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Brachial Plexus Nerve Stimulation with a High Frequency Electromagnetic Coupled (HF-EMC) Powered Implanted Receiver to Treat Complex Regional Pain Syndrome: A Case Series

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Background: Complex Regional Pain Syndrome (CRPS) at the brachial plexus occurs after damage in the neck or upper anterior shoulder, causing pain, decreased sensation, and decreased range of motion in the shoulder and arm, as well as significantly impairing the quality of life.

Case Report: Seven patients with CRPS were implanted with an externally powered peripheral nerve stimulation system at the brachial plexus and followed up at 3, 6 and 12 months. Pain, visual analog scale (VAS), Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), The European Quality of Life 5 Dimensions questionnaire (EQ-5D), and medication intake were analyzed. All assessed parameters improved from baseline to the last follow-up: VAS for pain (8.07 to 1.37 at 12 months [n = 4]-), EQ-5D (55.85 to 75.57), median PGIC was 7/7 (current scores, 6 months n = 3, 12 months n = 4) ; medication intake also improved.

Conclusion: Percutaneous placement of an externally powered neurostimulation device at the brachial plexus is a minimally invasive method of pain control.

Key words: Externally powered, high frequency, peripheral nerve stimulation, brachial plexus neuropathy, complex regional pain syndrome

BACKGROUND

The brachial plexus is the ventral rami of C5 to T1. The plexus runs through the anterior neck, beneath the clavicle, to the axilla and down the arm to the hand. Complex Regional Pain Syndrome (CRPS) at the brachial plexus occurs after damage in the neck or upper anterior shoulder where the nerves are closely bundled together, causing pain, decreased sensation, and decreased range of motion in the shoulder and arm, with limited range of motion of the shoulder, arm, and hand (1) as well as significantly impairing the quality of life of patients (2). CRPS can be diagnosed using the following criteria (3-4):

- Presence of an initiating noxious event or cause of immobilization
- Continuing pain, allodynia or hyperalgesia in which the pain is disproportionate to an inciting event
- Evidence at some time of edema, changes in skin blood flow or abnormal sudomotor activity in the region of pain
- Exclusion of the existence of other conditions that would otherwise account for the degree of pain and dysfunction.

Physiotherapy and nonsteroidal anti-inflammatory

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drugs (NSAIDs) are the first treatments of choice for patients with chronic pain. The next step in the treatment ladder is opioids, but these can result in dependence, addiction, abuse, overdose, opioid-induced hyperalgesia, constipation, respiratory or immune dysfunction, hormone imbalance, and death (5). Nerve blocks are effective, but only short-term, and have no predicting value when considering other irreversible therapies such as radiofrequency ablation (6).

Peripheral nerve stimulation (PNS), though considered a more invasive therapy modality, has been demonstrated to be an effective alternative for the management of neuropathic peripheral chronic pain (7,8) but a variety of difficulties have limited the widespread use of PNS, including cosmetic concerns and complications. New externally powered neuromodulation technology does not include implantable pulse generators (IPGs) but instead consists of a 4- or 8-contact electrode array with embedded electronics, a miniature receiver, and a small, externally wearable rechargeable transmitter. Thus, the potential complications related to the implant of an IPG, which can be up to 40%, are avoided.

METHODS

Device Description

The Freedom PNS System (Stimwave Technologies, Pompano Beach, FL) uses high frequency electromagnetic coupling technology to power the implanted receiver (Fig. 1). Each electrode array has 4 or 8 contacts (1.3 mm in diameter with 4 mm spacing) with embedded electronics and a receiver. A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in the clothing supplies the energy to power the implanted device through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Design

Seven patients (3 women and 4 men), from 4 centers in the US, with a mean age of 65 years, were included in this retrospective case series after obtaining informed consent. The patients presented with shoulder pain radiating to the upper arm and 6 of them experienced pain down to the hand. They were diagnosed with CRPS using the criteria for diagnosis. All patients had undergone physical therapy, analgesic injections, cryoneuroablation, NSAIDS, opioids and one patient had undergone cervical SCS with no success.

The programming protocol included a frequency of 1.499 Hz with a pulse width of 30 μs at the intensity (mA) preferred by the individual patients. The patients were assessed at 1, 3, 6, and 12 months for pain with the VAS, medication use, activity level, improved sleep and global impression of change using the Patient Global Impression of Change scale (PGIC).

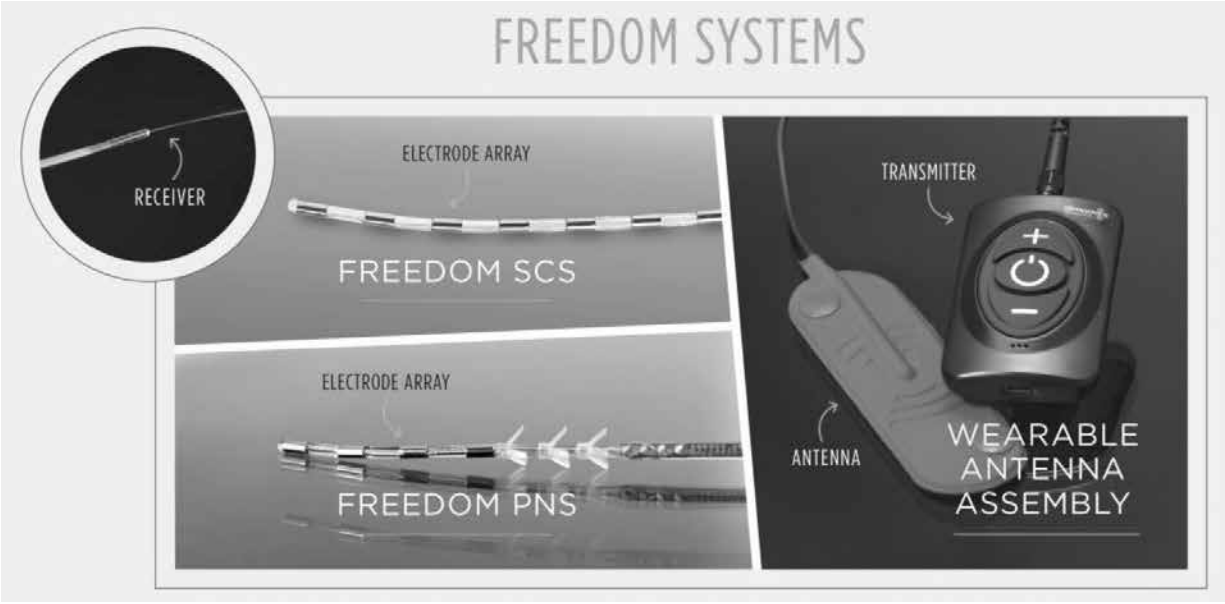

Fig 1. Freedom PNS system.

Implant Techniques

Trial implant: A small incision needle entry point was made at the anterolateral shoulder and a 13-gauge introducer was percutaneously advanced lateral to medial to cross over the midportion of the clavicle. An 8-contact, trial stimulator was placed through the introducer. The steering stylet was removed, and the receiver inserted into the inner lumen of the electrode array. The trial stimulator was then secured with Mastisol® (Ferndale Pharma Group, Ferndale, MI) and Steri Strips™ (3M, Maplewood, MN) and completely covered under a sterile Tegaderm™ (3M, Maplewood, MN).

All patients reported significant pain reduction during the trial, with mean pain scores reducing from 8.1/10 to 1.5/10. Given the excellent results of the trial, the patients agreed to move forward with a permanent implant.

Permanent implant: The patients were positioned supine and the area overlying the brachial plexus was identified under fluoroscopy and ultrasound. A small incision needle entry point was made at the anterolateral shoulder and the 13-gauge introducer was percutaneously advanced lateral to medial to cross over the midportion of the clavicle. The 4-contact electrode array with tines was threaded through the introducer and positioned at the target location; the needle and steering stylet were removed, and the receiver inserted into the inner lumen of the electrode array (Fig. 2). The neurostimulator was anchored in the incision. A receiver pocket was made in the upper arm, and the device was tunneled from the insertion site to the receiver pocket. A knot was made at the end of the neurostimulator to prevent dislodgment of the receiver. The tail of the system was secured into a looped coil with 2-0 silk sutures and then secured to the fascia in the receiver pocket using 2-0 silk sutures. The patients wore the transmitter and antenna over the upper arm and received stimulation at 1499 Hz and 30 μs with amplitudes customized to the needs of each patient. The patients were then followed for 12 months postimplant.

Data Analysis

Data were recorded at baseline and throughout the follow-up. VAS data were reported as raw scores and mean value. The European Quality of Life 5 Dimensions questionnaire (EQ-5D), medication use, the PGIC, and adverse events were recorded.

EQ-5D evaluates 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.

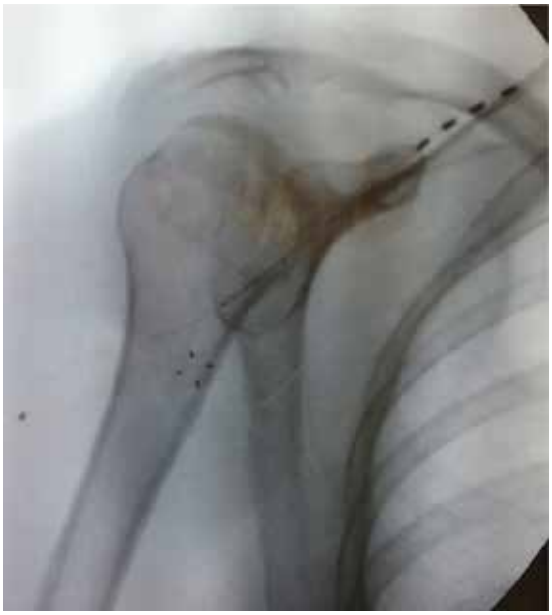

Fig 2. Image showing the four-contact neurostimulator at the brachial plexus.

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", and 7 = "A great deal better, and a considerable improvement that has made all the difference."

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

RESULTS

Up to the time in which this manuscript was written, all 7 patients had reached the 6-month follow-up and 4 patients had undergone the 12-month follow-up.

Safety

There was only one serious adverse event reported during the observation period. One patient developed an infection at the implant site 3 months after permanent implant. The device was explanted, the

infection treated with antibiotics, and a new device reimplanted.

Efficacy

The VAS for pain was 8.07 at baseline and improved to 1.07 at 1 month (n = 7) and 1.37 at 12 months (n = 4) (Table 1).

The PGIC which measures the change perceived by the patient compared to baseline, was assessed at the last follow-up (current scores, 6 months n = 3, 12 months n = 4) undergone by the patient and was 7 ("a great deal better, and a considerable improvement that has made all the difference") for 6 patients and 6 ("better, and a definite improvement that has made a real and worthwhile difference") for one patient, indicating an excellent improvement for the individual patients (10).

The EQ-5D was assessed at baseline and at the last follow-up undergone by the patient. The mean of the index score improved from 0.42 to 0.75 (current scores, 6months n = 3, 12 months n = 4) and the mean health value improved from 55.85 to 75.57. The minimal change of the index score was 0.09 and the maximal change was 0.7. The minimal change of the health value was 4 and the maximal change was 35.

Medication intake was assessed at baseline and at the last follow-up undergone by the patient. One patient was not using medication at implant since he had tried it without success; 6 patients reduced the overall intake of medication, and 4 out of 6 patients stopped the use of opioids altogether, while the other 2 patients continued with the same baseline medication regimen (Table 2).

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

Patient	Baseline	Trial	1 mo	3 mos	6 mos	12 mos[1]	Current[2]
1	10	1,00	0	0	0	–	–
2	7	0.50	0.50	0.50	0.50	2.00	1.5
3	6	0.50	0	0	0	1.00	--
4	8	2.25	2.50	2.50	2.50	2.50	2.5
5	8	0	1.00	1.00	1.50	–	–
6	8	2.00	0	0	0	0	0
7	9.50	3.50	3.50	3.50	3.00	–	–
Mean	8.07	1.39	1.07	1.07	1.07	1.37	1.00

[1] The cells with – mean that the patient did not reach this follow-up; [2] Current assessment after the 12 months follow-up. Abbreviation: mo/mos, months

DISCUSSION

Recent advances in neurostimulation include subthreshold stimulation, externally powered stimulation, and closed loop stimulation. While efficacy has been shown for spinal cord stimulation (SCS), little is known of the effects of these novel therapies for PNS. PNS has traditionally been performed with devices designed for SCS, resulting in a high complication rate (battery pocket infections, lead fractures, lead migration, intolerance to shock sensations) due to the different anatomical structures involved in PNS (8,10). With the HF-EMC stimulation technology (11), these complication rates are reduced or even eliminated, since percutaneous placement of a wireless stimulation device adjacent to affected peripheral nerve(s) is a minimally invasive and a reversible method of pain control in patients with neuropathic pain refractory to conventional medical management. This enables a more adequate study of the parameters and effects of PNS. In this case series, the technology used for PNS using 1499 Hz frequency was found to effectively control neuropathic pain due to CRPS at subthreshold amplitude levels without causing paresthesia.

Table 2. Medication use by each patient at baselines and last follow-up undergone by the patient.

Patient	Baseline	Last follow-up [1]
1	Meloxicam 15 mg x 2	Meloxicam 15 mg as needed
	Tizanidine HCL 4 mg as needed	
	Hydrocodone-acetaminophen 7.5 mg-325 mg x 1	
2	Hydrocodone-acetaminophen 10 mg-325 mg x 3	Ibuprofen 800 mg as needed
	Ibuprofen 800 mg x 2	
3	NO	NO
4	Aspirin 325 mg x 1	Aspirin 325 mg x 1
	Ibuprofen 200 mg x 6	Ibuprofen 200 mg x 6
	Tramadol 50 mg x 6	Tramadol 50 mg x 6
	Diclofenac Sodium 50 mg x 3	Diclofenac Sodium 50 mg x 3
5	Hydrocodone-acetaminophen 10 mg-325 mg x 4	Ibuprofen PRN
	Ibuprofen 800 mg x 2	
6	Oxycodone-acetaminophen 7.5 mg/325 mg x 4	No
7	Oxycodone 10 mg x 2	Oxycodone 10 mg x 2
	Gabapentin 600 mg x 3	Gabapentin 600 mg x 3

[1] Last follow-up undergone by each patient

CONCLUSION

Percutaneous placement of an externally powered neurostimulation device over the brachial plexus is a minimally invasive and reversible method of pain control in patients with CRPS refractory to conventional medical management. It enables neurostimulation in these cases, in which it would have been virtually impossible to implant a conventional neuromodulation system with an IPG. PNS using a subthreshold frequency was found to effectively control brachial plexus neuropathic pain at subthreshold amplitude levels.

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