Electrical Stimulation Promising for Limb Salvage

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — High-voltage, pulsed electrical stimulation is an effective adjunct to multidisciplinary attempts at limb salvage in diabetic patients with complex lower extremity wounds, results from a small study demonstrated.

Of 45 wounds in 30 patients, 78% of the wounds healed in a mean of 14 weeks using the electrical stimulation system, Dr. Jeremy J. Burdge reported at the annual meeting of the Wound Healing Society.

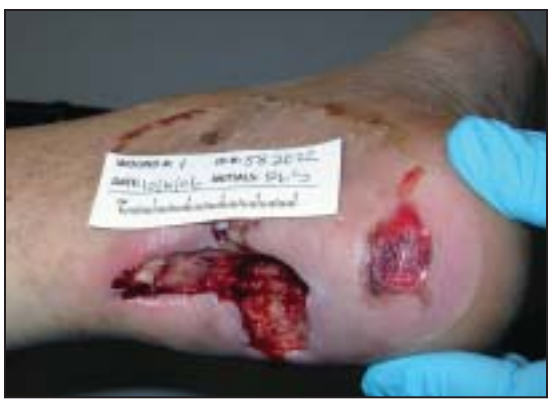
"This is a preliminary study," said Dr. Burdge, a plastic and reconstructive surgeon who practices in Columbus, Ohio. "Further research is warranted."

He and his associates evaluated the efficacy of a high-voltage electrical stimulation system manufactured by MicroVas Technologies Inc. (Tulsa, Okla.) in patients who failed to improve despite multidisciplinary treatment approaches, including vascular evaluation and surgical intervention as indicated, aggressive off loading, bacterial infection control, and wound debridement.

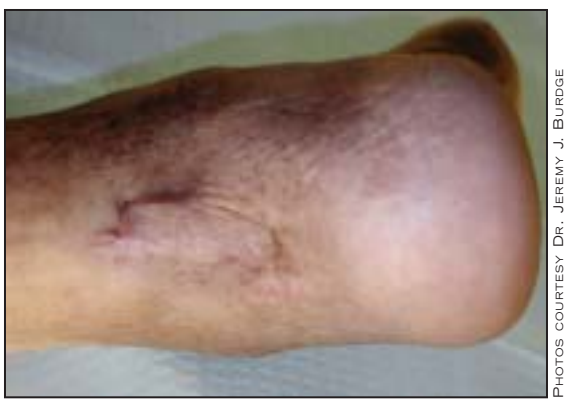
"There is a variety of ways in which people speculate that high-voltage pulsed current has improved wound healing," Dr. Burdge said at the meeting, which was held in conjunction with a symposium on advanced wound care. "They fall into several groups of either increasing blood flow through promoting microcirculation, increasing wound healing through attraction of proliferating different cell types, or bacteria inhibition by this type of pulsed current."

More than half (57%) of the patients in the study were men; their mean age was 66 years. Comorbidities included neuropathy (84%), peripheral vascular disease (77%), cardiac disease (37%), and infection (33%). "This was a fairly high-risk group of patients," Dr. Burdge noted. "The mean hemoglobin A_{1c} level was 8.2% and nine patients had undergone previous amputation."

The mean age of wounds was 25 weeks, and mean surface area was 7.8 cm^2. Most wounds were located on the foot (51%) and heel (28%), followed by the ankle (12%) and lower extremity (9%).



A 3-month-old heel wound is seen in a 66-year-old male with diabetes and neuropathy.



After 22 treatments and a supplemental skin graft, the wound was considered healed.

Photos courtesy Dr. Jeremy J. Burdge

Emitter pads were placed over each wound. Stimulation was delivered for 45 minutes 2-3 times per week by a narrow pulsed current with a width of 80-100 microseconds at a frequency of 55 Hz. Pulses were delivered for 1.5 seconds, with a 1.5-second interval between pulses. The amplitude was individualized for each patient to maximize fused tetanic muscular contraction.

Dr. Burdge reported that the mean number of stimulation treatments per wound was 23 and that 35 (78%) of the wounds healed in a mean of 14 weeks.

Wound healing was defined as either complete epithelialization of the wound or closure with supplemental skin grafts.

Wounds in eight patients failed to heal. One required a metatarsal amputation, four had below-the-knee amputations, one had necrotic tissue and was lost to follow-up, and two patients are continuing further therapy.

At a mean follow-up of 40 weeks, 88% of wounds had no evidence of recurrence. "We did have four patients who had recurrent wounds," he said. "Two went on to complete healing. One had osteomyelitis and went on to a below-the-knee amputation."

Treatment is pending for the fourth wound that recurred.

Dr. Burdge had no conflicts to disclose. ■

Recombinant Human Thrombin Controls Bleeding of Most Wounds

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Spray recombinant human thrombin achieved hemostasis within 20 minutes in 91.5% of patients following burn wound excision in a prospective safety study in 71 patients.

Recombinant human thrombin (rThrombin) was also minimally immunogenic, principal investigator Dr. David G. Greenhalgh said at the annual meeting of the American Burn Association (ABA).

One patient had specific, low-titer antibodies to rThrombin at baseline, but no increase in titer post treatment. A second patient developed non-neutralizing antibodies to rThrombin at day 29.

The findings are encouraging because rThrombin was developed as an alternative to bovine plasma-derived thrombin, which has been available since the 1940s, but carries a black box warning about severe bleeding risks associated with potential antibody development, explained Dr. Greenhalgh, professor and chief of burn surgery, University of California, Davis. Roughly 20%-90% of patients treated with topical bovine thrombin develop antibodies to the preparation.

In January 2008, the Food and Drug Administration approved Recothrom, the first and only rThrombin for use as a topical hemostat in combination with an absorbable gelatin sponge. The product is devoid of human or animal plasma proteins, which also minimizes the risk of pathogen transmission, he said.

The current open-label, multiple-site study evaluated the safety of spray rThrombin in 71 patients, aged 2-75 years, who received a partial- or full-thickness autologous sheet or mesh graft following excision of burn wounds covering 1%-4% of their total body surface area. The spray was applied at 5-minute intervals for up to 20 minutes. Sheet grafts were received by 53 patients and mesh grafts by 18.

Hemostasis was achieved without the use of tourniquets or clysis, which makes the 91.5% hemostasis rate even more impressive, because both reduce the rate of bleeding, Dr. Greenhalgh said.

At day 29, one graft was infected and four grafts failed. Other adverse events reported were pain (25 patients), pruritus (18), deep vein thrombosis (1), adult respiratory distress syndrome (1), and GI hemorrhage (1).

There were no study drug discontinuations or deaths in the study, which was sponsored by ZymoGenetics Inc. (Seattle); the company markets rThrombin in the United States as Recothrom.

Session moderator and former ABA president Dr. Glenn D. Warden asked whether immunogenicity might be a concern with repeated use of rThrombin over larger wounds.

Dr. Greenhalgh answered that it would be beneficial to conduct a study to evaluate repeated use, but that he felt better about human recombinant products than bovine plasma-based products because of their reduced risk of viral transfer and antibody development.

When asked if human recombinant products were too costly for regular use, Dr. Greenhalgh said, "It's not something that's going to break the bank . . . I think it's going to be reasonable, compared to what's available."

Dr. Greenhalgh, who reported no conflicts of interest, said he uses spray rThrombin in combination with tourniquets for excisions on hands or arms and in combination with topical and injected epinephrine and cautery for large tangential excisions on the trunk. ■

Supplemental Fluids May Not Improve Subcutaneous Oxygen

BY DOUG BRUNK
San Diego Bureau

SAN DIEGO — Although fluid intake can be safely increased in nursing home residents who have, or are at risk for, pressure ulcers and do not routinely ingest the prescribed amount of fluid, levels of subcutaneous oxygen may remain low, results from a multicenter study demonstrated.

"In the nursing home population, hydration is a serious issue," Nancy A. Stotts, R.N., Ed.D., said at the annual meeting of the Wound Healing Society. "Some of the estimates are that up to half of all nursing home residents are underhydrated."

The investigators recorded routine fluid intake for 5 days in 64 residents of five nursing homes in Northern California. The residents were then randomized to receive, for 5 days, the target amount of fluid prescribed by their physician or the target amount plus 10 mL/kg of body weight, said Dr. Stotts, professor of nursing at the University of California, San Francisco.

They also evaluated levels of subcutaneous oxygen in all study participants for 3 days during treatment. Hypovolemia was defined as 45 mm Hg or less, or a less-than-20% increase in response to an oxygen challenge.

Patients' mean age was 79 years; most were female (38) and cognitively impaired (51). Mean baseline daily fluid intake was 1,374 cc for the group who received prescribed fluid, and 1,707 cc for those who were randomized to the extra fluid. After treatment, the mean daily fluid intake increased significantly for both groups: to 1,787 cc for the group who received prescribed fluid, and to 2,380 cc for those who received the extra fluid.

The mean level of subcutaneous oxygen, however, was 40 mm Hg for patients in the target prescribed group, and 36 mm Hg for patients in the group that received supplemental fluid. Subcutaneous oxygen levels less than 45 mm Hg indicate tissue hypoxia that may be caused by hypovolemia, Dr. Stotts said at the meeting, which was held in conjunction with a symposium on advanced wound care.

No cases of fluid overload or heart failure were observed.

Increased fluid intake "did not reverse the low subcutaneous oxygen, perhaps because of chronic underhydration and osmoreceptor reset," she said. "Further work needs to address the optimal dose and duration of fluid for older adults and other factors that contribute to the low subcutaneous oxygen."

The study was funded by the National Institutes of Health. ■

Pages 38a—38b◊