Bioelectric dressings bring new energy to wound healing

by Susan Schaeffer, consulting editor

<u>Vomaris Innovations Inc.</u> is taking bioelectronic medicine into a field that has been a pharmaceutical graveyard for decades: wound healing. The company's bioelectric dressings aim to speed wound healing via V.Dox Technology, which creates an electric field over the wound.

V.Dox Technology uses a matrix of embedded microcell batteries composed of elemental zinc and silver. When the batteries come into contact with moisture, such as wound exudate, a redox reaction between the zinc and silver generates an electric field on the dressing's surface. The electric field is designed to mimic the skin's natural electric field, which is needed to initiate cell migration and wound healing.

Chronic wounds, in particular, have stymied drug developers for years. A flurry of drug candidates, including recombinant growth factors, failed in clinical testing in the 1990s. The failures were likely caused by two factors: Wound biology is too complex to be addressed by the single agents that were being tested, and high placebo responses were common because chronic wounds often begin to respond to standard care as applied in the rigorous setting of a clinical trial.

Biopharma interest in the field rekindled somewhat in the mid-2010s, thanks in part to the commercial success of the Vacuum Assisted Closure Device from Kinetic Concepts Inc., coupled with growth in chronic wounds driven by aging populations and an increase in diabetes. Even so, today only about 20 biopharma products are in clinical trials for wounds. And despite several approved drugs and devices, standard care remains cleaning the wound site and re-dressing it with clean gauze every few days. Antibiotics may be given to prevent infection; however, growing rates of antimicrobial resistance threaten their utility.

Vomaris and independent researchers have published numerous studies showing that V.Dox Technology kills a range of pathogens, including multidrug-resistant and biofilm-forming bacteria, and accelerates cell migration. In addition, published stud-

Vomaris Innovations Inc. Tempe, AZ www.vomaris.com ies have shown that the use of an external electric field can have an anti-inflammatory effect.

On October 18, Vomaris announced enrollment of the first patient into a clinical trial of the dressing to improve the rate of wound healing and reduce inflammation following surgical treatment of hidradenitis suppurativa. Hidradenitis suppurativa is a chronic inflammatory skin condition characterized by recurring abscesses that can develop tunnels under the skin, leading to pain and scarring. Inflammation, bacteria, and biofilms are implicated in the healing and recurrence of hidradenitis suppurativa lesions. When tunnels develop under the skin, a surgical procedure called deroofing is commonly done. The procedure removes the lesions, but leaves large open wounds.

The randomized study is being conducted in collaboration with the University of Miami Health System. Vomaris did not respond to requests for an interview. But according to clinicaltrials.gov, the study is targeting enrollment of 12 participants undergoing deroofing surgery. One group will receive Vomaris' dressing on the right armpit and a standard gauze dressing on the left. The treatment assignment will be reversed in a second group.

The primary endpoint is healing rate of post-surgical wounds reported as the reduction in wound area (cm² per day). Average time to complete healing, number of subjects with complete healing, nodule or tunnel recurrence, and pain are included among the secondary endpoints. The company's announcement said the study also aims to determine whether the dressing can reduce signs of inflammation.

In the announcement, president & CEO Mike Nagel said Vomaris hopes the study's results will provide the evidence needed to give hidradenitis suppurativa a new treatment option. He did not mention any further details on the development or regulatory strategy.

Antimicrobial bioelectric dressings using V.Dox have FDA 510(k) clearance and are marketed under the name Procellera for over-the-counter use on superficial wounds, and prescription use for partial and full-thickness wounds, including pressure sores and diabetic ulcers. The label does not include antiinflammatory claims.