

PERIPHERAL NERVE STIMULATION USING HIGH-FREQUENCY ELECTROMAGNETIC COUPLING TECHNOLOGY TO POWER AN IMPLANTED NEUROSTIMULATOR WITH A SEPARATE RECEIVER AT THE SUPRASCAPULAR NERVE FOR THE TREATMENT OF PAINFUL SPASTICITY: A CASE SERIES

Ellen Lin, MD

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- Background:** Painful spasticity in the shoulder is a debilitating condition that significantly impairs quality of life. Conservative treatments often fail to provide adequate relief, leaving patients with limited therapeutic options.
- Case Report:** A retrospective study was conducted on 8 patients treated with the permanent Freedom® Peripheral Nerve Stimulator (PNS) System at the suprascapular nerve (SN) for painful shoulder spasticity. At baseline, patients reported a mean pain score of 7.6 ± 1.6 . Following the trial phase, pain scores decreased to 2.9 ± 1.9 (62%; $P < 0.001$). At 3 months, the mean pain score was 3.2 ± 1.9 (58%; $P < 0.001$). Patient satisfaction was high, with 88% recommending the system and considering additional implants for other nerve targets. No adverse events were observed.
- Conclusions:** The Curonix Freedom PNS System, targeting the SN, is an effective and safe therapy for treating chronic shoulder pain with spasticity, resistant to conservative therapy.
- Key words:** Peripheral nerve stimulation, chronic pain, suprascapular, shoulder pain, spasticity
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BACKGROUND

Painful spasticity is a debilitating condition characterized by increased muscle tone and involuntary muscle contractions, often leading to chronic pain, functional limitations, and a diminished quality of life (1,2). Spasticity commonly occurs following neurological injuries or disorders, such as stroke, multiple sclerosis, or spinal cord injury (2). When conservative treatments, such as physical therapy, oral medications, and botulinum toxin injections, fail to provide adequate relief, patients are left with limited therapeutic options (2). The suprascapular nerve (SN), which innervates the supraspinatus and infraspinatus muscles, is a key target in the management of painful spasticity in the shoulder (3,4). Effective

modulation of the SN has been shown to alleviate both pain and muscle overactivity, thereby restoring function and improving patient outcomes (1,2).

The role of the SN for shoulder function is clear. It innervates the supraspinatus and infraspinatus muscles, which are essential for arm movement and stabilization. Pain and dysfunction involving this nerve are commonly observed in conditions, such as SN entrapment syndrome (SNES) (4). SNES presents with vague and variable symptoms, including posterolateral shoulder pain and muscle weakness, often making it a diagnostic challenge. The syndrome can result from a range of etiologies, including traction or compressive lesions caused by rotator cuff tears, anatomical variations, ganglion cysts, or

From: Advanced Spine and Pain Center, San Antonio, TX

Corresponding Author: Ellen Lin, MD, E-mail: paindoctorellen@gmail.com

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direct trauma. Distinguishing SNES from other causes of shoulder pain requires careful clinical evaluation and diagnostic precision (4-6).

Historically, SNES was regarded as a diagnosis of exclusion due to its nonspecific presentation and overlapping features with other shoulder pathologies (2). However, advancements in imaging and diagnostic techniques have facilitated earlier and more accurate identification. Magnetic resonance imaging (MRI) has become a cornerstone in evaluating SNES, as it provides detailed visualization of the SN, its surrounding structures, and potential compressive pathologies, such as cysts or rotator cuff tears (4,7) (Fig. 1). MRI also allows qualitative assessment of muscle atrophy in the supraspinatus and infraspinatus, further aiding in differentiation from similar conditions. Despite its utility, the diagnostic gold standard for SNES remains electromyography and nerve conduction velocity (NCV) studies, which enable precise localization of nerve lesions and evaluation of nerve function (4,5).

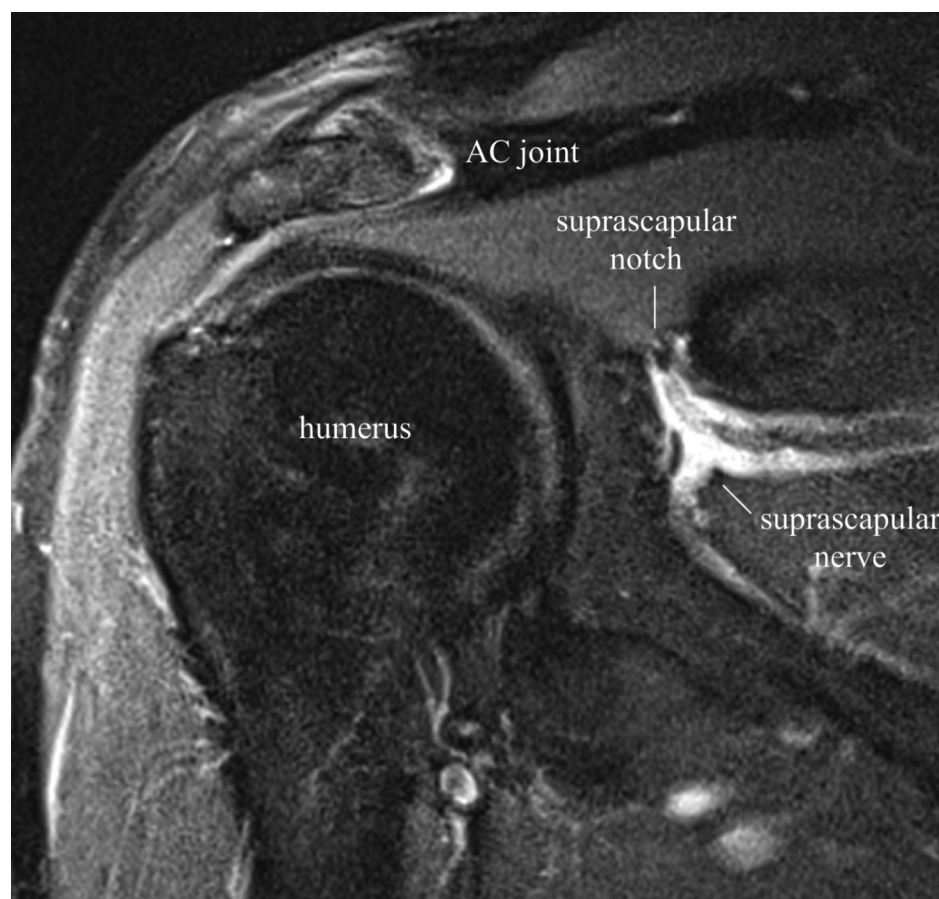


Fig. 1. MRI showing suprascapular nerve. MRI, magnetic resonance imaging.

Given the critical role of the SN in shoulder mechanics and the challenges in diagnosing and managing conditions like SNES, targeting this nerve through peripheral nerve stimulation (PNS) is a viable treatment option (2,3). Traditional PNS systems with an implanted battery deliver electrical pulses to modulate nerve activity, but they often require invasive implantation or involve complications associated with lead placement (8,9). High-frequency electromagnetic coupling (HF-EMC) technology offers a solution, allowing an externally powered transmitter to power an implanted neurostimulator with a separate connected receiver. This less invasive method simplifies the treatment process while maintaining efficacy in modulating nerve function (1,3).

This retrospective study investigates the application of HF-EMC-powered PNS for the treatment of painful spasticity involving the SN. By integrating insights from advanced imaging, NCV studies, and innovative neuro-

modulation technologies, this study aims to evaluate the safety, efficacy, and clinical outcomes of this approach. The findings will contribute to the growing evidence supporting the use of PNS in managing refractory spasticity and chronic pain, addressing an unmet need for patients with limited therapeutic options.

METHODS

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

Patient Selection

This retrospective study included 8 patients who received a permanent Freedom® PNS System (Curonix LLC, Pompano Beach, FL) at the SN for treating painful spasticity in the shoulder. After a successful diagnostic injection and PNS trial, all patients were treated with a permanent Freedom

PNS System. 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 painful spasticity in the shoulder. Patients with any additional implanted neurostimulation devices in addition to the Freedom PNS System were excluded.

Device Description

The PNS system used in this patient (Freedom® PNS System by Curonix LLC, Pompano Beach, FL) includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, as well as an external transmitter assembly and wearable accessory (Fig. 2). The external transmitter uses High-Frequency Electromagnetic Coupling (HF-EMC) technology to wirelessly transfer data and RF energy to the 2-component implant that the physician connects during the procedure. The physician must also create a separate pocket to anchor the device permanently.

Permanent Implant Surgical Technique

Informed consent was obtained from all patients. Patients were taken to the operating room and appropriately positioned prone 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 13G introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the SN 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 SN (Fig. 3).

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 permanently form the receiver coil. The end of the receiver coil was tucked underneath the coil to avoid protruding edges. Using a nonabsorbable suture, the receiver coil was sutured to the fascia in at least 2 locations, ensuring that the coil 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 with a pulse width of 30 μ s at variable intensities (mA). The transmitter assembly was worn in a wearable on the lower back (Fig. 2).

Demographics

Data was collected for 8 patients. All patients were diagnosed with painful spasticity in the shoulder. Mean pain scores at baseline were recorded at 7.6 ± 1.6 on the Verbal Rating Scale (VRS). The mean age was 76.5 ± 4.7 years; 5 patients (62%) were women, and 3 (38%) were men.

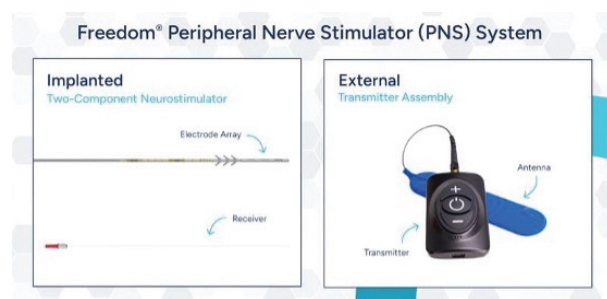


Fig. 2. Freedom PNS System. PNS, peripheral nerve stimulator.

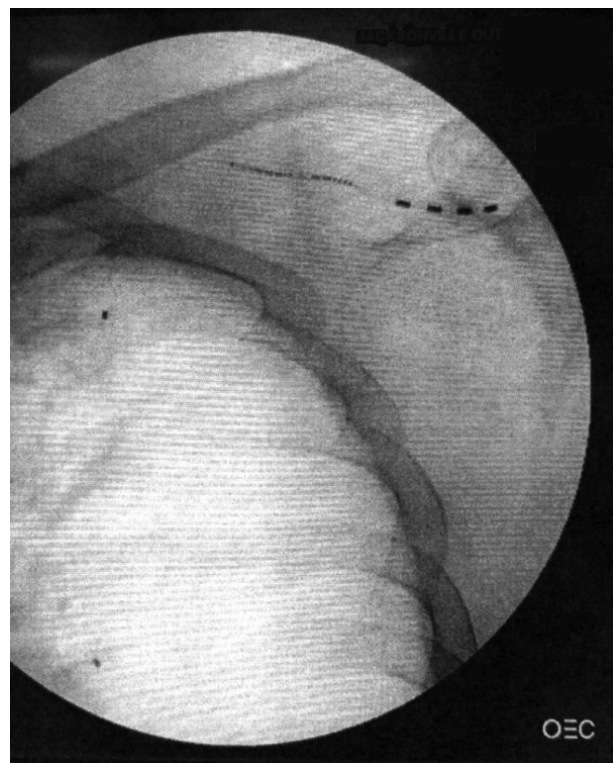


Fig. 3. X-ray of device positioning.

Data Analysis

The primary analysis utilized the VRS to assess 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 3-month follow-up was collected to assess current percent pain relief, percentage satisfaction, sleep, willingness to have the system in a different location if needed, and whether patients would recommend the system to a friend or family member (Fig. 4).

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 into 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

Trial Response Rate

At the end of the trial period, patients reported mean pain scores reducing from 7.6 ± 1.6 to 2.9 ± 1.9 (62%; $P < 0.001$). All 8 trial patients moved forward to permanent implantation.

Long-Term Follow-up

All 8 patients had a permanent implant for at least one month, with a last follow-up assessment at 3 months postpermanent implant. The mean VRS score decreased from baseline to 3.2 ± 1.9 (58%; $P < 0.001$) (Fig. 4). The average satisfaction was 66%. Four patients out of eight (50%) rated improvement in sleep as "much better"; 3 out of 8 (38%) rated sleep as "better" with only one patient reporting no improvement in sleep (12%).

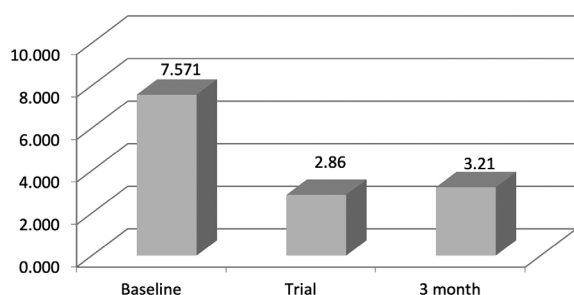


Fig. 4. Mean VRS pain scores. VRS, Verbal Rating Scale.

Seven out of eight patients (88%) would consider an additional implant at a different nerve target if needed. Seven out of eight patients (88%) would recommend the system to a friend or family member. No complications were reported.

DISCUSSION

Chronic shoulder pain, especially when compounded by spasticity, is a prevalent and debilitating condition that significantly impacts patients' quality of life. It is often refractory to conventional therapies, which typically include anti-inflammatory medications, physical therapy, and nerve block injections. In these cases, PNS offers a promising alternative for long-term management (4,7). This study evaluated the effectiveness of the Freedom PNS System for treating painful shoulder spasticity, particularly targeting the SN, a well-known source of chronic shoulder pain. Our findings indicate significant reductions in pain and improvements in functional outcomes, adding to a growing body of evidence supporting PNS as a viable treatment option for chronic shoulder pain. Much like other types of chronic pain, the treatment of SN pain can be complicated by central sensitization and neuropathy, making conventional therapies less effective over time (4,12). In such cases, PNS is a treatment option providing sustained relief through nerve stimulation (8). The SN, which innervates structures like the supraspinatus and infraspinatus muscles and the glenohumeral joint, plays a crucial role in shoulder pain and spasticity. Injury or irritation to this nerve, as seen in conditions, such as rotator cuff pathology, shoulder impingement, or suprascapular neuropathy, can lead to chronic pain that limits the range of motion and impairs daily activities. In our study, the implantation of the Freedom PNS System resulted in a 58% reduction in pain intensity ($P < 0.001$) at 3 months postimplantation, maintaining substantial relief compared to baseline pain scores. This consistent pain reduction supports that PNS, through its continuous electrical stimulation, can modulate nerve activity and block pain transmission along the nerve pathways (4).

A growing body of literature has examined the use of PNS in various clinical settings, including for shoulder pain. One such study by Chitneni et al (11) evaluated the effects of PNS for chronic shoulder pain and found a significant reduction in pain scores, similar to our findings. This study involved a larger cohort of patients

and demonstrated that PNS could provide long-term pain relief in patients with resistant shoulder pain (8). Likewise, a study by Xu et al (10) reviewed the use of PNS for chronic neuropathic pain and reported that patients treated with PNS experienced a “significant” reduction in pain intensity and improved shoulder function. This is in line with our observed reduction of 58%, further supporting the efficacy of PNS in managing shoulder-related pain (8).

The advantage of PNS lies not only in its ability to deliver sustained pain relief but also in its personalized approach to treatment. Unlike other interventions, such as nerve injections, which offer temporary relief and require repeat procedures, PNS provides continuous, adjustable electrical stimulation. This is especially important for managing chronic conditions, where long-term relief is a key goal (12). Moreover, the ability to fine-tune the stimulation parameters, such as frequency and intensity, allows for customized treatment, optimizing outcomes for each patient. Studies by Xu et al (10) have demonstrated the benefits of this adjustable stimulation approach, showing that it leads to better outcomes compared to fixed or one-size-fits-all interventions (9) like medications or nerve blocks.

The concept behind PNS and its application to the SN is rooted in the gate control theory of pain. According to this theory, nonpainful electrical impulses can inhibit the transmission of pain signals, effectively “closing the gate” to pain. This mechanism, as demonstrated in studies by Melzack et al (13), suggests that PNS works by stimulating the A-beta fibers of the nerve, which activate inhibitory dorsal horn interneurons and block the transmission of pain signals carried by A-delta and C fibers. Further studies by Strauss et al (5) and Garcia et al (14) have supported this theory, showing that PNS can modulate spinal cord processing of pain signals, effectively reducing pain perception. Moreover, research by Hao et al (15) indicated that PNS therapy for shoulder pain could also increase the release of serotonin and dopamine, neurotransmitters associated with mood regulation and pain relief, thus further contributing to the therapeutic effects of PNS.

In addition to pain relief, our study found significant improvements in sleep quality, with 50% of patients reporting that their sleep had improved markedly, and 38% reporting moderate improvements. Sleep disturbances are common in individuals with chronic pain, including shoulder pain, and are known to exacerbate

pain and reduce overall quality of life. The improvement in sleep observed in our study is consistent with findings from other PNS studies. This suggests that by alleviating pain, PNS can help break the cycle of pain-related sleep disturbances, providing patients with more restful and restorative sleep (7).

Another key finding from our study was the high level of patient satisfaction, with 88% of patients indicating that they would recommend the system to family or friends, and the same percentage stating that they would consider an additional implant for a different nerve target if needed. These high satisfaction rates are consistent with the findings of other studies, such as that of Abd-Elsayed et al (3), which reported high satisfaction rates among patients who underwent PNS treatment for chronic pain. The long-term nature of PNS therapy likely contributes to patient satisfaction, as it provides an alternative to short-term treatments like nerve blocks and oral medications, which may require repeated interventions.

Importantly, no AEs or complications were reported in our study, suggesting that the Freedom PNS System is a safe and reliable intervention for managing chronic shoulder pain. The safety and low complication rate of PNS makes it an attractive option for patients seeking long-term pain relief without the risks associated with opioid use or repeated injections (9).

In conclusion, our study provides strong evidence for the efficacy of the Freedom PNS System in reducing pain and improving the quality of life in patients with chronic shoulder pain and spasticity. These findings are consistent with a growing body of literature supporting the use of PNS in various pain syndromes, and they highlight the advantages of PNS as a long-term, adjustable, and minimally invasive treatment for chronic shoulder pain. By integrating PNS into clinical practice, health care providers can offer patients an effective, durable alternative to traditional pain management strategies, ultimately improving patient outcomes and enhancing the quality of life for those suffering from chronic shoulder pain.

Limitations

Despite the promising results of our study, some limitations must be addressed in future research. The most notable limitation is the small sample size ($n = 8$), which reduces the generalizability of our findings. Additionally, while pain reduction was a primary outcome in our study, future research should include functional

assessments, such as measures of range of motion and strength, to better understand the impact of PNS on shoulder function. Furthermore, studies that compare PNS with other treatment modalities, such as SN blocks (SSNB) and opioid therapy, would help elucidate the relative benefits and cost-effectiveness of PNS (9). A comparison between PNS and traditional treatments like SSNB is particularly relevant, as SSNB has been a mainstay for shoulder pain management. Although SSNB provides significant short-term pain relief, it lacks the long-term effectiveness and durability that PNS offers, making PNS a superior option for chronic pain management (8,10,11).

CONCLUSIONS

This study aimed to investigate the effects of PNS at the SN for the treatment of painful spasticity. These results show that PNS at the SN using the Curonix Freedom PNS System is an effective and safe therapy for treating spasticity, resistant to conservative therapy, and should be considered for further adoption.

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