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High-Frequency versus Conventional Spinal Cord Stimulation in Patients with Failed-Back Surgery Syndrome

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What is already known on this topic?

- *Failed-back surgery syndrome (FBSS) is common and associated with persistent pain and disability.*
- *1 Spinal cord stimulation is a recognized treatment option.*
- *Conventional and high-frequency stimulators are commonly used modalities with varying responses between patients in terms of pain relief and physical ability.*

What does this study add on this topic?

- *High-frequency stimulators provide quicker relief in pain and disability compared to conventional stimulators.*
- *At 12 months, both modalities show significant reductions in pain and disability, supporting their feasibility as treatment options for FBSS.*

Abstract

Objective: Failed-back surgery syndrome (FBSS) is characterized by chronic pain and disability. Spinal cord stimulation (SCS) is a viable treatment option, with conventional SCS (C-SCS) and high-frequency SCS (HF-SCS) being the most common modalities. This study aims to compare the effectiveness of HF-SCS and C-SCS in reducing pain and disability in patients with FBSS.

Methods: A total of 23 patients diagnosed with FBSS who had previously undergone either HF-SCS (n = 11) or C-SCS (n = 12) previously were included in this study. Pain intensity and disability were assessed using the Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI) at baseline and at the third, sixth, and 12th months post-implantation. The changes in ODI and VAS observed in both groups were then evaluated.

Results: Both HF-SCS and C-SCS were effective in reducing VAS and ODI scores over the 12-month follow-up period. Notably, HF-SCS demonstrated rapid improvement in VAS scores at the 3-month mark when compared to the C-SCS group (5.1 vs. 6.7, $P < .05$). Nevertheless, by 12 months, the difference in scores was non-significant. A similar pattern was observed in the ODI scores, which decreased significantly in both groups, with the HF-SCS group exhibiting a faster initial improvement (27 vs. 33, $P < .05$). At the 12-month mark, the ODI scores were comparable between the 2 groups.

Conclusion: This study found that both HF-SCS and C-SCS were effective in reducing pain and disability in patients with FBSS. While HF-SCS offers quicker relief, at 12 months the outcomes are similar between the 2 modalities. These findings suggest both treatment options are feasible for managing FBSS, with the choice of modality potentially guided by patient preferences. Further research is needed to explore the long-term benefits, cost-effectiveness, and patient-reported outcomes of these therapies.

Keywords: Back pain, chronic pain, failed back surgery syndrome, neuralgia, spinal cord stimulation

Introduction

Failed-back surgery syndrome (FBSS) is defined as persistent or recurrent pain following lumbar spinal surgery, with symptoms including chronic pain, disability, depression, and a consequent reduction in the patient's quality of life.[1] The causes of FBSS are multifactorial, involving factors such as epidural fibrosis, recurrent disc herniation, spinal stenosis, and inadequate surgical technique.[2] Despite the advancement of surgical techniques, the incidence of FBSS remains high, with studies estimating that it affects up to 40% of patients who undergo lumbar spine surgery.[2]

The management of FBSS is complex, involving a multidisciplinary approach that includes pharmacological treatment, physical therapy, interventional pain procedures, and, in some cases, revision surgery. However, such treatments often fail to provide satisfactory pain relief.[3] This has led to an increased interest in neuromodulation techniques, particularly spinal cord stimulation (SCS), which has emerged as a promising option for managing chronic pain associated with FBSS. Spinal cord stimulation involves the delivery of electrical impulses to the spinal cord, which modulates pain signals and reduces the perception of pain. Conventional SCS (C-SCS) typically operates at frequencies below 100 Hz and is effective in generating paresthesia, a tingling sensation

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that masks pain. However, the sensation of paresthesia can be uncomfortable for some patients, and its effectiveness varies widely.[4,5]

Recent advancements in neuromodulation technology have led to the development of high-frequency spinal cord stimulation (HF-SCS), which operates at frequencies up to 10000 Hz. Unlike C-SCS, HF-SCS provides pain relief without inducing paresthesia or a tingling sensation, which is considered a significant advantage by many patients. Preliminary studies have indicated that HF-SCS may offer superior outcomes, particularly in complex pain conditions such as FBSS.[3,6]

Despite these promising developments, the paucity of direct comparative analyses of HF-SCS and C-SCS in the treatment of FBSS is evident. The objective of this study is to compare the effectiveness of these modalities in reducing pain and disability, as measured by the Visual Analog Scale (VAS)[7] and the Oswestry Disability Index (ODI)[8] in patients with FBSS who have undergone either HF-SCS or C-SCS.

Methods

Study Design and Ethical Considerations

This retrospective study was conducted to compare the outcomes of patients diagnosed with FBSS who previously underwent HF-SCS or C-SCS, in the Department of Pain Medicine, XXXX University, Faculty of Medicine, in accordance with the Helsinki Declaration Principles.[9] Ethical approval was obtained from the Ankara University, Faculty of Medicine (Approval no: 01-10-16, Date: January 11, 2016). Informed consent was obtained from all participants included in the study.

Patient Population

The study included patients aged over the age of 18 who had been diagnosed with FBSS and who had received either HF-SCS or C-SCS therapy between 2012 and 2015. Each patient was followed up for 1 year following the implantation of the device. The choice of either conventional or high-frequency stimulator was determined by the preferences of both the patient and the clinician, as well as device availability. In order to be included in the analysis, patients had to satisfy a minimum follow-up period of 12 months post-implantation. Exclusion criteria included patients with incomplete medical records, those who underwent additional spinal surgeries during the follow-up period, those who missed their appointments, and those with significant comorbidities such as symptomatic heart failure or chronic obstructive pulmonary disease that could potentially compromise the validity of the study results.

Data Collection

Patient data, including demographic information (age, sex), clinical history (previous surgeries, duration of pain), and details of the spinal cord stimulator implanted (HF-SCS or C-SCS), were collected. Outcome measures included the VAS for pain intensity and the ODI for disability. Visual Analog Scale and ODI scores were recorded at baseline (pre-implantation) and at the third, sixth, and 12th months post-implantation during their follow-up appointments.

Statistical Analysis

Statistical analyses were performed using R version 4.0.2 (R Core Team (2024) R: A language and Environment for Statistical Computing. R Foundation for Statistical Computing, Vienna, Austria). Descriptive statistics were calculated for baseline demographic and clinical characteristics, including mean and standard deviation for continuous variables, and frequencies and percentages for categorical variables. Linear mixed-effect model analysis was conducted to compare the mean VAS and ODI scores between the HF-SCS and C-SCS groups over time. The analysis considered the main effects of group (HF-SCS vs. C-SCS), time (baseline, 3, 6, and 12 months), and the interaction between group and time. Coefficient *P*-values of less than .05 were considered to be statistically significant.

Results

Patient Characteristics

Patient characteristics are shown in Table 1. Briefly, a total of 23 patients were included in the analysis, with 11 patients in the HF-SCS group and 12 patients in the C-SCS group. The mean age of patients in the HF-SCS group was 53 ± 12 years, while in the C-SCS group, it was 56 ± 8. years. The sex distribution was also similar between the 2 groups, with a higher proportion of females in both groups (63.6% in HF-SCS and 83.3% in C-SCS). Baseline VAS and ODI scores were comparable between the groups, indicating similar levels of pain and disability prior to the intervention.

Patient Functional and Pain Status Over Time

The mean values of ODI and VAS of the patients are shown in Table 2. Both groups experienced a decrease in symptoms and an improvement in disability early in the course.

Oswestry Disability Index Scores

The progression of ODI over time is illustrated in Figure 1. Oswestry sisability index scores demonstrated a substantial reduction in disability over time for both groups. At the 3-month mark, the HF-SCS group exhibited a more pronounced reduction in ODI scores when compared to the C-SCS group (27 ± 5 vs. 33.8 ± 6.6, $P = .004$). This trend persisted at the 6-month follow-up; however, by the 12-month mark, the ODI scores were comparable between the 2 groups, indicating that both treatments were equally effective in reducing disability related to FBSS. The results of the analysis are presented in Table 3.

Visual Analog Scale Scores

Visual analog scale scores over time are shown in Figure 2. Visual analog scale scores demonstrated a significant reduction in pain intensity over time for both the HF-SCS and C-SCS groups. The HF-SCS group exhibited a more substantial decrease in mean VAS scores at 3 months compared to the C-SCS group (5.1 ± 1.2 vs. 6.7 ± 1.4, $P = .02$). However, at the 12-month follow-up, the

Table 1. Descriptive Statistics of Patients Included in the Study

Descriptive Statistics by Treatment Group			
Characteristic	**HF-SCS n = 11[1]**	**Conventional SCS n = 12[1]**	***P*[2]**
Age (years)	53 ± 12	56 ± 8	.8
Gender			.4
Female	7/11 (63.6%)	10/12 (83.3%)	
Male	4/11 (36.4%)	2/12 (16.7%)	

[1]Mean ± SD; n/N (%).
[2]Wilcoxon rank sum exact test; Fisher's exact test.

Table 2. Mean ODI and VAS Scores Over Time

Mean ODI & VAS Scores Over Time for HF-SCS and Conventional SCS Groups				
Time Point	**ODI (Conventional SCS)**	**ODI (HF-SCS)**	**VAS (Conventional SCS)**	**VAS (HF-SCS)**
Baseline	39.5 ± 3.9	40.2 ± 4.1	8.1 ± 0.7	8.4 ± 1
3 Months	33.8 ± 6.6	27.1 ± 5.1	6.7 ± 1.4	5.1 ± 1.2
6 Months	34.3 ± 6.5	30 ± 5.2	6.8 ± 1.2	5.8 ± 1.6
12 Months	34.3 ± 6.5	31.5 ± 5.7	6.8 ± 1.2	6 ± 1.5

C-SCS, conventional spinal cord stimulator; HF-SCS, high-frequency spinal cord stimulator; ODI, oswestry disability index; VAS, visual analog scale.

difference in VAS scores between the 2 groups was not statistically significant. Analysis of the VAS results is shown in Table 4.

Overall, the analysis revealed that both HF-SCS and C-SCS significantly reduced pain and disability in patients with FBSS. The HF-SCS group showed a faster initial response in pain and disability reduction, but the long-term outcomes were similar between the 2 groups.

Discussion

The findings of this study show the efficacy of both HF-SCS and C-SCS in the management of FBSS. The significant reductions in both VAS and ODI scores observed in both groups underscore the overall efficacy of SCS in alleviating pain and improving functional outcomes in patients with FBSS.

The initial advantage observed in the HF-SCS group, particularly in terms of faster pain relief at the 3-month follow-up, aligns with previous studies that have reported similar benefits of HF-SCS.[1] This advantage is likely due to the mechanism of HF-SCS, which involves delivering electrical pulses at a frequency high enough to block pain transmission without causing paresthesia, thereby offering a more comfortable experience for patients. However, by the 12-month follow-up, the differences in outcomes between HF-SCS and C-SCS diminished, suggesting that although HF-SCS may offer an early advantage in pain management, the long-term benefits of both modalities converge, leading to similar outcomes in terms of pain relief and disability reduction, with HF-SCS patients having marginally better results.[10] Conversely, Kapural et al[3] reported that HF-SCS patients compared to C-SCS were 1.9 (95% CI 1.4-2.5) times more likely to have a clinically significant response at 3 months which decreased to 1.5 (95% CI 1.2-1.9) after a year. It is noteworthy that both HF-SCS and C-SCS provided significant long-term benefits in the management of chronic pain.[3] Another study by Kapural[11] evaluated the long-term effects of HF-SCS and C-SCS on chronic low back and leg pain, demonstrating the long-term superiority of HF-SCS treatment at 24-month follow-up.[11] The observed differences in ODI and VAS scores at different time points may be indicative of the distinct mechanisms through which these modalities influence pain perception and functional recovery.[12,13] High-frequency SCS, by virtue of its capacity to circumvent the paresthesia associated with C-SCS techniques, might contribute to greater patient comfort and compliance, potentially leading to improved long-term outcomes. Moreover, the absence of paresthesia could potentially mitigate the psychological burden often linked to continuous stimulation, thus contributing to

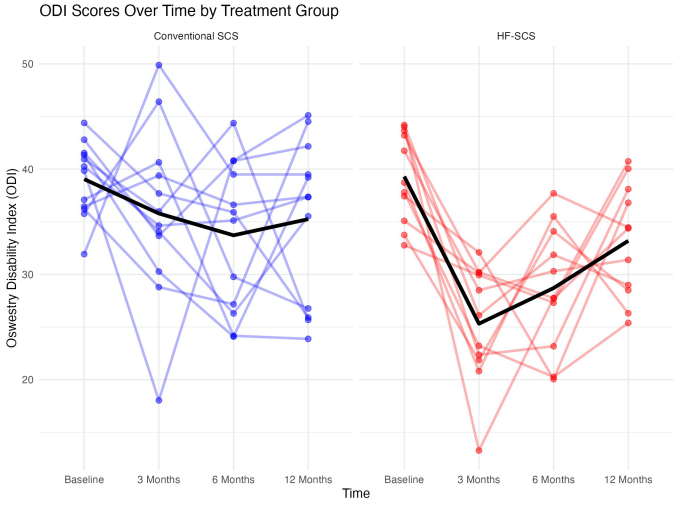

Figure 1. Oswestry disability index scores over time. The left-hand panel (blue) shows the trajectory of oswestry disability index scores for each patient in the conventional spinal cord stimulator group during the 12 month follow-up period. Right hand panel (red) shows the trajectory of high-frequency (HF) spinal cord stimulator patients.

Table 3. Mixed-Effects Model for Oswestry Disability Index Scores: Comparing HF-SCS vs. C-SCS

Characteristic	***β***	**95% CI**	***P***
Treatment group (HF-SCS vs. conventional SCS)	0.26	−4.9, 5.4	.92
Time (baseline vs. 3 months, 6 months, 12 months)			
3 months	−3.3	−8.3, 1.8	.20
6 months	−5.3	−10, −0.28	.04
12 months	−3.8	−8.9, 1.3	.14
Treatment group * time			
Treatment group * 3 months	−11	−18, −3.4	.004
Treatment group * 6 months	−5.3	−13, 2.0	.16
Treatment group * 12 months	−2.3	−9.6, 5.0	.53

Beta values indicate the change in the outcome for that timepoint. Interaction analysis shows whether High Frequency or Conventional SCS had different effect magnitude in reducing the symptoms for that timepoint.
C-SCS, conventional spinal cord stimulator; HF-SCS, high-frequency spinal cord stimulator.

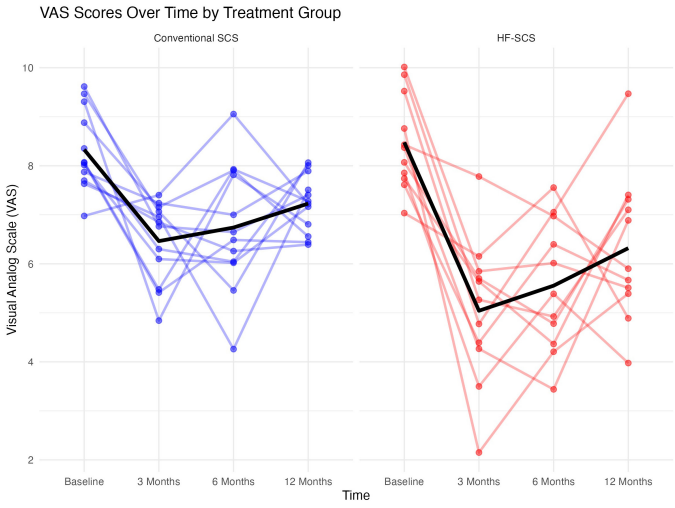

Figure 2. Visual analog scale over time: Left-hand panel (blue) shows the trajectory of visual analog scale (VAS) scores for each patient in the conventional spinal cord stimulator group during the 12 month follow up period. Right hand panel (red) shows the trajectory of high-frequency (HF) spinal cord stimulator patients.

reduced depression and anxiety, better pain management, and enhanced quality of life.[14-16] Consequently, HF-SCS may offer particular benefits for patients who are sensitive to the side effects of C-SCS or who have not responded optimally to it. However, the extent to which these benefits translate into clinically significant differences over extended periods remains to be fully elucidated in larger, long-term studies.

A number of studies evaluated the efficacy of transitioning from C-SCS to HF-SCS in cases where C-SCS has proven ineffective. A retrospective study of 256 patients treated with HF-SCS for various persistent chronic pain conditions, including back, head, neck, leg, and shoulder pain, has observed the effectiveness of HF-SCS as a treatment option, including for chronic pain that failed to respond to C-SCS.[17] Recent studies have also shown that switching to HF-SCS is a viable alternative treatment option for better and permanent pain relief in patients who initially responded but experienced a loss of effectiveness with C-SCS treatment.[18]

The choice between HF-SCS and C-SCS should be guided by patient-specific factors.[13] High-frequency SCS may be particularly well-suited for patients who are sensitive to paresthesia or require rapid pain relief.

High-frequency SCS systems are generally more costly than conventional systems, which could be a constraining factor in some healthcare settings, particularly in low- and middle-income countries where C-SCS remains a viable option.[4,19] Future research should focus on cost-benefit analyses that take into account not only the initial costs but also the long-term outcomes, including the need for revisions, complications, and overall patient satisfaction.[19-21]

This study has several limitations. Firstly, the financial burden of these systems was not analyzed. Secondly, we did not evaluate the etiology of the symptoms (e.g., lower back pain, leg pain, or both). Thirdly, the impact of surgical treatment on stabilization, post-laminectomy, or simple discectomy was not considered. Furthermore, the evaluation of chronic pain-associated depression, which is prevalent in FBSS patients, was not undertaken. Finally, comorbidities of the patients included in the study were not considered in the analysis.

In conclusion, this study shows that both HF-SCS and C-SCS are effective in the management of FBSS. While HF-SCS offers an early advantage in terms of pain relief, the long-term outcomes of both modalities are comparable. The decision to use one modality over the other should be guided by patient-specific factors, clinical goals, and economic considerations. Further research is needed to explore the long-term benefits, cost-effectiveness, and patient-reported outcomes associated with these therapies.

Table 4. Mixed-Effects Model for Visual Analog Scale Scores: Comparing HF-SCS vs. Conventional SCS

Characteristic	*β*	95% CI	*P*
Treatment group (HF-SCS vs. conventional SCS)	0.16	−0.76, 1.1	.74
Time (baseline vs. 3 months, 6 months, 12 months)			
3 months	−1.9	−2.8, −0.97	<.001
6 months	−1.6	−2.5, −0.69	<.001
12 months	−1.1	−2.0, −0.20	.02
Treatment group * time			
Treatment group * 3 months	−1.6	−2.9, −0.27	.02
Treatment group * 6 months	−1.3	−2.6, −0.03	.04
Treatment group * 12 months	−1.1	−2.4, 0.24	.11

[1]Beta values indicate the change in the outcome for that timepoint. Interaction analysis shows whether high-frequency or conventional SCS had different effect magnitude in reducing the symptoms for that timepoint.
C-SCS, conventional spinal cord stimulator; HF-SCS, high-frequency spinal cord stimulator.

Availability of Data and Materials: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was approved by the Ankara University, Faculty of Medicine (Approval no: 01-10-16, Date: January 11, 2016).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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