

ARTICLES

Electric Stimulation as an Adjunct to Heal Diabetic Foot Ulcers: A Randomized Clinical Trial

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ABSTRACT. Peters EJ, Lavery LA, Armstrong DG, Fleischli JG. Electric stimulation as an adjunct to heal diabetic foot ulcers: a randomized clinical trial. *Arch Phys Med Rehabil* 2001;82:721-5.

Objective: To evaluate high-voltage, pulse-galvanic electric stimulation as an adjunct to healing diabetic foot ulcers.

Design: Randomized, double-blind, placebo-controlled pilot trial.

Setting: University medical center.

Patients: Forty patients with diabetic foot ulcers, consecutively sampled. Twenty patients each assigned to treatment and placebo groups. Five patients (2 treated, 3 placebo) withdrew because of severe infection.

Interventions: Electric stimulation through a microcomputer every night for 8 hours. The placebo group used identical functioning units that delivered no current. Additional wound care consisted of weekly débridements, topical hydrogel, and off-loading with removable cast walkers. Patients were followed for 12 weeks or until healing, whichever occurred first.

Main Outcome Measures: Proportion of wounds that healed during the study period. Compliance with use of device (in hr/wk), rate of wound healing, and time until healing.

Results: Sixty-five percent of the patients healed in the group treated with stimulation, whereas 35% healed with placebo ($p = .058$). After stratification by compliance, a significant difference was identified among compliant patients in the treatment group (71% healed), noncompliant patients in the treatment group (50% healed), compliant patients in the placebo group (39% healed), and noncompliant patients in the placebo group (29% healed, linear-by-linear association = 4.32, $p = .038$). There was no significant difference in compliance between the 2 groups.

Conclusion: Electric stimulation enhances wound healing when used in conjunction with appropriate off-loading and local wound care.

Key Words: Diabetic foot; Diabetes mellitus; Electric stimulation; Rehabilitation; Ulcer; Wound.

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FAULTY WOUND HEALING of foot ulcers is among the most common scenarios that lead to foot and leg amputations in persons with diabetes mellitus.¹ Electric current has been shown to facilitate fracture healing, enhance migration of fibroblasts, provide antibacterial effect, and facilitate wound healing in animal models.²⁻¹⁰ In addition, vascular studies indicate that a subset of diabetic patients have an increase in blood flow to the foot after receiving electric stimulation. Theoretically, electric stimulation could improve common deficiencies that have been associated with faulty wound healing in diabetic foot wounds, such as poor blood flow, infection, and deficient cellular responses. Unfortunately, there is very little information in the medical literature that describes the effect of electric stimulation to facilitate the healing of ulcers and wounds in the diabetic foot. For the most part, existing work involves small case series of decubitus and venous stasis ulcers, improved survival of ischemic flaps^{9,11-13} and 1 study¹⁴ suggests that diabetic wounds heal faster when electric stimulation is used.^{9,11-14}

Most of these studies do not report such important potential confounding factors as peripheral blood flow, the severity of the wound, and adjunctive therapies (eg, off-loading). We have not been able to identify any randomized clinical studies that evaluate clinical outcomes of electric stimulation for treating diabetic foot ulcers. Therefore, this study sought to evaluate the effectiveness of electric stimulation to facilitate the healing of diabetic foot ulcers in persons with diabetes in a randomized clinical trial. We expected that a larger proportion of patients who received electric stimulation would heal and that they would heal faster compared with patients who received sham electric stimulation.

METHODS

This study was designed as a 12-week, double-blind, randomized, placebo-controlled clinical trial consisting of 2 groups of 20 diabetic patients with foot ulcers. The presence of diabetes was determined using World Health Organization criteria.¹⁵ All wounds were classified as grades 1A–2A using the University of Texas Diabetic Wound Classification System^{16,17} (table 1). All patients had a transcutaneous oxygen tension greater than 30mmHg measured at the dorsum of the affected foot. The Radiometer transcutaneous oxygen pressure measurement system^a consisted of a heated Clark oxygen sensor (electrode) and disposable membrane connected to a central processor and digital display unit. The electrode was heated to 43.5°C and calibrated at 157mmHg.

Subjects were excluded if they presented with any of the following: soft tissue or bone infection, malignancy, or any cardiac conductivity disorder. The presence of soft tissue infection was based on the presence of cellulitis, purulence, pain, or swelling. Osteomyelitis was ruled out based on plain film radiographs. If radiographs were not definitive, a bone biopsy was performed at a noncontiguous site to obtain a bone culture.

Other than the inclusion and exclusion criteria, screening of patients included assessment of protective sensation and vibratory perception threshold with a Semmes-Weinstein 10-gam

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Table 1: University of Texas Diabetic Wound Classification System*

Stage	Grade			
	0	1	2	3
A	Pre- or postulcerative lesion completely epithelialized	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	With infection	With infection	With infection	With infection
C	With ischemia	With ischemia	With ischemia	With ischemia
D	With infection and ischemia	With infection and ischemia	With infection and ischemia	With infection and ischemia

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monofilament and a biothesiometer.¹⁸ Neuropathy was defined as 1 or more missed test with the monofilament or a vibrator perception threshold of more than 25V. Plantar foot pressures were measured on the subjects' third step with the Novel EMED-SF platform system.^b Furthermore, initial glycosylated hemoglobin (HbA_{1c}) blood levels were obtained. Independent *t* tests and chi-square tests were used to identify possible differences between placebo and treatment groups in patient characteristics and clinical variables (table 2). No significant differences were noted between the treatment and the placebo groups as far as age, gender, glycosylated hemoglobin, peak plantar pressure, duration of diabetes, initial wound area, and neuropathy were concerned (table 2). Wound location is shown in figure 1.

We used the Micro-Z™,^c a small 5.5 × 6cm electric stimulation device, that delivers current via a microcomputer to a Dacron-mesh silver nylon stocking to provide nocturnal electric stimulation to patients randomly assigned to the treatment group. A dose of 50V with 80 twin peak monophasic pulses per second was delivered for 10 minutes. This was followed by 10 minutes of 8 pulses per second of current. The exact resistance is unknown because of the unknown epidermal resistance of each patient. However, the resistance of the stocking itself was 0.6Ω · cm⁻². The total surface of the stocking was approximately 176 square inches. The pulse width was 100μs. After electric stimulation, the device was programmed to be on standby for 40 minutes to prevent a burn injury secondary to electrolysis. The total program was designed to run at night for an 8-hour period. A slowly evaporating electrolyte fluid was

applied to reduce skin resistance. Because no previous clinical information was available using the Micro-Z and Dacron-mesh silver stocking application system, the decision to use this dosing regimen was based on clinical observations with 15 patients during the 6 months before initiating the project. Providing a dosing schedule that could be used at night was thought to improve patient compliance with electric stimulation therapy.

The placebo group used electric stimulation units that looked and acted identically to an active electric stimulation unit but did not deliver any current. The light and function keys of both devices responded identically. Because the current was delivered at a subsensory level and all patients suffered from sensory neuropathy, it was impossible for the physician or patient to determine if the unit was real. Placebo and electric stimulation units were randomly distributed among the study patients by the investigators, with no one aware which device was a

Table 2: Characteristics of Patients Who Received Placebo and Electric Stimulation

	Placebo Group	Treatment Group
Age (yr)	59.9 ± 7.0	54.4 ± 12.4
Gender (M/W)	16/4	19/2
History of diabetes (yr)	17.0 ± 7.5	16.4 ± 11.6
Ulcer duration (mo)	5.5 ± 13.0	5.0 ± 6.4
With neuropathy (%)	100	100
Cross-sectional wound area (cm ²)	3.54 ± 5.56	1.63 ± 1.51
Glycosylated hemoglobin (%)	9.5 ± 2.4	9.2 ± 2.1
Peak plantar pressure (Ncm ²)	81.5 ± 21.9	91.1 ± 15.7
Transcutaneous oxygen measurements (mmHg)	43.4 ± 10.6	47.1 ± 13.0
Semmes-Weinstien monofilament	1.9 ± 2.4	3.2 ± 3.0
Vibratory perception threshold (V)	41.5 ± 12.1	38.5 ± 9.6
Compliance per week (hr)	27.9 ± 13.0	30.2 ± 11.9

NOTE. Values presented as means ± standard deviations (except gender and neuropathy).

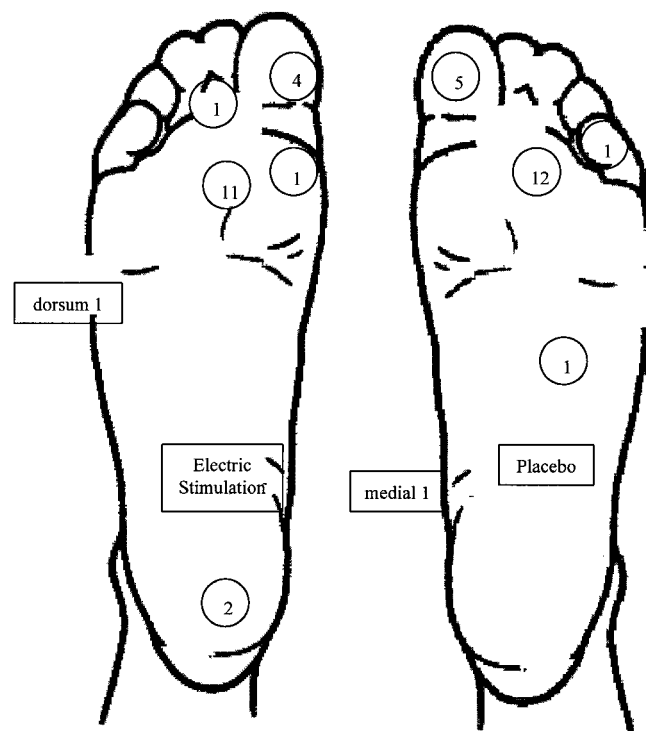


Fig 1. Circled areas represent wound locations and number of occurrences at each location in patients with diabetic foot ulcers treated with electric stimulation and placebo.

placebo and which was a real unit. The manufacturer of the units was not informed which patient received which unit. Each unit was coded with a unique identification number, and the manufacturer units revealed their status, placebo or electric stimulation, only at the end of the data collection for the last patient. Subsequently, the investigators could match the status of the identification numbers with the corresponding units to start analyzing the data. Compliance was post hoc stratified into compliant patients who used the electric stimulation device for 20 hours or more a week on average and noncompliant patients who used the device for less than 20 hours per week. The number of hours that the device was used each week was monitored by downloading this information from the micro-computer of the electric stimulation devices.

Both the treatment and placebo group received traditional wound care consisting of débridement, NU-GEL™ collagen wound gel,⁴ and pressure reduction at the site of the ulceration. Dressings were changed twice a day by the patient, their family members, or home health care providers, depending on the patient's individual capabilities and resources. Patients were seen every week to evaluate the wound healing process. Wound size was evaluated with a VERG videometer,⁶ a commercially available system that incorporates a standard Hi-8 video camera and VEV software⁶ designed for the Microsoft Windows 95 operating system to measure digitally wound surfaces. A DH Pressure Relief walker^f was used to off-load the effected foot and protect the ulcer from repetitive trauma. This device has been shown to decrease peak foot pressures at the site of neuropathic ulcers by about 85%.^{19,20} Patients were evaluated every week until the ulcer healed or for 12 weeks, whichever occurred first.

Outcomes included the proportion of patients with complete wound healing in 12 weeks, the rate of wound healing, and complications such as infection or need for amputation. Further application of electric stimulation was aborted in cases of infection or amputation. Furthermore, we used a linear-by-linear association (Mantel-Haenszel test) to evaluate the proportions of patients that healed in both placebo and treatment groups stratified by use of electric stimulation for more or less than 20 hours a week.²¹ In addition, we used a Student's *t* test and a Kaplan-Meier survival analysis to compare the time to complete healing among patients with complete epithelialization in both treatment arms.

RESULTS

Whereas 13 (65%) of the patients healed in the electric stimulation treatment group, 7 (35%) healed in the group that received a sham unit ($\chi^2 = 3.60, p = .058$). When patients were stratified by compliance, a significant difference was identified among compliant patients in the treatment group (10/14, 71% healed), noncompliant patients in the treatment group (3/6, 50% healed); compliant patients in the placebo group (5/13, 39% healed), and noncompliant patients in the placebo group (2/7, 29% healed) (fig 2, linear-by-linear association = 4.35, $p = .037$). Compliance in the treatment (14/20, 70%) and placebo group (13/20, 65%) was essentially the same.

There was no significant difference in the rate of wound healing and the average time until wounds healed among treatment and placebo groups. The total change in ulcer cross-sectional area was 86.2% versus 71.4% in treatment and control groups, respectively, over the 12-week duration of the study. Among patients who healed, the average healing times for patients with an electric stimulation unit and a placebo unit were 6.8 ± 3.4 weeks and 6.9 ± 2.8 weeks, respectively. Two

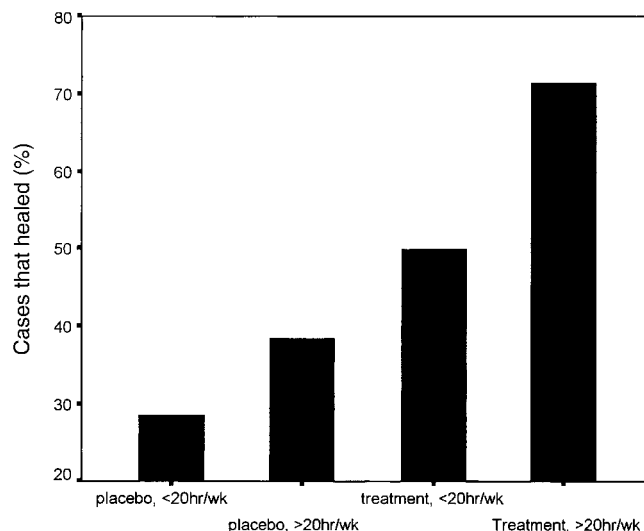


Fig 2. Results of electric stimulation on wound healing, stratified by compliance. Patients who used electric stimulation for 20 hours or more a week were more likely to heal than those who used the device less than 20 hours a week or patients who used the placebo device (χ^2 for trend = 4.35, $p = .037$).

of the subjects who used the electric stimulation unit failed to complete the study because they were treated for soft tissue infection, as did 2 subjects in the placebo group. Furthermore, 1 subject in the placebo group received an amputation of the fifth digit because of osteomyelitis. The remaining 5 patients in the electric stimulation group and 10 patients in the placebo group failed to heal within the 12-week duration of the study.

DISCUSSION

The results of this pilot study suggest that high-voltage, pulsed galvanic electric stimulation, used for more than 20 hours per week, may enhance wound healing when used with local wound care and appropriate pressure and shear reduction. The results of this study are quite promising and compare favorably with several recent reports in the medical literature on wound healing in persons with diabetes mellitus. In a meta-analysis of diabetic ulcer healing, Margolis et al²² found that, after 12 weeks of good wound care, 24% of wounds healed and, after 20 weeks, approximately 31% of diabetic foot ulcers healed. Both the treatment and placebo groups in our study had better rates of healing than either the 12- or 20-week healing rates in the meta-analysis. One factor that probably significantly influenced the results was the method of off-loading used. Many of the meta-analysis studies used off-loading strategies that have been shown to be less effective than the removable cast walker we used in this randomized trial.^{19,20}

Innovations in Ulcer Care

Other innovations to enhance ulcer healing have been less successful compared with those cited in the literature on total-contact and with the results observed in this study with electric stimulation. For instance, recombinant platelet-derived growth factor has been shown to heal 50% of diabetic foot ulcers in 20 weeks.²³ Autologous platelet-derived wound healing factor has been shown to heal 33% of wounds in 12 weeks.²⁴ And bioengineered tissue has been shown to heal 50% of wounds in a 12-week randomized clinical trial.²⁵

Animal Models

Several clinical and laboratory reports using electric stimulation support the observations made in this study. Studies using animal models have shown that electric stimulation can increase perfusion in specimens without diabetes or peripheral arterial occlusive disease.^{11,13,26-32} Kjartansson and colleagues^{9,13} reported on the use of external electric stimulation to improve tissue oxygenation in skin flaps. Both studies found a significant increase in the perfusion of skin flaps, as measured with a laser Doppler flowmeter.^{8,13} In addition, Mohr et al³³ showed that using high-voltage pulsed stimulation in some cases altered vascular perfusion in rat hindlimbs. Kjartansson et al⁸ investigated different types of electric stimulation and their relationships to flap necrosis. They found that the frequency of stimulation had little effect on flap survival. In other studies, electric stimulation has been shown to facilitate an increase in capillary density within stimulated muscle. Myrhage and Hudlicka³⁴ reported a capillary bed increase of 20% at day 4 and 50% at day 14 in rabbit muscle.

Electric Stimulation in Humans

Electric stimulation has also been reported to accelerate wound healing and enhance flap survival in nondiabetic humans.¹² However, clinical studies in this area are mostly descriptive reports with ill-defined patient populations and wide variations in the type and method of delivery of electric current. The impaired functional microcirculation and neuropathy, often endemic to the diabetic population, make it difficult to compare results with nondiabetic population. It is interesting to note that several clinical studies excluded patients with evidence of peripheral vascular disease from their investigations.^{11,14,35} In addition, none of the available studies provided consistent operational definitions of peripheral vascular disease or wound severity.^{11,12,14,26,35} A deficiency in local tissue perfusion and the localized tissue hypoxia are contributing factors in many diabetic ulcerations and amputations.^{1,36,37}

Several investigators¹¹⁻¹³ have associated changes in wound healing with an increase in tissue perfusion after the application of an electric field. Electric stimulation has been shown to increase significantly tissue perfusion measured by laser Doppler flowmetry in persons with diabetes and peripheral vascular disease.³⁸ Another study³⁹ reported that diabetic patients with peripheral vascular disease experienced a significant rise in transcutaneous oxygen pressure during the first 5 minutes of stimulation. Because blood flow is a pivotal factor in the healing process, this may be the mechanism that enhanced the prevalence of complete epithelialization.

Limitations

Several limitations were identified in this pilot study that should be considered in future projects. One factor that may influence wound healing is variability of the current. The impedance of the skin is a key element that influences current. The resistance in itself is dependent on such factors as the presence, thickness, and function of adnexa-like sweat glands; skin thickness; and hair growth. In our study, we attempted to standardize these factors by applying a slowly evaporating electrolyte spray solution to the foot and leg before using electric stimulation. We were unable to measure these factors and the exact voltage of the current at the wound site. However, it is likely that the actual electric current received by each patient was variable.

Dosing of electric current in this study was based on observations made in a 6-month period before initiating this study.

Because the microcomputer and Dacron-mesh silver nylon stocking system were relatively new, no previous clinical studies had been performed in diabetic patients with foot ulcers. Most of this type of therapy is currently performed in health care centers or by home health care providers in the patients' home. The current and duration of therapy reported in the medical literature are diverse and no clear standard seems to exist. The dose regimen we used exceeds what is often reported in the literature.

Part of the rationale for using a regimen that can be used at night was the expectation that patients would be more compliant. Compliance seemed to be an important issue because even patients who were classified as being compliant (>20hr/wk) in our study used the device correctly only about half the time. Unfortunately, the available information from the microcomputer did not allow us to determine if patients used the device every day for a few hours or for only a few nights. The microcomputer may have made it difficult for patients to sleep with the device strapped to their leg, and so they simply decided not to use the device. Another explanation is that many of these patients sleep only a few hours at night, and therefore they used the device for only a few hours every day. Compliance with the electric stimulation therapy may also suggest some patients were not compliant with other pivotal elements in the treatment program, such as off-loading or wound care. The question of whether improved healing outcomes can be fully attributed to electric stimulation is beyond the scope of this study. Results of this study are quite promising; however, this pilot study should be repeated in a large multicenter trial to evaluate more thoroughly this adjunct to ulcer healing.

CONCLUSION

The data suggest that electric stimulation may enhance wound healing when used with appropriate off-loading and local wound care. It may, therefore, contribute to the early return to function and help minimize the need for lower extremity amputation.

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Suppliers

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- b. Novel Electrics, Inc, 964 Grand Ave, St. Paul, MN 55105.
- c. Prizm Medical Inc, 3400 Corporate Way, Ste 1, Duluth, GA 30096.
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