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Peripheral Nerve Stimulation With a High-Frequency Electromagnetic Coupled Powered Implanted Receiver at the Posterior Tibial Nerve for the Treatment of Chronic Pain in the Foot

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ABSTRACT

Introduction: Peripheral neuropathy has several causes, with diabetes being the most common. Conservative management may fail to control pain. Our study aimed at evaluating the use of peripheral nerve stimulation of the posterior tibial nerve for treating peripheral neuropathy.

Materials and Methods: This was an observational study of 15 patients who received peripheral nerve stimulation at the posterior tibial nerve to treat peripheral neuropathy. Outcomes measured were improvement of pain scores and Patient Global Impression of Change (PGIC) at 12 months compared with before the implant.

Results: Mean pain scores with the verbal rating scale were 3 ± 1.8 at >12 months compared with 8.6 ± 1.2 at baseline, a reduction of 65% ($p < 0.001$). Median satisfaction with the PGIC at >12 months was 7 of 7, with most subjects reporting a 6 (better) or a 7 (a great deal better).

Conclusion: Peripheral nerve stimulation of the posterior tibial nerve can be a safe and effective modality for treating chronic pain symptoms related to peripheral neuropathy of the foot.

Keywords: Diabetic neuropathy, idiopathic peripheral neuropathy, peripheral nerve stimulation, peripheral neuropathy, posterior tibial nerve

Conflict of Interest: Alaa Abd-Elsayed and Ryan Pollina have received consulting fees from Curonix. Gabriela Betanzons reported no conflict of interest.

INTRODUCTION

The posterior tibial nerve is among the three primary nerves in the ankle and foot region. Direct trauma or pressure on the nerve for extended periods[1,2] may result in posterior tibial nerve injuries and neuropathy. Posterior tibial nerve neuropathy also occurs in patients with diabetes. Ultimately, posterior tibial nerve injuries or neuropathies give rise to symptoms affecting the quality of life, such as loss of sensation at the bottom of the foot, vasomotor changes that can include toe deformities due to paralysis of surrounding muscles of the foot, and recurrent ulcerations.[3] Traditional treatment may include icing treatments, physical therapy, ankle-foot orthosis, ankle injections, and rest.[4] Surgical measures may also be implemented, including tarsal tunnel expansion or nerve decompression. Despite such treatments, peripheral nerve stimulation of the lower extremities has only progressed over recent decades, and ultrasound-guided percutaneous implantation has not only led to significant growth in the field but is an appropriate and effective modality for nerve pain.

Novel peripheral nerve stimulator (PNS) systems have proven to be the optimal choice when considering peripheral nerve stimulation for treating chronic pain owing to the absence of an implantable battery. Because the technique includes a less invasive procedure, these systems offer flexibility in placement and cosmetic outcomes.

MATERIALS AND METHODS

Device Description

The Freedom® PNS System (Curonix LLC, Distributor of Stimwave Freedom Products, Pompano Beach, FL) (Fig. 1) uses high-frequency electromagnetic coupling technology to power the

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Figure 1. Freedom spinal cord stimulation/peripheral nerve stimulation systems.

implanted neurostimulator. Each stimulator comprises an electrode array(s) with four or eight contacts, and the electrode array is connected to a separate implanted receiver(s). A small, external rechargeable transmitter supplies the energy and data to the implanted neurostimulator through the skin. The device uses pulsed electric current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Design

The study received institutional review board (IRB) approval from the WIRB-Copernicus Group IRB, study number: 1335256. The purpose of this study was to observe the efficacy of stimulation on overall pain relief as reported in a cohort of 15 patients treated with the Freedom PNS System at the posterior tibial nerve for foot pain. This was an observational study in which patients who had a Freedom PNS System for at least 12 months before entering the study were included. Subjects presented with chronic, intractable foot pain refractory to standard medical treatment. Stimulators were placed at the posterior tibial nerve. A retrospective chart review was conducted to assess baseline parameters in those patients who were previously implanted with the Freedom PNS system at the posterior tibial nerve. One more visit occurred at least 12 months after implant to assess the outcome.

The following inclusion criteria were used: Subject was aged ≥18 years at the time of informed consent; subjects were diagnosed with chronic, intractable pain of the lower legs with a verbal rating scale (VRS) >5 cm; subjects received a successful PNS trial with >50% improvement in pain; subjects were implanted with the Freedom PNS system for at least 12 months; subjects were willing to attend visits as scheduled and comply with the study requirements; and subjects were capable of giving informed consent.

The exclusion criteria were current infection; currently enrolled in or plans to enroll in any concurrent drug and/or device study while participating in this study; any active implanted devices in addition to the Freedom PNS system; and having more than one Freedom PNS system.

Procedure Methods

The patient was placed in the supine position on the operating table. The target area was prepared and draped in the usual sterile manner. The capsule of the posterior tibial nerve on the medial ankle was identified, and a needle entry point and pathway were applied using palpation and ultrasound. The electrode array was laid with the distal electrode midcalf and the remainder of the electrode array running vertically caudal toward the malleolus, parallel to the posterior tibial nerve. The skin was marked over the needle entry location proximally and anesthetized. Under live ultrasound guidance, the PNS introducer needle was passed through the subcutaneous tissues toward the posterior tibial nerve target through a first incision. The needle was advanced subcutaneously, and the electrode array was inserted through the cannula and placed parallel to the posterior tibial nerve.

The steering stylet was removed, and a separate receiver was connected to the electrode array. A pocket was created using a second incision, and the neurostimulator was tunneled beneath the skin from the first incision to the pocket. A knot was tied to connect the separate receiver and electrode array permanently. The distal portion of the receiver was coiled and sutured to itself. Next, the coil was anchored to the fascia with multiple sutures in the pocket to prevent migration. The pockets were then closed with subcutaneous and subcuticular sutures, Tegaderm (3M, Maplewood, MN) was placed over the incision, and the wound was closed.

Programming Protocol

The programming protocol included frequencies up to 1499 kHz with a pulse width of up to 500 500 μs at the intensity (mA) preferred by the individual patients. The external antenna and transmitter were worn on the lower leg. After the initial post-operative visit, patients were assessed for pain with the VRS and Patient Global Impression of Change (PGIC) at least 12 months after the permanent implant.

Demographics

Fifteen subjects were enrolled. All subjects were diagnosed with peripheral neuropathy of the posterior tibial nerve. The mean age was 65 ± 9.3 years; eight subjects (53%) were men, and seven (47%) were women. Nine patients were diagnosed with idiopathic neuropathy, five with diabetic neuropathy, and one with alcoholic neuropathy of the posterior tibial nerve.

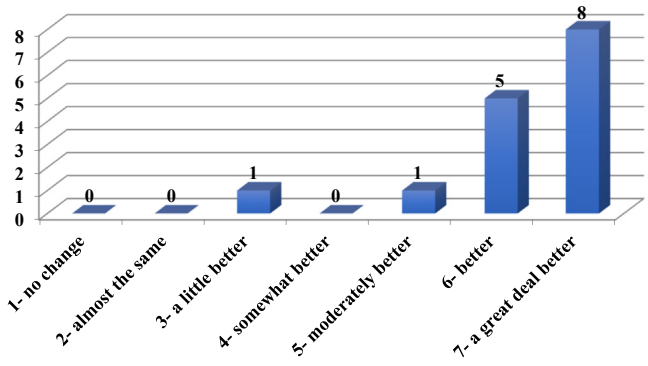

Figure 2. PGIC distribution at >12 months.

Twelve subjects preferred stimulation pulse rates of 1499 Hz; two preferred 1000 Hz, and one preferred 500 Hz. Amplitudes were programmed between 0.5 and 4 mA. Clinically, we have found subthreshold stimulation with pulse rates between 500 and 1499 Hz to be most effective in the treatment of chronic pain of peripheral nerve origin.[5]

Data Analysis

Data were recorded at baseline and at least 12 months after permanent follow-up. Results for follow-up visits at 12 months were pooled to present current means. Pain intensity was measured using VRS data. In addition, PGIC and adverse events were recorded.

The PGIC consists of seven points: 1 = "No change (or condition has worsened)," 2 = "Almost the same, hardly any change at all," 3 = "A little better, but no noticeable change," 4 = "Somewhat better, but the change has not made any real difference," 5 = "Moderately better, and a slight but noticeable change," 6 = "Better, and a definite improvement that has made a real and worthwhile difference," and 7 = "A great deal better, and a considerable improvement that has made all the difference."

Adverse events (AEs) were reported descriptively and classified as serious AEs or nonserious AEs and as related or nonrelated AEs.

The data were collected from electronic medical records and 12-month follow-up case report forms and entered in an Excel sheet (Microsoft Office, Microsoft, Redmond, WA). Statistical analysis was performed using descriptive statistics and paired *t*-tests for comparing pre- and postprocedure pain scores. The *p* value was considered significant if ≤0.05. SPSS (version 26, IBM, Armonk, NY) was used to perform the analysis.

RESULTS

Mean pain scores with the VRS were 3 ± 1.8 at >12 months compared with 8.6 ± 1.2 at baseline, a decrease of 65% ($p < 0.001$). Median satisfaction with the PGIC at >12 months was 7 of 7, with most subjects reporting a 6 (better) or a 7 (a great deal better) (Fig. 2). Subjects reported a considerable improvement in mobility and quality of life. Nine of 15 subjects were still taking pain medication at the time of the report.

Only one subject in 15 reported a complication since being implanted with a permanent PNS system. The subject experienced erosion and required a single revision (Table 1).

DISCUSSION

Peripheral neuropathy can be classified in several ways; it is commonly classified on the basis of the distribution of the affected nerves. There are many causes of neuropathy, with diabetes being the most common. Other causes include vitamin deficiency, alcohol use, chemotherapy, and other systemic diseases such as thyroid disease. Sometimes, no etiology can be found, which is called idiopathic peripheral neuropathy.[6,7]

Peripheral neuropathy can be resistant to pharmacologic treatment, and there are limited options in interventional pain management.

Recent advances in PNS hardware and software, in combination with detailed patient input and personalized care management, allow more effective and timely pain alleviation that is better understood. Alternative treatment modalities failed for the enrolled subjects who were left with no other options. This could potentially lead to initiating the use of opioids or an increase in their use of opioids (if they are already on opioids), which in turn could have led to addiction if PNS had not been used. In addition to the risk of addiction to opioids, our patients had poor quality of life, which put

Table 1. Summary of All Cases.

Age	Sex	VRS at baseline	VRS at 12 months	PGIC	Complications
55	Female	10	0	7	None
72	Male	8.5	3	7	Erosion, revision
73	Male	8	2	7	None
81	Male	7	0	7	None
68	Male	8	2	6	None
53	Male	7.5	5	5	None
78	Female	8	5	3	None
72	Female	10	5	6	None
62	Male	10	4.5	6	None
57	Female	10	4	7	None
68	Male	7	3	6	None
58	Female	8	1	7	None
50	Male	10	2	7	None
62	Female	7.5	3	7	None
66	Female	9	5	6	None

them at risk of depression and other psychiatric problems. Patients were prompted to discuss even the smallest improvements or increases in pain after 12 months of consistently wearing the device. Qualitative feedback analysis revealed overall satisfaction in pain relief. Metrics such as a VRS score for leg and foot pain indicate the device's capabilities for long-term pain relief and functionality. The results of our study agree with other published reports.[8]

The PGIC results confirm such a finding because the definite improvement seen in most patients was reflected in a median score of 7 of 7. Additional patient comments during the data collection range from "modest improvement" to "life-saving," denoting that the device is at least beneficial for most users. Because the Freedom PNS device is both minimally invasive and reversible, complication risks decrease drastically owing to the percutaneous location of the device, and there is an increased benefit due to the device being placed at the affected nerve. This feature decreases complication factors that may result in necessary revisions that can ultimately cause more pain and greater susceptibility to infection. The relatively small and sleek design of the device is ideal for patients with supplementary modalities to offer relief, such as orthotic devices, icing, compression socks, or any other physical exterior method that may cause shifting of the device that leads to decreased efficacy.

Several reports have documented the efficacy and safety of PNS in the literature.[9–11] PNS provides a minimally invasive, effective, and safe modality for treating resistant pain conditions.

Limitations

This was a retrospective study, so we counted on data from electronic medical records, but we were able to call patients to obtain needed data that were missing in charts.

CONCLUSION

Our study showed that subthreshold peripheral nerve stimulation at the posterior tibial nerve was successful for this series of patients suffering from chronic, debilitating pain in the foot due to peripheral neuropathy.

Authorship Statements

All authors contributed equally to the analysis, drafting, and writing of final manuscript.

How to Cite This Article

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COMMENTS

Peripheral nerve stimulation offers a minimally invasive treatment option to many painful syndromes. The prevalence of peripheral neuropathy in the general population is also significant, with one study reporting a prevalence of 28.4% in persons with diabetes and 11.8% in those without diabetes. Despite robust numbers of positive observational studies for PNS and 50+ years of established usage, the strength of the evidence remains inferior to that for spinal cord stimulation for many painful conditions. This study is one step in the right direction, but to change the overall payor determination for PNS, a prospective randomized controlled trial is required, and with this data, further encouraged.

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Observational studies such as this showing the real-world efficacy of peripheral nerve stimulation on focal neuropathic pain are necessary steps toward level 1 data in the second infancy of the field. Evolution of hardware, now specifically designed for use in the periphery, promises better outcomes and staying power this time around.

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