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Spinal Cord Stimulator with High-Frequency Electromagnetic Coupling-Powered Implanted Electrode Array and Receiver to Treat Intractable Chronic Back and Leg Pain of Different Etiologies

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Background: Recently, externally powered spinal cord stimulation has been introduced for clinical use and has been shown to have good long-term outcomes in treating chronic back and leg pain (CBLP).

Case Report: Twelve patients with CBLP of different etiologies were included in this case series. All patients underwent percutaneous implantation of a permanent spinal cord stimulator (SCS) device. All patients were programmed with a pulse rate of 1,499 Hz with a 32 μs wavelength and followed for up to 12 months.

Conclusion: Externally powered spinal cord simulation is a good option for debilitating back and/or leg pain.

Key words: Chronic back and leg pain, failed back surgery syndrome, high frequency, phantom limb pain, spinal cord stimulation, spinal deformity, wireless

BACKGROUND

Intractable chronic back and leg pain (CLBP) is common and not always easy to treat. CLBP is a debilitating condition that highly impacts quality of life (1,2). Physiotherapy and nonsteroidal anti-inflammatory drugs (NSAIDs) are the first treatments of choice for chronic pain patients, followed by opioids, but opioids can result in dependence, addiction, abuse, overdose, opioid-induced hyperalgesia, constipation, respiratory or immune dysfunction, hormone imbalance, and death (3). Nerve blocks can be effective, but may only provide short-term relief, and may have limited predictive value when considering other irreversible therapies such as radiofrequency ablations.

Spinal cord stimulation (SCS) is a clinically well-established and evidence-based therapy for CBLP (2). Currently, almost all SCS systems depend on an implantable pulse generator (IPG), an internal power source to stimulate the spinal cord via one or more leads placed in the epidural space, but these systems have complications related to the size of the system, extension leads, and IPG pocket that frequently require reinterventions (e.g., pocket pain, battery replacement, lead migration extension disconnection, etc.), reducing the quality of life of the affected patients (4,5). Recently, externally powered neurostimulation (6) has been introduced into clinical use and has been shown to have good long-term outcomes in treating CBLP.

METHODS

Device Description

The Freedom SCS System (Stimwave LLC, Pompano Beach, FL) (Fig. 1) treats chronic intractable pain by

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targeting the central nervous system. The technology uses a wireless energy transfer with high-frequency electromagnetic coupling (HF-EMC) from the wearable antenna assembly (WAA) to the implanted electrode array and separate receiver. Each electrode array contains 4 or 8 contacts (1.3 mm in diameter with 4-mm spacing) with an embedded MicroStimTM chip, circuitry, and a receiver. The WAA is comprised of a flexible, fabric antenna and a rechargeable transmitter worn as needed. The neurostimulator device relieves pain by sending electrical stimulation to specific nerve locations where the pain is present and then blocks those pain signals from reaching the brain.

Design

Twelve patients (4 women, 8 men) from one center, with a mean age of 62 years, were included in this case series. The patients presented with failed back surgery syndrome (FBSS) (9 patients; 3 complicated with spinal stenosis), scoliosis and spinal stenosis (one patient), phantom limb pain due to ongoing infections after knee replacement (one patient), and syringomyelia (one patient). All patients complained of chronic back pain and 11 of the 12 patients reported pain spreading to the legs. All patients had undergone at least one alternative treatment option such as physical therapy, analgesic injections, cryoneuroablation, NSAIDS, or opiates.

Implant Techniques

All patients underwent percutaneous implantation of a permanent epidural SCS device (electrode array and separate receiver). Patients were positioned prone under intravenous anesthesia. Using a paramedian approach a Tuohy needle was used to enter the interlaminar space at T12-L1 through a first incision leading to the epidural space under fluoroscopic guidance. Once the electrode array was placed with the tip at T8, the steering stylet was replaced with a separate receiver, which was connected to the electrode array (Fig. 2). The neurostimulator was fixed using a percutaneous anchor injected through the fascia at the primary implant site. A receiver pocket was created approximately 2 centimeters long using a second incision, 10 cm distal from the stimulator entry point, and a needle was used to tunnel the neurostimulator the full length of the track to this secondary subcutaneous receiver pocket. A knot was tied to permanently connect the separate receiver and electrode array. The distal portion of the neurostimulator, was coiled, sutured to itself while eliminating any sharp ends, and then the coil sutured to the fascia within the pocket to prevent migration. The pocket was then closed with subcutaneous, and subcuticular sutures.

Programming Protocol

The programming protocol included a frequency of 1,499 kHz with a pulse width of 30 μs at the intensity (mA) preferred by the individual patients. After the initial postoperative visit, patients were assessed at 6 or 12 months for pain with the Visual Analog Scale (VAS), medication use, activity level, improved sleep, and global impression of change. The patients wear the external antenna on their back and the small battery pack on their hip (Fig. 3).

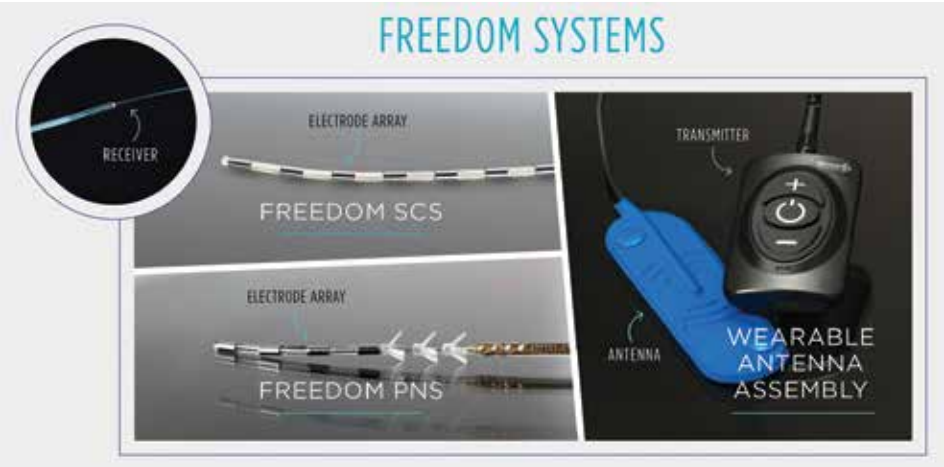

Fig. 1. Freedom Systems.

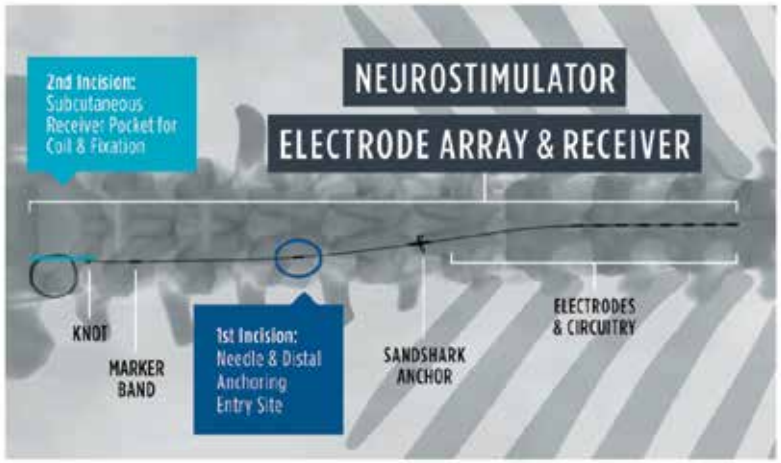

Fig. 2. Freedom Neurostimulator Electrode Array & Receiver

Data Analysis

Data were recorded at baseline and at 6- or 12-months' follow-up. Results for follow-up visits at 6 or 12 months were pooled to present current means. Pain reduction was measured using VAS data. These were reported as raw scores and mean values. The Oswestry Disability Index (ODI), the European Quality of Life 5 Dimensions questionnaire (EQ-5D), medication use, the Patient Global Impression of Change (PGIC), quality of sleep, and adverse events were recorded.

The ODI is an index derived from the Oswestry Low Back Pain Questionnaire. The self-completed questionnaire contains 10 topics concerning intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, and ability to travel. The ODI has the following scoring: 0%-20% is minimal disability, 21%-40% moderate disability, 41%-60% severe disability, 61%-80% is crippling pain, and patients scoring 81%-100% are either bed-bound or have an exaggeration of their symptoms.

EQ-5D evaluates the generic quality of life. The EQ-5D descriptive system includes one question for each of the 5 dimensions that include mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

The PGIC consists of 7 points: 1 = "No change (or condition has got worse)", 2 = "Almost the same, hardly any change at all", 3 = "A little better, but no noticeable change", 4 = "Somewhat better, but the change has not made any real difference", 5 = "Moderately better, and a slight but noticeable change", 6 = "Better, and a definite improvement that has made a real and worthwhile difference", 7 = "A great deal better, and a considerable improvement that has made all the difference".

Fig. 3. Wearable antenna assembly (WAA) as worn by the patient.

Quality of sleep was assessed in terms of hours of sleep per night.

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

RESULTS

Twelve patients were implanted and after an initial postoperative visit, patients were seen again at 6- or

12-months post implant. Twelve patients underwent evaluation at their 6-month visit, while 7 patients were assessed at their 12-month visit (follow-up for 5 patients is ongoing).

Safety

There was only one adverse event reported during the observation period; a device had to be replaced due to a fractured stimulator resulting from a confined lamina. No other complications were reported.

Efficacy

Mean overall pain scores (as measured by the VAS) were reduced at their last follow-up visit (either 6 or 12 months) to 26 mm from a baseline 89 mm, corresponding to a reduction of 71% (see Table 1).

The ODI for each patient was assessed at baseline and at the last follow-up visit. At baseline, the ODI mean score was 50 (min = 40, max = 59) and at the last follow-up, the mean value had decreased to 22 (min = 18, max = 40) indicating a clear improvement in the functional disability of the 12 patients.

Table 1. Pain VAS assessments during the available follow-ups for each patient and mean values

Patient	Baseline	Trial	Current[1]
1	7.5	4	4
2	10	4	1,5
3	8	3	3
4	9	0	1
5	10	2	2
6	9	3	3
7	9	3	2.5
8	8.5	3.5	3.5
9	9.5	5	4
10	9.5	3	2.5
11	10	2	1
12	7.5	4	3.5
Mean	8.94	2.95	2.62

[1]Current assessment after 6 or 12 months' follow-up.
Abbreviation: VAS, Visual Analog Scale

The PGIC (measures the change perceived by the patient compared to baseline) was assessed at the patient's last follow-up visit and was 7 ("a great deal better, and a considerable improvement that has made all the difference") for 9 patients and 6 ("better, and a definite improvement that has made a real and worthwhile difference") for 3 patients, indicating an excellent improvement for the individual patient (7).

The EQ-5D was assessed at baseline and at their last follow-up visit. The mean of the index score improved from 0.35 to 0.79 and the mean health value improved from 30.41 to 92.41. The minimal change of the index score was 0.34 and the maximal change was 0.63. The minimal change of the health value was 50 and the maximal change was 80.

Sleep improved significantly with hours slept per night increasing from 3.7 to 6.5.

The medication intake was assessed at baseline and at the last follow-up undergone by the patient. Two patients were not using medication pre-implant since they had tried it without success. All patients were able to reduce their medication significantly and 6 out of 7 patients who were using opioids at baseline were able to stop their opioid medication (Table 2).

Discussion

Conventional IPG-based systems are associated with several types of complications related to the implanted components. Such complications include lead migration/fracture, infections, failed stimulation, and IPG-related issues such as pocket pain. There have been recent advances with nanotechnology and externally powered approaches to SCS. An externally powered device reduces the complexity of the system as well as the complexity of the surgical procedure, which does not involve creating a large pocket for the pulse generator.

CONCLUSION

Externally powered spinal cord simulation is a good option for a mostly elderly population suffering from debilitating back and/or leg pain. The procedure is more straightforward for the physician and less cumbersome for patients as compared to conventionally wired systems.

Table 2. Medication use by each patient at baseline and last follow-up

Patient	Baseline	Last Follow-up[1]
1	Tilidine 200 mg/16 1 - 1/2 - 1/4 - 0	Tilidine 200 mg/16 3/4 -1/2 - 1/4
	Pregabalin 4 x 50 mg	Same
	Novalgin 3 x 40 drops	3 x 30 drops
	Gabapentin 3 x 600 mg	Stopped
	Citalopram 1 x 12.5 mg	Same
2	Hydrocodone 10/325 mg x3	Stopped
3	Drugs had no effect, no medication	No medication
4	Oxycodone/naloxone 20/10 mg x3	Stopped
	Cetirizine 10 mg	Stopped
	Pregabalin 150 mg x3	Same
5	Hydromorphone 24 mg 1/2 -0-0-0	Stopped
	Hydromorphone 8 mg x3	Stopped
	Baclofen 25 mg x2	Same
	Cetirizin 10 mg x1	Same
	Pramipexole 0.170 mg x4	Same
	Gabapentin 300 mg x9	300 mg x2
	Diazepam 10 mg	Same
6	No medication	No medication
7	Buprenorphine 10 µg x1	Stopped
8	Tapentadol 100 mg x2	Tapentadol 50 mg x2
	Amitriptyline 25 mg x1	Amitriptyline 10 mg x1
	Ibuprofen 600 mg x3	Ibuprofen 400 mg x2
9	Gabapentin 400 mg x3	Gabapentin 400 mg x2
10	Pregablin 300 mg x2	Stopped
	Oxycodone 40 mg x2	Stopped
11	Metamizole 500 mg x8	Stopped
	Oxycodone/Naloxone 10/5 x2	Stopped
12	Dronabinol 5 mg x3	Stopped
	Fentanyl	Stopped

1Last follow-up undergone by each patient

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