

## Retrospective Study

# Peripheral Nerve Stimulation Uses High-Frequency Electromagnetic Technology to Power an Implanted Neurostimulator with a Separate Receiver for the Treatment of Chronic Pain in the Lower Extremities

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**Background:** Lower extremity pain is one of the most common types of chronic pain and can be very challenging to treat using conservative management modalities.

**Objectives:** Our study intends to present the effective management of chronic neuralgias in the lower extremities through peripheral nerve stimulation (PNS).

**Setting:** This retrospective study included 21 patients who received a permanent Curonix Freedom® PNS System for treating chronic pain in the lower extremities. A retrospective chart review was conducted to assess the baseline and follow-up parameters.

**Methods:** Fourteen of the patients (67%) received one neurostimulator at either the superficial peroneal or posterior tibial nerve. Seven patients (33%) received 2 neurostimulators at either the sural and superficial peroneal, posterior tibial and superficial peroneal, or common and superficial peroneal nerves. The data were collected from electronic medical records, followed by case report forms. Pain scores and complications were reported up to 6 months after permanent implantation. Adverse events (AEs) were reported descriptively and classified as serious or nonserious AEs and related or unrelated AEs.

**Results:** At the end of the trial visit, 21 of the 21 patients (100%) reported more than 50% pain relief, with mean pain scores reducing from  $7.29 \pm 0.9$  to  $2.81 \pm 0.7$  (61%;  $P < 0.001$ ). Nineteen patients completed the long-term follow-up. Fourteen of those 19 patients (74%) experienced at least a 50% improvement in pain. The average NRS score decreased significantly to  $3.66 \pm 1.8$  (50%;  $P < 0.001$ ). No complications were reported.

**Conclusion:** PNS done with the Curonix Freedom® PNS System is an effective and safe therapy for lower-extremity neuralgias.

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

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**N**europathic pain remains one of the most challenging pain conditions to treat. The affliction's incidence is relatively high, estimated to affect 8% of the United Kingdom's (UK) population, 17.9% of the Canadian population, and 12.4% of the population of the United States (US) (1-3).

Neuropathic pain can lead to reduced functioning

in the affected limb or body part, which can impact the patient's quality of life and daily activities, leading to the development of psychological conditions and other comorbidities. Furthermore, neuropathic pain can be difficult to treat, since it may not respond to conservative pain management techniques such as physical therapy, medications, and steroid injections (4).

Historically, spinal cord stimulator systems were placed on peripheral nerves to treat different peripheral neuropathic pain conditions that were not feasible to treat with traditional spinal cord stimulation. This practice presented many challenges because the hardware was not designed for that purpose. One major challenge was the difficulty in placing the implantable pulse generator (IPG) in certain areas of the body (5).

Despite the aforementioned issues, several studies showed the efficacy of using spinal cord stimulation systems on peripheral nerves. Consequently, the efficacy of spinal cord stimulation was well established long ago, but the technology saw limited use because of the lack of hardware that could fit such an indication (6).

The development of new peripheral nerve stimulation (PNS) systems customized for spinal-cord indication increased physicians' interest in using the technology. The peripheral-nerve-stimulating hardware is now more suitable for implantation.

We are presenting 21 patients who suffered from peripheral neuralgia and pain in their lower extremities, did not respond to conservative management techniques, and exhibited satisfactory responses to PNS through the Curonix Freedom® PNS System.

## **METHODS**

This retrospective study received an exemption for review from the Institutional Review Board (IRB).

### **Patient Selection**

This retrospective study included 21 patients who received a permanent Curonix Freedom® PNS System for treating chronic pain in the lower extremities. These patients had been given PNS with the Freedom® PNS System for at least 3 months after permanent implantation before entering the study. A retrospective chart review was conducted to assess the baseline and follow-up parameters.

All patients were required to be at least 18 years old and have a confirmed diagnosis of peripheral neuralgia responsible for pain presentation. Patients with any active implanted devices intended to treat chronic pain in addition to the Freedom® PNS System were excluded.

### **Device Description**

The Freedom® PNS System uses high-frequency electromagnetic coupling (HF-EMC) technology. The Freedom PNS System includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver as well as an external transmitter assembly and

wearable accessory. The Freedom PNS System is comprised of a two-component implant that the physician connects during the procedure. The physician is also required to create a pocket.

### **Permanent Implant Surgical Technique**

Informed consent was obtained from all patients. After a diagnostic injection, followed by a positive temporary trial, patients received a permanent system. Patients were taken to the operating room and appropriately positioned on the table. The implant site was cleaned and 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 small incision was made with an 11-blade scalpel, and the 13-gauge introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the target nerve under imaging guidance, using small amounts of local anesthetic. A 4-contact electrode array with tines was inserted through the cannula and advanced to the target nerve. Using the same technique, some patients received a secondary electrode array at a different nerve target.

Receiver pockets were created using blunt dissection through a second incision. The steering stylet 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 connect the separate receivers and electrode arrays permanently. 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 coil to avoid protruding edges. Using nonabsorbable sutures, the receiver coils were sutured to the fascia in 2 locations ensuring it was flat in the pocket. The receiver pocket was then closed with deep and superficial absorbable sutures.

### **Programming Protocol**

The programming protocol included a frequency of 1,499 Hz with a pulse width of 32  $\mu$ s at variable intensities (mA). The external antenna and transmitter were worn on the lower leg.

**Demographics**

Data was collected for 21 patients. All patients were diagnosed with peripheral neuropathy that caused chronic pain in the lower extremities, presenting at the dorsum, bottom, and/or outside of the foot. Fourteen (67%) of the patients received one neurostimulator at the superficial peroneal (7) or at the posterior tibial (7) nerve. Seven (33%) of the patients received neurostimulators at both the sural and superficial peroneal (4), posterior tibial and superficial peroneal (2), or common and superficial peroneal nerves (1) (Fig. 2). The mean age was  $74 \pm 9.4$  years; 17 patients (81%) were men, and 4 (19%) were women.

**Data Analysis**

The primary analysis utilized the Numeric Rating Scale (NRS) to assess the responder rate. Secondary analysis included pain reductions with the NRS, an 11-point scale ranging from 0 (no pain) to 10 (extreme pain). Patients filled out the NRS before they received treatment with the Freedom® PNS System and again after a trial period. A long-term follow-up was collected at 6 months post-implantation to assess patients' current percentiles of pain relief.

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

The data were collected from electronic medical records, followed by case report forms, and entered in an Excel spreadsheet. Statistical analysis was performed using descriptive statistics and paired t-tests for comparing pre- and post-procedure pain scores. The *P* value was considered significant if greater than 0.05.

**RESULTS**

**Primary Outcome Responder Rate**

At the end of the trial visit, 21 out of 21 (100%) patients reported more than 50% pain relief, with mean pain scores reducing from  $7.29 \pm 0.9$  to  $2.81 \pm 0.7$  (61%; *P* < 0.001).

**Long Term Follow-Up**

Nineteen patients completed the long-term follow-up. All patients had their Freedom® PNS Systems permanently implanted for at least 6 months. Fourteen out of the 19 patients (74%) experienced at least a 50% improvement in pain. The average NRS score decreased to  $3.66 \pm 1.8$  (50%; *P* < 0.001) (Fig. 3). No complications were reported. One subject who received neurostimu-

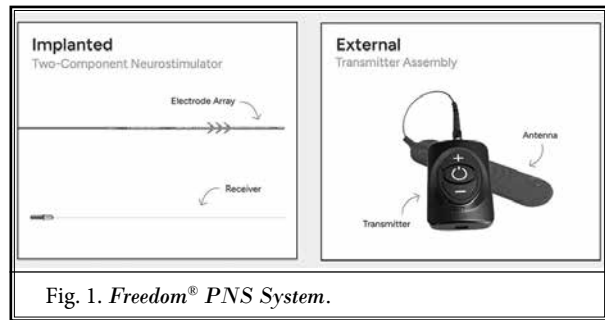


Fig. 1. Freedom® PNS System.

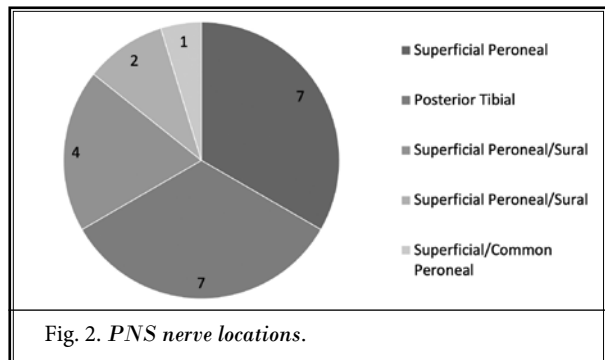


Fig. 2. PNS nerve locations.

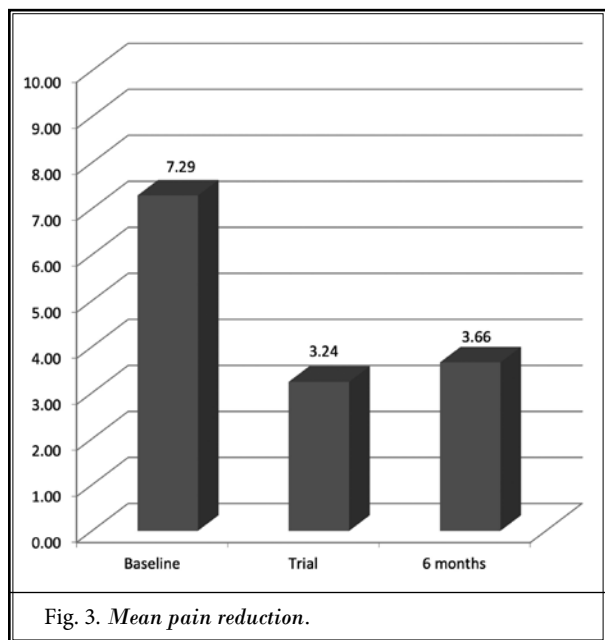


Fig. 3. Mean pain reduction.

lators (2) at the sural and peroneal nerves had the permanent devices explanted due to lack of efficacy.

**DISCUSSION**

There are several causes of chronic lower extremity neuropathic pain, including trauma, compression, and entrapment; sometimes the cause is unknown (7,8).

Lower extremity pain is a very common type of pain, estimated by the Center for Disease Control (CDC) to be the second most common manifestation of pain rooted in neuropathies and neuralgias, affecting about one-third of all patients who have chronic pain. If a patient is left untreated, pain can lead to depression, anxiety, and other psychological conditions. In addition, lower extremity pain can cause musculoskeletal impairment and significant limitation of functioning. For these reasons, it is critically important to treat lower extremity pain to prevent its associated comorbidities (9).

Treatment of lower extremity pain starts with conservative management, including nonpharmacological modalities and medications such as tricyclic antidepressants, antiepileptics, and pain medications. If these measures fail, patients may receive various injections, which may include corticosteroids, producing variable and usually temporary efficacy (10).

PNS is a particularly desirable choice for patients failed by conservative measures, medications, and interventional management, but this type of treatment can also be considered earlier if needed for the appropriate patients. The process starts with patient agreement, the completion of a psychological evaluation, and the performance of a trial. A permanent implantation will be the next step if the patient achieves 50% or more pain relief. The efficacy of the Curonix Freedom® PNS System in treating peripheral neuralgia and associated painful conditions has been well described and published (4,11,12).

This study is unique because it includes 21 patients who received a successful PNS trial and underwent a permanent implantation with an externally powered

system for the treatment of chronic pain originating from peripheral nerves in the lower extremities. Patients were followed up on for 6 months, and all were implanted to treat lower extremity pain related to different peripheral neuralgias. Externally powered PNS systems can be used to target peripheral nerves all throughout the body. Multiple studies are required to investigate all individual nerve targets to assess for the technique's safety and efficacy.

The study showed both the efficacy and safety of the procedure and the device. Only one case was explanted for lack of efficacy. There were no reports of any other complications, such as bleeding or infections.

It is also important to note that no patients reported any issues related to using the external antenna. This absence of reported complications can be attributed to the antenna's flexibility, its ease of placement over clothing in the required location, and the presence of several wearables to fit different patients depending on their needs.

## CONCLUSION

PNS is an evolving procedure gaining an increasing amount of interest each year. Appropriate training in and implementation of the procedure can help alleviate pain in patients with different pain conditions. PNS using the Curonix Freedom® PNS System is an effective and safe therapy for treating chronic lower extremity pain that resists conservative management.

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