Original Research Article

Treatment of FBSS Low Back Pain with a Novel Percutaneous DRG Wireless Stimulator: Pilot and Feasibility Study

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Disclosure: Drs. Weiner and Yeung along with Ms. Perryman and Mr. Speck designed the study. All physicians treated patients at the study site. Dr. Montes recruited patients and collected the data. An independent medical writer, Claudia Frumento, PhD, prepared the manuscript. All authors reviewed the manuscript critically and approved the final version.

Abstract

Objectives. Test a miniaturized neurostimulator transforaminally placed at the dorsal root ganglion (DRG) and evaluate the device’s safety and efficacy in treating failed back surgery syndrome (FBSS) low back pain.

Design. Pilot, two-phase study.

Results. Overall pain reduction was 59.9%, with only one device placed at one location, covering only a portion of the painful areas in the majority of the subjects. In Phase 1, the non-anchored stimulators migrated a mean of 8.80 mm and in Phase 2 a mean of 1.83 mm. Stimulator migration did not correlate with changes in pain relief. Mean time-to-implant duration was 10 minutes and no adverse events were reported during implant, follow-up period, or after explant.

Conclusions. The pain reduction results indicate that the Freedom-4 spinal cord stimulation (SCS) Wireless System is a viable treatment of low back pain through stimulation of the DRG, and better overall pain reduction may be achieved by implanting multiple devices. With short percutaneous implant times and excellent safety profile, this new system may offer health cost savings.

Key Words. Wireless SCS; Low Back Pain; Transforaminal; DRG Stimulation; Miniaturized Neurostimulator; Cost Effectiveness

Introduction

Chronic low back pain due to failed back surgery syndrome (FBSS) is a debilitating state that negatively
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impacts the quality of life of affected patients and generates an increasing social burden with high treatment costs and many lost working days. Prevalence and incidence of FBSS are approximately the same as for rheumatoid arthritis—prevalence 5800 per 100,000 inhabitants and incidence 10 per 100,000 inhabitants [1].

Treatment options include physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDs), opioids, repeated back surgery, and minimally invasive techniques such as radiofrequency (RF) ablation, neural blocks, and spinal cord stimulation (SCS). Despite these many treatment options, low back pain still poses an unmet medical need, since only 60% of patients treated with SCS (which is often used as last resource) report over a 50% reduction of their pain [2]. Although, more recent studies using newer stimulation paradigms and waveforms have reported 79% of patients with > 50% reduction in pain at 12 month follow-up [3]. A new approach to low back pain treatment through stimulation of DRG has been previously explored with epidural device placements [4,5].

The DRG is located within the spinal foramen in the epidural space and contains the cell bodies of the primary sensory neurons. The primary sensory neurons transduce the pain signals from the peripheral nerves to the central nervous system and are affected by chronic pain, exhibiting multiple pathophysiological changes [6]. These changes indicate that the DRG could be a promising neurostimulation target and in fact, the stimulation of the DRG has already been tested in studies with positive results. In 32 patients treated with DRG stimulation more than 50% of the patients experienced more than 50% pain relief in the back, leg, and feet during a 6-month follow-up period [7]. Another study showed more than 50% pain relief in 50% of the patients with back pain, 69% relief in one patient with discogenic back pain, and 80% pain relief in one patient with post herpetic neuralgia [8].

Since the implant technique of traditional SCS systems for DRG stimulation is difficult and eventually may result in motor stimulation, new technologies are required to explore and take full advantage of this stimulation target.

The objective of this feasibility study was to test a wireless miniaturized stimulator, which enables faster placement of the device at the DRG through a transforaminal approach similar to a DRG nerve block procedure for the treatment of FBSS pain.

Study Design and Objectives

This was an exploratory, single center, prospective, two-phase study to assess the feasibility, performance, and safety of the Stimwave spinal nerve stimulation system (SNS) and implant procedure. This was a clinician research study in Mexico. At the time of the study, the device was not FDA cleared for commercial use. The first phase of the study consisted of the temporary implant (45 days) of the stimulator without anchoring and the second phase of the study consisted of the temporary implant (45 days) of the device and fixation of the device with a percutaneously injected wing anchor. In both Phases 1 and 2 the devices were explanted after 45 days of treatment.

The objective of this study was to evaluate device migration, efficacy of stimulation parameters, and over all pain relief as reported by the subjects treated with the Stimwave SNS system for low back and/or leg pain.

Methods

Subject Selection

Subjects were recruited from the site’s patient pool and were included in the study once they had signed the informed consent form. The study was conducted in accordance to the Declaration of Helsinki and reviewed by the hospital’s regional Institutional Review Board. Subjects were not charged for the procedure or device costs, and they were not compensated for participation in the study.

To be enrolled in the study, subjects had to speak English or Spanish, be at least 18 years old, suffer of chronic intractable neuropathic pain of the trunk and/or lower limbs due to FBSS, have a back pain visual analog scale (VAS) of more than 5, pass a psychological evaluation, and have the cognitive ability to use the external transmitter. Exclusion criteria were visceral pain, hyperalgesia or allodynia of the lower back, allergies to system components, active cancer treatment, drug dependence, pregnancy, and inability to comply with the study requirements.

In both phases of the study the treatment duration was 45 days.

Devices Used

The Stimwave Technologies Incorporated (Stimwave) Freedom SCS System was used for neural stimulation. The device utilizes pulsed electrical current to create an electrical energy field that acts on nerves to inhibit the transmission of pain signals to the brain. Traditional neural stimulation systems use a fully implanted battery that is hardwired under the skin to the electrodes that provide therapy. In comparison, the Freedom SCS System uses an electrode with built in receiver that communicates wirelessly through the skin with a patient worn transmitter and battery. The System is comprised of an implantable stimulator (Freedom Stimulator) and an externally worn transmitter [Wearable Antenna Assembly (WAA)] to power the device. The WAA provides the power and stimulation parameters using a proprietary pulse-amplitude modulation and pulse width modulation scheme.

The Freedom Stimulator is a small, cylindrical (45-cm length and 1.35-mm diameter) sealed device without a connector that includes an embedded receiver within
Figure 1 Freedom Stimulator showing the receiver, the antenna, and the electrode configuration. The proximal metal band is a fiducial marker, and is not an active electrode.

Figure 2 Once the WAA device is turned on and the back of the WAA placed near the Freedom Stimulator at a distance of less than 6.0 cm, the receiver in the stimulator processes the wireless signal received from the WAA and generates the current to be delivered via the electrodes.

A wing anchor was used to fixate the devices used in Phase 2 of the study. The anchor was provided with a dispensing tool and plunger. Once the device is in the desired location, the dispensing tool and anchor are placed over the device and puncture the tissue. The anchor was delivered percutaneously over the top of the device so that when it was deployed it cinched tightly over the device and collapsed lengthwise creating a wing shape (Figure 3).

Implant Technique

The stimulator was placed targeting only one dermatome level and one side of the body and not covering secondary pain areas or bilateral pain. The stimulator was implanted unilaterally at a single level in the axilla of the targeted foramen (L1 to L5) containing the traversing and exiting nerves (Figures 4 and 5). The foramen level that was chosen for each patient was the best estimate of the nerve root signature if the patient’s main pain component was radicular down the leg. L2 was cannulated in patients with predominately low back pain. A 14-gauge RX-2 Coudé® Epidural Needle (Epimed International) was used with the regular and obturator stylet (blunt tip extending beyond needle tip).

The needle entry point is 8 to 10 cm lateral to the midline at the inferior edge of the disc space immediately below the targeted foramen. Needle placement utilizing anterior-posterior (AP), lateral, and oblique fluoroscopic imaging with the patient lightly sedated allowed electrode placement aimed at the superior, posterior open side of the foramen. The blunt obturator stylet is important to this technique to avoid vascular puncture of any radiculomedullary arteries. Stimulation settings were set for a pulse width of 500 microseconds with a frequency of 100 Hz to target sensory nerve fibers. The needle was retracted after functional verification of the system and the subject had reported satisfactory paresthesia.
During Phase 1 of the study, the stimulators were not anchored, whereas during the Phase 2 of the study, the percutaneous wing anchor was deployed after the needle was retracted. The anchor was provided with a dispensing tool, which allows for the anchor to be "deployed" percutaneously. After the stimulator was in place, the inner cannula of the dispensing tool was threaded over the stimulator. The dispensing tool’s tip, and anchor, puncture the tissue around the stimulator and is inserted to the desired deployment depth. A lateral image fluoroscope image was to confirm anchor depth before deployment. A hand-operated plunger then activated the dispensing tool and the anchor was deployed over the stimulator. The anchor was then cinched tightly over the stimulator body to prevent migration of the device and be sutured if considered appropriate by the implanter. Sutures were applied to underlying fascia over the posterolateral musculature.

Subjects from both phases had their stimulators fully implanted by cutting off tubing proximal of the fiducial marker (Figure 1). All subjects were bandaged closed and bandaged without a percutaneous port, as is customary seen in Spinal Cord Stimulation trials. After the implant, the subjects were sent home and they could use the device on demand throughout the day.

Follow Up and Evaluation

During the first phase of the study, AP and lateral X-rays were done every seven to 10 days to monitor device migration.

During the second phase of the study, the subjects participated in four follow up visits. The first visit was to sign the informed consent, check inclusion and exclusion criteria and evaluate the pain at baseline.

The second visit was to implant the stimulator and train the subject on the handling of the WAA.

The third visit was to check the subject’s recovery, pain relief, and stimulation parameters. If a change in stimulation location occurred, then an AP and lateral X-ray image was to be taken to visualize the stimulator location. On the fourth visit, all endpoint measurements were recorded and the stimulator was explanted through an incision over the proximal end of the device. The subjects returned for a follow-up visit two weeks after the device was explanted to check the recovery from the procedure.

Stimulation parameters were recorded immediately after implant and at all follow-up visits. The overall pain for each patient was calculated as the mean pain intensity of the targeted stimulated area and all other painful areas still present. The pain intensity of the different painful areas was measured with a VAS (0 to 10 with a selection of 0 correlating to no pain, and a selection of 10 correlating to the worst pain possible). The overall pain was recorded at baseline before implant, after implant and at all follow-up visits. The stimulator position was recorded after implant and at the last visit with an AP and lateral fluoroscopic image. The adjacent vertebrae provided the landmarks used to monitor device placement throughout the trial. If any subject reported a change in stimulation coverage or parameters, a fluoroscopy image was taken at that visit to evaluate device migration or displacement.

The mean and variance of the registered values were calculated for overall pain relief and stimulation amplitude.

Results

Eleven subjects—five during Phase 1 and six during Phase 2—were included and completed the study. Subjects had a mean age of 63 years and 55% were female. All subjects had low back or buttocks pain and were implanted with a single stimulator to cover his or her primary pain area. Four wireless stimulators were implanted at L1, one at L2, four at L3, and two at L4 (Table 1) nerve roots. Implantation with or without anchoring could be achieved percutaneously via the Touhy needle with no complications, eliminating the need for open surgery.

Seven of the eleven patients (63%) reported good to excellent overall pain relief (≥50% reduction in VAS), two patients reported fair overall intensity pain relief (25–50% reduction), and two patients reported poor or no overall pain relief (0–25%), primarily due to migration of the device in Phase 1 subjects. The average overall pain reduction was 59.9%, regardless of device placement (Figures 6 and 7). The average threshold of stimulation perception was reported as 1.26V (0.5–2.0V).

In the Phase 1 cohort subjects the stimulator migrated an average distance of 8.80 mm (1.53 mm to 21.00 mm) which was considered not recommendable for chronic implants. Therefore a stimulator anchor was tested in
Phase 2 of the study. In the Phase 2 cohort subjects the stimulator migrated an average of 1.83 mm (0.00 to 6.0 mm). The minimal migration in the second cohort did not correlate with changes in the paresthesia coverage or pain relief. No patients reported motor stimulation at any point in the study.

No adverse events were reported during the implant procedure, follow-up period, or after explant.

Discussion

The main objectives of this two-phase study were to evaluate the feasibility of transforaminally introducing a wireless DRG stimulator and to evaluate the efficacy of the Freedom SCS System to treat chronic back pain. Eleven subjects were implanted, five in Phase 1 and six in Phase 2 of the study. The main difference between the two phases was that in Phase 1 the devices were not anchored after implant, whereas in Phase 2 the stimulators were anchored after the implant to prevent migration as observed in Phase 1 of the study.

In general and for all SCS systems, minimal device migration is a requirement, since the stimulating electrodes must be near the nerve in order to provide therapy appropriately. The migration distance reported for Phase 1 (8.80 mm) could have resulted in a displacement of the electrode that could have affected the therapy effectiveness. Though no correlation between stimulator migration and inadequate pain relief was observed, the average migration of the device during Phase 1 was not considered ideal for chronic implants, which is the long-term development goal for the system. Therefore, the anchoring of the stimulator was incorporated as part of the implant procedure. This dramatically improved the migration of the stimulator after implant during Phase 2, which was only 1.83 mm and can be considered part of the normal settling of the stimulator in the first few days after implant. Anchoring the stimulator to a suitable tissue is necessary for the transforaminal technique to be successful. The average overall pain relief reported was 63% at the end of a 6-week study period, which is similar to the mean values reported for other neurostimulation devices in use. It should be noted that in this study, the subjects were implanted unilaterally and at one dermatome level and that the overall pain reported included all painful areas. The qualitative feedback of the subjects suggests that overall pain reduction could be improved with bilateral stimulation using a second stimulator and/or using more stimulators unilaterally.

With the WAA device used in the study, subjects with multi-level implants could benefit from a single WAA device while subjects requiring bilateral stimulators would require two WAA devices.

As with any procedure, the clinician must be skilled in the procedure and familiar with the associated risks. The needle trajectory is important to stay away from the traversing anterior spinal radiculomedullary vessels. It is highly recommended to use the blunt tipped plastic needle stylet to avoid vascular puncture.

The results suggest that a transforaminal DRG is a good location to stimulate resulting in targeted pain reduction.

Table 1 Demographics, stimulator location, and pain relief by subject

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Sex</th>
<th>Implant Location</th>
<th>% Pain Relief</th>
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<tbody>
<tr>
<td>1</td>
<td>63</td>
<td>M</td>
<td>L3</td>
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<tr>
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<td>74</td>
<td>M</td>
<td>L4</td>
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<td>F</td>
<td>L1</td>
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</table>

Figure 6 VAS scores reported by patients at 5/6 weeks by stimulator location (implant level).

Figure 7 VAS scores reported by patients.
In addition, the stimulation amplitude, which affects the overall power usage of the system, was lower than when stimulating traditional SCS targets. This would also translate into extended battery life and decreased costs for chronic implants using non-rechargeable pulse generators. Furthermore, re-chargeable systems have been reported saving substantial costs throughout the patients’ lifetime. These savings have been estimated between $100,000 and $300,000 per patient lifetime [9,10], demonstrating that the battery life of the non-rechargeable pulse generators is a major driver of the health care costs associated with SCS. Additional long-term studies with this device would help identify the impact on cost of device, durability of equipment, rate of revisions, and health care visits.

Main limitation of this study was the low number of subjects included in the study. This is often the case in feasibility studies of new technologies, due to ethical considerations and the required learning curve for new implant procedures and handling of the devices. The other limitation of the study is that the stimulators were implanted temporarily and long-term overall pain relief could not be assessed.

Conclusion

The remotely powered stimulator allows for transforaminal implantation directly at the DRG to achieve pain relief. A wing anchor and standard suturing techniques are effective in maintaining the device in the appropriate position near the DRG.

The Freedom SCS System is a viable alternative approach to low back pain management through stimulation of the DRG. The shorter and straightforward implant procedure (no pulse generator pocket, no tunneling) and the sleek system (no percutaneous connection, no implantable pulse generator or separate RF receiver device) may potentially impact long-term cost considerations of pain treatment with minimally invasive procedures.

Further studies are required to assess long-term pain relief and confirm the cost effectiveness of the system with chronic implants.

Acknowledgments

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References