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Peripheral Nerve Stimulation Using High-Frequency Electromagnetic Coupling Technology to Power an Implanted Neurostimulator With a Separate Receiver for the Treatment of Peripheral Neuropathy

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Background: Chronic pain impacts multiple facets of daily life, including mental health, mobility, and ability to work. Conservative management strategies often fail to control pain adequately, and pharmaceutical treatments involve unwanted side effects. With the development of specialized technology, peripheral nerve stimulation (PNS) has emerged as a treatment for pain caused by peripheral neuralgias that cannot be managed with conservative strategies.

Case Report: This was a retrospective study collecting data from the electronic medical records of patients. A chart review was conducted for all eligible study patients. Patients who underwent a PNS trial for the treatment of peripheral neuropathy were recruited to participate in this study. Verbal Rating Scale (VRS) scores decreased from 7.8 ± 1.6 to 1.6 ± 1.1 after the trial. At 3 months, VRS scores decreased to 2.1 ± 2.7.

Conclusions: The Freedom® PNS System is a safe and effective treatment modality for the management of pain caused by peripheral neuropathy.

Key words: Peripheral nerve stimulation, chronic pain, foot, ankle, knee, shoulder, suprascapular, peroneal, infrapatellar saphenous, peroneal

BACKGROUND

Chronic pain is one of the most common causes of disability. Pain leads to numerous negative consequences, including depression, anxiety, and inability to perform daily activities. Additionally, pain can impact the socioeconomic status of a patient as it can reduce the ability to work. Conservative management often fails to control the pain, and medications, such as tricyclic antidepressants, antiepileptics, and opioids, can cause a variety of side effects that can make their use undesirable (1,2).

Peripheral nerve stimulation (PNS) is an evolving technology that can treat chronic pain as a result of different peripheral neuralgias and pain conditions resistant to conservative therapy. PNS treatment for chronic pain was established decades ago; however, only in recent years have advancements in devices come to the market that bring ease of use with the appropriate software and waveforms (3,4). Early PNS Systems were plagued by significant rates of complications due to the use of spinal cord stimulation leads that could not

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withstand the extra impact of mobility in the periphery (5). Modern PNS Systems now have specialized leads that have minimized the risk of complications.

The mechanism of action for PNS is largely based on the gate control theory (6). Several other theories have also been proposed for their efficacy in treating different pain conditions. This includes altering higher central nervous system centers (e.g., anterior cingulate cortex), endogenous neurotransmitters, and N-methyl-D-aspartate pathways (7).

Our current study examined the outcomes of PNS using the Freedom® PNS System for treating chronic pain as a result of a variety of peripheral neuralgias and pain conditions in different anatomical locations of the body. The Freedom PNS System is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Freedom PNS System is intended to treat pain of the peripheral nerve origin and can be used in the treatment of chronic pain resulting from complex regional pain syndrome, neuropathy, etc.

Our primary outcome of interest was the patient response rate to the trial. Our secondary outcomes of interest included changes in pain intensity after 3 months of using the permanent system as well as adverse events (AEs) experienced by patients.

METHODS

This retrospective study received exemption for review from the Institutional Review Board.

Patient Selection

Our study included 14 patients who received a permanent Freedom PNS System for treating chronic pain related to peripheral neuropathy. Patients had to be treated with PNS using the Freedom System for at least 3 months postpermanent implantation to be considered for the study. A retrospective chart review was conducted to assess the baseline and follow-up parameters up to 3 months postpermanent implantation (Table 1).

Study patients were diagnosed with chronic, intractable pain that originated from a peripheral nerve with a Verbal Rating Scale (VRS) score of at least 5/10. Patients with any additional active implanted devices were excluded from the study.

Eight patients experienced a trial with the neurostimulator at the peroneal nerve for chronic foot (n = 4), ankle (n = 3), or foot and ankle pain (n = 1). Two patients received neurostimulators at the sural and peroneal nerves for chronic foot (n = 1) or foot and ankle pain (n = 1). Two patients received a neurostimulator at the suprascapular nerve for chronic shoulder pain, and 2 patients received a neurostimulator at the infrapatellar saphenous nerve (IPS) for chronic knee pain.

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. After the successful trial, patients received a permanent system. Patients were taken to the operating room and positioned appropriately 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/or 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. The 13G introducer needle was then 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(s) and advanced to the target nerve. Two patients received a secondary electrode array at a secondary nerve target using the same technique.

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 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 coils to avoid protruding edges. Using a nonabsorbable suture, 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 (Fig. 2).

Programming Protocol

The programming protocol included a frequency of 1,499 Hz with a pulse width of 32 μs; amplitude (mA) was variable based on the nerve target.

Demographics

Data was collected for 14 patients. All patients were diagnosed with peripheral neuropathy, causing chronic pain of various peripheral nerve origins. The mean age was 68.4 ± 11.4 years; 13 patients (93%) were women, and one (7%) was a man.

Data Analysis

The primary analysis utilized the VRS to assess the responder rate. Secondary analysis included pain reductions with the VRS, a verbal 11-point scale ranging from 0 (no pain) to 10 (extreme pain). VRS scores were documented in the patient files.

Table 1. Pain scores.

RSN	Indication	Location PNS	Baseline	Trial	Three Months
1	Ankle Pain	Peroneal Nerve	8	1.6	6
2	Ankle Pain	Peroneal Nerve	7	0.7	0
3	Foot Pain	Peroneal Nerve	9	3	3
4	Foot and Ankle Pain	Peroneal Nerve	8	0.8	3
5	Foot Pain	Peroneal Nerve	10	4	9
6	Foot Pain	Peroneal Nerve	4	0	0
7	Ankle Pain	Peroneal Nerve	9	2	0
8	Foot Pain	Peroneal Nerve	6	1.8	1
9	Foot Pain	Sural/Peroneal Nerve	8	1.6	6
10	Foot and Ankle Pain	Sural/Peroneal Nerve	8	1.2	1.2
11	Shoulder Pain	Suprascapular Nerve	7	3	4
12	Shoulder Pain	Suprascapular Nerve	8	1	1
13	Knee Pain	IPS	10	1	0
14	Knee Pain	IPS	7	0.5	0

Abbreviations: RSN, resting-state networks; PNS, peripheral nerve stimulation; IPS, infrapatellar saphenous nerve.

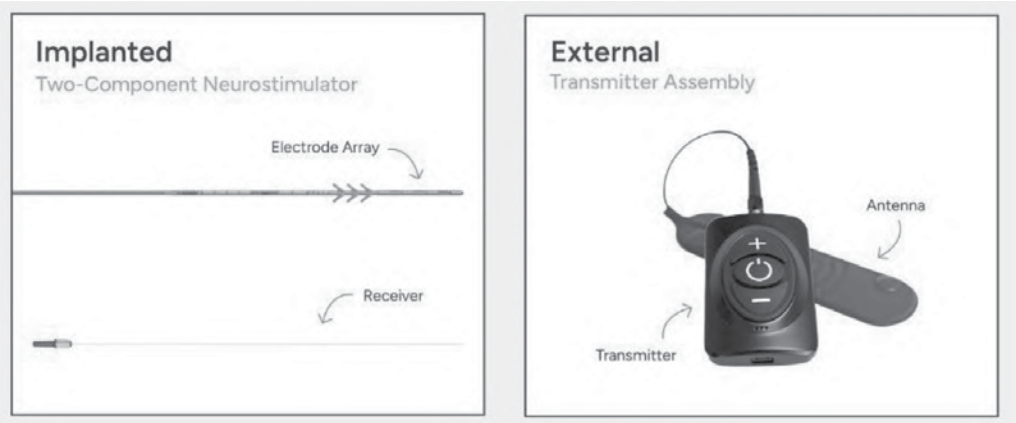

Fig. 1. Freedom PNS System.
PNS, peripheral nerve stimulation.

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 into an Excel spreadsheet (Microsoft Corporation, 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.

RESULTS

Primary Outcome Responder Rate

At the end of the 7-day trial visit, all (100%) patients reported > 50% pain relief, with mean pain scores reducing from 7.8 ± 1.6 to 1.6 ± 1.1 (80%; $P < 0.001$). Patients with chronic foot and/or ankle pain (n = 10) had a score reduction at the end of the trial from 7.7 ± 1.7 to 1.7 ± 1.2 (78%; $P < 0.001$). Patients with chronic shoulder pain (n = 2) reported reduced pain scores from 7.5 ± 0.7 to 2 ± 1.4 (73%; $P < 0.001$). Lastly, patients with chronic knee pain (n = 2) reported reduced pain scores from 8.5 ± 2.1 to 0.75 ± 0.4 (91%; $P < 0.001$) (Table 1).

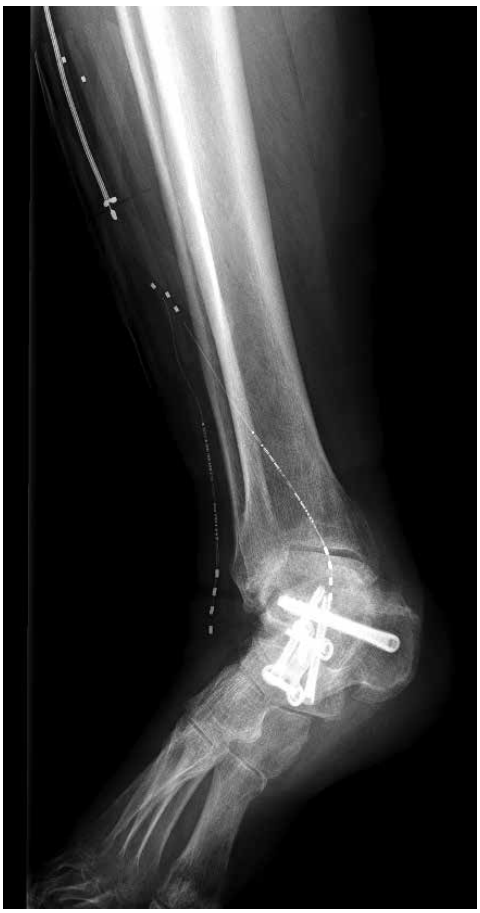

Fig. 2. Freedom PNS System at the sural/peroneal nerves AP. PNS, peripheral nerve stimulation; AP, anteroposterior.

Permanent Implant Follow-up

Fourteen patients completed a 3-month postpermanent implantation follow-up. All patients had their PNS Systems permanently implanted for at least 3 months. The average VRS score decreased to 2.1 ± 2.7 (73%; $P < 0.001$) (Fig. 3). Patients with chronic foot and/or ankle pain (n = 10) reported reduced pain scores at the 3-month follow-up of 2.48 ± 3.0 (68%; $P < 0.001$). Patients with chronic shoulder pain (n = 2) reported pain scores that reduced to 2.5 ± 2.1 (68%; $P < 0.001$). Lastly, patients with chronic knee pain (n = 2) reported reduced pain scores of 0.00 ± 0.0 (100%; $P < 0.001$).

Adverse Events

One patient was reimplanted after persistent irritation at the wound site was resolved. Two patients had their devices removed after 3 months due to loss of relief (n = 1) or irritation at the wound site (n = 1).

DISCUSSION

Our study included 14 patients who received PNS using the Freedom PNS System for managing pain caused by peripheral neuralgias in both the lower and upper extremities (Table 1). All patients were responders to trial stimulation (i.e., experienced > 50% pain relief) and reported significant pain relief at the 3-month follow-up. None of the patients in this study experienced

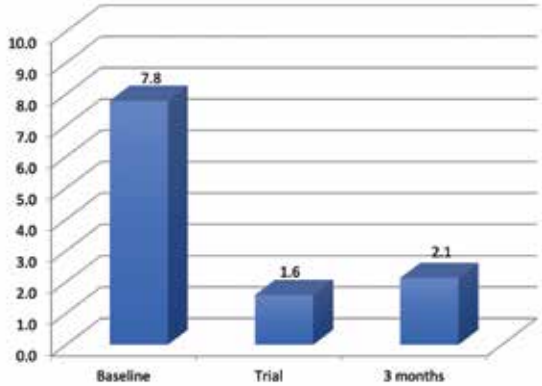

Fig. 3. Mean pain reduction.

serious AEs, but 2 patients required an explant due to irritation at the wound site.

Our study results are consistent with previously published articles using the same system and for similar indications. Abd-Elsayed (3) published one of the first articles examining the use of the Freedom PNS System to treat pain for various indications. Recently, Pollina et al (8) published an article using the same PNS system for treating neuralgias causing foot pain, and the results were consistent with our study, where patients received an average pain relief of > 50% at the one-year follow-up. Another study by Abd-Elsayed et al (9) on using PNS for treating several pain conditions produced similar results. This study provided up to 24 months of follow-up for patients, which demonstrated continuous improvement in pain.

The evolution of PNS has led to the development of guidelines and curricula to educate on the best practices for using PNS, both during training and clinical practice (10,11). The use of PNS has been on the rise due to the prevalence of several pain conditions that can be effectively managed by the stimulation of one or two nerves. The use of PNS for those indications provides the coverage needed by stimulating target nerves that can be located almost anywhere in the body (5,12-14). In addition to pain management, PNS also has the potential utility of accelerating peripheral nerve regeneration after injury (15).

The Freedom PNS System has the advantage of utilizing an external transmitter without implanting a battery. This allows for the use of PNS in different locations within the body without having to worry about battery implantation, which can be challenging in certain anatomical locations in the body, such as near joints. The absence of an implanted battery also means there is no need for battery replacement surgeries. There were no patient complaints about the use of the wearable external antenna and transmitter (i.e., transmitter assembly) that allowed them to use the device effectively and comfortably.

Future studies should include a larger patient population with a prospective study design. Included patients should also present the same indication, or the sample size of different indications should be similar so that the outcomes can be compared and analyzed. Additional outcomes that should be assessed include changes in opioid consumption, physical function questionaries, and overall patient satisfaction with the system.

CONCLUSIONS

PNS using the Curonix Freedom PNS System is an effective and safe therapy for treating chronic pain in the shoulder, ankle/foot, and knee with the neurostimulator at the suprascapular, sural, peroneal, and IPS nerves.

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