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Peripheral Nerve Stimulation Uses High-Frequency Electromagnetic Coupling Technology to Power an Implanted Neurostimulator With a Separate Receiver for the Treatment of Chronic Knee Pain: A Retrospective Study

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Background: Chronic knee pain is highly prevalent in the United States, especially within the older population. The condition negatively impacts overall quality of life and can be a substantial financial burden. Current conservative and surgical interventions are not always effective in managing chronic knee pain. Peripheral nerve stimulation (PNS) can be an alternative to current management strategies.

Case Report: Data was retrospectively extracted from the electronic medical records of patients who received a permanent Freedom® PNS System for treating chronic knee pain. Systems were implanted for at least one month. Outcomes of interest included pain levels and occurrences of adverse events.

Seven patients were included in this analysis. Pain scores decreased from 9.8 ± 0.3 to 1.6 ± 1.5 after the trial. The average pain score was 1.3 ± 0.8 at one month, with no adverse events reported.

Conclusions: Chronic knee pain can be safely managed with the Freedom PNS System.

Key words: Peripheral nerve stimulation, chronic pain, CRPS, infrapatellar saphenous neuralgia

BACKGROUND

Knee pain is one of the most prevalent chronic pain conditions in the United States. Over 27 million Americans experience chronic knee pain (1). In the population over 65, 70% present evidence during examination and 12% experience symptoms. Chronic knee pain compromises function and mobility, resulting in reduced quality of life and increased disability (2). In addition to physical detriments, chronic knee pain contributes to a significant economic burden with patients spending an average of $3,000 each year on prescriptions (3).

Treatment for chronic knee pain initially involves conservative management strategies. This includes physical therapy, weight loss, intraarticular injections, exercise, and oral analgesics (1,4). Total knee arthroplasty (TKA) may be pursued following the failure of conservative treatments. However, TKA is not always effective, and

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some patients are not suitable for the procedure. An estimated one-third of patients after TKA still experience residual knee pain afterward (5). As with any surgical interventions, it may not be advisable for patients who are at high risk for cardiovascular comorbidities to undergo TKA (4). Radiofrequency ablation (RFA) has been introduced as a possible treatment for residual knee pain after TKA and for patients who do not or cannot undergo TKA (6,7). However, pain relief from RFA is not permanent and lasts up to 12 months (8).

Peripheral nerve stimulation (PNS) is an emerging treatment modality for chronic knee pain. It represents an alternative nonpharmacologic and minimally invasive treatment that can reduce opioid consumption and provide satisfactory pain relief for many patients (9). Updated designs of leads have lowered the prevalence of lead migration and infection, 2 factors that previously hindered the widespread use and research of PNS (10,11).

We present a retrospective case series of patients with chronic knee pain treated with a wireless PNS system.

METHODS

This small, short-term retrospective study received exemption for review from the Institutional Review Board.

Patient Selection

This retrospective study included 7 patients who received a permanent Freedom® PNS System for treating chronic knee pain. Patients reported chronic, intractable pain in the knee with a Verbal Rating Scale (VRS) rating of at least 5/10. Patients had been treated with PNS with the Freedom PNS System for at least one month postpermanent implant to be considered for the study. A retrospective chart review was conducted to assess baseline and follow-up parameters. Patients with any active implanted devices in addition to the Freedom PNS System were excluded from the study.

Device Description

The Freedom® PNS System (Curonix LLC, Pompano Beach, FL) uses high-frequency electromagnetic coupling (HF-EMC) technology. The Freedom PNS System includes an implanted electrode array (with 4 or 8 contacts) (Fig. 1), 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 positive 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 13G 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(s) and advanced to the target nerve. Using the same technique, one patient received a secondary electrode array at a different nerve target.

The steering stylets were removed, and separate receivers were connected to the electrode arrays. A receiver pocket was created using a second incision, and the neurostimulators were tunneled beneath the skin from the first incisions to the receiver pocket. A knot was tied to connect the separate receivers and electrode arrays permanently. The neurostimulators were coiled, and the coils were sutured to the fascia and secured within the pocket. The receiver pockets were closed in 2 to 3 layers of suturing (Fig. 2).

Programming Protocol

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

Demographics

Data was collected for 7 patients. All patients were diagnosed with complex regional pain syndrome (CRPS) type 2 and infrapatellar saphenous neuralgia (6), or osteoarthritis (1) causing chronic knee pain. Three out of seven patients presented with chronic knee pain after TKA. Four patients were not considered for TKA due to medical restrictions. Six patients (86%) received one neurostimulator with one patient (14%) receiving 2 neurostimulators. The mean age was 74 ± 7.8 years; 5 patients (71%) were women, and 2 (29%) were men.

Fig. 1. Freedom PNS Systems.

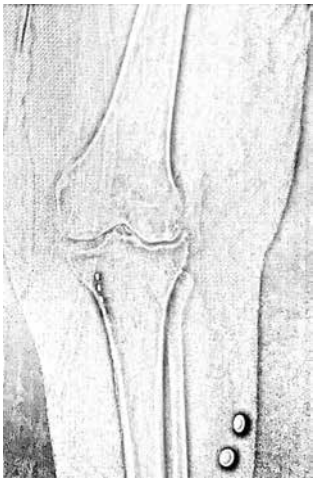

Fig. 2. Freedom PNS at the infrapatellar saphenous nerve AP.
AP, anteroposterior

Data Analysis

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

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

The data was collected from electronic medical records, followed case report forms, and entered into an Excel spreadsheet. 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 trial visit, all 7 (100%) patients reported > 50% pain relief, with mean pain scores reducing from 9.8 ± 0.3 to 1.6 ± 1.5 (84%; $P < 0.001$).

Permanent Implant Follow-up

Seven patients completed a one-month postpermanent implant follow-up. All patients had their PNS systems permanently implanted for one month. All patients experienced at least a 50% improvement in pain. The average VRS score decreased to 1.3 ± 0.8 (87%; $P < 0.001$) (Fig. 3). No complications were reported.

DISCUSSION

Our study demonstrated that PNS provides significant pain relief without AEs in patients with chronic knee pain. Specific etiologies included CRPS type 2, infrapatellar saphenous neuralgia, and osteoarthritis. Our average 86.73% pain relief at one month postpermanent implantation is similar to previous literature. McRoberts et al (12) presented data from 2 patients, with one patient reporting 50% to 70% decrease in pain during the day and a 100% decrease during the night. The other patient reported 80% to 90% pain relief after the procedure. Ilfeld et al (13) reported 5 patients who experienced a 93% average reduction in pain at rest. Chitneni et al (14), in a case report, demonstrated their patient experienced 80% relief after one month and 90% relief after 2 months. Most recently, Fruh et al (15) utilized the same wireless PNS system in our study for 25 patients who experienced an average 75% reduction in pain after 3 and 6 months. Similar improvement in pain at rest was seen for 9 patients at 12 months, although breakthrough pain was reported in motion (15).

The Freedom PNS System's use of HF-EMC to wirelessly power the implanted electrode array has been previously demonstrated to be effective for other indications. Abd-Elsayed et al (16) reported evidence that supports the system's safety and efficacy for managing chronic knee pain (n = 19), low back pain (n = 15), ankle pain (n = 14), sacroiliac joint pain (n = 7), hand pain (n = 1), and foot pain (n = 1). Similarly, Pollina et al (17) found in 15 patients that the novel wireless PNS system is effective in managing chronic foot pain. Abd-Elsayed (18) has also demonstrated evidence utilizing the Freedom PNS System in 5 patients diagnosed with superior cluneal, sural, ilioinguinal, and genitofemoral neuralgias.

Unlike conventional or wired systems, wireless PNS systems do not require the implantation of a battery, thus avoiding additional procedures to replace them (19). Wireless technology is valuable for highly mobile joints, such as the knee, because it allows for lead placement to be optimized without the need to accommodate additional connection wires that increase the risk of migration and disconnection. Additionally, with the development of current lead design, previous lead

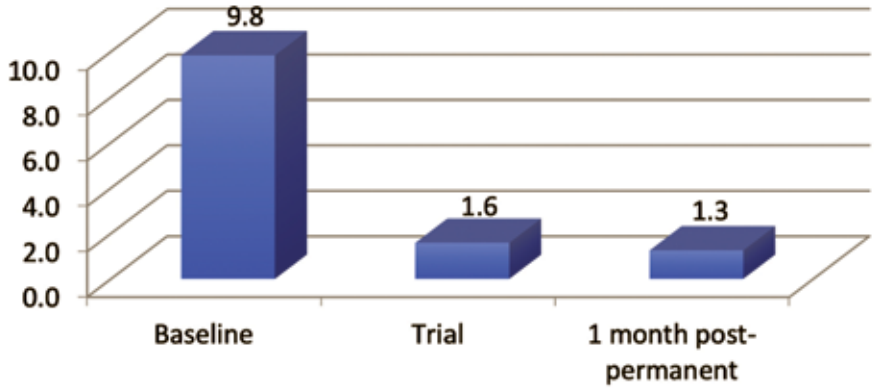

Fig. 3. Mean pain reduction.

migration and infection risks can be further reduced or avoided (10). Prior to wireless PNS systems, common nerve targets to treat knee pain were the femoral and sciatic nerves because these nerves do not require lead placement across the knee joint. The development of wireless systems has allowed for safe lead implantation at the genicular and infrapatellar saphenous nerves, which may offer greater coverage of specific neural generators of pain (15,16).

Limitations

Limitations in this study included the lack of alternative (objective) measures, relatively small sample size, short-term follow-up, and randomization due to the retrospective nature of the design.

CONCLUSIONS

PNS using the Curonix Freedom PNS System is an effective and safe therapy for treating chronic knee pain as a result of CRPS, causalgia, and osteoarthritis before or after TKA.

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