Retrospective Study

Peripheral Nerve Stimulation Using High-frequency Electromagnetic Coupling (HF-EMC) Technology to Power an Implanted Neurostimulator With a Separate Receiver for Treating Peripheral Neuropathy

Ellen Lin, MD

From: Advanced Spine and Pain Center, San Antonio, TX

Address Correspondence:
Ellen Lin, MD
Advanced Spine and Pain Center,
21 Spurs Ln, Ste 240
San Antonio, TX 78240
E-mail:
paindoctorellen@gmail.com

Disclaimer: There was no external funding in the preparation of this article.

Conflict of interest: Dr. Lin is a consultant for Curonix.

Article received: 09-25-2023
Revised article received: 12-04-2023
Accepted for publication: 01-29-2024

Free full article: www.painphysicianjournal.com

Background: Peripheral neuropathy is estimated to be prevalent in up to 12% of the population, increasing to 30% in older demographics. This makes peripheral neuropathy one of the most common neurological diseases in the United States.

Objectives: This retrospective study aims to report on the efficacy and safety of peripheral nerve stimulation (PNS) on the treatment of peripheral neuropathy in a commercial setting.

Study Design: This was a retrospective study. A chart review was conducted for all eligible study patients.

Setting: This study was conducted at the Advanced Spine and Pain Center in San Antonio, a center focused on physical medicine and rehabilitation, pain management and advanced interventional procedures that effectively ease pain.

Methods: From September 2018 through July 2022, a total of 63 consecutive patients with peripheral neuropathy who presented with chronic pain symptoms originating from the shoulder, hip, knee, ankle, and groin were trialed in this study. All patients were required to be at least 18 years old. These patients underwent PNS therapy via implantation of the Freedom® PNS System (Curonix LLC) in order to treat their chronic pain related to or due to peripheral neuropathy from various peripheral nerve origins.

Results: The mean Numeric Rating Scale (NRS-11) score of 63 patients at baseline was 7.24 (SD, 1.80). At 2-3 weeks postimplantation, the mean NRS-11 score decreased to 3.43 (SD, 2.38). A total of 53 out of the 63 patients reported a reduction in their NRS-11 score at the 2-3 week follow-up. A total of 24 patients completed a long-term follow-up. The mean follow-up time was 763.13 days (SD, 428.42); all patients had their PNS system permanently implanted for at least 8 months (range, 255-1,592 days).

Limitations: This was a retrospective study investigating the efficacy and safety of the Freedom® PNS System in patients with peripheral neuropathy. We were limited to the data available in the patient charts.

Conclusion: PNS effectively treats chronic pain due to peripheral neuropathy for patients who have failed other conservative treatments.

Key words: Peripheral nerve stimulation, chronic pain, neuropathic pain, peripheral neuropathy

Pain Physician 2024: 27:E725-E730

Peripheral neuropathy is estimated to be prevalent in up to 12% of the population, increasing to 30% in older demographics (1). This makes peripheral neuropathy one of the most common neurological diseases in the United States. Peripheral neuropathy can present at different anatomical locations, including suprascapular, genicular, tibial, and cluneal nerves. It can be diagnosed after total knee arthroplasty, post-shoulder surgeries, complex regional pain syndrome, and others. In addition to sensory defects and pain symptoms, patients with peripheral neuropathy also suffer from overall decreased function, which inevitably leads to a reduced quality of life (2). Additional common comorbidities experienced by patients with peripheral neuropathy include depression, weight loss, and impotence (3).

Current peripheral neuropathy treatment consists primarily of pharmaceutical interventions (4,5). This includes the following: acetaminophen, nonsteroidal anti-inflammatory drugs, anticonvulsants, and antidepressants, such as tricyclics, as first-line therapies; opioids as second-line therapy; and cannabinoids and topical agents as third-line therapies. A major issue with current therapies is that their effectiveness is limited and may not adequately address all symptoms presented by patients.

A permanent treatment modality is peripheral nerve stimulation (PNS). PNS has received significant research attention in the last 5 years thanks to the development of PNS-specific technology that replaced prior spinal cord stimulation technology adapted for peripheral use (6). PNS works through electrical modulation of peripheral nerves that alter peripheral and central pain transmission pathways (7). A recent systematic review found promising evidence supporting using externally powered PNS for peripheral neuropathies (8).

Our retrospective study aims to report the effect of PNS for treating peripheral neuropathy.

Methods

This retrospective study received an exemption for review from the Institutional Review Board. The IRB submission was sponsored by Curonix.

Patient Selection

Patients who underwent a PNS trial for treating peripheral neuropathy from September 2018 through July 2022 were recruited to participate in our study. All patients were required to be at least 18 years old and have a confirmed diagnosis of peripheral neuralgia/neuropathy responsible for pain presentation. Patients with any additional active implanted devices in addition to the PNS system were excluded.

Device Description

The Freedom® PNS System (Curonix LLC, Pompano Beach, FL) uses high-frequency electromagnetic coupling (HF-EMC) technology. It includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, an external transmitter assembly, and a wearable accessory. The Freedom PNS System is comprised of a 2-component implant that the physician connects during the procedure (Fig. 1). The physician is also required to create a pocket.

Permanent Implant Surgical Technique

Informed consent was obtained from all patients. Patients were taken to the operating room and appropriately positioned on the table. The implant site was cleaned with chlorhexidine and then covered with sterile drapes. The electrode array was placed on the skin, with the distal electrode at the target nerve. The needle entry point and pathway were planned using palpation and fluoroscopy.

The skin and deeper tissues were anesthetized using a local anesthetic. The initial introducer path was also infiltrated with a local anesthetic. A first incision was made with an 11-blade scalpel, and a 13G introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the target nerve under imaging guidance. Small amounts of local anesthetic were injected as needed. One or two 4-contact electrode arrays with tines were inserted through the cannula(s) and advanced to the target nerve.

Receiver pockets were created using blunt dissection through a second incision. The steering stylets were removed from the previously implanted electrode arrays and separate receivers were connected to the electrode arrays. The electrode arrays and receivers were tunneled beneath the skin from the first incision to the second incision receiver pocket. A knot was tied to permanently secure the connected separate receivers and electrode arrays. The receivers were coiled into small diameter coils and 2 nonabsorbable sutures were used to permanently form the receiver coils. The edges of the receiver coils were tucked underneath the coils to avoid protruding edges. Using a nonabsorbable su-

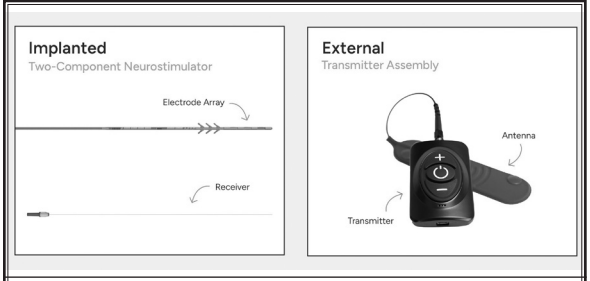

Fig. 1. *Freedom Peripheral Nerve Stimulation System.*

ture, the receiver coils were sutured to the fascia in 2 locations ensuring they were flat in the pocket. The receiver pocket was closed with deep and superficial absorbable sutures.

Outcome Assessments

The primary analysis utilized the Numeric Rating Scale (NRS-11) to assess pain. The NRS-11 is an 11-point scale that ranges from 0 (no pain) to 10 (extreme pain). Patients filled out the NRS-11 before PNS treatment and 2-3 weeks postimplantation. A long-term follow-up was collected on May 1, 2023, to assess the current percent of pain relief, sleep quality changes, and overall treatment satisfaction.

Results

A total of 63 consecutive patients agreed to participate in this study; they underwent a PNS therapy trial to treat peripheral neuropathy (Fig. 2). There were 30 men and 33 women (mean age, 75 years). Patients presented chronic pain symptoms originating from the shoulder, hip, knee, ankle, and groin.

The PNS treatment was trialed at the following nerves: suprascapular (n = 21), cluneal (n = 9), femoral/obturator (n = 2), genicular (n = 23), and sural/deep peroneal (n = 8) (Fig. 3). Fifty-five out of 63 patients (87%) had a succesful trial. So far, 48 patients received a permanent implant. At the long-term follow-up, data for 24 patients was not captured for various reasons, including explant (n = 1), lost to follow-up (n = 14), not actively using PNS (n = 4), different doctor (n = 1), deceased (n = 2), or opted for joint replacement (n = 2). The remaining 24 patients completed the long-term follow-up.

Attrition

Out of the 14 patients lost to follow-up, 12 (86%) reported > 50% pain relief at their last recorded visit.

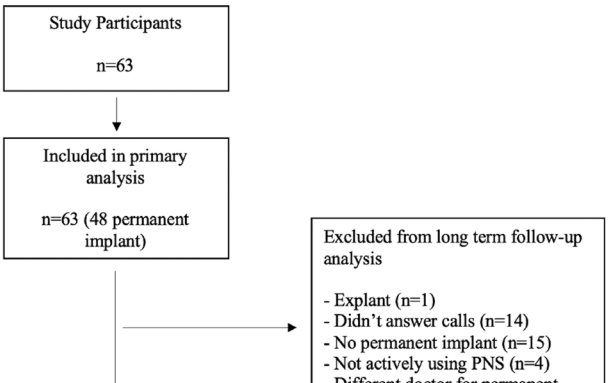

Fig. 2. *Patient flow chart.*
PNS = peripheral nerve stimulation

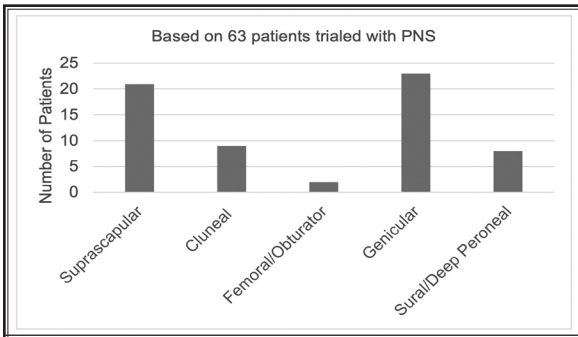

Fig. 3. *Peripheral nerve stimulation nerve locations.*

Primary Pain Outcome

The mean NRS-11 score of the 63 patients before PNS treatment was 7.24 (SD, 1.80) (Fig. 4). At 2-3 weeks post-trial implantation, the average NRS-11 score decreased to 3.43 (SD, 2.38; $P < 0.001$) (Fig. 5).

Long-term Follow-up

A total of 24 patients completed the long-term follow-up. The mean follow-up time was 763.13 days (SD, 428.42). All of them had their PNS systems permanently implanted for at least 8 months (range, 255 – 1,592 days).

A total of 19 of the 24 patients (79%) experienced a ≥ 50% improvement in pain (Fig. 6), with 13 patients (54%) reporting a ≥ 70% improvement (Fig. 7). The average NRS-11 score decreased to 3.92 (SD, 2.48; $P < 0.001$).

Regarding sleep quality, 18 patients (75%) reported their sleep to be "better" or "much better," while the remaining experienced no change (Fig. 8). Nineteen patients (79%) reported ≥ 50% satisfaction (Fig. 9). No complications were reported.

Discussion

Our retrospective study examined the effect of the Freedom® PNS System on peripheral neuropathy. We found significant improvements in pain in both short-term (2-3 weeks) and long-term (> 8 months). Additionally, the majority of the long-term cohort was satisfied with the treatment and experienced "better" or "much better" sleep quality. These results support previous findings for similar pain conditions treated by both externally powered (9-12) and conventional PNS (8).

PNS is unique in that its results can be sustained for at least 12 months (13-15). Forty-eight patients in this study underwent permanent implantation and reported a mean NRS-11 score of 3.93 (SD, 2.54) in May 2023.

Our study has limitations. Patients presented symptoms originating from several locations that resulted in different nerve targets across patients. Due to different treatment timelines (i.e., different permanent implant dates), there was also a large variation in the length of long-term follow-up, with the shortest follow-up being 1,337 days less than the longest.

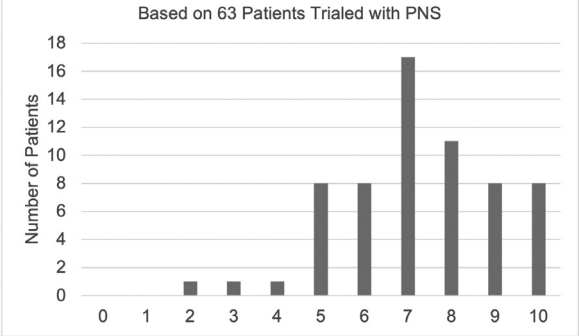

Fig. 4. *Peripheral nerve stimulation (PNS) Numeric Rating Scale (NRS-11) preoperative scores.*

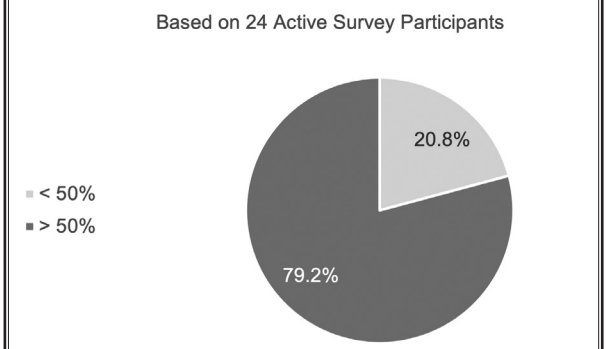

Fig. 6. *Percent of patients reporting long-term pain relief.*

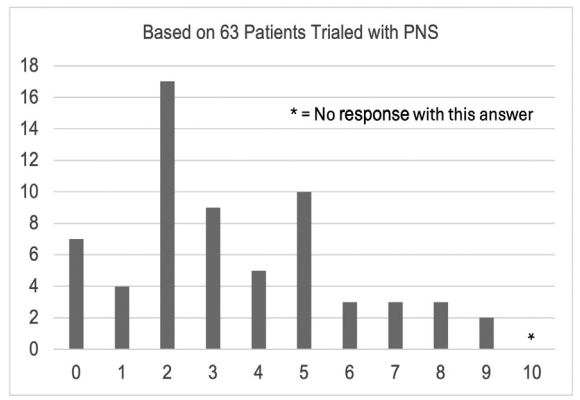

Fig. 5. *Numeric Rating Scale (NRS-11) scores at postoperative 2-3 weeks.*
PNS = peripheral nerve stimulation

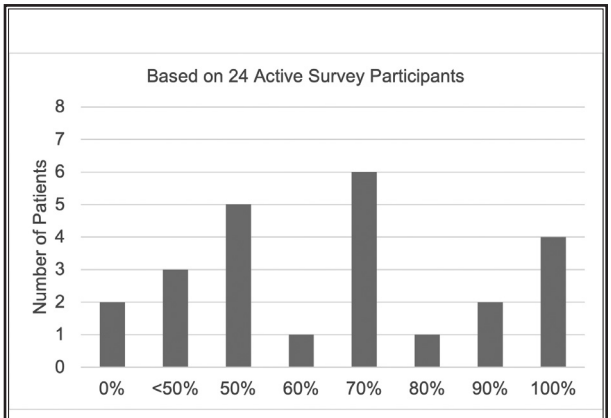

Fig. 7. *Specific percent of long-term pain relief.*

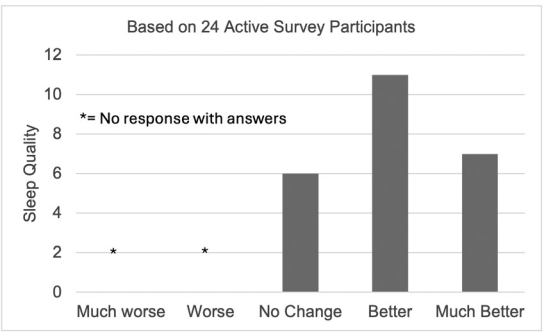

Fig. 8. *Long-term postimplant sleep quality.*

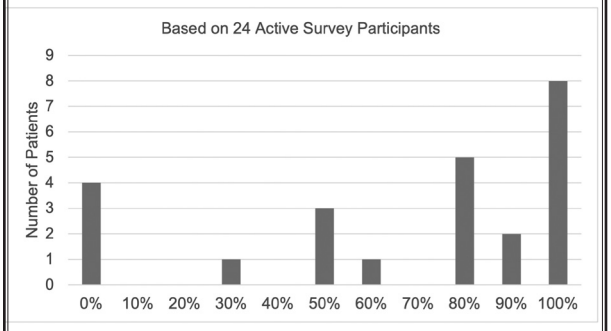

Fig. 9. *Percent satisfaction long-term.*

Another limitation is that there was no control group. However, this limitation is hard to overcome as PNS requires a surgical procedure, and groups would be susceptible to a placebo effect if not blinded. A control group is also difficult to implement because patients are already nonresponsive to conservative treatments prior to using PNS (12).

On the other hand, this is a compelling study as it has a large number of patients and good follow-up data that measure outcomes of interest with a follow-up of longer than 12 months. Additional analyses should be conducted to determine if target nerve choice affects results. Stimulation settings should also be investigated with regard to wavelength, amplitude, and frequency.

Limitations

Limitations in this study included the lack of alternative (objective) measures and randomization due to the retrospective nature of the design.

Conclusion

Peripheral neuropathy is one of the most common neurological disorders in the United States. Permanent PNS is one of the standard treatments for patients experiencing chronic pain due to peripheral neuropathy as this treatment has been a well-established modality. This study confirms that permanent PNS is a safe and effective option and retrospective results reported in a private practice setting are similar to reported outcomes from prospective randomized trials.

Acknowledgment

We would like to acknowledge and thank the Curonix Clinical team for their participation support in writing, data analysis and technical editing of the manuscript.

References

1. Lehmann HC, Wunderlich G, Fink GR, Sommer C. Diagnosis of peripheral neuropathy. *Neurol Res Pract* 2020; 2:1-7.
2. Win MMTM, Fukai K, Nyunt HH, Hyodo Y, Linn KZ. Prevalence of peripheral neuropathy and its impact on activities of daily living in people with type 2 diabetes mellitus. *Nurs Health Sci* 2019; 21:445-453.
3. Zafeiri M, Tsioutis C, Kleinaki Z, Manolopoulos P, Ioannidis I, Dimitriadis G. Clinical characteristics of patients with co-existent diabetic peripheral neuropathy and depression: A systematic review. *Exp Clin Endocrinol Diabetes* 2021; 129:77-85.
4. D'Souza RS, Her YF, Jin MY, Morsi M, Abd-Elsayed A. Neuromodulation therapy for chemotherapy-induced peripheral neuropathy: A systematic review. *Biomedicines* 2022; 10:1909.
5. Khdour MR. Treatment of diabetic peripheral neuropathy: A review. *J Pharm Pharmacol* 2020; 72:863-872.
6. Kalia H, Abd-Elsayed A, Malinowski M, et al. Educational curriculum for peripheral nerve stimulation developed by the North American Neuromodulation Society. *Neuromodulation* 2023; 26:483-489.
7. Ong Sio LC, Hom B, Garg S, Abd-Elsayed A. Mechanism of action of peripheral nerve stimulation for chronic pain: A narrative review. *Int J Mol Sci* 2023; 24:4540.
8. Char S, Jin MY, Francio VT, et al. Implantable peripheral nerve stimulation for peripheral neuropathic pain: A systematic review of prospective studies. *Biomedicines* 2022; 10:2606.
9. Bellini V, Baciarello M, Cascella M, et al. Wireless peripheral nerve stimulation for the upper limb: A case report. *Int J Environ Res Public Health* 2023; 20:4488.
10. Herschkowitz D, Kubias J. Wireless peripheral nerve stimulation for complex regional pain syndrome type I of the upper extremity: A case illustration introducing a novel technology. *Scand J*

Pain 2018; 18:555-560.

11. Chauhan G, Levy I, DeChellis D. Superior cluneal neuralgia treated with wireless peripheral nerve stimulation. *Cureus* 2022; 14:e23711.
12. Abd-Elsayed A. Wireless peripheral nerve stimulation for treatment of peripheral neuralgias. *Neuromodulation* 2020; 23:827-830.
13. Ferguson K, Abd-Elsayed A. Peripheral nerve stimulation trial and implantation. In: Sacroiliac Joint Pain: A Comprehensive Guide to Interventional and Surgical Procedures. Oxford Academic, New York, 2021, pp 135-146. https://academic.oup.com/book/35980/chapter-abstract/311805222?redirectedFrom=fulltext
14. Pollina R, Betanzons G, Abd-Elsayed A. 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. *Neuromodulation* 2023; 27:126-129.
15. Abd-Elsayed A, Moghim R. Efficacy of peripheral nerve stimulation with a high frequency electromagnetic coupled (HF-EMC) powered implanted receiver in treating different pain targets/neuralgias. *J Pain Res* 2023; 16:589-596.