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

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Background: Chronic knee pain following total knee arthroplasty (TKA) is a challenging condition that can persist despite various treatment modalities. Treatment with a peripheral nerve stimulator (PNS) with a separate implanted receiver is an effective approach for managing this type of pain.

Case Report: Seven patients with chronic knee pain following TKA underwent a 7-day trial with the Freedom® PNS System, followed by permanent implantation. All 7 patients reported > 50% pain relief during the trial phase, with a significant reduction in mean Verbal Rating Scale (VRS) scores from 9.5 pre-implant to 1.3 post trial (86%, $P < 0.001$). Long-term follow-up showed sustained pain relief, with VRS scores decreasing to 2.9 at one month, 3.5 at three months, and 4 at twelve months. No adverse events were reported.

Conclusions: PNS targeting the infrapatellar saphenous nerve with the Freedom PNS System demonstrates efficacy and safety in managing chronic knee pain after TKA.

Key words: Peripheral nerve stimulation, chronic knee pain, total knee arthroplasty, infrapatellar saphenous nerve

BACKGROUND

Chronic pain remains one of the most challenging health issues globally, significantly impacting quality of life and contributing to disability and economic loss due to missed work and reduced productivity. It is estimated that > 85% of patients diagnosed with chronic pain have an unknown or nonspecific cause, complicating the path to effective management. Traditional therapies for chronic pain, including pharmacologic interventions, like opioids, antidepressants, and antiepileptics, as well as nonpharmacologic methods, such as physical therapy and nerve blocks, often fail to provide long-term relief or come with significant side effects (1).

Osteoarthritis (OA), particularly knee OA, is one of the leading contributors to chronic pain and disability worldwide. Being the most common progressive musculoskeletal condition, knee OA affects approximately 10% of men and 13% of women over the age of 60, making it one of the leading causes of disability in the elderly population (2). Furthermore, a recent study (3) predicted that between 2006 and 2030 there will be a 17-fold increase in the number of total knee arthroplasties (TKAs) performed in the age group younger

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than 55 years old. Today, it is recognized that OA is not just a disease characterized by cartilage loss due to mechanical loading, but involves all joint tissues. This results in detectable changes in tissue architecture, metabolism, and function, driven by a complex interplay of proinflammatory and anti-inflammatory cytokines, chemokines, growth factors, and adipokines. These biomarkers can be measured in serum, synovium, and histological samples, offering insights into disease stage and progression (2). Given the impact of OA, knee-related health care expenses are immense, costing roughly $20 billion (4), and the United States is estimated to spend $139.8 billion annually on outpatient OA care (5,6).

In more severe cases, TKA becomes the treatment of choice for end-stage OA. However, despite its success, 15% to 30% of patients experience persistent pain following TKA, leaving a substantial subset of patients searching for effective solutions to manage ongoing pain (7). The need for effective pain management becomes evident in these cases, as untreated or inadequately managed chronic pain after surgery can significantly limit mobility, quality of life, and long-term outcomes. Chronic anterior knee pain, often experienced by active individuals, remains prevalent. In a study conducted by Kusnezov et al (8), chronic anterior knee pain had an incidence rate of 4.32 cases per 1,000 person-years among US military personnel, with demographic factors, such as age, gender, race, and military branch, influencing the risk of developing the condition.

Traditional pain management strategies often fall short, particularly in cases of postoperative or chronic knee pain. Pharmacologic interventions, like opioids, are associated with significant risks, including dependency, while nonpharmacologic methods, such as physical therapy and nerve blocks, offer inconsistent long-term relief. Permanent peripheral nerve stimulation (PNS) has demonstrated to be an effective therapeutic approach for patients refractory to conservative treatments. PNS involves the electrical stimulation of peripheral nerves to modulate pain signals, thereby providing pain relief (9). By delivering sustained electrical stimulation to targeted peripheral nerves, PNS modulates nociceptive signaling and provides durable analgesia. Crucially, PNS also offers a meaningful therapeutic alternative for patients with intractable knee pain who are either not candidates for, or choose to avoid, TKA (10). Technological advancements have made 2-component receiver based PNS with a separate implanted receiver requiring connection during the procedure a minimally invasive and effective option for managing various pain syndromes of peripheral nerve origin, offering efficacy where other interventions have failed.

Our study provides a comprehensive overview of PNS, including its historical context, technological advancements, current applications, mechanisms, clinical evidence, and future directions. The Freedom® PNS System (Curonix LLC, Pompano Beach, FL) is a 2-component minimally invasive device with a multicontact electrode array and separate implanted receiver, which is connected during the procedure, designed to target peripheral nerves. Utilizing high-frequency electromagnetic coupling (HF-EMC) technology, the Freedom PNS System utilizes high-frequency stimulation (sub-threshold) for therapy, removing the discomfort often associated with traditional nerve stimulation techniques.

Our retrospective study aims to evaluate the effectiveness and safety of the Freedom PNS System in patients with residual chronic knee pain following TKA. All patients had 12 month follow-ups. Seven patients who demonstrated > 50% pain relief after a successful diagnostic injection and a 7-day PNS trial were selected for permanent implantation of the Freedom PNS System targeting the infrapatellar saphenous (IPS) nerve. Data was collected through a retrospective chart review to assess baseline and follow-up pain scores, responder rates, and any adverse events (AEs).

The primary objective of this study is to determine the responder rate, defined as a reduction in pain of > 50% as measured by the Verbal Rating Scale (VRS). Secondary outcomes include long-term pain reduction, improvements in mobility and quality of life, and the occurrence of any AEs. Our study provides evidence for PNS at the IPS nerve as an effective and safe therapeutic option for managing chronic knee pain in patients who remain symptomatic after TKA.

METHODS

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

Patient Selection

This small retrospective review includes 7 patients who received a permanent Freedom PNS System at the IPS nerve to treat residual chronic knee pain after TKA. All patients were treated with a permanent Freedom PNS System and followed for 12 months, after a successful diagnostic injection and 7-day PNS trial, at which point all patients reported > 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, received a TKA, but reported chronic residual knee pain. 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). It includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, a transmitter assembly, and a wearable accessory. The Freedom PNS System is comprised 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. 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 (Fig. 2).

The steering stylet was removed, and the separate receiver was connected to the electrode array. A receiver pocket was created using blunt dissection through a second incision. 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 permanently secure the receiver and electrode array. The receiver was coiled into a small diameter coil, and 2 nonabsorbable sutures were used to permanently form the receiver coil. 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 on the lower leg in a wearable accessory.

Demographics

Data was collected for 7 patients. All patients were diagnosed with residual chronic knee pain after TKA. Mean pain scores at baseline were recorded at 9.5 ± 0.5 with the VRS. The mean age was 68 ± 13.2 years; 5 patients (71%) were women, and 2 (29%) were men (Table 1).

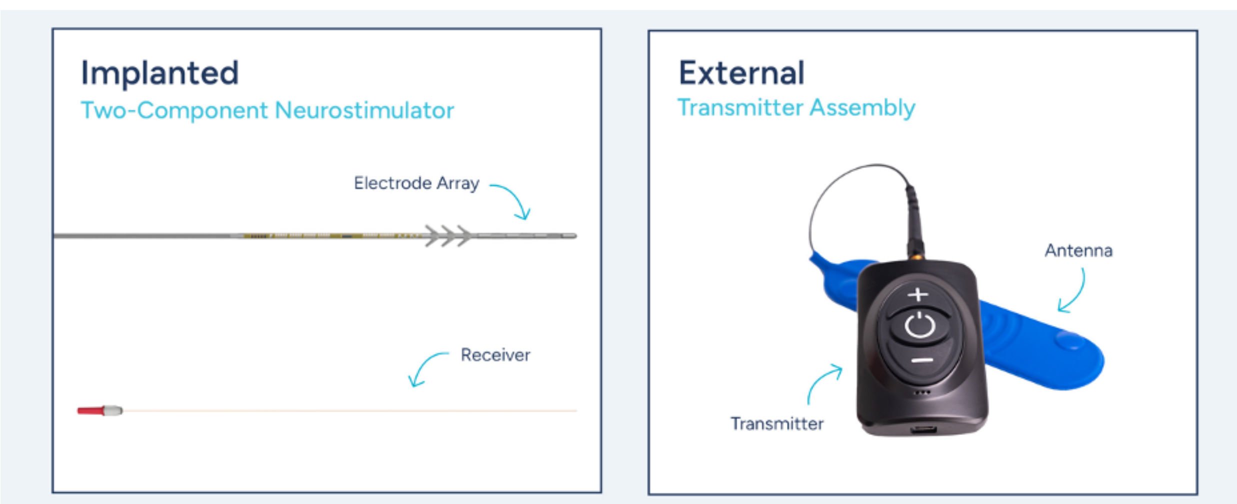

Fig. 1. Freedom PNS System.

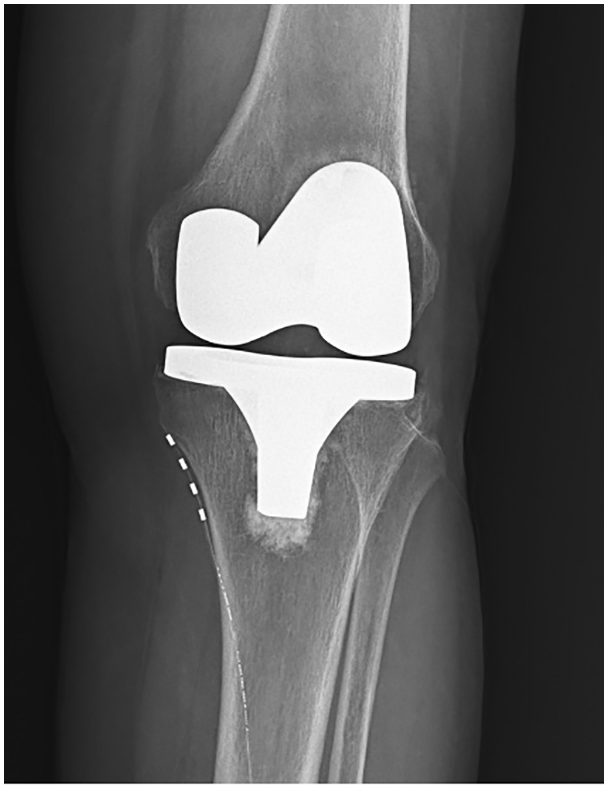

Fig. 2. X-ray of device positioning at the IPS nerve.
IPS: infrapatellar saphenous.

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) (Fig. 3). Patients reported the VRS before treatment with the Freedom PNS System and after a trial period. A long-term follow-up was collected to assess current percent pain relief and possible complications.

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

The data was 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 post-procedure pain scores. The P value was considered significant if $P < 0.05$.

RESULTS

Primary Outcome Responder Rate

At the end of the 7-day trial period, all 7 (100%) patients reported > 50% pain relief, with mean pain scores reducing from 9.5 ± 0.5 to 1.3 ± 0.5 (86%; $P < 0.001$).

Table 1. Demographics and pain scores.

Gender	Age	Nerve Target	Baseline	Trial	1 Mo	3 Mo	6 Mo	12 Mo
Woman	78	Infrapatellar Saphenous Nerve	9.5	1	2			
Man	66	Infrapatellar Saphenous Nerve	9	2	4	8	8	8
Woman	73	Infrapatellar Saphenous Nerve	10	1	3	4	4	
Woman	78	Infrapatellar Saphenous Nerve	9	1	2	2	2	3
Woman	40	Infrapatellar Saphenous Nerve	10	2	2	2		
Woman	69	Infrapatellar Saphenous Nerve	9	1	2	2	2	2
Man	73	Infrapatellar Saphenous Nerve	10	1	1	3	3	3

Long-Term Follow-Up

All 7 patients had a permanent implant for at least one month. The average VRS score at one-month postpermanent implant decreased to 2.9 ± 0.9 (69%; $P < 0.001$). Six patients reported a mean VRS of 3.5 ± 2.1 (63%; $P < 0.001$) at 3 months. Five patients reported a mean VRS of 3.8 ± 2.2 (60%; $P < 0.001$) at 6 months, with 4 patients reporting a mean pain score of 4 (58%; $P < 0.001$) after 12 months. All patients reported improved mobility and quality of life. No AEs were reported.

DISCUSSION

Our study examines the efficacy and benefits of the permanent 2-component Freedom

PNS System with a separate implanted receiver, which is connected to the electrode array during the procedure, for chronic pain following TKA.

Nonsteroidal anti-inflammatory drugs (NSAIDs) are frequently used to manage pain, including those associated with OA and rheumatoid arthritis (RA). However, their use is often complicated by gastrointestinal (GI) side effects (1). According to Butt et al (1), NSAIDs can cause significant GI issues, leading 2% to 10% of patients to discontinue their use. Although nonaspirin NSAIDs have reduced these side effects, GI problems remain a concern. Prophylaxis for GI side effects is feasible for selected populations, but may not be cost-effective broadly (1).

The concept of electrical stimulation for pain relief has evolved over decades. It was first brought to modern clinical practice in the mid-20th century when Shelden et al (11) used implanted peripheral nerve electrodes to treat trigeminal neuralgia, achieving temporary pain suppression at 14,000 Hz. This breakthrough set the stage for subsequent developments in PNS for managing various neuropathic and chronic pain conditions (9).

Advances in technology have made PNS procedures less invasive, with percutaneous approaches now performed in outpatient settings. These improvements have enhanced safety profiles, reduced complications, and increased patient comfort. Receiver based PNS systems are designed for greater accuracy, selectively targeting neuronal structures to minimize unwanted side effects while maximizing therapeutic benefits (9).

The American College of Rheumatology's (ACR) 2012 guidelines for OA emphasize a balanced treatment approach, including nonpharmacologic strategies, like exercise and weight loss, and pharmacologic options, such as acetaminophen and NSAIDs (12). For hand OA, the ACR conditionally recommends joint protection techniques, assistive devices, and topical NSAIDs, aligning with broader efforts to minimize drug side effects (12). Meanwhile, RA patients face additional challenges, including sarcopenia due to inflammation and corticosteroid use. Onishi et al (13) stress the importance of resistance training to mitigate muscle loss, underscoring the need for personalized exercise programs to improve function in RA patients.

A study by Malfait et al (14) developed an in vivo model using tumor necrosis factor-alpha (TNF-α) injections to assess cartilage degradation, advancing the study of pharmacological interventions for cartilage protection. While NSAIDs, like indomethacin, proved ineffective, promising results were seen with treatments, such as dexamethasone and aggrecanase inhibitors (14).

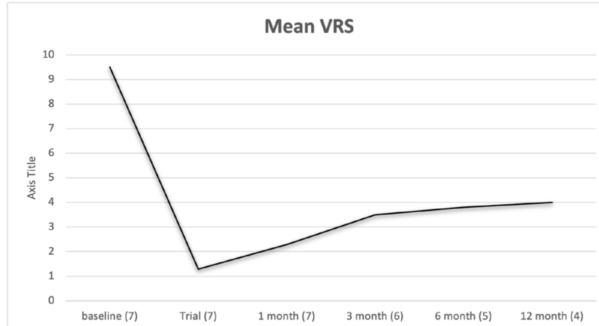

Fig. 3. Mean VRS. VRS: Verbal Rating Scale.

It is very important that we mention the treatment of OA, as patients who fail all those modalities end up with TKA as a last resort for pain relief and restoration of function. When the pain continues after TKA, the options for management are very limited.

The mechanisms of PNS are only partially understood, but they likely involve both central and peripheral pathways. Centrally, PNS may inhibit pain signals through dorsal horn interneurons (per the gate control theory), modulate wide dynamic range neurons, and affect serotonergic, γ-aminobutyric-acid-releasing, and glycinergic pathways (15). These effects reduce central sensitization and hyperalgesia, contributing to long-term pain relief. Peripherally, PNS disrupts nociceptive afferents and downregulates inflammatory mediators, leading to fewer ectopic discharges, a key factor in chronic pain (15). Beyond analgesia, accumulating evidence suggests that neurostimulation may exert anti-inflammatory effects through modulation of neuroimmune interactions. While much of the current research has focused on vagus nerve stimulation, emerging data indicate that peripheral and spinal neurostimulation may similarly influence inflammatory responses by downregulating proinflammatory cytokines (e.g., TNF-α, IL-1β, IL-6) and potentially upregulating anti-inflammatory or proresolving mediators, such as IL-10 and specialized proresolving lipid mediators. These mechanisms suggest that PNS could not only reduce nociceptive transmission but also promote a systemic shift toward an anti-inflammatory or proresolving state, thereby addressing one of the underlying drivers of chronic pain (16-18).

In this retrospective study, we provide preliminary evidence supporting the efficacy of the Freedom PNS System for managing chronic knee pain following TKA. The use of HF-EMC technology in this system has demonstrated significant benefits, aligning with prior research indicating the potential of PNS in refractory pain conditions. Advances in neuromodulation technology have further enhanced the therapeutic potential and patient experience associated with PNS. In particular, HF-EMC represents a significant improvement in delivering PNS therapy. While traditional systems rely on implanted pulse generators and inductive coupling, which are often associated with complications, such as pocket pain, infection, lead migration, or inconsistent power transfer, HF-EMC systems eliminate these drawbacks through a wireless power transfer mechanism. More importantly, HF-EMC provides superior energy transmission stability compared to traditional inductive coupling. Because EMC does not rely on perfect coil alignment or proximity, it maintains more consistent communication between the transmitter and the receiver minimizing signal loss and ensuring steady, uninterrupted stimulation (20). Our study selected 7 patients with persistent knee pain post-TKA based on specific inclusion criteria. All patients had previously undergone a diagnostic trial with the Freedom PNS System, during which they reported at least 50% pain relief. Following implantation, patients were programmed with a frequency of 1,499 Hz at variable intensities, reflecting a tailored approach to pain management. The marked reduction in pain observed highlights the meaningful clinical impact of the Freedom PNS System in managing refractory postoperative knee pain.

The results presented align with existing literature, reinforcing the efficacy of PNS as a minimally invasive alternative for managing chronic pain. Beyond the quantitative improvement, these outcomes illustrate how the system's HF-EMC technology enhances both efficacy and patient comfort. For example, a study by Abd-Elsayed et al (19) involving 57 patients reported sustained pain relief over 24 months post-PNS placement, with only 2 patients requiring device explantation due to loss of efficacy. These findings confirm that PNS provides immediate pain relief and long-term benefits for many patients, highlighting that permanent PNS is an excellent therapy for chronic pain.

Moreover, a review focusing on chronic knee pain transmitted via the IPS nerve found that various PNS modalities, including radiofrequency ablation, cryoablation, and nerve blocks, could provide targeted pain relief for patients unresponsive to conservative treatments. These findings align with the broader evidence base indicating the utility of PNS in managing refractory pain conditions. Früh and Bayerl et al (20) demonstrated that peripheral nerve stimulation targeting branches of the saphenous nerve can significantly reduce chronic postoperative knee pain and improve quality of life in patients with refractory postsurgical pain. Similarly, Abd-Elsayed (21) highlighted the success of receiver based PNS in managing difficult-to-treat neuralgias, reporting significant pain score reductions, a finding consistent with our own results.

This case series also emphasizes the versatility of the Freedom PNS System. By utilizing a 2-component implant system (an electrode array and separate receiver) and programming the system to subthreshold stimulation frequencies, the device offers precise and targeted stimulation while minimizing side effects. This is particularly important in managing chronic pain conditions where accurate nerve targeting is crucial. The system's noninvasive nature and ability to provide long-term pain relief position it as an effective solution for patients who have exhausted traditional pharmacologic and surgical options.

Furthermore, the promising results in our case series are in line with those reported by McLean (22), who demonstrated the importance of precise nerve targeting in optimizing therapeutic outcomes. Their study on the IPS nerve highlights the necessity of accurately locating and stimulating the target nerve for successful treatment, a principle mirrored in the use of the Freedom PNS System. Similarly, Abd-Elsayed et al's (23) literature review evaluated various therapeutic options for chronic IPS-mediated pain, including neuroma excisions, nerve blocks, and PNS, particularly for cases refractory to conservative measures. Both aforementioned studies emphasize the importance of PNS in offering targeted, long-lasting pain relief in patients with chronic knee pain, underscoring the noteworthiness of precise nerve targeting in optimizing treatment outcomes.

Overall, our findings reinforce the substantial evidence supporting PNS as a viable treatment for chronic peripheral neuralgias. The Freedom PNS System offers a minimally invasive approach that reduces pain and improves the quality of life for patients suffering from chronic knee pain post-TKA. This case series confirms that PNS can be considered a crucial tool in the future of chronic pain management.

The future of PNS is bright, with technology advancements, expanded indications, and a deeper understanding of its mechanisms of action. Research is elucidating how PNS interacts with both peripheral and central nervous systems to modulate pain pathways, enhance analgesia, and reduce central sensitization. This knowledge is crucial for optimizing treatment protocols, improving patient-specific outcomes, and tailoring interventions to individual needs.

PNS technology should be considered a cornerstone of chronic pain treatment. Its minimally invasive nature and ability to offer personalized and effective relief position PNS as a transformative option in pain management. With these developments, PNS offers a beacon of hope to patients worldwide, providing sustained relief from chronic pain.

Limitations

Limitations include limited data points due to its retrospective nature and a relatively small sample size.

CONCLUSIONS

Using the receiver based Curonix Freedom PNS System is an effective and safe therapy for treating patients with chronic residual knee pain after TKA who are resistant to conservative therapy. This therapy should be considered for patients presenting with persistent chronic knee pain after surgery.

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