Is Electrical Stimulation Effective in Reducing Neuropathic Pain in Patients with Diabetes?

Pulsed-dose electrical stimulation is evaluated as an analgesic modality in patients with painful diabetic neuropathy. Using a knitted silver-plated nylon/dacron stocking electrode, patients were given electrical stimulation over the course of 1 month. Pain was measured weekly, using a 10-cm. visual analog scale. Pain measurements at the end of the 4-week therapy and at 1 month after complete discontinuation of therapy were significantly lower than at the initiation of therapy. The results of this pilot study suggest that nocturnal doses of pulsed-electrical stimulation may be effective in alleviating subjective, burning, diabetic neuropathic pain in a population consisting of patients with grossly intact protective sensation, relatively good distal vascular perfusion and less than ideal glucose control. To the authors' knowledge, this is the first analytic report of pulsed-dose electrical nerve stimulation delivered through a stocking electrode for treatment of symptomatic diabetic neuropathy in medical literature. (The Journal of Foot & Ankle Surgery 36(4):260–263, 1997)

Key words: diabetes mellitus, neuropathy, pain

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It has been estimated that up to 20% of patients with diabetes suffer from painful neuropathy (1, 2). The pathogenesis of this pain is complex; treatment for this often debilitating condition is equally so. Numerous pain management protocols have been advocated to ameliorate neuropathic pain (3). These have included antidepressants, anticonvulsants, α-adrenergic agonists, aldose reductase inhibitors, intravenous insulin, intravenous anesthetics, and topical counterirritants, among others (4–10). While all of these treatment regimens have met with varying degrees of clinical success, they have also been associated with either less than ideal patient tolerance, a high-complication profile, or potential drug interactions.

There are a number of descriptive articles indicating that electrical stimulation may be an effective pain-relieving modality (11–13). However, we are unaware of any studies in medical literature that report on the ability of pulsed-electrical stimulation to reduce painful diabetic neuropathic symptoms. Therefore, the purpose of this prospective study was to evaluate pulsed-dose electrical stimulation as an analgesic modality in patients with painful diabetic neuropathy.

Materials and Methods

We enrolled 10 subjects, 7 male, presenting for evaluation and treatment of painful nocturnal diabetic neuropathy. Patients in this study were all categorized using the University of Texas Diabetic Foot Classification System (14). All patients were in foot category II or lower. One patient had neuropathy, deformity, and no history of ulceration or amputation (category II). All other patients had no loss of protective threshold as defined by the above classification (category 0). Descriptive data for this population are: all enrolled patients described their pain as burning in quality; patients presenting with any other subjective description of pain quality (*e.g.*, tingling, formicating, lancinating) were excluded from the study; no subjects had received prior treatment for this malady before enrollment.

For all subjects, the diagnosis of diabetes mellitus was made based on World Health Organization criteria. The vibration perception threshold (VPT) was evaluated using the Biothesiometer™[5] and the tech-

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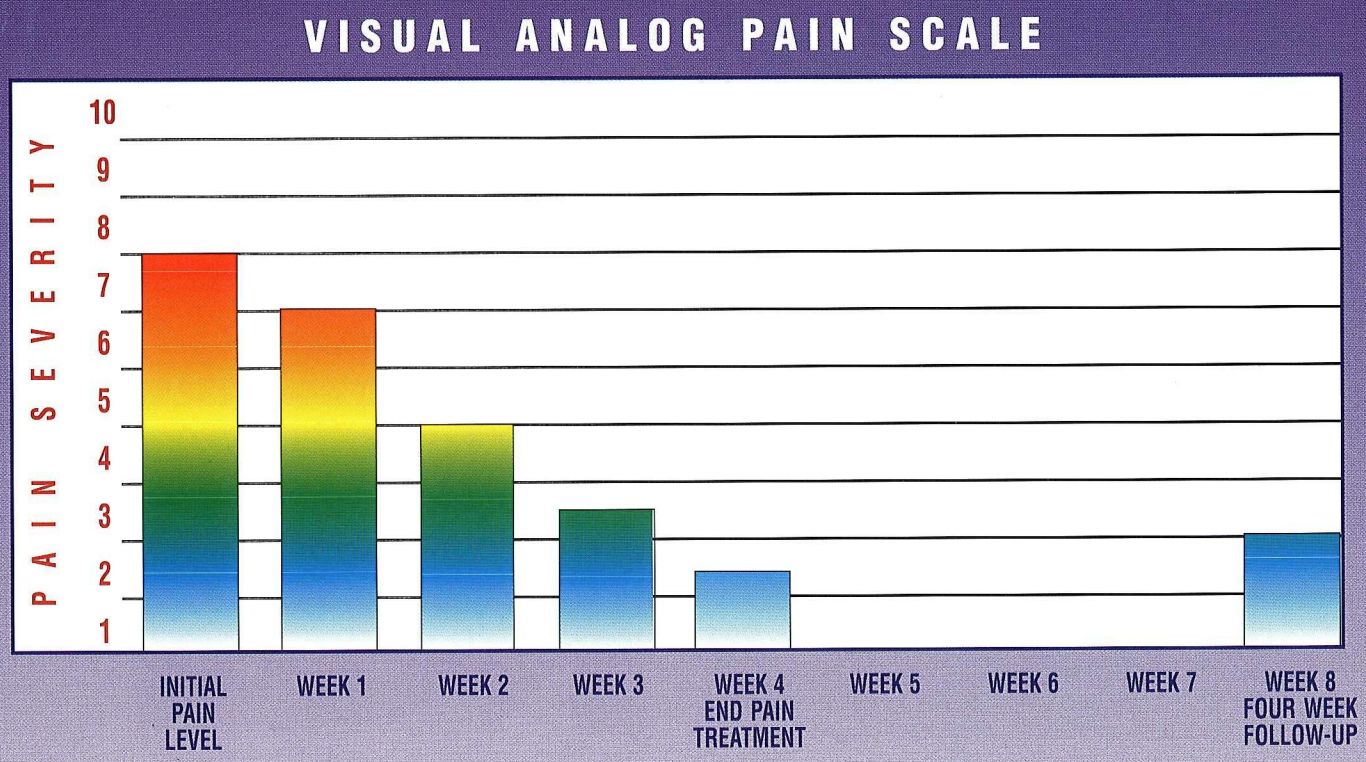
"Nocturnal doses of pulsed electrical stimulation may be effective in alleviating subjective burning, diabetic neuropathic pain." [2]



- *Prizm's* **Micro-Z™** *pulsed DC NMS allows for pre-set dosing regimens while sleeping.*
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TABLE 1 Descriptive characteristics

Subjects (N)	Age (years)	Duration of diabetes (years)	Duration of symptoms (weeks)	HgbA1C	VPT	ABI	TBI
Males = 7 Females = 3	52.4 ± 10.2	15.0 ± 9.4	10.0 ± 8.1	7.6 ± 0.5	19.3 ± 7.6	0.92 ± 0.22	0.66 ± 0.16

Note—ABI, ankle/brachial systolic pressure index; TBI, toe/brachial systolic pressure index.

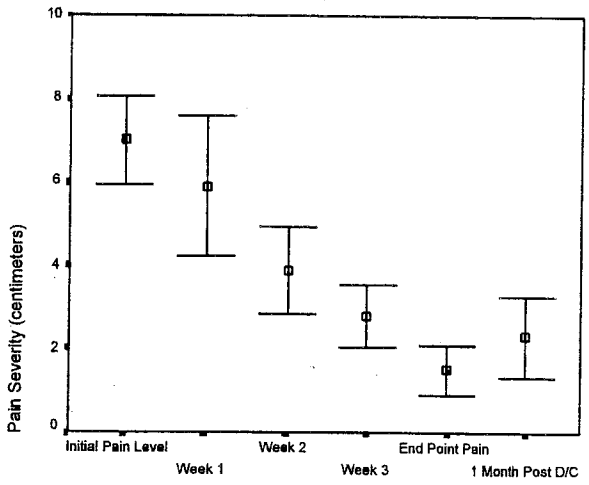
nique defined by Young *et al.* (15). The instrument used to conduct the VPT testing was a hand-held device with a rubber tactor that vibrates at 100 Hz. The hand-held unit was connected by an electrical cord to a base unit. This unit contains a linear scale which displays the applied voltage, ranging from 0 to 50 V. The method of testing was standardized. The device was held with the tactor balanced vertically on the pulp of the toe. At this time, the voltage was slowly increased on the base unit until the patient could perceive a vibration. A mean of three readings (measured in volts) was used to determine the VPT for each foot (15). The noninvasive vascular assessment consisted of an ankle/brachial systolic pressure index, and toe/brachial index measurement (16, 17). Additionally, all patients received a glycohemoglobin assay at enrollment to evaluate their long-term glucose control.

Electrical stimulation was administered through a knitted silver-plated nylon/dacron stocking electrode (Micro-Z™[6]).[7] Following the manufacturer's instructions regarding appropriate use, a dose of 50 V of pulsed direct current (approximately 50 μA) at 100 pulses per sec. for 10 minutes, then 10 pulses per sec. for 10 minutes was delivered each hour over an 8-hr. period nightly for 1 month. The electrical stimulation device is constructed from a nylon-silver/dacron fiber that is knitted into a stocking configuration and is applied after the lower extremity is moistened with an electrolyte spray to improve the uniformity of conduction. The garment contains one snap connector with a standard pin end opening which is used to connect a lead wire to the stocking. The unit is powered by two AA alkaline batteries. No other adjunctive therapy was provided during the study period.

Patients were followed weekly for 4 weeks during electrical stimulation and then 1 month following discontinuation of stimulation. To monitor subjective pain severity, we used a standard 10-cm. visual analog scale (18). The patient was asked to mark a point along a 10-cm. line ranging from no pain (the 0-cm. point of the scale) to the worst pain ever experienced (the 10-cm. point of the scale). This scale was administered at each clinical visit and at 1 month following discontinuation of electrical stimulation. We used Wilcoxon signed ranks test for matched pairs to evaluate the change in symptoms from initiation of therapy to the 4-week end point, and Pearson's test for linear correlation to measure differences in pain based on level of glycohemoglobin, or the ankle or toe brachial index. For all analyses we used an alpha of 0.05 (19). Data are provided as mean ± standard deviation.

Results

On initial enrollment, the pain score as measured on the visual analog scale was 7.0 ± 1.5 cm. At the end of the 4-week evaluation period, the mean pain score was 1.5 ± 0.9 cm. ($p < 0.005$). At 1 month following discontinuation of electrical stimulation, the mean pain score was 2.3 ± 1.3 cm. This was significantly lower than the pain score at the initial presentation ($p < 0.006$), but higher than at the therapy's end point ($p < 0.04$). These data are summarized in Fig. 1. There was not a significant difference in pain severity in any 1-week interval, nor was there a significant difference in the glycohemoglobin level, the ankle or toe brachial index, VPT, sex,



D/C = discontinuation of therapy

FIGURE 1 Reduction of neuropathic burning pain with pulsed electrical stimulation.

[6] Prizm Orthopaedics, Duluth, GA.

[7] The authors have no financial interest in the device used in this study.

age, or presenting or final pain scores. Subjective evaluation of pain decreased in a relatively linear fashion over the 4-week period.

Discussion

The results of this pilot study suggest that nocturnal 8-hr. cyclic doses of pulsed-electrical stimulation through a total contact stocking electrode may be effective in alleviating subjective diabetic neuropathic pain in a population consisting of patients with grossly intact protective sensation and relatively good distal vascular perfusion. This pain relief may be sustained to some degree following discontinuation of therapy. To our knowledge, this is the first analytic report of pulsed-dose electrical nerve stimulation delivered through a stocking electrode for treatment of symptomatic diabetic neuropathy in the medical literature.

One of the potential shortcomings of this study was the lack of a control group. It may be postulated that patients receiving a stimulation device for treatment of subjective pain may have been exposed to a powerful placebo effect. This has been reported in other studies (20–22). In their study of phantom limb pain, Finsen *et al.* found that, while there was a considerable placebo effect, the functioning stimulation units provided significantly more pain relief (11). We believe that this may indeed have played a role in the outcomes of our study, but we believe that the striking degree of pain reduction over a relatively lengthy period makes this possibility less likely.

Indirectly, this study adds credence to the often stated observation that "subjective" or "painful" diabetic neuropathy frequently precedes overt "objective" or "painless" sensory neuropathy. The VPT was used in this study to objectively and quantitatively measure protective sensation. This tool has a very high inter- and intrarater reliability (23, 24). Young and colleagues reported that a value of greater than 25 V indicates a 6-fold greater increase for ulceration (15). The mean VPT in our study was substantially below this threshold.

In conclusion, results from this pilot study suggest that pulsed-dose electrical nerve stimulation appears to have promise as an analgesic for use in painful burning diabetic neuropathy. Large randomized trials are needed to evaluate this modality in greater detail, and the effectiveness of various dosages and frequencies of application need to be more thoroughly delineated. Other types of neuropathic pain should also be evaluated in addition to nocturnal burning pain. Additionally, enrollment of a placebo group in future investigations may confirm both our team's and other investigators' belief that the modality has a physiologic as well as a psychosomatic basis in analgesia.

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