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PERIPHERAL NERVE STIMULATION AT THE INFRAPATELLAR SAPHENOUS NERVE FOR THE TREATMENT OF CHRONIC KNEE PAIN WITH KELLGREN-LAWRENCE GRADE 4: A RETROSPECTIVE CASE SERIES

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Background: Chronic knee pain associated with advanced osteoarthritis (OA) presents a significant challenge in pain management, especially when conservative treatments fail to provide relief.

Case Report: Four patients with chronic knee pain due to Kellgren-Lawrence OA grade 4 (severe) classification were selected for permanent implantation of the Freedom® Peripheral Nerve Stimulation (PNS) System at the infrapatellar saphenous (IPS) nerve. Pain reduction and responder rates were assessed before and after treatment. Long-term follow-up data were collected to evaluate pain relief, function, quality of life, and medication usage. All 4 patients experienced > 50% pain relief following the trial period, significantly reducing mean pain scores from baseline. Long-term follow-up revealed sustained pain reduction and functional improvement, with no reported adverse events associated with the procedure.

Conclusions: PNS targeting the IPS nerve with the Freedom PNS System demonstrates efficacy and safety in managing chronic knee pain associated with Kellgren-Lawrence OA grade 4 classification.

Key words: Peripheral nerve stimulation, chronic knee pain, infrapatellar saphenous nerve, Kellgren-Lawrence grade 4

BACKGROUND

Osteoarthritis (OA) is a significant global health problem. One of the most common symptoms of OA is chronic knee pain, which has a significant impact on the activities of daily living and the general well-being of patients. Despite the numerous therapeutic options available, controlling OA-related knee pain, especially in its advanced stages, remains a daunting undertaking. Traditional conservative approaches, such as analgesic medicines, physical therapy, and intraarticular injections, form the cornerstone of treatment (1). However, many therapies have limitations and adverse effects (AEs).

Nonsteroidal anti-inflammatory drugs and opioids are typical analgesics used to manage OA pain (1,2).

Physical therapy (1), which includes exercises, manual therapy, and procedures, such as ultrasound and electrical stimulation, seeks to increase joint mobility, muscular strength, and function while relieving pain (3). However, those modalities may also fail to provide satisfactory pain relief.

Intraarticular injections (1), such as corticosteroids and hyaluronic acid derivatives, relieve localized inflammation by lubricating the joint space. However, their efficacy varies by case and is not without side effects.

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While corticosteroid injections provide temporary pain relief, continuous use can lead to cartilage degradation (4) and joint infection. Hyaluronic acid injections, on the other hand, may result in temporary local reactions, such as discomfort and edema at the injection site. Radiofrequency ablation is another option for treatment, but the duration of relief is still limited (5).

Given the challenges and limitations associated with traditional therapies, it is critical to explore alternative methods to meet the unfulfilled needs of patients experiencing severe knee pain related to OA. Peripheral nerve stimulation (PNS) is an established therapeutic method, providing focused pain relief with potentially fewer systemic AEs than pharmaceutical therapies by selectively altering neuronal circuits involved in pain perception. It is very important to consider other therapeutic options, as PNS can improve the treatment of chronic knee pain caused by severe OA.

This retrospective study evaluates the efficacy and safety of using PNS at the infrapatellar saphenous (IPS) nerve to treat chronic knee pain attributed to Kellgren-Lawrence OA grade 4 in a patient population that has limited surgical candidacy due to age and comorbidities. Our study focuses on evaluating the results of patients treated with the Freedom® PNS System (Curonix LLC, Pompano Beach, FL), an established system for treating severe, intractable chronic pain of peripheral nerve origin.

METHODS

This retrospective study was exempted from the Institutional Review Board.

Patient Selection

This small retrospective series included 4 patients who received a permanent Freedom PNS System at the IPS nerve (Fig. 1) to treat chronic knee pain with Kellgren-Lawrence OA grade 4 (severe) classification (Fig. 2). The patients reported chronic, intractable knee pain. After a successful (> 50% pain relief) diagnostic injection and PNS trial at the IPS nerve, all patients were treated with a permanent Freedom PNS System after reporting ≥ 50%pain relief. 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 OA, Kellgren-Lawrence grade 4, responsible for pain presentation. Patients with any additional implanted neurostimulation devices in addition to the Freedom PNS System were excluded.

Device Description

The Freedom PNS System 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 (Fig. 3), and a wearable accessory. The Freedom PNS System comprises a 2-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. Patients were taken to the operating room and appropriately positioned supine on the table. The implant site was cleaned and covered with sterile drapes. The needle entry point and pathway were planned using palpation. 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 13G introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the IPS nerve using small amounts of local anesthetic. A 4-contact electrode array with tines was inserted through the cannula and advanced to the IPS nerve.

A receiver pocket was created using blunt dissection through a second incision. The steering stylet was removed from the previously implanted electrode array, and a separate receiver was connected to the electrode array. The electrode array and receiver were tunneled beneath the skin from the first incision to the second incision receiver pocket. A knot was tied to connect the separate receiver and electrode array permanently. The receiver was coiled into a small diameter coil, and 2 nonabsorbable sutures were used to form the receiver coil permanently. The edges of the receiver coil were tucked underneath the coil to avoid protruding edges. Using a nonabsorbable suture, the receiver coil was sutured to the fascia in 2 locations, ensuring it was flat in the pocket. The receiver pocket was closed with deep and superficial absorbable sutures.

Programming Protocol

Patients were programmed subthreshold with a frequency of 1,499 Hz at variable intensities (mA). The transmitter assembly was worn in a wearable on the lower leg.

Demographics

Data was collected for 4 patients. All patients were

diagnosed with chronic knee pain with OA, Kellgren-Lawrence grade 4. Mean pain scores at baseline were recorded at 7.8 ± 0.5 with the Verbal Rating Scale (VRS). The mean age was 81 ± 4.9 years; 2 patients (50%) were women, and 2 (50%) were men. The mean patient height was 67 inches, and the mean weight was 196 pounds. The average body mass index was 30.3, classifying it as Obese Class 1 (Table 1). These patients were not candidates for total knee replacement.

Data Analysis

The primary analysis utilized the VRS to assess the responder rate. The secondary analysis included pain reductions with the VRS, which is an 11-point scale that ranges from 0 (no pain) to 10 (extreme pain). Patients filled out the VRS before treatment with the Freedom PNS System and after a trial period. A long-term follow-up was collected to assess the current percentage of pain relief, function, quality of life, and medication usage.

AEs were reported descriptively and classified as serious AEs or nonserious AEs and related or unrelated AEs.

The data were collected from medical records using case report forms and entered into a Microsoft Excel® spreadsheet (Microsoft Corporation, Redmond, WA). Statistical analysis was performed using descriptive statistics and paired t tests to compare 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 period, all 4 (100%) patients reported > 50% pain relief, with mean pain scores reducing from 7.8 ± 0.5 to 1.0 ± 0.8 (87%; $P < 0.001$). The confidence interval (CI) was 0.96 with a confidence level of 90%.

Long-Term Follow-Up

All 4 patients had a permanent implant for at least one month. The average VRS score decreased to 0.5 ± 0.6 (94%; $P < 0.001$) with a CI of 0.67. Two patients reported a mean VRS of 1.5 ± 0.7 (81%; $P < 0.001$) with a CI of 0.83 at 6 months after the permanent implant, with one patient reporting a pain score of 1 (87%) after 12 months. No AEs were reported.

DISCUSSION

Persistent knee pain is a common and incapacitating ailment that is frequently linked to severe OA or develops after knee surgery. Chronic knee pain is significantly influenced by the IPS nerve, especially after knee surgery or in cases of severe OA. In a study by McLean et al (6) in 2019, they emphasized the significance of employing PNS to focus on the IPS nerve for treatment, indicating its potential as a therapeutic target in the management of persistent knee pain.

A significant decrease in the quality of life and limitations in function result from the persistent nature of chronic knee pain in many patients, even after surgical treatments have been performed. A study by Chitneni et al (7) focused on the effectiveness of PNS for the saphenous and superior lateral genicular nerves in reducing chronic knee pain after knee surgery. Accord-

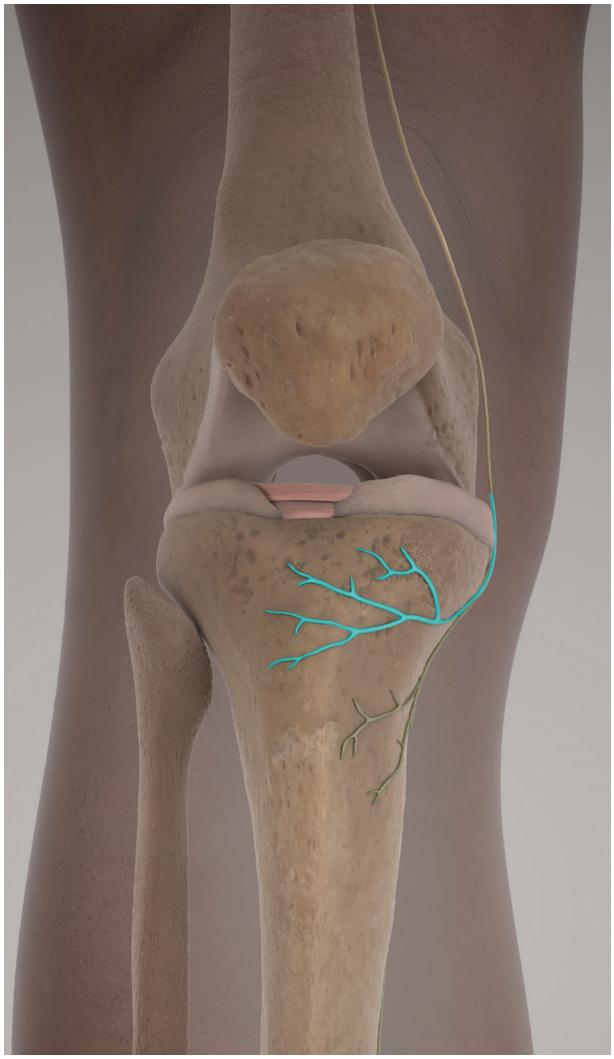

Fig. 1. Infrapatellar saphenous (IPS) nerve.

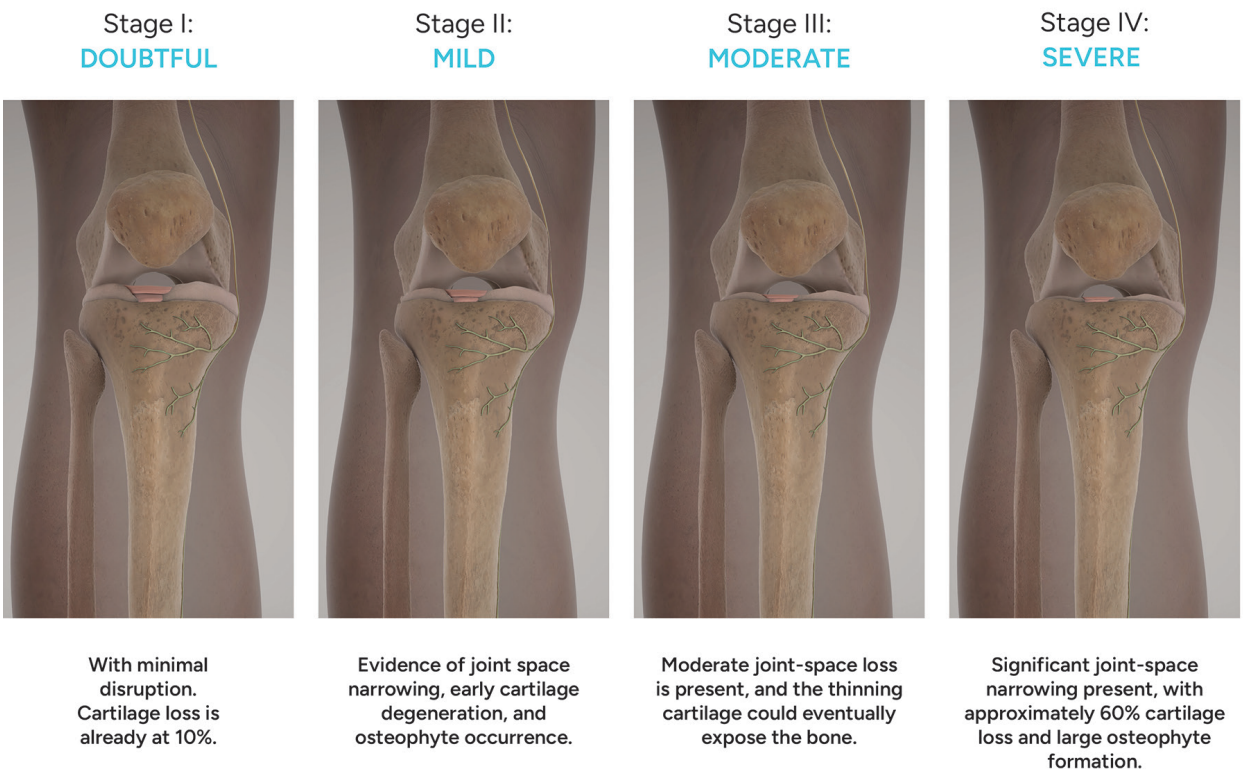

Fig. 2. Kellgren-Lawrence Scale, cartilage loss.

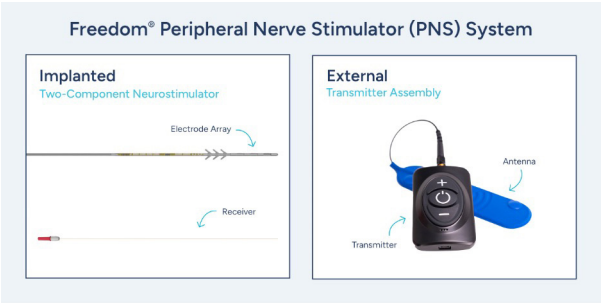

Fig. 3. Freedom® PNS System.

ing to their findings, PNS may be a viable strategy for treating knee pain following surgery, filling a significant need in treating this patient population (7).

Several studies (8-16) indicated the efficacy of PNS in treating several peripheral nerve targets for treating different pain conditions. These studies, taken together, provide insight into the complex nature of chronic knee pain and the application of PNS as a treatment approach.

The IPS nerve covers an ample anatomical nerve supply to the knee, which makes it an interesting and compelling target for treating knee pain (10). Targeting this nerve alone can provide satisfactory and effective relief of knee pain.

PNS provides a focused and minimally invasive method of pain management by focusing on particular nerves linked to persistent knee pain, such as the IPS nerve.

The IPS nerve has been a therapeutic target for treating acute and chronic knee pain. We agree that when the pain is on the medial and lateral sides of the knee, more nerves may need to be targeted, but in our cases, the pain was medial and a diagnostic IPS nerve block controlled the pain by > 50%, which confirmed that using it as the only therapeutic target is sufficient. This was also confirmed by the trial period, as patients got the pain relief they were satisfied with without complaining of any other pain locations covered by other nerves (10,17).

Chronic knee pain due to advanced OA, particularly when it reaches Kellgren-Lawrence grade 4, is a significant clinical challenge. Our retrospective study examined PNS as a treatment strategy in such circumstances, focusing on the IPS nerve. The results of this retrospective study indicate that the Freedom PNS System can manage chronic knee pain. The significant

Table 1. Demographics.

Research Number	Age At Implant	Gender	BMI	BMI Class	Baseline VRS	Trial	1 Mo	6 Mo	12 Mo
1	81	W	30.89	Obese Class 1	8	1	0	1	1
2	80	W	29.81	Overweight	8	0	1	2	
3	87	M	28.55	Overweight	7	1	0		
4	75	M	30.33	Obese Class 1	8	2	1		

Abbreviations: BMI, body mass index; VRS, Verbal Rating Scale; MO, month; M, man; W, woman.

finding, the responder rate, showed that all patients had > 50% pain reduction following the trial period, indicating the efficacy of PNS in this patient population.

Additionally, the long-term follow-up data showed that patients' pain levels continued to decrease over several months, with some even reporting greater improvements over time. The procedure's safety profile is suggested by the lack of documented AEs, which strengthens the argument in favor of its use as a minimally invasive intervention or as an option for patients with few surgical options, such as total knee replacement. The study included both surgical and nonsurgical candidates. For those patients who would eventually need or want total knee arthroplasty, the PNS system would need to be removed in advance.

This study's methodology, encompassing patient selection criteria, device description, and surgical techniques, offers significant insights into the pragmatic application of PNS for managing persistent knee pain. A novel approach to neuromodulation therapy is provided by using HF-EMC technology to power the implanted neurostimulator with a separate receiver at the IPS nerve.

Limitations

Given its retrospective nature and limited number of patients, it is imperative to recognize various limitations associated with this research. One of the major limitations is the lack of a control group and additional metrics, such as functionality and satisfaction.

CONCLUSIONS

PNS at the IPS nerve using the Curonix Freedom PNS System can be considered an effective and safe therapy for treating patients with chronic knee pain due to OA, Kellgren-Lawrence grade 4, which has been resistant to conservative therapy. This therapy can be considered for patients with limited surgical options or patients presenting with persistent chronic knee pain after surgery.

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