Treatment of Open-Skin Wounds with Electric Stimulation

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ABSTRACT. Mulder GD: Treatment of open-skin wounds with electric stimulation. Arch Phys Med Rehabil 1991;72: 375–7.

• A randomized double blind multi-center study of electric stimulation compared with sham units enrolled 59 patients (67 wounds) with open wounds of pressure, vascular and surgical etiology at nine sites. The 14-week study consisted of a four-week phase, randomized, parallel-group, double blind, sham stimulation controlled group comparing effectiveness and tolerance of electric and sham stimulation of open wounds. Patients with wounds not completely closed at the end of the four weeks were allowed to cross over to actual treatment. After four weeks of treatment, the electric stimulation group showed a 56% decrease in size with only a 33% decrease in size with sham treatment. Available data suggest that pulsed electric stimulation should be considered by health care practitioners as an adjunct for treating open wounds.

KEY WORDS: Electric stimulation; Ulcer; Wound

The management of open skin wounds constitutes an important clinical problem. Few alternative therapies are available for wounds that do not heal adequately in response to conventional therapy. The use of electric stimulation should be considered as a therapeutic option for treating skin wounds.

Several investigators[1–5] have reported a beneficial effect resulting from treatment of a variety of skin wounds with electric stimulation. Unfortunately, these reports are from unblinded or uncontrolled clinical studies and case histories.

Carley and Wainapel[1] compared low-intensity direct current with conventional wound therapy, consisting of gauze dressings. Patients receiving electric stimulation were given two hours of stimulation, twice daily, five days a week. The negative polarity was placed at the wound site for the first three days, then replaced by positive polarity for the remainder of the study. Wounds receiving electric stimulation healed twice as fast as those in the control group. The treated wounds required less debridement, healed with stronger scar tissue, and were without wound infections. Patients whose wounds had been treated with electric stimulation experienced decreased pain and discomfort. No harmful effects were reported.

The purpose of this double-blind, multi-center study was (1) to compare the healing of open-skin wounds treated with electric stimulation with the healing of similar wounds treated with sham stimulation and, (2) to evaluate patient tolerance to the therapeutic regimen.

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This study was supported by a grant from Staodynamics, Inc.

Submitted for publication May 6, 1989. Resubmitted January 30, 1990 and accepted in revised form June 17, 1990.

No commercial party having a direct or indirect interest in the subject matter of this article has conferred or will confer a benefit upon the author or upon any organization with which the author is associated.

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METHOD

Subjects

Fifty-nine patients with 67 wounds were enrolled at nine investigational sites. The skin wounds were classified as (1) pressure ulcers, (2) vascular lesions, or (3) surgical wounds. All wounds were clinically evaluated and classified as Stages I, II, III or IV according to the following criteria:

Stage I — Inflammation and reddening of tissue
Stage II — Full-thickness skin defect extending into the subcutaneous tissue
Stage III — Defect extending into muscle
Stage IV — Defect extending to bone or joint structure

Wounds included for study were between 4cm^2 and 100cm^2. Wounds were excluded if they were cancerous or were located near the eyes, larynx, or other areas where electric stimulation might not be safe, if they were completely occluded by eschar, or if hemorrhaging from major blood vessels was involved.

Patients were excluded if they had peripheral vascular problems involving clots (eg, phlebitis), active osteomyelitis, or severe systemic diseases (eg, diabetes mellitus or cardiovascular conditions) that might be associated with adverse experiences from electric stimulation. Patients also were excluded if they were pregnant, used a cardiac pacemaker, were extremely obese, or were on long-term steroid therapy, chemotherapy, or radiation therapy. Patients were treated either in their home as outpatients or in medical institutions. All patients signed an Informed Consent Statement, and Institutional Review Board approval was obtained before initiating the study.

Equipment

The electric stimulator was a self-contained, portable unit (Dermapulse) that delivered low-intensity, pulsed, direct current powered by a six-volt battery. Three intensity levels were used: 30, 35, and 40mA, with a pulse width of 140μsec and a charge per pulse of 4.2, 4.9 and 5.6 microcoulombs respec-

tively. Frequencies of 64 and 128pps were used. The treatment pad polarity could be positive or negative depending upon the protocol.

The sham stimulator was identical in appearance and function to the active stimulator; however, no output current was produced by this unit.

Procedures

The 14-week, multicenter clinical study was conducted in two phases. The first phase consisted of a four-week, randomized, double-blinded parallel-group, comparing the effectiveness and tolerance of electric and sham stimulation of open-skin wounds. Patients from either group whose wounds were not completely closed at the end of the first phase were allowed to cross over to actual treatment. Each wound was monitored for four subsequent weeks to detect recurrence of the wound or any adverse effects associated with the treatment regimen.

At the initial visit, patients were evaluated in accordance with the inclusion and exclusion criteria. Patients entered into the study were randomly assigned to receive either electric or sham stimulation. A patient/wound history was completed, which included wound etiology, previous wound therapy, and any concomitant medications being used by the patient. The wound length, width, and depth (when possible) were measured, and a photograph of the wound was taken.

Patients were evaluated at least once a week during the study. This time wounds were measured and a clinical evaluation of wound appearance was made.

Treatment regimen. Wounds were treated twice a day for 30 minutes with electric or sham stimulation. The second daily treatment was given between four and eight hours after the first treatment. After each treatment, a log was completed which recorded rate, intensity, and pad polarity used to treat the wound. Adverse experiences that might have occurred were noted by the patients or their family members.

Before each treatment with electric or sham stimulation, the wound was flushed with saline solution, and gauze pads moistened with saline solution were applied directly over the wound. The stimulator dispersive pad was saturated with tap water or saline solution and placed on a large muscle group located at a minimum of 12 inches from the wound site. The dispersive pad was secured with Velcro belts.

Wounds considered infected at the study initiation were treated with continuous stimulation at a pulse rate of 128pps and an intensity of 35mA peak. The polarity of the output was negative. This treatment regimen was followed until the wounds were free of necrotic tissue and clean, or until a serosanguinous drainage appeared.

Stage II wounds which were not infected at study initation were treated similarly to infected wounds, with the exception that after the first three days of treatment with negative polarity, positive polarity was applied. The polarity was then alternated as dictated by the stage of wound repair.

Statistical analyses of pretreatment differences between the two groups for wound size and duration of wound were performed using the student *t*-test. The chi-square test was used to compare wound stage and clinical response to treatment (poor, good, or excellent). The statistical comparison between groups for reduction in wound size was attained using the Mann-Whitney test.

Table 1: Pretreatment Wound Characteristics*

	Treatment	Control
Number of wounds	26	24
Median duration (months)	3.4	6.0
Initial wound size (cm^2)	15	17
Wound stage (number of wounds)		
Stage II	0	2
Stage III	22	17
Stage IV	4	5

*There were no statistically significant pretreatment differences between treatment and control wounds ($p > .25$).

RESULTS

Patient/Wound Eligibility

Fifty-nine patients with 67 wounds enrolled in the study. Twelve patients with 17 wounds were not included in the analysis. Wounds were excluded if wound measurements were inconsistent ($n = 5$), patients did not complete the first four-week double-blind phase of the study ($n = 4$), wounds were not within the specified pretreatment range ($n = 3$), patients missed visits ($n = 2$) or protocol violations occurred ($n = 2$). The results of this study include evaluations from 47 patients with 50 wounds.

Pretreatment Wound Characteristics

The pretreatment characteristics of the 50 wounds included in the data analysis are presented in table 1.

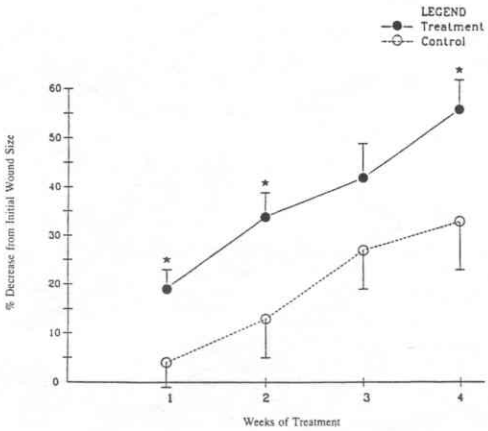
Twenty-six wounds were treated by electric stimulation and twenty-four wounds were treated by sham stimulation. The size of wounds in the treatment group was not statistically different from that in the control group. Wounds in both groups were primarily classified as Stage III. Wounds in the treatment group had been present for a median period of 3.4 months, with a range of two days to 2.1 years, and wounds in the control group had been present for a median period of six months, with a range of four days to 6.6 years.

Characteristics of patients in the two treatment groups were comparable. No statistically significant differences were found to exist between groups for any of the patient or wound characteristics ($p > .25$).

Wound Healing Assessments

Wound healing was evaluated by the percentage decrease in initial wound size and by the clinical response to treatment (fig). Wounds in the treatment group showed a 56% decrease in the initial size, as compared with a 33% decrease for wounds in the control group (table 2). A good or excellent response was reported for 92% of wounds in the treatment group, as compared with 54% of wounds in the control group.

Wound assessments from the ten-week, open phase of the study are presented in table 3. Twenty-six wounds were treated with electric stimulation for at least two weeks, using the same protocol as that used in the blinded phase. The original wound



Percentage decrease (± SEM) in initial wound size during the double-blind treatment phase. (*$p < .05$ compared with the control group Mann-Whitney U test.)

size between the stimulated and control groups was characterized as poor (≥75% reduction in size); good (25% to 74%); or excellent <25%). Ninety-six percent of wounds had shown a good or excellent response to treatment with electric stimulation.

Adverse Experiences

No significant complications or adverse effects associated with the treatment regimen or use of the stimulator were reported during the study. No complaints or complications were reported for 61 of the 72 ulcers originally investigated. The most frequent complaint was a tingling or prickly sensation reported in seven wounds in the treatment group and one in the control group. Adverse experiences included:

1. Bleeding with one ulcer. Examination of the patient records indicates that the reported bleeding is more accurately characterized as dark bloody exudate from a necrotic ulcer which, as expected, reduced to serosanguinous drainage upon further treatment.
2. Warm and cool sensations for one ulcer in the sham control group. This subject also reported pain while on the sham device.
3. Discomfort during treatment for one ulcer in the stimulated treatment group.
4. One case of skin irritation. This case involved an incontinent patient in the stimulated treatment group. The treatment area had not been adequately cleansed of urine and the urine caused the irritation. Adequate cleansing of the area before treatment prevented any recurrence of the irritation.

Significant complications or adverse effects during stimulation treatment were not reported.

Table 2: Clinical Response of Treatment and Control Wounds at Week Four*

Response	Percent of Wounds: Treatment ($n = 26$)	Control ($n = 24$)
Excellent	38.5	20.8
Good	53.8	33.3
Poor	7.7	45.8

*$p < .05$; chi-square test

Table 3: Clinical Response After Ten Weeks of Electric Stimulation During the Open Treatment House

Response	Percent of Wounds ($n = 26$)
Excellent	50.0
Good	46.2
Poor	3.9

DISCUSSION

This study was designed and conducted as a double-blind, randomized clinical trial. No significant differences existed between treatment groups which would be expected to affect treatment outcome.

Since the two groups received identical ulcer management, any difference in healing between the two groups may be attributed to the effects of the electric stimulation provided by the pulsed electric stimulator.

The increased healing that occurred in the sham control group may be attributed to the intensive care received by the sham group. The mechanism by which electric stimulation promotes wound healing is not yet clearly understood. Antibacterial effects of electric stimulation on wound healing have been reported by several investigators.[4,6] Increased bacterial burden has been associated with delayed wound closure.

An increase in tensile strength may be occurring with electric stimulation as suggested by the work of Assimacopoulous.[5] Alvarez and associates[2] reported increased collagen synthetic capacity in the dermis of wounds treated with direct current. These investigators suggest that the increase in collagen biosynthesis is due to an increased number of collagen-producing cells at the wound site.

Our studies suggest electric stimulation may induce an increase in tensile strength and reepithelization and a decrease in bacterial burden, thereby contributing to rapid wound closure.

The electric stimulator unit is a lightweight, portable unit that can be easily used by patients, family members, and health care practitioners. Available data suggest that pulsed electric stimulation should be considered by health care practitioners as an option for treating open wounds.

References

1. Carley PJ, Wainapel SF. Electrotherapy for acceleration of wound healing: low intensity direct current. Arch Phys Med Rehabil 1985;66:443–6.
2. Alvarez OM, Mertz PM, Smerbeck RV, Eaglstein WH. The healing of superficial skin wounds is stimulated by external electrical current. Invest Dermatol 1968;115:683–7.
3. Gault WR, Gatens PF Jr. Use of low intensity direct current in management of ischemic ulcers. Phys Ther 1976;56:265–9.
4. Wolcott LE, Wheeler PC, Hardwicke HM, Rowley BA. Accelerated healing of skin ulcers by electrotherapy: preliminary clinical results. South Med J 1969;62:795–801.
5. Assimacopoulous D. Low intensity negative electric in the treatment of ulcers of the leg due to chronic venous insufficiency. Am J Surg 1968;115:683–7.
6. Rowley BA, McKenna JM, Chase GR, Wolcott LE: The influence of electrical current on an infecting micro-organism in wounds. Ann NY Acad Sci 1974;238:543–50.