to BED's electric fields demonstrated increased signaling and production of H_2O_2 (required for cell migration).

Study Area
Anti-bacterial properties
Design
In vitro

Antibacterial Efficacy Testing of a Bioelectric Wound Dressing Against Clinical Wound Pathogens

Kim H, Makin I, Skiba J, et al.; *Open Microbiol J*. 2014 Feb 21;8:15-21.

- Examined *in vitro* antibacterial efficacy of bioelectric dressing against 13 wound pathogens.
- The bioelectric dressing demonstrated bactericidal activity against antibiotic-sensitive multidrug-resistant strains and multiple antibiotic-resistant strains of wound pathogens; bacteriostatic activity against *Enterococcus* species.

Vomaris Wound Care, Inc.
1911 East Fifth Street | Tempe, AZ 85288 USA
+1 (480) 921-4948 | (866) 496-8743

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