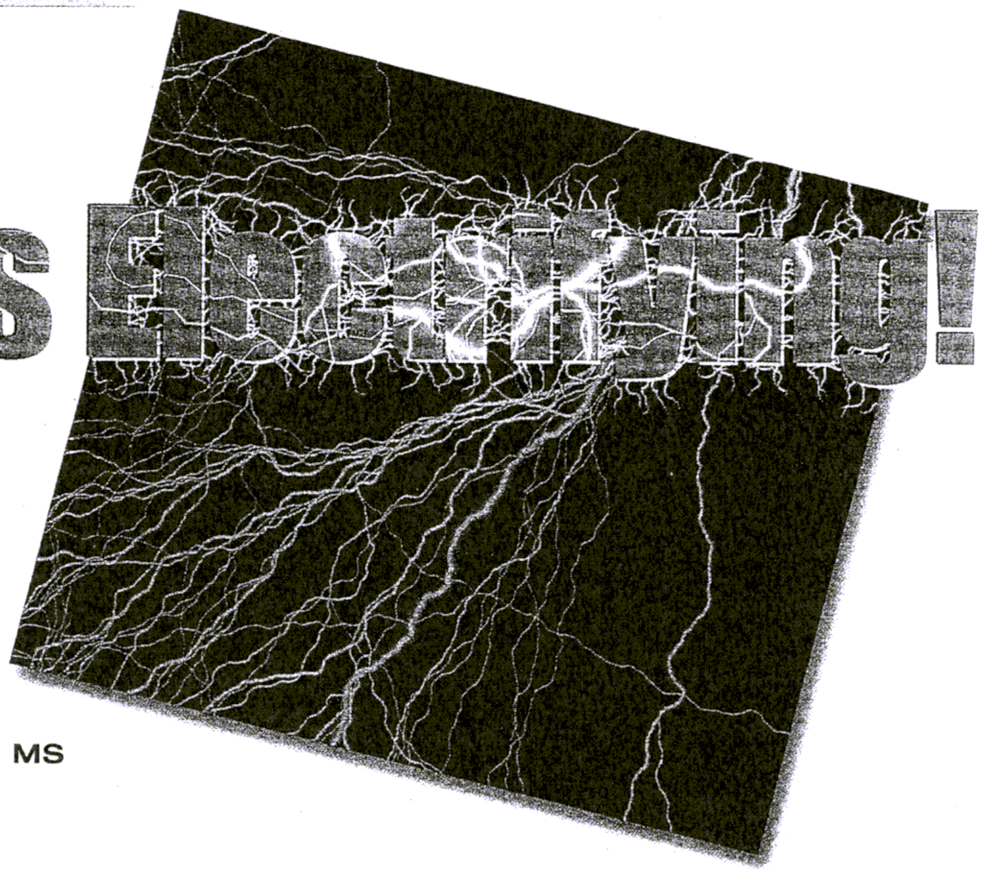
It's Electrifying!



by Carl Van Gils, DPM, MS

In existence for many centuries, electrical stimulation is a viable, adjunctive method for treatment of diabetic ulcers.

THERE ARE 15.7 MILLION PEOPLE WITH DIABETES MELLITUS in the United States, representing 5.9 percent of the population. Diabetes is one of the most costly health problems in the United States with some estimates as high as $138 billion to include all healthcare costs incurred by people with diabetes. Approximately 67,000 lower extremity amputations are performed each year in the United State at a rate of 8.6 per year per 1,000 diabetic patients and accounts for up to 83 percent of all nontraumatic lower extremity amputations. Foot ulceration has been identified as a key component in the causal pathway to lower extremity amputation in diabetic patients.[1] Ulcerations leave patients with diabetes at a 15 to 46 times greater risk for receiving a lower extremity amputation than people without diabetes.[2,3]

> ***"Prompt and efficient treatment of the diabetic ulcer is vital to limb salvage."***

The long-term prognosis for diabetic patients undergoing major lower extremity amputation is poor. Twenty to 50 percent of these patients will have amputation of the remaining leg in one to three years, and more than 50 percent will require amputation in five years.[4-6] Many patients with diabetes will not live long enough to undergo a second amputation. The mortality rate within three years following the first lower extremity amputation ranges from 20 to 50 percent, while the five-year mortality rate is reported as high as 39 to 70 percent.[7,8]

Efforts to decrease the rate of lower extremity amputation focuses on prevention, education and treatment. Prompt and efficient treatment of the diabetic ulcer is vital to limb salvage. Ulcers allow bacteria to enter and multiply in the body leading to infection and the spread of disease. Decreased oxygenation due to vascular embarrassment further exacerbates the threat as viable tissue can rapidly deteriorate into tissue necrosis and gangrene. In addition, poor wound healing secondary to the chronicity of many diabetic ulcers and a compromised systemic ability to combat infection increases the likelihood of amputation.

New and innovative methods of treating diabetic ulcers are welcome to the prevention of lower extremity amputation in the high-risk population. Coupled with time-honored modalities such as local debridement and off-weighting pressure lesions, adjunctive therapies can improve the treatment of the diabetic high-risk foot. Options in wound healing include hyperbaric oxygen, growth factors, bioengineered tissue equivalents, vacuum assisted closure and electrical stimulation.

Electrical Stimulation

The concept of electrical stimulation therapy has existed for centuries and has been successfully utilized in the bone-healing arena; and for the treatment of pain and acute, chronic injuries. The first description of the use of electrical stimulation in wound healing dates as far back as the 1700s when gold leaves were placed over wounds.[9] In the early 1950s, electrical stimulation was used at Walter Reed Hospital to heal wounds and decrease edema. The current literature describes a variety of uses and protocols for electrical stimulation in healing of soft tissue injuries.

> ***"For wound healing to become an FDA approved indication for electrical stimulation and to allow access to HCFA reimbursement as a wound healing modality, more clinical data must support anecdotal evidence."***

Several laboratory and animal studies have evaluated the effect of cellular behavior when exposed to an electrical field. These studies demonstrate the promotion of angiogenesis, fibroblastic proliferation, collagen synthesis and epithelial cell migration.[10-14] Other studies have investigated the antimicrobial effects of electrical stimulation. Electrical fields have been shown to diminish in vitro growth of Staphylococcus aureus and other anecdotal reports claim similar results in human subjects.[15,16] The application of a negative electrode to the wound site suppressed infection, increased rate of epithelialization, and increased fibroblastic response and a wound contracture in animal models.[17,18]

Three clinical treatment regimens of electrical stimulation are used today: direct current, low frequency pulsed currents and high voltage pulsed currents. The type of stimulation that has been most consistently evaluated clinically and found to be efficacious in wound healing is high-voltage pulsed current. High volt pulsed current (HVPC), also referred to as high volt pulsed galvanic current, has continued to be used, primarily in physical therapy and occupational therapy clinics, as a therapeutic modality to reduce edema, break muscle spasm, soften tissue, increase localized blood flow, attract nutrients, relieve pain and stem bacterial infection to assist in healing tissue. HVPC was developed to produce a wave form that offered polarity benefits inherent in galvanic stimulation, but at a much lower level of microamperage for patient comfort and smooth muscle contraction. HVPC is a twin peak monophasic spiked wave form with fixed pulsed intervals up to 200 microseconds. The sharp edge of the twin peak wave form allows easy penetration through the resistance of the skin and high voltages allow for deep penetration into the tissue. Voltage levels utilized are dependent on the condition and the body area being treated. Stimulators producing 50V to 500V of very short pulse duration are currently available.

While used extensively in Canada and Europe, electrical stimulation is not currently approved for use in wound healing by the Food and Drug Administration (FDA). However, the FDA recognizes six other claims for HVPC stimulators. They are:

- Relieving pain
- Increasing range of motion
- Retarding disuse atrophy
- Increasing blood circulation
- Preventing venous thrombosis
- Relaxing muscle spasm

In contrast, Transcutaneous Electrical Nerve Stimulation (TENS) is only indicated for the treatment of acute and chronic pain. Of the six FDA claims for HVPC stimulators, the most important factor in wound healing is the improvement of microvascular circulation. By increasing blood flow, soft tissue injuries have an opportunity to heal. In the diabetic high-risk extremity, with below-knee dominated arterial disease, this becomes crucial to healing chronic ulcers.

A recent study measured the effect of electrical stimulation on vascular perfusion in diabetic patients.[19] Patients with impaired blood flow demonstrated a significant rise in tissue oxygenation during the first five minutes of stimulation as compared to patients without peripheral vascular disease. This transient rise in skin perfusion in persons with diabetes and impaired peripheral perfusion could account for improved healing in similar cohorts. Other researchers also describe an increase in ischemic skin flap perfusion although their methods of electrical stimulation delivery were different.[20,21]

For wound healing to become an FDA approved indication for electrical stimulation and to allow access to HCFA reimbursement as a wound healing modality, more clinical data must support anecdotal evidence. Important pilot work was recently completed to evaluate the effectiveness of high-voltage pulse-galvanic electrical stimulation as an adjunct to diabetic wound care. A 12-week randomized, double blind, placebo-controlled trial consisting of 40 subjects with diabetic neuropathic foot ulcers suggests a positive healing response when electrical stimulation was used in conjunction with appropriate offloading and local wound care.[22] Sixty-five percent of the patients healed in the electrical stimulation test group com-

Suggested HVPC Wound Care Protocol

Documentation
- Measure the wound dimensions including depth.
- Describe wound characteristics (i.e. tissue, exudates, odor).
- Photograph and trace the wound pre-stimulation weekly and monthly.

Wound Preparation
- Cleanse the wound
- Debride necrotic tissue
- Determine type of electrode set-up
  - Tunneling wounds-saline dressing packed into depth of wound with an alligator clip attached to the protruding gauze;
  - Shallow wounds: Hydrogel impregnated electrode can be used directly over the wound bed with an optional second electrode placed just distal to the wound;
  - Multiple wounds: use an electrotherapy sock to treat numerous areas simultaneously.
    - Dress wounds with a thin occlusive film (i.e. tegaderm, opsite). Spray the surrounding skin with saline spray.
    - Apply electrotherapy sock and attach negative and positive leads.

Treatment Parameters
- Rate: 80 to 100 pulses per second (pps).
- Intensity: Subthreshold to light stimulation for optimal efficiency.
- Polarity
  - Negative: Initially for three days or until the wound is debrided and shows signs of a granulating base.
  - Positive: Keep switching polarity to re-activate the healing process after reaching healing plateaus.
- Treatment time: Q.D. to T.I.D, 30 to 60 minutes per treatment with at least four hours in between treatments, minimum of five times per week.

pared to 35 percent healing in the control group. When results were stratified for compliance, healing rates in the test group reached 71 percent. However, the small sample size of this pilot work limited the validity and significance of this investigation. A study, funded by the American Podiatric Medical Association and designed to capture a larger patient group, is currently underway at the Carl T. Hayden VAMC in Phoenix, Arizona, to test the validity and reproducibility of this pilot work.

Additional investigations of electrical stimulation have drawn similar conclusions. Baker et al., found that diabetic wound healing could be accelerated with the use of asymmetric biphasic electrical stimulation.[23] Gault reported that wound healing rates could be "doubled" with electrical stimulation, however, no description of wound analysis or selection is presented.[24] A study of stage IV decubitus ulcers demonstrated that 45 minutes of high voltage monophasic, pulsed current per day effectively accelerated healing rates in these hard to heal wounds.[25] A 1991 multicenter, randomized, double-blind study of 67 wounds demonstrated a decrease in wound size of 56 percent in the low frequency pulsed current group compared to 33 percent for the control group.[26]

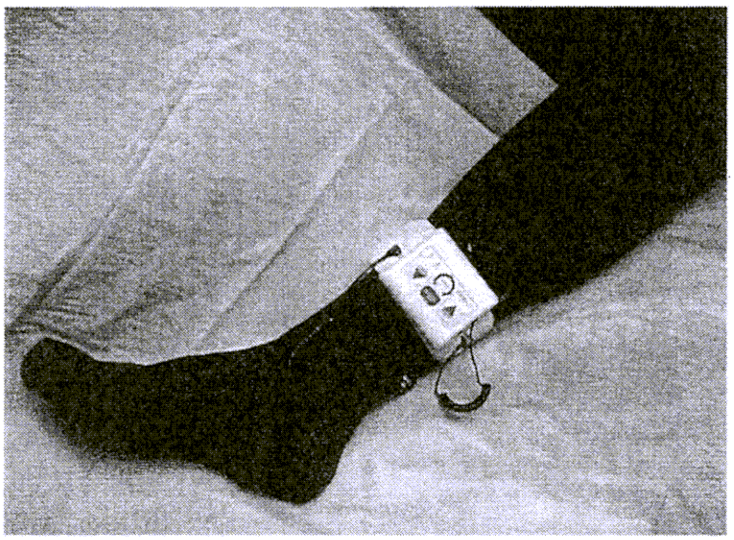


Figure 1

Promotion of Healing

Intact living skin contains endogenous electrical properties and inherent polarity. When the integrity of skin is disrupted, a potential difference or electrical imbalance between intact and injured skin occurs. During wound healing, this potential difference decreases and completely disappears when skin integrity is restored. Ion exchange is induced by injury and energy travels from cell to cell. When electrical stimulation is externally applied, electrical currents stimulate biologic homeostasis feedback mechanisms and can accelerate tissue repair and replacement.

Negative current decreases edema around the electrode and liquefies necrotic tissue in the wound. Negative polarity also stimulates granulation, increases blood flow, increases fibroblast proliferation and induces epidermal cell migration. Positive current promotes epithelial growth, denatures protein, attracts macrophages and decreases mast cell aggregation. Consequently, changing polarity when wound healing plateaus or stalls rejuvenates the healing process.

"Electrical stimulation therapy provides an alternative method to improve wound healing and benefit the high-risk foot."

An electrotherapy sock is currently available that can provide therapy while the patient is sleeping. This Dacron-mesh silver nylon stocking is an electrode that covers the surface of the foot and lower leg, providing electrotherapy to the total surface area (Figure 1). A pulsed neuromuscular stimulator is attached to the garment and can be worn to increase circulation in the leg. Jim Johnson, president of the company that manufactures this stocking, says that this sock "mimicks" normal human electrophysiology. Johnson says, "...blood circulation is a round trip ticket. If circulation is disrupted through diabetes, you can't efficiently get oxygen to heal, and you can't get waste to leave."[27] Johnson agrees that his company's device does not replace good wound care and proper disease management including nutrition, exercise and glucose management.

Contraindications

Careful evaluation of the medical history and a patient review of systems is important when considering patients for electrical stimulation intervention. Contraindications to this type of therapy include malignancy, active osteomyelitis, electronic implants or pacemakers and metal ion containing topical substances such as silver sulfadiazine.

Case Study

A 52-year-old caucasian woman with Type 1 diabetes mellitus and hypertension presented with an infected blister and ulceration plantar to the fifth metatarsophalangeal joint of the right foot. Following debridement, the ulcer measured 3.3 x 3.9 centimeters in diameter (Figure 2). Infection was cleared with two weeks of amoxicillin clavulanate. Her HbA1C was 12.0; and she had TcPO2 measurement of 59 around the wound site. The ulcer failed to respond to local wound care including weekly debridement, saline dressings, offloading and silvadene dressings.

Figure 2

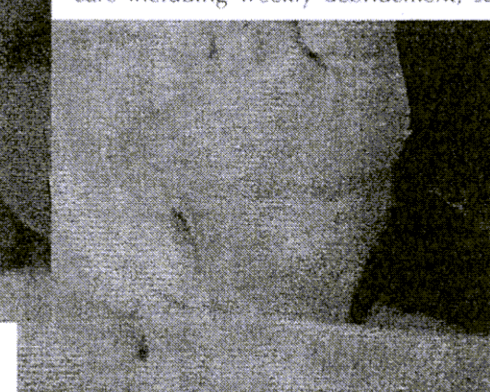


Figure 3

Electrical stimulation was later added to the wound care routine. The electrical stimulation was delivered for eight hours

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every evening through a Dacron-mesh silver nylon stocking at a dose of 50 volts with 80 twin peak monophasic pulses per second for 10 minutes, followed by 10 minutes of an eight-pulse-per-second current. The patient was compliant with therapy and had no complaints of pain from the delivery at a subsensory level. The wound was irrigated daily with normal saline and dressed with a hydrogel. The ulcer was offloaded in a removeable cast walker. Six weeks later the ulcer was defined as healed by the presence of full epithelialization and wound closure without drainage (Figure 3). One year later, there has been no re-ulceration and healed skin remains intact.

Conclusion

Diabetic foot disease is becoming a national medical concern. As lower extremity ulceration and amputation becomes more prolific, researchers and clinicians continue to search for adjunctive modalities to improve wound healing. Electrical stimulation therapy provides an alternative method to improve wound healing and benefit the high-risk foot. Current data is persuasive, but additional clinical studies are needed to convince insurance payors of this exciting, yet "not so new" treatment. ■

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