Retrospective Study

Spinal Cord Stimulation Using High Frequency Electromagnetic Coupling (HF-EMC) Technology to Power an Implanted Neurostimulator With a Separate Receiver for Treating Chronic Back and Leg Pain: A Retrospective Study

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Disclaimer: There was no external funding in the preparation of this article.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 06-04-2024
Revised article received: 07-30-2024
Accepted for publication: 09-09-2024

Free full article: www.painphysicianjournal.com

Background: Chronic low back and lower limb pain occurs in 13% of Americans, and is the leading cause of disability. Patients with this condition have a reduced quality of life, have mental health disorders, and cognitive disfunction. While back pain alone is difficult to manage, back pain with associated leg pain results in further reduced outcomes. Spinal cord stimulation (SCS) is a minimally invasive therapy that has been used for a variety of chronic pain disorders when conservative management strategies have failed. The therapy is appealing because of its ability to provide long-term relief at a reduced cost and it has low rates of serious adverse events.

Objective: The objective of this retrospective study was to examine the safety and efficacy of the Freedom® SCS System for treating patients who have chronic bilateral back and leg pain.

Study Design: This retrospective study included 32 patients who received a permanent Freedom® SCS System to treat their chronic bilateral back and leg pain due to nerve compression due to complex regional pain syndrome (CRPS) Type I and/or II. A retrospective chart review was conducted to assess baseline and follow-up Verbal Rating Scale (VRS) pain scores as well as complications.

Setting: This study was conducted at a single center in the United States.

Methods: The data were retrospectively collected from patients' medical records. Pain was assessed using the 11-point VRS scores; these scores were collected at baseline, post-trial, 6 months post-implantation, and 12 months post-implantation. Adverse events were reported descriptively and classified as serious or nonserious and either related or nonrelated to the implantation.

Results: The post-trial VRS scores for the 32 patients were reduced by 73% ($P < 0.001$). At 6 months post-implantation, the VRS scores were reduced by 71% ($P < 0.001$) for 30 patients and at 12 months by 74% ($P < 0.001$) for 19 patients. No adverse events were reported.

Limitations: Our study's retrospective design limited us to the data available in the patients' charts.

Conclusion: The Freedom SCS System is an effective and safe therapy for treating patients with chronic back and leg pain that is resistant to conservative therapy due to nerve compression and CRPS Type I and/or II. These types of patients often report aggravation of symptoms with surgery. Minimal invasive surgery should decrease the chance of extra symptoms.

Key words: Spinal cord stimulation, chronic back and leg pain, complex regional pain syndrome (CRPS), nerve compression

Pain Physician 2025: 28:E43-E47

In the United States, chronic low back pain is prevalent in 13% of adults; it is by far the leading cause of disability (1). People with chronic low back pain experience a reduced quality of life and a reduced ability to independently engage in activities of daily living (2). These patients are also at greater risk for depression and anxiety. Furthermore, they may experience reduced cognitive function (3). The economic consequence of low back pain in the United States has been estimated to be as high as $624.8 billion (4). The main contributing factors to this cost include the loss of work productivity and health care resource usage.

Current nonpharmacological treatment options include exercise, physical therapy, massage therapy, acupuncture, heat application, spinal manipulation, and yoga (5). Pharmacological options include nonsteroidal anti-inflammatory drugs, acetaminophen, skeletal muscle relaxants, selective norepinephrine reuptake inhibitors, benzodiazepines, and gabapentinoids (5,6). Opioids have been prescribed as a management strategy, but should be avoided as dependence or misuse has been reported in 24% of cases (7). When conservative management strategies are insufficient, radiofrequency ablation and surgery (e.g., spinal fusion) are additional treatment options (8,9).

Spinal cord stimulation (SCS) is a minimally invasive intervention that has been used for a variety of chronic pain disorders when conservative management has failed (10-14). SCS is appealing because it provides long-term pain relief, often at a fraction of the cost of other interventions (15). Additionally, low rates of serious adverse events have been reported, with lead migration being the most common. These adverse events can often be resolved with system reprogramming or revision surgery (16). The exact mechanism for how SCS induces analgesia remains unclear, but has been hypothesized to be based partly on Melzack and Wall's gate control theory (17,18).

While chronic low back pain alone is difficult to manage, back pain with associated leg pain can result in further poor outcomes and increased management difficulty (19). Thus, it is important to explore potential therapies. We present a retrospective analysis of patients with chronic bilateral back and leg pain who were treated with SCS using high-frequency electromagnetic coupled (HF-EMC) technology.

Methods

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

Patient Selection

This retrospective series included 32 patients who received a permanent Freedom® SCS System (Curonix LLC) to treat refractory chronic bilateral back due to nerve compression and leg pain due to complex regional pain syndrome (CRPS) Type I and/or II. Patients considered for this treatment had failed alternative options such as rhizotomies, and sacroiliac joint, epidural, and facet injections. After a successful SCS trial, determined as at least a 50% reduction in pain, patients were implanted with a permanent Freedom SCS 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 permanent Freedom SCS System. Patients with any additional implanted neurostimulation devices in addition to the Freedom SCS System were excluded.

Device Description

The Freedom SCS system (Curonix, LLC, Pompano Beach, FL) includes an implanted electrode array with eight contacts, a separate implanted receiver, as well as an external transmitter assembly and wearable accessory (Fig. 1). The external transmitter uses high-frequency electromagnetic coupling (HF-EMC) technology to wirelessly transfer data and stimulation energy to the two-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

Written, informed consent was obtained from all patients. Patients were taken to the operating room and positioned prone on the table. The implant site was prepped 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 a number 11 scalpel blade. A 13G Tuohy needle was passed through the incision and advanced percutaneously into the epidural space while injecting small amounts of local anesthetic. An 8-contact electrode array was inserted through the cannula and advanced in the epidural space covering T7–T9. Using the same technique, a second electrode array was placed covering T9–T11 (Fig. 2).

A receiver pocket was created using blunt dissection through a second incision. The steering stylets were removed from the previously implanted electrode arrays, and separate receivers were connected to the electrode arrays. The electrode arrays and receivers were fixed at the primary implant site using a percutaneous anchor injected through the fascia. The electrode arrays and receivers were tunneled beneath the skin from the first incision to the second incision receiver pocket. Knots were tied to connect the separate receivers and electrode arrays permanently. The receivers were coiled into small diameter coils and 2 nonabsorbable sutures were used to permanently form the receiver coils. The receiver coil edges were tucked underneath the coils to avoid protruding edges. Using a nonabsorbable suture, the receiver coils were sutured to the fascia in 2 locations, ensuring they were flat in the pocket. The receiver pocket was closed with deep and superficial absorbable sutures.

Programming Protocol

Systems were programmed subthreshold with a frequency of 1,499 Hz at variable intensities (mA) between T9 and T10. The transmitter assembly was worn in a wearable on the lower back (Fig. 1).

Demographics

Data were collected for 32 patients. All patients had been diagnosed with chronic bilateral back pain due to nerve compression and leg pain due to CRPS. Mean pain scores at baseline were recorded at 7.5 ± 1.8 with the Verbal Rating Scale (VRS). The mean age was 69 ± 15.9 years; 19 patients (59%) were men, and 13 (41%) were women.

Data Analysis

Our 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 reported the VRS at pre- and post-trial. A long-term follow-up was collected to assess the current percentage of pain relief.

Adverse events were reported descriptively and classified as serious or nonserious and either related or nonrelated to the implantation.

The data were collected from medical records using case report forms and entered into an Excel version 16.87 (Microsoft Corporation) spreadsheet. Statistical analysis was performed using descriptive statistics and paired t tests to compare pre- and post-procedure pain scores. A P value of ≤ 0.05 was considered significant.

Results

Primary Outcome Responder Rate

At the end of the trial period, all 32 (100%) patients reported more than 50% pain relief, with mean pain scores reducing from 7.5 ± 1.8 to 2.0 ± 0.6 (73%; $P < 0.001$) (Fig. 3).

Fig 1. *Freedom SCS System.*

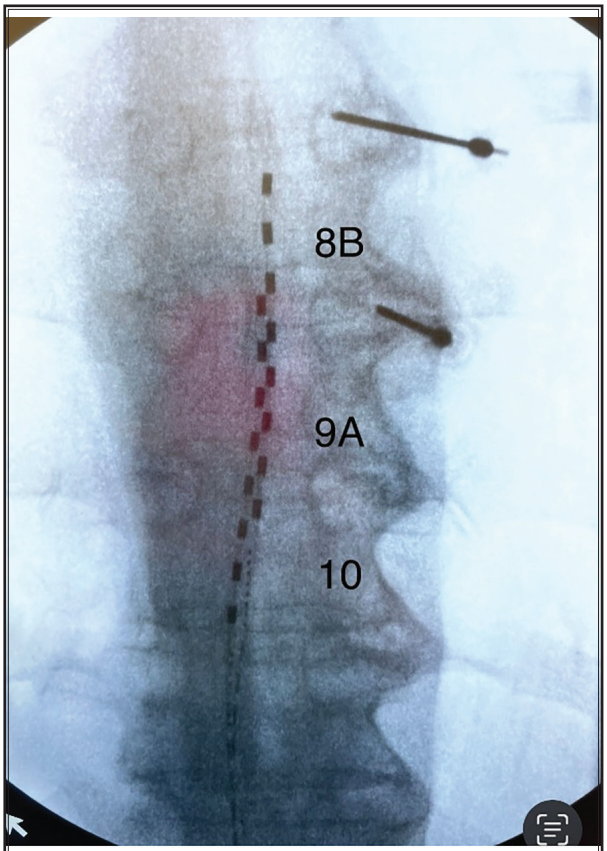

Fig 2. *X-ray of device positioning in the epidural space.*

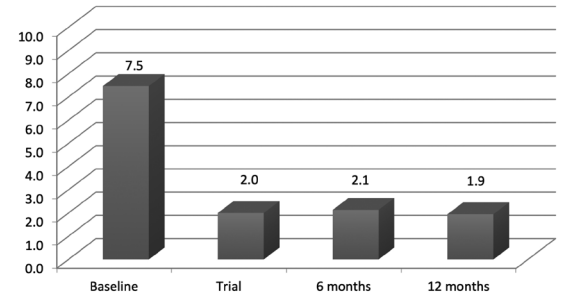

Fig 3. *Verbal Rating Scale pain scores.*

Long Term Follow-up

Thirty patients had a permanent implant for at least 6 months, with the remaining 2 still being followed. The average VRS score decreased to 2.1 ± 1.2 (71%; $P < 0.001$). Nineteen patients reached the 12-month follow-up post-permanent implant and reported a mean VRS of 1.9 ± 1.3 (74%; $P < 0.001$). Study patients also report an improved quality of life and reduced pain. No complications due to the procedure or device were reported.

Discussion

While there have not been any studies that specifically examined chronic back pain due to nerve compression and leg pain caused by CRPS, our results of significant pain improvements align with what has been previously reported in the use of SCS for treating lumbar radiculopathy or CRPS. Mehta, et al (20) used SCS to treat 20 patients with lumbar radiculopathy. They reported a 63.1% improvement in pain scores at one month, 40.9% improvement at 3 months, and 48.9% improvement at 12 months. Atallah, et al (21) also treated lumbar radiculopathy in a case report where the patient experienced 100% pain relief. Risson, et al (22) treated 33 patients with CRPS, reporting a 70% reduction in pain postoperatively. In another study examining the use of SCS for CRPS, Kumar, et al (23) treated 25 patients and reported a 42.9% pain improvement at 3 months. At their long-term follow-up, an average of 88 months, the average pain improvement was 33.3% (23).

The externally powered SCS system used in our study has also been reported to be beneficial in previous studies. Bolash, et al (24) successfully treated 38 patients with HF-EMC SCS for failed back surgery syndrome (24). Ahmadi, et al (25) reported pain reductions in their patients with either CRPS Type 2 (n = 1), painful diabetic polyneuropathy (n = 1), or brachialgia (n = 1) (25). In 9 patients treated for failed back surgery syndrome, 7 experienced an improvement in pain (25).

The externally powered design is beneficial due to its minimal invasiveness. This avoids complications and risks associated with surgical implantation of an implantable battery especially since patients with CRPS have often been reported to have aggravated post-surgery symptoms. Minimally invasive surgery should decrease these extra symptoms (26).

Furthermore, this means that no pulse generator replacement procedures are needed and the risk of revision surgery may be reduced. With pulse generators, the average lifespan before replacement surgery required is between 8 and 9 years (27). For patients with pulse generators, the rate of revision surgery has been reported to be 21.5% (28). In addition to the externally powered design, the Freedom SCS's high frequency (1499 Hz) output may also be advantageous. Previous studies have found some evidence supporting that the high frequency waveform results in enhanced outcomes and reduced adverse events (29,30).

Limitations and Future Directions

Various limitations associated with our study must be recognized, such as its retrospective nature contributing to potential bias and the limited results data. Still, our study provides good data for future trials/research related to SCS with an externally powered system for treating back and knee pain.

Conclusion

SCS using the Curonix Freedom SCS System is an effective and safe therapy for treating patients with chronic back pain and leg pain due to nerve compression and CRPS that is resistant to conservative therapy.

Acknowledgment

We would like to acknowledge and thank the Curonix Clinical team for their participation support in writing, data analysis and technical editing of the manuscript.

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