# The effects of non–thermal pulsed electromagnetic energy on wound healing of pressure ulcers in spinal cord–injured patients: A randomized, double–blind study

*Although its benefits in wound healing have been well documented, the efficacy of non–thermal pulsed electromagnetic energy in the treatment of pressure ulcers in individuals with spinal cord injuries remains unproven.*

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*The authors are grateful for the assistance provided by the Castle Point Veterans Medical Center, John George, Chief of SCI Services, members of the Institutional Review Board, and the SCI Nurses. We are indebted to Vivian Beyda, Dr. PH, and the Eastern Paralyzed Veterans Association who supported this study with a research grant.*

*Abstract*

*The objective of this randomized, double–blind study was to determine if non–thermal pulsed electromagnetic energy treatment significantly increases the healing rate of pressure ulcers in patients with spinal cord injuries. Subjects included volunteers admitted to a Veteran's Administration Hospital in New York over a 2 year period and consisted of 30 male spinal cord–injured patients, 20 with Stage II and 10 with Stage III pressure ulcers. Subjects were given non–thermal pulsed high–frequency electromagnetic energy treatment for 30 minutes twice daily for 12 weeks or until healed. The percentage of pressure ulcers healed was measured at one week. Of the 20 patients with Stage II pressure ulcers, the active group had a significantly increased rate of healing with a greater percentage of the ulcer healed at one week than the control group. After controlling for the baseline status of the pressure ulcer, active treatment was independently associated with a significantly shorter median time to complete healing of the ulcer. Stage III pressure ulcers healed faster in the treatment group but the sample size was limited. For spinal cord–injured men with Stage II pressure ulcers, active non–thermal pulsed electromagnetic energy treatment significantly improved healing.*

## Introduction

Pressure ulcers and associated complications are major sources of morbidity and mortality among spinal cord–injured (SCI) patients. In addition, acute and chronic osteomyelitis, delayed wound healing, and sepsis all prolong hospitalization. Treatment of pressure ulcers ranges from medical and local treatment to surgical intervention. Recurrences, which may be attributable to diminished tissue resistance to

ischemia, are all too frequent and the potential surgical options become limited due to extensive scarring. The current literature lacks well controlled studies proving effectiveness of new types of dressings and pharmacological agents. Based on the understanding that the body is as much electrical as it is chemical, the use of non–thermal pulsed electromagnetic energy* (PEE) was considered.

Previous animal and clinical studies have demonstrated significant benefit of PEE treatment in the healing of various types of acute and chronic wounds.[1,2] In 1960, Erdman showed that PEE increased peripheral blood flow without causing hyperpyrexia.[3] In following years, histological studies of wounds demonstrated that it increased collagen formation, WBC infiltration, phagocytosis, histiocytic activity, fat activity, and hematoma canalization.[4] PEE has also been reported to increase reabsorption of experimental and postoperative hematomas.[5,6]

Double–blind studies have shown that PEE has a definite biological effect on recently injured soft tissues especially in the reduction of edema, pain, and disability.[7,8] A double–blind study of children undergoing orchidopexy, demonstrated a significant reduction of edema, hematoma, and bruise resolution with the active PEE unit.[9]

PEE treatment has been reported to significantly accelerate healing of donor site wounds[10] and tissue in oral surgery.[11] It was found to increase neural regrowth of peripheral nerves.[12,13] Its hepatic effects have been described in animal and human studies.[14,15]

The positive influence of PEE treatment on superficial and deep pressure ulcers has been known since 1978 and it has been shown to accelerate healing of pressure ulcers; however, no previous double–blinded study has been published.[16,17,18] Although its benefits in wound healing have been well documented, its efficacy in the treatment of pressure ulcers in individuals with spinal cord injuries remains unproven. The purpose of this study was to evaluate the effect of PEE in treatment of pressure ulcers in spinal cord–injured patients using a randomized, prospective, double–blind design to minimize the influence of confounding factors.

## Methods

Treatment consisted of non–thermal, pulsed, high–frequency, high peak power, electromagnetic energy*. The equipment operated on a radio frequency of 27.12 MHz and provided pulse repetition rates of 80 to 600 pulses per second, a pulse width (duration) of 65 microseconds, a duty cycle between 0.5 percent and 3.9 percent, and a per pulse power range between 293 and 975 peak watts. The energy was delivered through a treatment head placed in light contact with the wound site and tuned to resonance in the area of the wound. Treatment was non–invasive and delivered through wound dressings.

*Patient population*

Spinal cord–injured patients with pressure ulcers admitted to the Veterans Administration Medical Center at Castle Point, New York, over a two–year period (January 1, 1991 to December 31, 1992) were offered the opportunity to participate in this study. Patients with more than one ulcer, recent ulcer surgery, with a cardiac pacemaker, intercurrent disease, active cellulitis, sepsis, terminally ill or end stage disease, total joint replacement (or metal implants), and those with Stage I or IV pressure ulcers were omitted from the study.

After obtaining informed consent, patients were stratified according to ulcer stage (II or III) at baseline. Stage II was defined as a partial thickness skin loss involving epidermis or dermis, the ulcer was superficial and clinically presented as a deep crater, abrasion, blister, or shallow crater. Stage III was defined as full thickness skin loss involving damage or necrosis of subcutaneous tissue which may have extended down to, but not through, underlying fascia. The ulcer presented clinically as a deep crater with or without undermining of adjacent tissue.

*Procedure/protocol*

During the study, all patients received the same topical treatment which consisted of moist saline gauze dressing.

Within each stage (II and III), patients were randomly assigned to receive therapy from either an active or control sham. Patients, staff, and authors were blinded to the identity of the functioning unit until after all patients completed the 12 weeks of treatment. The sham unit was identical in operation, appearance, and sound to the active unit.

Table 1. Baseline comparison of active non-thermal pulsed electromagnetic energy vs. sham for 20 Stage II patients

| Treatment: | Sham (N = 10) | Active (N = 10) | P Value* |
|---|---|---|---|
| Median age (range): | 50 (29–67) | 58 (24–69) | 0.343 |
| Median area in $cm^2$ of pressure ulcer (range): | 33 (9–140) | 15 (4–200) | 0.089 |
| Median granulation percentage (range): | 45 (0–100) | 23 (0–100) | 0.210 |
| Median epithelialization percentage (range): | 10 (0–30) | 8 (0–50) | 0.222 |

* P values based on Mann–Whitney U test

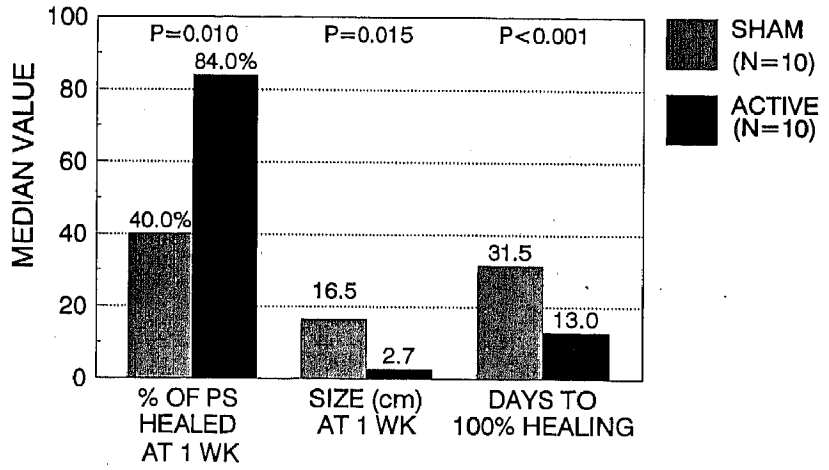


Figure 1. Healing comparisons of active non-thermal pulsed electromagnetic energy vs. sham treatment for 20 Stage II patients.

Baseline parameters examined included duration of ulcers prior to admission, degree of edema, erythema, epithelialization, and ulcer size. Hemoglobin, hematocrit, protein, and albumin levels were evaluated prior to treatment.

Pressure ulcers were assessed, measured (width x length), and photographed weekly by a single observer (MGV). The focal distance from lens to ulcer was constant (12 inches) for all photographs thereby avoiding objects/image discrepancies. All patients were assessed and photographed weekly.

*Statistical methods*

The null hypothesis was: After controlling for the patient's age and baseline stage and size of pressure ulcer, there will be no statistically significant difference in the healing rates between patients who receive active therapy and those who receive a sham therapy. Categorical variables were analyzed with the Chi-square statistic. Continuous variables that were normally distributed were assessed with the Student's t-test. The non-parametric Mann-Whitney U test was used for the continuous variables that were not normally distributed and medians were reported in place of means.

Multiple regression analysis was used to control for the baseline status of the patient and pressure ulcer. After the patient's age and the pressure ulcer size, percent epithelialization and percent granulation were forced into the model. Treatment (Active vs. Sham) was tested using a stepwise procedure. The statistical package SPSS/PC+ was used for all analyses. [19]

## Results

Of the 30 spinal cord-injured (SCI) patients who met the study criteria, 20 had a Stage II pressure ulcer and 10 had a Stage III.

**Stage II.** Among the Stage II patients there was no statistically significant difference for the baseline parameters between the 10 patients randomized to active PEE and the 10 patients in the

Table 2. Stage II patients: Comparison of healing

| Pt. No. | Group* | Percent healed at one week | Days until 100% healed |
|---|---|---|---|
| 1 | S | 78% | 20 |
| 2 | S | 0% | 83 |
| 3 | S | 10% | 34 |
| 4 | S | 10% | 29 |
| 5 | S | 47% | 35 |
| 6 | S | 71% | 22 |
| 7 | S | 50% | 35 |
| 8 | S | 83% | 23 |
| 9 | S | 33% | 42 |
| 10 | S | 23% | 27 |
| 11 | A | 100% | 7 |
| 12 | A | 100% | 9 |
| 13 | A | 60% | 14 |
| 14 | A | 100% | 8 |
| 15 | A | 47% | 21 |
| 16 | A | 88% | 13 |
| 17 | A | 87% | 15 |
| 18 | A | 81% | 14 |
| 19 | A | 71% | 13 |
| 20 | A | 40% | – |

* S denotes sham, A denotes active treatment

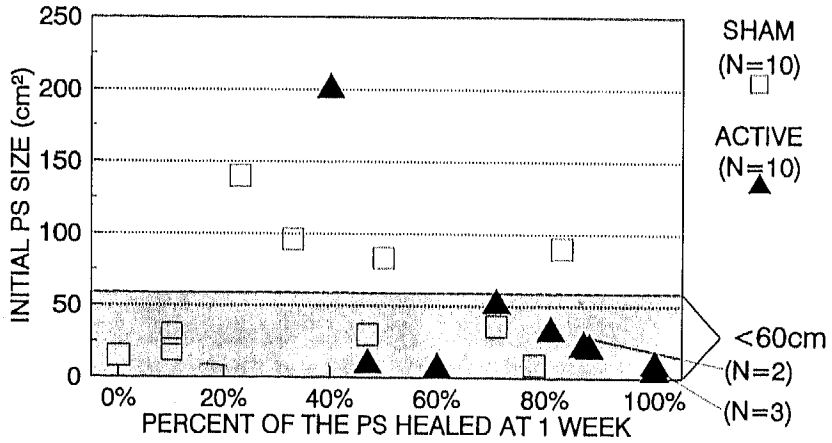


Figure 2. Initial size of pressure ulcers for Stage II patients by percent of the ulcer healed after one week of active treatment.

sham group. (Table 1) The active group had significantly better healing. (Figure 1) At one week, the active group had a greater percentage of their ulcer healed compared with the sham group (84.0 percent vs. 40.0 percent, P = 0.01). The median size of the pressure ulcer at one week after treatment began was also significantly smaller in the active group (2.7 vs. 16.5 cm², P = 0.015). The median for days to complete healing was only 13.0 for the active group compared with 31.5 days for the sham (P < 0.001). One Stage II patient (#20) in the active group was missing data on days to 100 percent healing. (Table 2) This patient dropped out of the study after one week and died of unrelated causes. There were several patients who, when evaluated on day eight and nine, were noted to be completely healed prior to the evaluation and were categorized as 100 percent healed at one week.

Although the baseline median ulcer size was not statistically different between the 10 active and 10 sham in the Stage II, the randomization process did not provide for an even distribution of large pressure ulcers. Of the five pressure ulcers greater than 60 cm², only one was in the active group. (Figure 2) Since four of the five patients with Stage II ulcers larger than 60 cm2 were randomized into the sham treatment group, two additional analyses were performed on the 15 patients with ulcers < 60 cm² in the shaded region. First, the subset of patients with pressure ulcers less than or equal to 60 cm² were analyzed. Among the 15 patients with Stage II pressure ulcers < 60 cm², there was

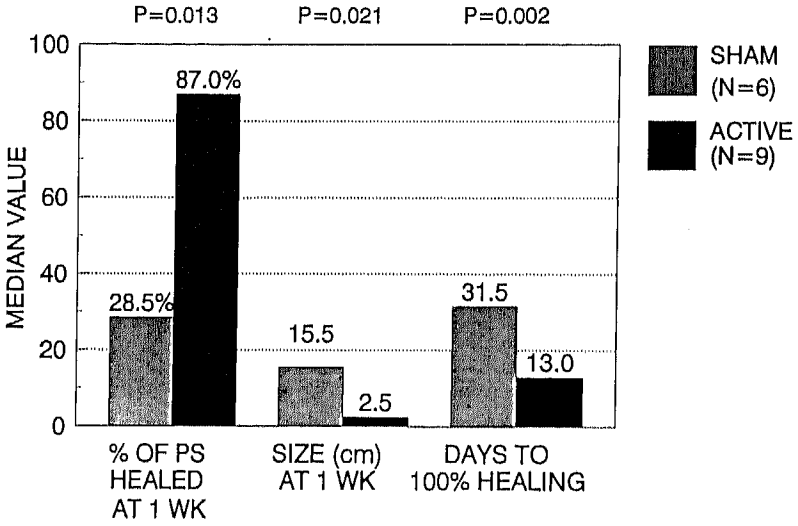


Figure 3. Healing comparisons of active treatment vs. sham treatment for 15 Stage II patients with ulcers < 60 $cm^2$.

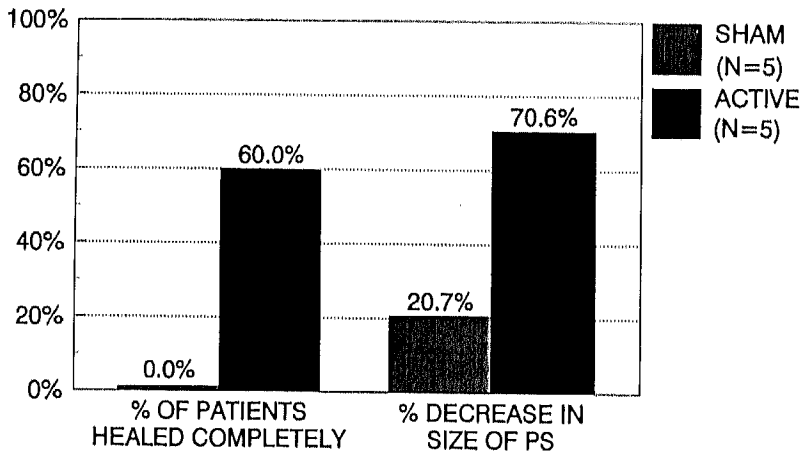


Figure 4. Comparison of healing in active treatment vs. sham treatment.

significantly accelerated healing associated with the active treatment. (Figure 3) Median days to 100 percent healing was identical to the results in Figure 1 for all 20 Stage II patients. Secondly, a multiple regression analysis was used to control for the baseline size of the pressure ulcer for all 20 Stage II patients. After controlling for the patient's age and the pressure ulcer's size, granulation, and epithelialization, PEE treatment was found to be independently associated with percent healed at one week (P = 0.002), and days to 100 percent healing (P = 0.007).

*Stage III*

Among the patients with Stage III pressure ulcers, improved wound healing was again associated with the active treatment. (Figure 4) Three of five patients in the active group healed completely whereas none of the five control subjects healed.

The patients who healed completely, did so after an average of 43 days treatment. Patients with partial ulcer resolution exhibited an average increase in epithelialization of 38.3 percent during a mean treatment duration of 38.3 days. In the Stage III pressure ulcer population, ulcer area decreased an average of 70.6 percent; whereas in the control, the ulcer area decreased by only 20.7 percent. Hemoglobin, hematocrit, protein, and albumin levels were similar between active and control groups in both Stage II and Stage III patients. No adverse side effects were noted in our study population. After the 12 weeks of treatment, two of the Stage III patients in the control group who remained unhealed received PEE treatment and healed completely within 43 days.

## Discussion

This is the first study to substantiate PEE healing effects on Stage II and Stage III pressure ulcers in SCI patients in a placebo-controlled, prospective method. Patients in the treated group (active machine) experienced accelerated healing compared to the control group (placebo machine).

The most difficult variable to control in a wound healing trial is that of initial wound size. However, it has been suggested that the relative rate of closure is remarkably independent of initial wound size.[7] Moreover, an analysis of two variables heavily

influencing healing rates, i.e. initial granulation and initial epithelialization, reveals an advantage for the placebo group regarding initial granulation (average 48 percent vs. 31 percent in treated group). There was no difference in initial epithelialization (11 percent average in both groups). Thus, with some conservatism, the measurement selected for analysis was percentage of healing achieved after one week. This percentage is defined as the reduction in wound area (width x length) from the initial measurements.

Average percentage healing achieved at one week was 77 percent in the treated group (standard deviation of 21 percent) vs. 40 percent in the control group (standard deviation of 28 percent). This accelerated rate of healing translated in an advantage of almost three to one for the active PEE treated group in number of days until complete healing (12.67 in the treated vs. 35 with the placebo group). Prolonged tissue ischemia caused by external pressure exceeding tissue capillary pressure may be exacerbated by the development of edema. The rate of diffusion of oxygen and nutrients to the cells is decreased due to impaired capillary and micro–circulation and lack of proper oxygenation of tissue.[20] PEE accelerates the elimination of edema[2,7–11,17,18] permitting restoration of normal blood flow, nutrients, and re–establishing oxygenation to tissue. The mode of action of non–thermal pulsed radio waves produced by PEE are created through electromagnetic induction. The RF field generates ionic currents in the organism. Lazarev[21] has proposed the hypothesis that the influence of the field increases the ion concentration in the vicinity of cell membranes. The action of the electrical field on charged particles leads to forced motion. Herrick observed the pearl chain effect on cells when exposed to PEE.[22] It has been demonstrated that PEE eliminated edema in acute and chronic wounds.[7,9–11,16–18,23,24] Through the piezoelectric response to PEE, it appears that damaged cells recover more quickly due to repolarization and increased sodium pump reaction times.

To further educate and evaluate the use of PEE on wound healing of pressure ulcers among spinal cord–injured patients, the following areas remain open for additional research with large numbers of patients: Stage II pressure ulcers > 60 $cm^2$, Stage III pressure ulcers, patients with multiple pressure ulcers, women, and post–surgical debridement. Future research could also include a pressure ulcer index for SCI patients.

In conclusion, these results suggest that non–thermal pulsed electromagnetic energy* treatment is safe and accelerates wound healing in SCI patients with Stage II and Stage III pressure ulcers. The improved healing rate also suggests that non–thermal pulsed electromagnetic energy* may be a cost–effective treatment for a very expensive problem.[25]

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