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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 Chronic Pain: A Case Series

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Background: Chronic pain of peripheral nerve origin is a prevalent condition that often remains resistant to conservative therapies. Peripheral nerve stimulation (PNS) has proven to be an effective intervention for managing this type of pain. Receiver based PNS is a neuromodulation therapy designed to alleviate chronic pain by targeting specific peripheral nerves. This system involves implanting an electrode array and separate receiver to target pain-causing nerves, offering relief for patients with persistent pain.

Case Report: A case series involving 9 patients with chronic peripheral nerve pain treated with a peripheral nerve stimulation system with a separate receiver is presented. These patients had pain localized to specific nerve targets, including the suprascapular, infrapatellar saphenous, and superior cluneal nerves. After successful trials, the Freedom® PNS System (Curonix LLC) was implanted permanently. Pain relief was assessed using the Verbal Rating Scale (VRS), showing significant improvement in pain scores from baseline to follow-up periods of one, 3, and 6 months.

Conclusion: PNS is a safe, effective method for treating chronic pain that originates in the peripheral nerves and is resistant to conservative therapy.

Key words: Chronic pain, peripheral nerve stimulation, case series, superior cluneal nerves, lumbar medial branches, infrapatellar saphenous (IPS) nerve

BACKGROUND

Chronic pain originating in peripheral nerves remains a significant cause of long-term disability, with many patients experiencing insufficient relief from conservative therapies. Peripheral nerve stimulation (PNS) provides targeted neuromodulation for various pain conditions, including limb mononeuropathies, nerve entrapments, post-surgical neuropathic pain, complex regional pain syndrome, and post-amputation pain. The nature of receiver based PNS, typically involving the placement of electrodes near the target nerve, makes it an appealing and accessible option for both clinicians and patients (1,2).

Advancements in PNS technology have further expanded its clinical utility. In particular, using high-frequency electromagnetic coupling (HF-EMC) to power an implanted neurostimulator through a separate subcutaneous receiver introduces an important approach to pain management. The receiver based PNS system described in this case series combines a 2-component

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implant with a transmitter to deliver programmable stimulation without implanted batteries. This system is indicated for pain management in adults who have severe intractable chronic pain of the peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach.

Chronic pain's persistent nature not only diminishes patients' quality of life but also often resists traditional treatment approaches. While established evidence-based guidelines for managing axial pain, such as those described by Manchikanti et al (3), provide clear protocols for diagnosis and intervention, particularly through facet joint procedures, there is an urgent need to develope strategies that specifically tackle chronic pain from peripheral sources. Historically, PNS has been employed to assess and treat various medical disorders. According to Ong Sio, accumulated recent evidence has demonstrated the effectiveness of PNS for a myriad of chronic pain conditions, including limb mononeuropathies, nerve entrapments, peripheral nerve injuries, phantom limb pain, complex regional pain syndrome and back pain (4). The clinical appeal of PNS lies in its receiver based nature, the placement of electrodes near target nerves, and its versatility in stimulating diverse nerve pathways. These factors have contributed to high compliance and widespread adoption of PNS. Although the precise mechanisms underlying neuromodulation remain to be fully elucidated, the gate control theory proposed by Melzack and Wall in the 1960s continues to offer a foundational explanation for the analgesic effects observed when PNS is used (5).

In 2024, the American Society of Interventional Pain Physicians (ASIPP) published evidence-based guidelines supporting the use of implantable PNS systems in patients with chronic pain of peripheral nerve origin. These robust guidelines provide a comprehensive review as related to the evidence supporting the use and long-term effectiveness of PNS in clinical practice (3). In parallel, Strand and colleagues have contributed to advancing PNS by developing a consensus guideline through a systematic review process. Their comprehensive analysis, which spanned multiple electronic databases from their inception to March 2021, included randomized controlled trials and prospective observational studies. This review provided Level I evidence supporting the use of PNS for a range of pain conditions—from chronic migraine headaches via occipital nerve stimulation to chronic hemiplegic shoulder pain and lower extremity neuropathic as well as post-amputation pain. Integrating high-quality evidence with advanced electrode placement techniques positions PNS as a safe, effective adjunct for managing complex pain disorders, provided that patient selection is meticulous and confirmed by positive diagnostic nerve blocks or stimulation trials (6).

Building on this foundation, the receiver based PNS system uses high-frequency electromagnetic coupling (HF-EMC) technology to power an implanted neurostimulator through a separate receiver, delivering tailored, sub-threshold stimulation to interrupt aberrant pain signals. In our retrospective series, 9 patients suffering from chronic peripheral nerve pain experienced significant pain relief following a successful diagnostic injection, a PNS trial, and subsequent permanent implantation with the Freedom® PNS System (Curonix LLC).

CASE

This retrospective study was exempted from the need to receive approval from the Institutional Review Board (IRB).

Patient Selection

This retrospective study included 9 patients who received a permanent Freedom® PNS System (Curonix LLC) at various nerve targets for treating chronic pain of peripheral nerve origin. After a successful PNS trial, all patients were treated with a permanent Freedom® PNS System (Curonix LLC). A retrospective chart review was conducted to assess baseline and follow-up parameters.

All patients were required to be at least 18 years old and have a confirmed diagnosis of chronic pain originating in a peripheral nerve. Patients with any other implanted neurostimulation devices in addition to the Freedom® PNS System (Curonic LLC) were excluded.

Device Description

The PNS system used in this study (the Freedom® PNS System by Curonix LLC,) includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, as well as an transmitter assembly and wearable accessory (Fig. 1). The transmitter uses HF-EMC technology to wirelessly transfer data and stimulation energy to the 2-component implant that the physician connects during the procedure. The physician is also required to create a separate, distinct pocket to permanently anchor the device.

Permanent Implant Surgical Technique

Informed consent was obtained from all patients. Each patient was taken to the operating room and positioned appropriately on the table. The implant site was cleaned and covered with sterile drapes. 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. The first 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 nerve target 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 nerve target.

A receiver pocket was created using blunt dissection through a second distinct incision. The steering stylet was removed from the previously implanted electrode array. A separate receiver was connected to the electrode array. After being connected, the electrode array and receiver were tunneled to the receiver pocket. The receiver was coiled utilizing 2 nonabsorbable sutures to form the permanent receiver coil. The end of the receiver coil was tucked underneath the coil to avoid protruding edges. Through the use of a nonabsorbable suture, the receiver coil was sutured to the fascia in at least 2 locations, ensuring the coil was flat in the pocket. The receiver pocket was closed with deep and superficial absorbable sutures.

Programming Protocol

Patients were programmed at a subthreshold level, using a frequency of 1,499 Hz with a pulse width of 30 µs at variable intensities (mA). The transmitter assembly was worn in a wearable accessory.

Demographics

Data was collected for 9 patients. All patients were diagnosed with chronic pain of peripheral nerve origin. Mean pain scores at baseline were recorded at 7.9 ± 1.0 on the Verbal Rating Scale (VRS). Two patients reported chronic pain in the gluteal region and were treated with PNS at the superior cluneal nerve. Another 2 patients reported chronic pain in the lower back and were treated with PNS at the superior cluneal nerve at the lumbar medial branches. Three patients reported pain in the knee and were treated with PNS at the infrapatellar saphenous (IPS) nerve; 2 were treated at the suprascapular nerve for shoulder pain. The mean age was 64.8 ± 12.9 years; 5 patients (55.6%) were men, and 4 (44.4%) were women (Table 1). At the time of this report, all patients were followed for at least one month, with 7 followed for 3 months and 2 followed for 6 months.

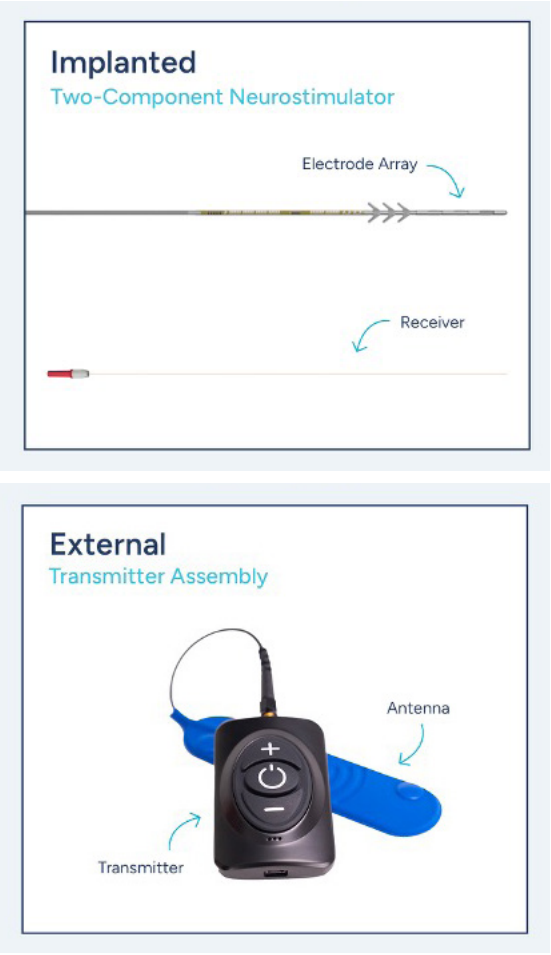

Fig. 1. Freedom® PNS System (Curonix LLC).

Data Analysis

The primary analysis assessed pain reductions on the VRS, an 11-point scale ranging from 0 (no pain) to 10 (extreme pain). Patients filled out the VRS before treatment with the Freedom® PNS System (Curonix LLC) and after a trial period. A one-, 3- and 6-month follow-up was collected to assess the percentage of pain relief at the time.

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

Table 1. Demographics and pain scores.

RSN	Age	Gender	Chronic Pain Location	Nerve Target
1	67	female	shoulder pain	suprascapular nerve
2	83	male	low back pain	superior cluneal nerve
3	76	female	knee pain	IPS nerve
4	76	female	low back pain	superior cluneal nerve
5	69	male	low back pain	superior cluneal nerve
6	62	male	shoulder pain	suprascapular nerve
7	43	male	knee pain	IPS nerve
8	43	female	low back pain	superior cluneal nerve
9	73	male	knee pain	IPS nerve

The data were collected from electronic medical records and entered into case report forms on an Excel spreadsheet. Statistical analysis was performed using descriptive statistics, a parametric analysis of the change-from-baseline (ΔBL) pain, and a nonparametric analysis of the ΔBL. The nonparametric test did not require normally distributed differences. *P*-values were considered significant if ≤ 0.05.

Trial Response Rate

At the end of the trial period, patients reported that their mean pain scores decreased from 7.9 ± 1.0 to 1.4 ± 1.3 (82%; $P < 0.001$). All 9 trial patients moved forward to permanent implantation.

Long-Term Follow-Up

All 9 patients had a permanent implant for at least one month, with follow-up assessments at one month (n = 9), 3 months (n = 7), and 6 months (n = 2) after that implantation. The mean VRS score decreased from baseline to 3.6 ± 3.2 (55%; $P < 0.001$;) at one month, to 1.7 ± 2.0 (78%; $P < 0.001$) at 3 months, and 2.0 ± 2.8 (75%) at 6 months (Fig. 2). No complications were reported.

The ΔBL was analyzed parametrically as a function of the number of months after the implantation, using a maximum-likelihood regression analysis. When the age and gender of the patient were controlled for, the ΔBL was affected significantly by the number of months ($P < 0.001$). The nonparametric analysis of the same data used a Skillings-Mack analysis to compare the pain over time. Although the changes from baseline over months were not significantly different ($P = 0.65$), the VAS scores, which included the baseline score, were: $P < 0.001$.

DISCUSSION

As technology has advanced, PNS has become an increasingly popular method for treating various chronic pain conditions. Based on the gate control theory of pain proposed by Wall and Melzack in 1965, PNS delivers electrical impulses to targeted peripheral nerves, modulating pain signals before they reach the central nervous system. In this article, we have performed a comprehensive literature review to explore the mechanisms of action of PNS in managing chronic pain, focusing on its peripheral and central effects (7).

PNS has been used effectively to treat a range of chronic pain conditions, such as neuropathic pain, complex regional pain syndrome, and post-surgical pain. The ability of PNS to target specific nerves with minimal invasiveness has contributed to its popularity as an alternative treatment among patients who have not found relief with more traditional therapies. The Freedom® PNS System (Curonix LLC), a 2-component implantable device, is an example of technology that allows for precise targeting and stimulation of pain-causing nerves, relieving conditions such as chronic low back pain (CLBP) and post-amputation pain (8).

The mechanism of PNS likely involves both peripheral and central analgesic effects. PNS works by stimulating the nerve fibers near the target site, which modulates how pain signals are transmitted to the brain. At the peripheral level, PNS helps to regulate inflammatory pathways and affects the autonomic nervous system, which plays a crucial role in pain processing. Studies have shown that PNS can modulate these pathways, potentially reducing pain and inflammation (9).

Furthermore, PNS also triggers the body's endogenous pain inhibition pathways. This process involves activating systems that naturally suppress pain signals within the body, providing a form of internal analgesia. Additionally, animal and human studies and imaging studies suggest that PNS can alter the function of cortical and subcortical regions involved in pain perception. These areas of the brain are responsible for processing sensory information and managing emotional responses to pain. By engaging these regions, PNS may reduce pain and improve the patient's emotional and cognitive response to chronic pain (10).

For instance, CLBP, one of the most common pain conditions treated with PNS, has been shown to impact cognitive function. Patients with CLBP often experience decreased problem-solving abilities, slower information-processing speeds, and memory impairments. The

presence of chronic pain also frequently contributes to psychological conditions such as depression and anxiety, which can further worsen cognitive function (11). By managing pain effectively, PNS may not only reduce the intensity of pain but also potentially improve cognitive functions that are typically affected by the persistent nature of chronic pain. This possibility could have profound implications for patients' quality of life, since the outcome could reduce the cognitive and emotional burden of chronic pain (12).

Helm and colleagues conducted a systematic review that assessed the high-quality evidence supporting the use of PNS in treating chronic pain of peripheral nerve origin. The evidence suggests that approximately two-thirds of patients with peripheral neuropathic pain have at least 50% sustained pain relief with PNS (13). The American Society of Interventional Pain Physicians (ASIPP) recently (2024) published evidence-based guidelines for the use and long-term effectiveness of implantable PNS systems in patients with chronic pain refractory to conventional treatments (2). The guidelines included 4 Freedom® PNS (Curonix LLC) studies representing 213 patients, and the guideline authors concluded that the data provided reliable and reproducible evidence of successful PNS treatments (3).

Regarding safety, our study showed no significant AEs, which was consistent with other research suggesting that PNS was a well-tolerated treatment. However, variability in patient response and the need for precise implantation techniques highlight the importance of tailored treatment approaches. The use of advanced technologies, such as the Freedom® PNS System (Curonix LLC), is key to optimizing the precision and effectiveness of this treatment.

PNS is a neuromodulatory technique with the potential to reduce chronic pain significantly, particularly in conditions of peripheral nerve origin. This method's mechanisms of action involve both the peripheral modulation of pain and central effects on brain areas responsible for processing pain. By influencing inflammatory pathways, the autonomic nervous system, and endogenous pain inhibition systems, PNS can alleviate pain and improve cognitive function and emotional responses in patients suffering from chronic pain (14).

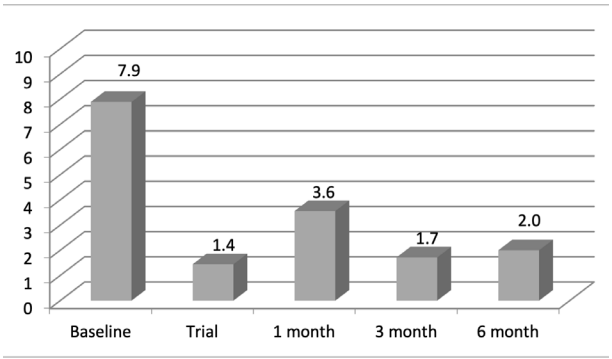

Fig. 2. Mean Verbal Rating Scale (VRS) pain scores.

Limitations

This study was a retrospective case series without prospective data, and the patients were not randomized. Follow-up times for data collection were not standardized. No functional outcomes were measured. The small sample size of 9 patients limits generalizability and statistical power. Selection bias, documentation variability and missing data potentially influence the eventual results of a retrospective study.

CONCLUSION

Receiver based PNS at various nerve targets is an effective and safe therapy for treating chronic pain that originates in peripheral nerves and is resistant to conservative therapy.

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