

Wireless High-Frequency Spinal Cord Stimulation (10 kHz) Compared with Multiwaveform Low-Frequency Spinal Cord Stimulation in the Management of Chronic Pain in Failed Back Surgery Syndrome Subjects: Preliminary Results of a Multicenter, Prospective Randomized Controlled Study

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Funding sources: Stimwave Technologies Incorporated, 1310 Park Central Boulevard South, Pompano Beach, FL 33064, USA.

Conflicts of interest: Mr. Vanquathem is an employee of Stimwave. Dr. Calodney and Dr. Panchal are consultants for Stimwave. Dr. Panchal is a shareholder of Stimwave. Dr. Bolash is a consultant for Medtronic, Nuvectra, Jazz Pharmaceuticals, and Pfizer. His institution receives research funding from Stimwave, St. Jude, Nuvectra, Pfizer, and Mesoblast. All sites received research funding from Stimwave. There are no other conflicts to report.

Abstract

Background. This study aimed to evaluate the wireless Freedom Spinal Cord Stimulator (WSCS) System for the treatment of chronic back and/or leg pain associated with failed back surgery syndrome (FBSS) refractory to standard medical treatment utilizing 10-kHz stimulation (high-frequency [HF]) in comparison with 10–1,500-Hz stimulation (low-frequency [LF]) waveforms. **Methods.** Ninety-nine subjects were randomized in a 1:1 ratio to receive either HF or LF stimulation waveforms utilizing the same Freedom WSCS System. All subjects were implanted with two 8-electrode arrays in the exact same anatomical positions within the dorsal epidural spinal column, with the top electrode positioned at the T8 and T9 vertebrae levels, respectively, and the wireless receiver placed under the skin in a subcutaneous pocket. **Results.** Seventy-two (HF: N = 38; LF: N = 34) subjects had completed the six-month follow-up after an initial 30-day trial period at the time of this report. For both the HF and LF arms, mean visual analog scale (VAS) scores for back and leg pain decreased significantly: 77% and 76%, respectively, for the HF arm and 64% and 64%, respectively, for the LF arm. In addition, most subjects experienced significant improvements in VAS, Oswestry Disability Index, European Quality of Life 5 Dimension questionnaire, Patient Global Impression of Change, and sleep duration. **Conclusions.** These preliminary results demonstrate that WSCS devices can reduce FBSS chronic pain substantially with both LF and HF stimulation waveforms over a seven-month period (30-day trial period and six-month post-trial evaluation).

Key Words: Wireless; High Frequency; Failed Back Surgery Syndrome; Spinal Cord stimulation; Chronic Back Pain

Introduction

Chronic pain as a result of recurring surgical procedures can have a devastating effect on patients, resulting in not

only physical impairment or functional disability, but also in long-term depression and emotional distress [1,2]. The direct and indirect annual cost of chronic pain in the

United States is estimated to be over \$635 billion, affecting more than 90 million Americans (2016 #14). Chronic pain is the number one reason for loss of work [3], and chronic pain sufferers have a 70% greater risk of mortality, surpassing even cardiovascular disease as the leading cause of death [4]. The first steps in the therapy ladder for treatment of chronic pain are usually physiotherapy and prescription of nonsteroidal anti-inflammatory drugs (NSAIDs). If these are not successful, opioids are prescribed. Unfortunately, opioids can result in subject dependence, addiction, abuse, overdose, opioid-induced hyperalgesia, constipation, respiratory or immune dysfunction, hormone imbalance, and even death. Interventional procedures such as nerve blocks are also used, but often have a limited effectiveness duration and do not predict the results of other therapies such as radiofrequency ablation [5]. If these therapy options are unsuccessful, spinal cord stimulation (SCS) is considered as a more invasive yet effective alternative therapy modality for the management of chronic pain.

Researchers have been studying therapeutic effects of neurostimulation with receiver technologies for over 40 years in order to identify the most beneficial therapies available [6]. Conventional SCS products have either a receiver or an implanted pulse generator (IPG) that can provide a stimulation waveform comprised of a certain amplitude, duration (pulse width), and frequency, resulting in tissue response and nerve innervation [7]. LF stimulation produces paresthesia that overlaps with a subject's pain in a specific area of the body [8]. HF SCS has been reported to be "paresthesia-free," since the resulting waveform is typically applied at amplitudes below the subject's level of perception. This study is the first multicenter, prospective, randomized controlled study of subjects with chronic low back or back and leg pain as a result of FBSS to compare wireless LF (active control arm) and HF (test arm) stimulation with the Freedom SCS System and demonstrate the noninferiority of HF therapy.

Methods

Device Description

The Freedom SCS System utilizes wireless neuromodulation technology: eight-contact stimulators with embedded electronics and a separate, mated receiver component (Figure 1). A small, externally wearable rechargeable transmitter provides the energy to power the device wirelessly through the skin, thereby avoiding the potential complications related to the implant of IPG, for which complications in up to 40% of recipients have been reported [9,10]. This novel, minimally invasive technology has been approved in the US by the Food and Drug Administration to deliver pulse rates of up to 1500 Hz and has a CE Mark approval to deliver pulse rates of up to 10 kHz.



Figure 1. The Freedom-8A spinal cord stimulation neurostimulator with eight electrodes, a microchip, and a separate miniature receiver (not shown).

Study Design

The study was conducted at seven sites, and it was approved by the corresponding investigational review boards. Ninety-nine subjects were recruited into the study with chronic back or back and leg pain refractory to medical management for at least 12 months after spinal surgery (Appendix). After informed consent, subjects were randomized (1:1) in two parallel arms to receive either LF (10–1500 Hz, N = 49) or HF (10 kHz, N = 50) stimulation for the duration of the study. Study subjects were block-randomized with a 1:1 ratio of test to control group. Variable block sizes (4 and 6) with complete randomization assignment were sent to each site in an opaque and numbered sealed envelope. A site representative opened the sealed envelopes and assigned programming parameters during the visit. Blinding of the patients was not feasible as tonic stimulation generates paresthesia whereas HF stimulation does not.

Subjects were implanted with two separate wireless stimulators positioned with the electrodes between the T8 and T11 vertebral levels regardless of the randomization assignment (Figure 2). All subjects were immediately implanted with a permanent wireless system using a Tuohy needle, placing the stimulator electrodes in the epidural space. Two small incisions were used to place the receiver component in a separate subcutaneous pocket. All subjects were implanted with a permanent device to avoid complications related to a separate trial procedure and the need for reoperation. Nonresponder subjects (<50% relief from back pain under stimulation) could opt for explant of the permanent lead or to leave it in situ, as the lead is magnetic resonance imaging compatible.

Subjects were programmed according to their randomization assignment with either LF stimulation (10–1500 Hz and 50–500 μ s) or HF stimulation (10 kHz and 30 μ s) at the time of implantation. Figure 3 summarizes the different stimulation schemes that were used in the HF and LF groups.

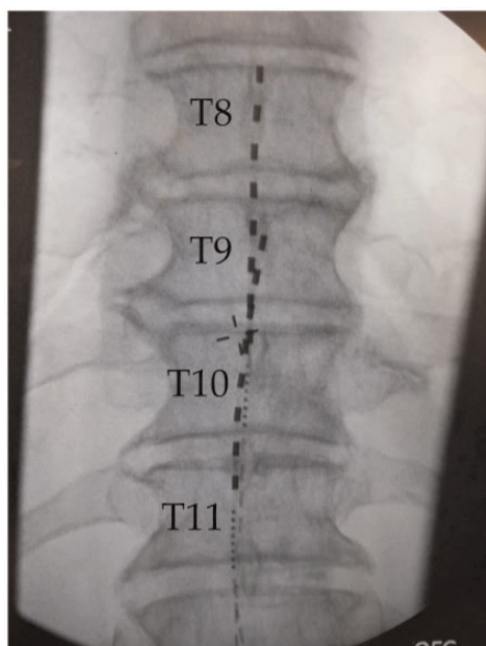


Figure 2. Anteroposterior image showing distribution of two octopolar neurostimulator electrode arrays spanning the T8–T11 vertebral levels in the epidural space consistent for all subjects in the study.

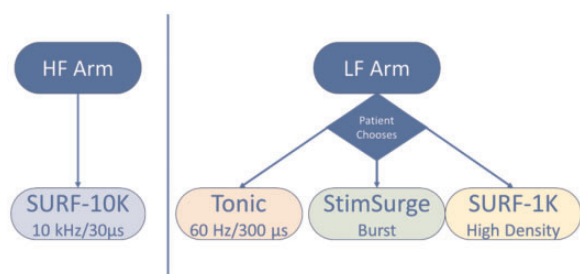


Figure 3. Low-frequency (LF) and high-frequency stimulation schemes used during the SURF study. In the LF arm, the subject could choose between the three stimulation schemes shown.

The external antenna was placed over one layer of clothing covering the area over the implanted receiver, which provided the energy required for stimulation as needed throughout the entirety of the study. Patients were instructed to use stimulation 24 hours per day.

After an initial trial period of 30 days after implantation of the permanent device, subjects were classified as responders or nonresponders. Responders who had a $\geq 50\%$ change in VAS for back pain continued in the study and were followed and evaluated at one, three, and six months. Nonresponders could opt for other therapies and exited the study.

Data Collection and Analysis

Data were secured on paper case report forms or questionnaire instruments at baseline and throughout the

study. The integrity of the data was regulated via periodic monitoring by an independent research organization and a data safety monitoring board. VAS data were reported as raw scores, means, and percent change from baseline. Additional data collected included the Oswestry Disability Index (ODI), Patient Global Impression of Change (PGIC), European Quality of Life 5 Dimension questionnaire (EQ-5D-5L), frequency of sleep disturbances, and prescribed pain medications.

The primary end point was the percentage of subjects who responded to wireless SCS therapy for back pain ($\geq 50\%$ reduction in VAS score) in the HF arm as compared with the percentage of subjects who responded to wireless SCS in the LF arm. Primary end point analysis was performed on the per-protocol (PP) sample (subjects completing a primary end point assessment). Subjects who did not have a successful trial phase were considered nonresponders for the PP analyses. A sample size of 80 subjects (80% statistical power) was determined based on a noninferiority analysis of the primary end point with a 10% noninferiority margin. At the time of this report, 72 subjects had completed the six-month end point.

Secondary end points were evaluated with noninferiority *t* tests in a hierarchical sequence that preserved the study-wide error rate at $\alpha = 0.05$. A *P* value of $\leq 5\%$ ($P \leq 0.05$) was considered statistically significant in each test; subsequent tests were not executed unless all previous tests were significant. Secondary end points included changes from baseline in VAS back pain, VAS leg pain, ODI, and EQ-5D-5L.

Adverse events (AEs) were reported descriptively in the modified intent-to-treat population (mITT $N = 99$) and were classified as serious AEs (SAEs; defined as any undesirable clinical occurrence in a subject leading to death or to a serious deterioration in the health of the patient that resulted in life-threatening illness or injury, in permanent impairment of a body structure or a body function, that required in-patient hospitalization or prolongation or existing hospitalization, or that resulted in medical or surgical intervention to prevent permanent impairment to body function) or nonserious adverse events and as related or unrelated adverse events.

Results

At the time of this report, 83 subjects had reached the three-month end point, and 72 subjects had reached the six-month end point (Figure 4). All subjects were immediately implanted with a permanent system; there was no trial device, thus avoiding multiple procedures for the subjects.

Eleven subjects were considered nonresponders. One subject withdrew consent immediately after implantation, three additional subjects withdrew consent even though they were able to report $>50\%$ pain relief, and one subject withdrew because of lack of efficacy. One of the investigators excluded another subject from further

Table 1. Demographics and characteristics

Baseline Demographics and Characteristics			
	HF (N = 38)	LF (N = 34)	Whole Group (N = 72)
Age, y at enrollment			
Mean (SD)	58.5 (12)	58.17 (12)	58.5 (12)
Gender, No. (%)			
Male	18 (47)	20 (58)	38 (53)
Female	20 (53)	14 (42)	34 (47)
Height, in			
Mean (SD)	68.86 (16)	62.85 (16)	66.02 (16)
Weight, lb			
Mean (SD)	201.3 (43)	189.43 (64)	195.9 (54)
Duration of pain, y			
Mean (SD)	10.01 (9)	11.2 (8)	10.6 (9)
Primary region of pain, No. (%)			
Lower back	24 (63)	25 (74)	49 (68)
Leg	14 (37)	9 (26)	23 (32)

HF = high-frequency; LF = low-frequency.

participating in the study even though this subject reported >50% pain relief.

Table 1 shows baseline demographics, pain duration and primary pain region, for the 72 patients at the six-month end point. Baseline demographics and characteristics were comparable between the two randomized treatment arms. There was no statistical evidence that the groups were different at baseline (P values not significant). The mean age of the subjects was 58.5 ± 12 years, and 34 of the subjects were female. The subjects' mean pain duration was 10.6 ± 9 years before entering the study.

Trial Phase Results

The trial success rate ($\geq 50\%$ reduction VAS for back pain) was 92% (46/50) for the HF arm and 84% (41/49) for the LF arm.

Primary End Point

At the time of this report, the study is meeting the primary end point, defined as noninferiority of responder rate ($\geq 50\%$ reduction in VAS pain scores from baseline) in the HF arm compared with the responder rate in the LF arm at the end of six months. For the PP population, the upper bound is lower (-20%) than the 10% noninferiority margin (NIM), indicating noninferiority of HF stimulation vs LF stimulation ($P = 0.00008$). The chi-square test is currently not indicative of superiority ($P = 0.2$). For the PP population, 92% (35/38) of the subjects with HF stimulation were responders, as compared with 82% (28/34) of subjects who responded to LF stimulation. Additionally, back pain remission, defined as a VAS for back pain of ≤ 25 mm, was analyzed. In the HF arm, 84% of the subjects experienced back pain remission, compared with 47% of subjects in the LF arm (Figure 5).

Secondary End Points

At the six-month primary end point, the mean back pain VAS reduction for the HF arm ($N = 38$) was 77% (from 75.8 ± 13.1 mm to 17.8 ± 14.1 mm), and the LF arm ($N = 34$) was 64% (from 77.5 ± 9.9 mm to 27.8 ± 23.2 mm) (Figure 6). Leg pain-associated mean VAS reductions were 76% for HF (from 55.1 ± 27.2 mm to 13.3 ± 14.1 mm) and 64% for LF (from 61.5 ± 24.1 mm to 22.3 ± 24.4 mm) (Figure 7). Thus, VAS reductions from baseline were statistically significant ($P < 0.0001$) for both arms. HF was noninferior to LF in leg and back pain. P values were significant, with an NIM of 10% for change in both back ($P = 0.0006$) and leg pain ($P = 0.03$). Currently, the HF arm results are slightly more favorable but are not indicative of superiority. All secondary end points sequentially meet noninferiority criteria.

The subjects' mean level of disability, as measured by the Oswestry Disability Index (ODI), improved significantly for both treatment arms, with 43% for the HF and 42% for the LF arm (Figure 8). At six months, the scores decreased from 53% (severe disability) at baseline to 30% for the HF arm and from 55% to 32% for the LF arm (moderate disability), a reduction of one category in both arms. Improvements were also seen in the number of subjects reporting to be bedridden, crippled, or who had severe disability, decreasing from 63 at baseline to only 23 subjects at six months, indicating a substantial decrease of 63%. HF was noninferior to LF for disability. The P value was significant, with an NIM of 10% ($P = 0.02$).

Reflecting the subjects' personal assessment about the efficacy of treatment at six months, both arms documented significant improvements, as measured by the PGIC. Both HF and LF subjects reported a median score of 6 out of 7. HF was noninferior to LF in the change in PGIC. The P value was significant, with an NIM of one point, so there was adequate evidence that the true difference between LF and HF was less than one point.

Significant improvements in quality of life (QoL) were revealed by the EQ-5D-5L questionnaire, with 79% reporting a better QoL compared with baseline, and 0%, 14%, and 7% experiencing an equal, mixed, or worse QoL following treatment, respectively (Figure 9). In the HF arm, QoL was better in 79% of the subjects, equal in 0%, mixed in 18%, and worse in 3% of the subjects. Among the LF subjects, QoL was better in 79% of the subjects, equal in 0%, mixed in 9%, and worse in 12% of the subjects. The subjects with mixed QoL all reported that it was either better or equal to baseline, with one exception. The overall number of subjects reporting worse QoL was minimal, at 7%. The health value mean results for the HF arm were 60.3 at baseline and 81.5 at six-month follow-up, with an increase of 36%. The mean results were 51.8 and 78.4 at baseline and at six-month follow-up, respectively, for the LF subjects, with an increase of 51%. There was no statistical evidence that HF

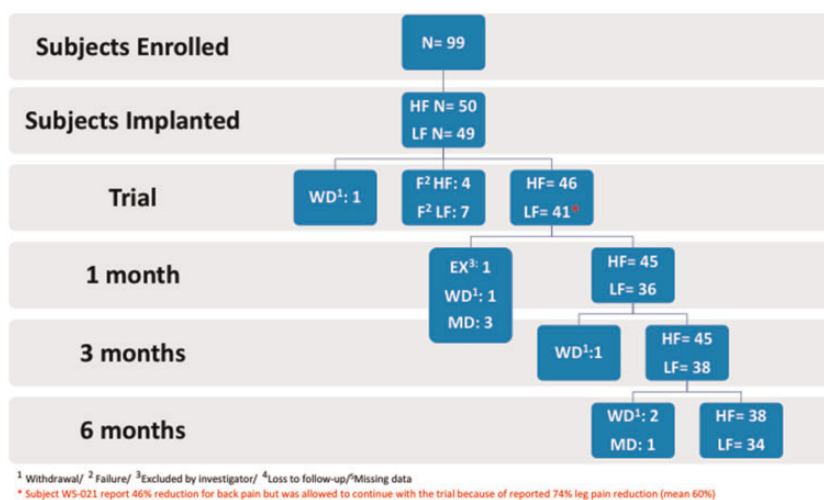


Figure 4. Subject flowchart (current study status).

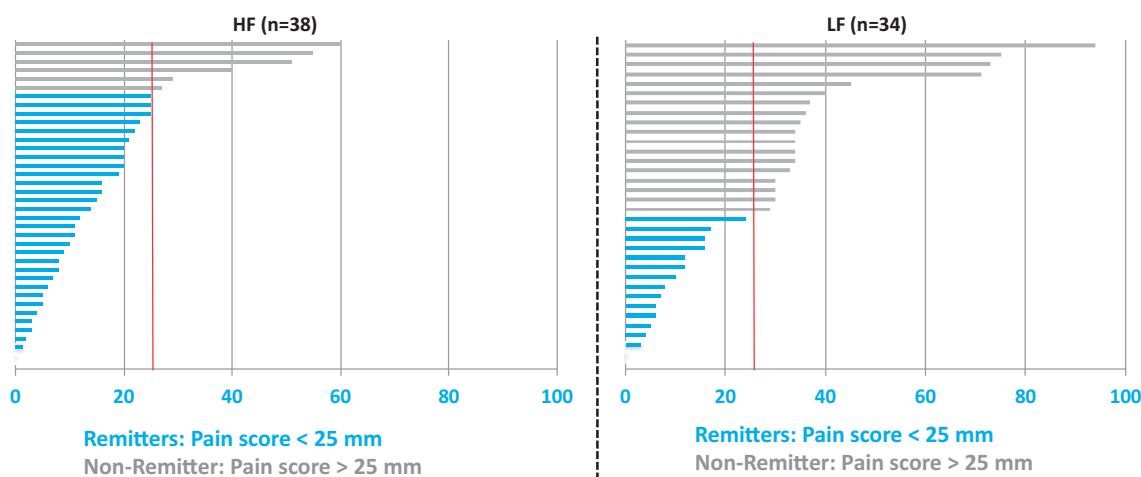


Figure 5. Frequency of subjects reporting remission for back pain following six months of stimulation was 84% and 47%, respectively, for the high-frequency and low-frequency arms. Remitter rate was defined as having a visual analog scale of ≤ 25 mm.

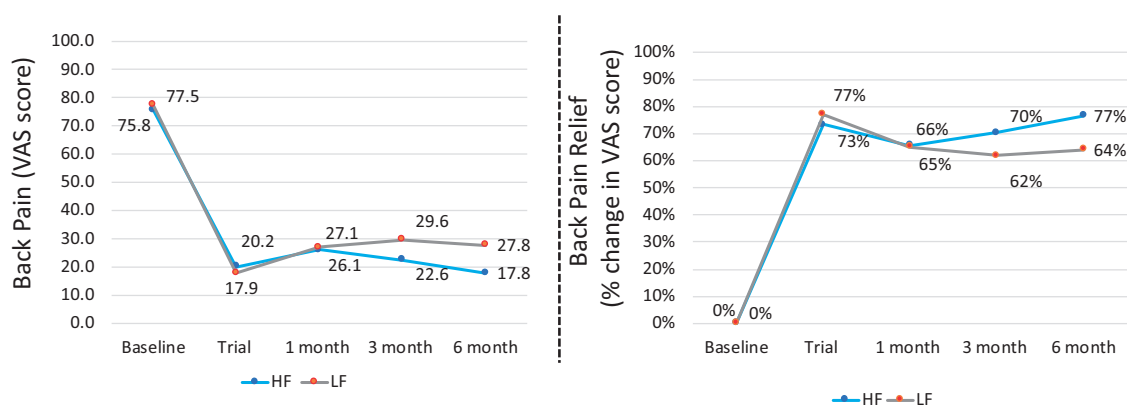


Figure 6. Visual analog scale score/back pain relief (percent change). Pain relief was sustained throughout six months of therapy. A total of 72 subjects completed the six-month visit. Following six months of stimulation, mean pain relief was obtained with 17.8 ± 14.1 mm (76%) and 27.8 ± 23.2 mm (64%), respectively, for the high-frequency and low-frequency arms.

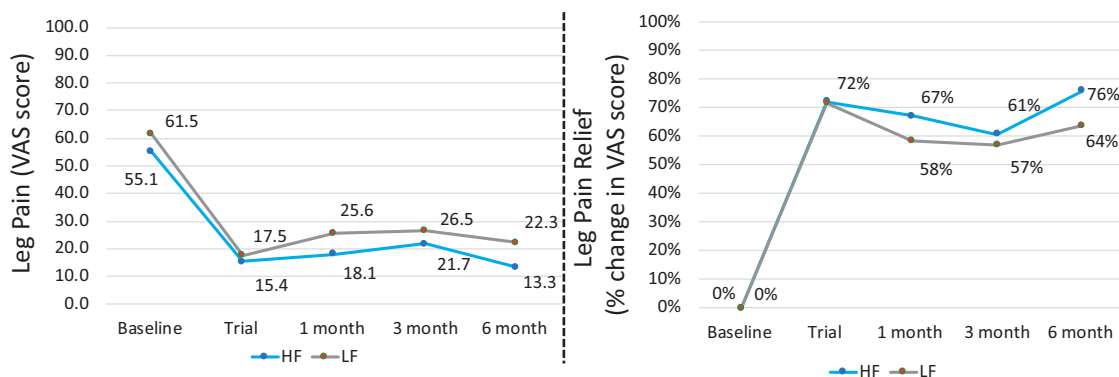


Figure 7. Visual analog scale score/leg pain relief (percent change). Pain relief was sustained throughout six months of therapy. A total of 72 subjects completed the six-month visit. Following six months of stimulation, mean pain relief was obtained with 13.3 ± 14.1 mm (76%) and 22.3 ± 24.4 mm (64%), respectively, for the high-frequency and low-frequency arms.

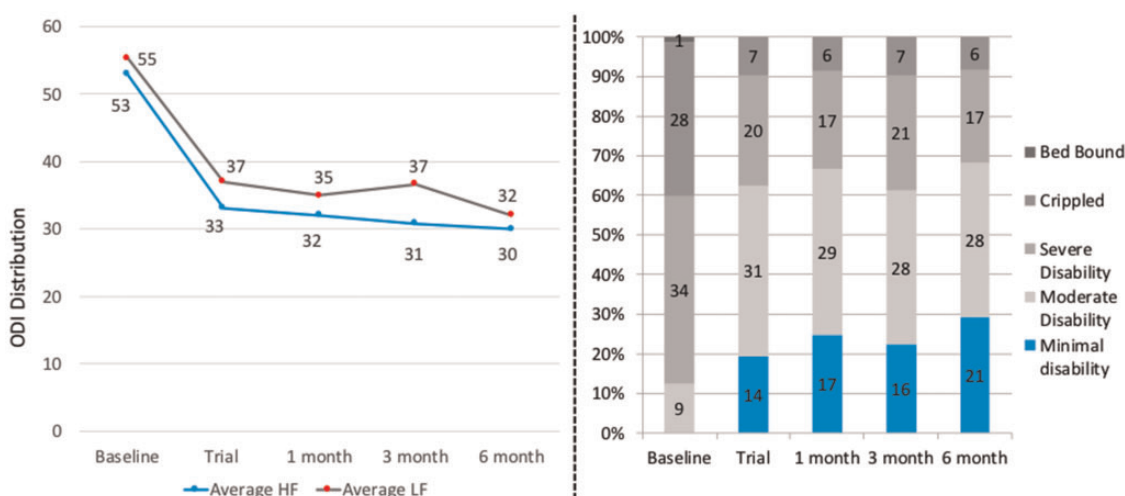


Figure 8. Functionality (measured by the Oswestry Disability Index). Mean reduction of 43% for high frequency and 42% for low frequency, from severe to moderate disability. Sixty-three subjects at baseline reporting being either bed bound, crippled, or severely disabled, as compared with 23 at six months.

Classification	Total	HF	LF
Better	79%	79%	79%
Equal	0,00%	0,00%	0,00%
Mixed	14%	18%	9%
Worse	7%	3%	12%

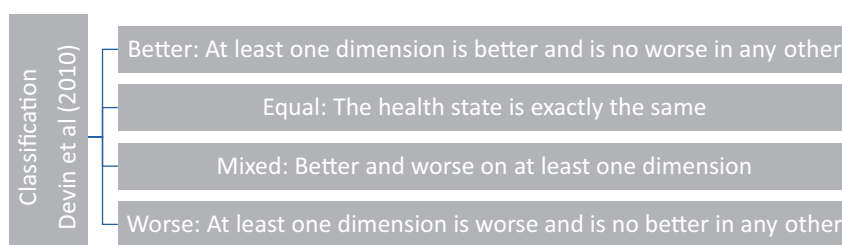
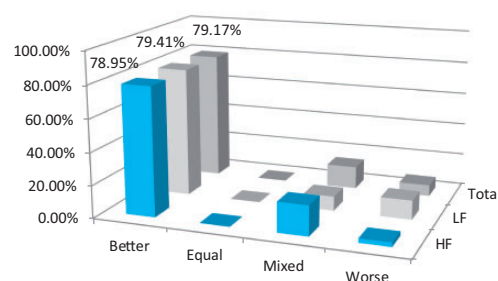


Figure 9. Graphical representation of European Quality of Life 5 Dimension questionnaire results; 79% of high-frequency subjects reported being better, as compared with 79% in low-frequency subjects.

Table 2. Adverse events ITT (N = 99)

Summary of Adverse Events for all Implanted Subjects (N = 99)			
	HF (N = 50)	LF (N = 49)	Total (N = 99)
SAEs (treatment-related)			
Subjects (%)	0 (0)	1 (2)	1 (1)
AEs (treatment-related)			
Events (%)	12 (24)	25 (53)	37 (37)
Subjects (%)	11 (22)	15 (31)	26 (26)
Type of adverse event, No. (%)			
Lead migration	5 (10)	10 (20)	15 (15)
Loss of stimulation	1 (2)	4 (8)	5 (5)
Unintended stimulation	0 (0)	3 (6)	3 (3)
Lead breakage	0 (0)	2 (4)	2 (2)
Incisional pain	2 (4)	5 (10)	7 (7)
Infection (SAE)	0 (0)	1 (2)	1 (1)
Other	4 (8)	0 (0)	4 (4)

AE = adverse event; HF = high-frequency; LF = low-frequency; mITT = modified intent-to-treat population; SAE = severe adverse event.

was noninferior to LF in the change in EQ-5D, with an NIM of 10 points ($P = 0.2$).

Subjects from both arms reported that they slept one hour longer on average, with a reduction in number of awakenings during the night from 3.7 to 2.11 (43%) and 3.06 to 2.44 (20%) for the HF and LF arms, respectively.

Study Safety Results

The preliminary results show that there was only one treatment-related SAE (infection, defined as serious by the need for hospitalization) in the intent-to-treat population (N = 99). Treatment-related complications occurred in 26 subjects with a total of 37 AEs, including electrode array migration (N = 15), loss of stimulation (N = 5), unintended stimulation (N = 3), incisional pain (N = 7), infection (N = 1), lead breakage (N = 2), or other minor complications (N = 4) (Table 2). Eleven subjects had to be revised due to the complications mentioned above; the rest did not need a surgical intervention or were resolved by reprogramming.

This study shows that the AE profile for subjects receiving LF stimulation is similar to other SCS studies (31% of subjects reporting an AE). The subjects in the HF stimulation arm, however, had a better AE profile, with 11 (22%), compared with other SCS studies [11].

Discussion

Efficacy

The preliminary results of this ongoing study were analyzed for subjects at the end of six months to report on the safety and efficacy of the wireless Freedom SCS System. Earlier experience has shown the feasibility of this wireless technology for pain management [12].

The preliminary analysis of this study shows important positive results. VAS scores decreased significantly from baseline, indicating meaningful reductions in pain

intensity (71% for combined group, 76% for HF arm, 64% for LF arm). These results are equivalent to those reported in previous studies for both HF and LF, thus validating the efficacy of the Freedom SCS System.

The ODI scores decreased (44% for combined group, 45% for HF arm, 44% for LF arm), demonstrating improvements in functionality. The questionnaire is used to identify an individual subject's degree of disability, where lower scores are more favorable and higher scores relate to crippling disability or the subject being bedridden. Shifts in ODI scores are additional measurements, demonstrating that the therapy is impacting subjects on a day-to-day basis and allowing them to return to normal activities (i.e., ability to walk, sit, sexual function, social life).

Confidence in the system's effectiveness is bolstered through the scores reported by the PGIC. This metric is a self-reported measure of the subject's belief about the efficacy of treatment using a seven-point scale (7 being very much improved and 0 being very much worse). Subjects reported a median of 6 ("better, and a definite improvement that has made a real and worthwhile difference") for the combined group, the HF arm, and the LF arm.

The EQ-5D-5L is a simple, generic measure of the health status of subjects. Subjects indicated an improved QoL state and general health (79% for the combined group, the HF arm, and the LF arm). Further analysis of the EQ-5D scores shows the "health state" of the subjects related to five areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

Analysis of the current data is consistent with noninferiority of HF when compared with LF treatment, but there is still no conclusive statistical evidence that QoL improvement for the HF arm is noninferior to that of the LF arm. The noninferiority trend can be seen in responder rates, changes in the VAS score for back and leg pain, ODI, and PGIC.

Safety

The use of wireless stimulation with no IPG eliminates complications related to the IPG implant, which requires a second procedure with extensive tunneling. With the wireless system, the most frequently reported adverse event was device migration. Adverse event rates may have been inversely associated with implanter experience, which can be demonstrated by the event-to-subject ratio at the highest-enrolling site (N = 29, 14%; four events for four subjects). One implanter (RB) had the rate of migration decrease to 0% after modifying the surgical technique.

While this study demonstrates the effectiveness of HF SCS, conventional SCS devices with IPGs are responsible for a large percentage of adverse events. Device-related complication rates using IPGs in traditional SCS have occurred in 32% of subjects [13], which is significantly

higher than the complication rates seen in this trial for the HF arm (HF = 22%). Serious adverse events (this study LF: 2%; HF: 0%) were recorded in the SENZA-RCT trial in 4% of the HF subjects and 7.2% of the conventional LF subjects; 27.7% and 33% of subjects experienced nonserious, study-related adverse events in the HF and LF groups, respectively.

Limitations

Adverse event rates were inversely associated with implanter experience, and the highest-enrolling sites reported the lowest incidence rates of adverse events. Surveillance radiographs were obtained to assess electrode array position at defined intervals throughout the study. As such, asymptomatic device migration was noted and reported, even in the absence of a clinical manifestation.

Additional limitations include the lack of subject and investigator blinding, which was impossible due to the nature of LF stimulation and the industry sponsoring of the study.

Conclusions

The SURF study is the first multicenter, prospective randomized controlled study demonstrating the effectiveness of the wireless Stimwave Freedom SCS system for the treatment of chronic back or back and leg pain associated with FBSS refractory to standard medical management using HF (10 kHz) stimulation waveforms in comparison with LF stimulation waveforms from 10 Hz to 1500 Hz without the need for a separate trial procedure.

The use of a WSCS system capable of programming HF and LF stimulation resulted in significant pain reduction in subjects with intractable back pain with or without leg pain as a result of FBSS refractory to standard medical treatment, with improved disability and QoL. Wireless, one-stage implantation procedures allow for longer trial periods, providing more time to test for the most optimal programming options for each individual subject. This opens up a wider spectrum of therapeutic paradigms in the management of neuropathic pain syndromes. Further research in larger groups with improved instruments for metrics may prove valuable in understanding the response of pain to stimulation parameters.

Authors' Contributions

Drs. Bolash, Creamer, Rauck, Vahedifar, Calodney, Fox, and Özaktay treated patients and collected the data at the study sites. Dr. Panchal is chairman of the Data Safety Monitoring Board (DSMB) for this study. Niek Vanquathem prepared the manuscript. All authors reviewed the manuscript critically and approved the final version.

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Appendix. Inclusion and Exclusion for the SURF Study

Inclusion Criteria

- A. Subject is ≥ 18 years of age at time of informed consent.
- B. Subjects have been diagnosed with chronic back or back and leg pain with an average Pain Rating Scale ≥ 5 (on a 10-point scale) over the course of the last 14 days for back pain based on baseline pain diary.
- C. Subject diagnosis with chronic back or back and leg pain associated with failed back surgery syndrome refractory to conventional medical management for at least 12 months before enrollment.
- D. Based on the medical opinion of the Principal Investigator, subject has a stable pain medication regimen.
- E. Based on the medical opinion of the Principal Investigator, there is no evidence of anatomic abnormalities that could jeopardize the placement of the device or pose a hazard to the subject.
- F. Based on the opinion of the Principal Investigator, subject is willing and able to operate the patient programmer, recharging equipment, and diary and has the ability to undergo study assessments and provide accurate responses.
- G. Based on the opinion of the implanter, subject is a good surgical subject for the implant procedure.
- H. Subject is willing to undergo surgical implant procedure, attends visits as scheduled, and complies with the study requirements.
- I. Subject is male or nonpregnant female.
- J. Subject is deemed to be neuropsychosocially appropriate for implantation therapies based on the assessment of a clinical psychologist, using face-to-face encounters and the psychological testing described in the measures.
- K. Subject is capable of giving informed consent.
- L. Subject lives within reasonable distance from the study site.

Exclusion Criteria

- A. Obvious mechanical instability related to pain (diagnosed by imaging taken within the past six months).
- B. Unresolved malignancies in last six months.
- C. Subject has post-herpetic neuralgia (shingles).
- D. Subject has an active systemic infection or is immune-compromised.
- E. Based on the medical opinion of the Principal Investigator, psychologist, and/or psychiatrist, the subject has other psychological conditions (e.g., psychosis, suicidal ideation, borderline personality disorder, somatization, narcissism), other health conditions (e.g., substance abuse, another chronic condition requiring the regular use of opioid medication), or other legal concerns that would preclude his/her enrollment in the study or potentially confound the results of the study.
- F. Subject is currently enrolled in or plans to enroll in any concurrent drug and/or device study while participating in this study.
- G. Insulin-dependent diabetic who is not controlled through diet and/or medication (determined by the physician) or non-insulin-dependent diabetic who is not well controlled through diet and/or medication.
- H. Bleeding complications or coagulopathy issues.
- I. Pregnant/lactating or not using adequate birth control.
- J. A life expectancy of less than one year.
- K. Any active implanted device whether turned off or on.
- L. A previous spinal cord stimulation experience.
- M. Conditions requiring magnetic resonance imaging evaluation or diathermy procedures.