Research papers

Spinal cord stimulation for failed back surgery syndrome: Outcomes in a workers' compensation setting

Judith A. Turner [a,*], William Hollingworth [b], Bryan A. Comstock [c], Richard A. Deyo [d]

[a] Department of Psychiatry & Behavioral Sciences and Department of Rehabilitation Medicine, University of Washington, Seattle, WA, USA
[b] Department of Social Medicine, University of Bristol, Bristol, UK
[c] Department of Biostatistics, University of Washington, Seattle, WA, USA
[d] Department of Family Medicine and Department of Internal Medicine, Oregon Health and Science University, Portland, OR, USA

ARTICLE INFO

ABSTRACT

Questions remain concerning effectiveness and risks of spinal cord stimulation (SCS) for chronic back and leg pain after spine surgery ("failed back surgery syndrome" [FBSS]). This prospective, population-based controlled cohort study evaluated outcomes of workers' compensation recipients with FBSS who received at least a trial of SCS (SCS group, n = 51) versus those who (1) were evaluated at a multidisciplinary pain clinic and did not receive SCS (Pain Clinic, n = 39) or (2) received neither SCS nor pain clinic evaluation (Usual Care, n = 68). Patients completed measures of pain, function, medication use, and work status at baseline and 6, 12, and 24 months later. We also examined work time loss compensation over 24 months. Few (<10%) patients in any group achieved success at any follow-up on the composite primary outcome encompassing less than daily opioid use and improvement in leg pain and function. At 6 months, the SCS group showed modestly greater improvement in leg pain and function, but with higher rates of daily opioid use. These differences disappeared by 12 months. Patients who received a permanent spinal cord stimulator did not differ from patients who received some pain clinic treatment on the primary outcome at any follow-up (<10% successful in each group at each follow-up) and 19% had them removed within 18 months. Both trial and permanent SCS were associated with adverse events. In sum, we found no evidence for greater effectiveness of SCS versus alternative treatments in this patient population after 6 months.

© 2009 International Association for the Study of Pain. Published by Elsevier B.V. All rights reserved.

1. Introduction

Spinal cord stimulation (SCS) has been used since the 1960s to treat intractable pain, including chronic back and leg pain that has failed to improve after spine surgery ("failed back surgery syndrome" [FBSS]). SCS devices and implantation methods vary, but all involve insertion into the epidural space of electrodes connected to an electrical pulse generator. A trial is performed and is followed by a permanent implantation only if the trial is successful in relieving pain.

The first of two randomized controlled trials (RCT) of SCS for FBSS reported more favorable results for SCS than for lumbar spine reoperation at long-term follow-up (mean 2.9 years, range 1.8–5.7 years) [19]. However, 39% of eligible patients did not participate in the study because they preferred reoperation and patients receiving workers' compensation benefits were less likely than those with other insurance to be randomized and treated. These factors may limit the study's generalizability. Furthermore, the study design did not allow comparisons to other treatments; reoperation may have worsened patient outcomes [31].

In an international multi-center RCT, 100 patients with FBSS were randomized to conventional medical management with or without SCS [14]. At 6 months, 48% of the patients randomized to SCS but just 9% of the patients randomized to conventional management only achieved ⩾50% improvement in leg pain. The SCS group also had better back pain, physical functioning, and other quality of life outcomes. The study is commendable for many strengths [28], although one limitation is that the comparison condition was treatment patients had already failed rather than an alternative new treatment. Also, conclusions regarding the long-term efficacy of SCS are hampered by the high crossover rate after 6 months [15]. Workers' compensation recipients were not included in this study. Such patients may have worse outcomes with any pain therapy [1,3,12].

Thus, there is a need for evidence concerning the long-term effectiveness of SCS as compared with alternative treatments for

* Corresponding author. Address: University of Washington School of Medicine, Department of Rehabilitation Medicine, Department of Psychiatry & Behavioral Sciences, 1959 NE Pacific St., Room BB1517a, Box 356560, Seattle, WA 98195-6560, USA. Tel.: +1 206 543 3997; fax: +1 206 685 1139.
E-mail address: jturner@u.washington.edu (J.A. Turner).

patients with FBSS in the context of a workers' compensation environment. In 2004, the Washington State Workers' Compensation Program began to cover SCS for patients with FBSS who were receiving work time loss compensation provided that they met specific clinical criteria and agreed to participate in an independent study to evaluate the outcomes of patients referred for SCS. In a prospective controlled cohort study, we compared the pain, functioning, medication use, and work outcomes of this group of patients to those of other workers' compensation recipients who met the same criteria, but who: (1) were evaluated at a multidisciplinary pain clinic and did not receive a trial of SCS (Pain Clinic group) or (2) received neither trial SCS nor pain clinic evaluation (Usual Care group). We also examined adverse events associated with SCS. This pragmatic study was designed to assess the effectiveness and risks of SCS for Washington State workers' compensation claimants under usual practice conditions.

2. Methods

2.1. Overview of participants, setting, and procedures

Health care providers registered with the Washington State Department of Labor and Industries (which administers the workers' compensation program) were notified of the study in November 2004. Providers were informed that the Department would cover SCS for patients who had a current workers' compensation claim administered by the State Fund (which insures approximately two-thirds of non-federal Washington workers) provided that the patient met eligibility criteria (listed below) for and agreed to participate in a study of SCS outcomes. Physicians referred patients who were candidates for SCS and who appeared to meet the study eligibility criteria for administrative review. Patients who still appeared to meet the study entry criteria after administrative review were referred to the research team for final screening and enrollment. The Pain Clinic and Usual Care cohorts were assembled by approaching patients identified as potentially eligible from administrative data reviews, as described in Sections 2.3–2.5. Patients were enrolled in the study between December 2004 and June 2006. The University of Washington Institutional Review Board reviewed and approved the study methods, and all participants provided informed consent. All participants were informed that the study was being conducted by the University of Washington independent of the workers' compensation program, that all information provided by patients would be kept strictly confidential, that no individual patient data would be released to the workers' compensation program, and that the decision to participate or not in the study would not affect their workers' compensation benefits (other than participation being necessary to receive coverage for SCS).

To participate in the study, all patients were required to have an open Washington State workers' compensation claim for a back injury and to be receiving work time loss compensation due to temporary total inability to work because of the injury. In Washington State, workers' compensation claims are closed when an injured worker is judged to be able to work or to be permanently disabled. At that time, medical benefits and work time loss compensation end; the worker may receive a permanent partial disability award or a pension for permanent total disability.

Other study inclusion criteria for all patients were: (1) pain radiating into one or both legs for more than 6 months; (2) radicular pain greater than axial pain; (3) average leg pain in the last month rated 6 or greater on a 0–10 scale; (4) no previous SCS surgery; (5) no current diagnosis of diabetes or cancer; and (6) ability to speak English or Spanish. In the initial phase of subject recruitment, additional inclusion criteria were age between 18 and 55 years, claim of less than 3 years' duration, and one or two previous open lumbar spine operations during the current claim. After slow initial enrollment, these three criteria were broadened to age 18–60 years, claim of any duration, and 1–3 previous open lumbar spine operations during the claim.

2.2. SCS group

Washington State workers' compensation claimants who potentially were good candidates for SCS, appeared to meet the study inclusion criteria, and did not have progressive motor deficit, bony deformity, or any contraindication for surgery were initially identified by their physicians. Physicians who recommended a trial of SCS to such patients informed them that the workers' compensation program would cover SCS only if the patient agreed to participate in the independent study. Patients who desired a trial of SCS and were willing to participate in the study were referred for administrative review, involving examination of the medical and administrative records to confirm that the patient met the study inclusion criteria. Patients provisionally accepted for SCS were mailed a study information statement and were telephoned by the research team for screening on the study inclusion criteria. If the patient met the study inclusion criteria and consented to participate, the physician and patient were informed that the SCS procedure could be scheduled. Patients referred to the study were free to decline to participate and to change their mind about undergoing a trial of SCS. The workers' compensation fund did not cover SCS if a patient declined to participate in the study, but patients could still receive SCS if they paid for it themselves or had other insurance coverage.

2.3. Pain Clinic group

Patients potentially eligible for the Pain Clinic group were identified from workers' compensation administrative databases at the time they were approved for pain clinic evaluation. Patients who met the claim, time loss compensation, past surgery, and age inclusion criteria were sent a letter with study information and were telephoned by research staff for eligibility screening, informed consent, and enrollment.
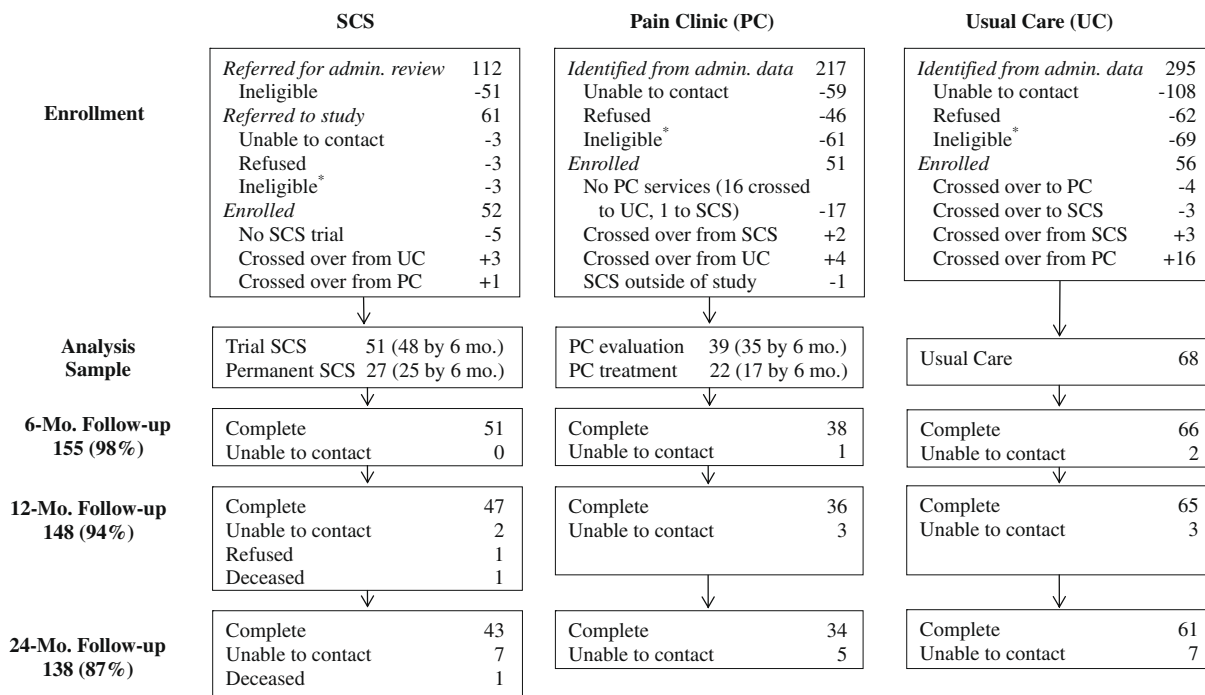
2.4. Usual Care group

Each month the research team received a list of all workers' compensation recipients who currently met the claim, time loss compensation, past surgery, and age inclusion criteria, and who had not been referred for SCS or pain clinic evaluation. Each week, eight patients were selected randomly from this list, sent a letter with study information, and telephoned for screening. Patients who met the inclusion criteria, provided informed consent, and enrolled in the study formed the Usual Care group.

2.5. Initial study enrollment

Our enrollment goal was 50 patients in each group. Among 573 claimants approached for participation, 170 could not be contacted, 111 declined to enroll, 133 were not eligible, and 159 enrolled in the study (Fig. 1). The most common reason for exclusion was leg pain not worse than back pain.

Among 112 patients who underwent administrative review for SCS, 51 (46%) were not eligible for the study (e.g., did not have 1–3 prior lumbar spine operations). The remaining 61 patients were referred to the research team for final study screening and consent procedures; 52 (85%) patients (referred by 19 physicians) were eligible and enrolled in the study. Enrollment rates in the Pain Clinic ($n = 51$) and Usual Care ($n = 56$) groups were much lower than in the SCS group due to higher rates of patients who (1) could not

	SCS	Pain Clinic (PC)	Usual Care (UC)

Enrollment

SCS		Pain Clinic (PC)		Usual Care (UC)	
Referred for admin. review	112	*Identified from admin. data*	217	*Identified from admin. data*	295
Ineligible	-51	Unable to contact	-59	Unable to contact	-108
Referred to study	61	Refused	-46	Refused	-62
Unable to contact	-3	Ineligible*	-61	Ineligible*	-69
Refused	-3	*Enrolled*	51	*Enrolled*	56
Ineligible*	-3	No PC services (16 crossed		Crossed over to PC	-4
Enrolled	52	to UC, 1 to SCS)	-17	Crossed over to SCS	-3
No SCS trial	-5	Crossed over from SCS	+2	Crossed over from SCS	+3
Crossed over from UC	+3	Crossed over from UC	+4	Crossed over from PC	+16
Crossed over from PC	+1	SCS outside of study	-1		

Analysis Sample

SCS		Pain Clinic (PC)		Usual Care (UC)	
Trial SCS	51 (48 by 6 mo.)	PC evaluation	39 (35 by 6 mo.)	Usual Care	68
Permanent SCS	27 (25 by 6 mo.)	PC treatment	22 (17 by 6 mo.)		

6-Mo. Follow-up 155 (98%)

SCS		Pain Clinic (PC)		Usual Care (UC)	
Complete	51	Complete	38	Complete	66
Unable to contact	0	Unable to contact	1	Unable to contact	2

12-Mo. Follow-up 148 (94%)

SCS		Pain Clinic (PC)		Usual Care (UC)	
Complete	47	Complete	36	Complete	65
Unable to contact	2	Unable to contact	3	Unable to contact	3
Refused	1				
Deceased	1				

24-Mo. Follow-up 138 (87%)

SCS		Pain Clinic (PC)		Usual Care (UC)	
Complete	43	Complete	34	Complete	61
Unable to contact	7	Unable to contact	5	Unable to contact	7
Deceased	1				

* Reasons for ineligiblity were no leg pain (n=17 across groups), leg pain < 6 months (n=4), leg pain not worse than back pain (n=72), leg pain intensity < 6 on 0-10 scale (n=17), diabetes or cancer (n=15), and unable to complete interviews due to language barrier (n=2). No reason was recorded for 6 patients.

Fig. 1. Subject flow through study.

be contacted, (2) were contacted but ineligible, and (3) were eligible but declined to enroll.

2.6. Interventions

Decisions regarding treatments were left to the patients and their health care providers. In the case of SCS, the physicians determined the SCS trial procedures and equipment, any requirements for patient psychological screening, the criteria for proceeding with a permanent implant, and the permanent implant procedures and equipment. Similarly, in the Pain Clinic group, the pain clinic clinicians decided whether the patient would be treated in the pain clinic program and if so, the program length and content.

2.7. Measures

2.7.1. Baseline characteristics

Workers' compensation administrative databases were used to obtain information regarding patient age, gender, industry, county of residence, claim submission date, and legal representation. In baseline interviews, patients reported on their demographic characteristics, work status, injury history, and medications used for pain. SCS patients also rated their expectations of efficacy of SCS for their pain on a 0–10 scale where 0 = 'not at all helpful' and 10 = 'extremely helpful.'

2.7.2. Outcome measures
2.7.2.1. Self-report measures. Patients completed measures of pain, functioning, work status, medication use, and mental health at baseline (study enrollment) and 6, 12, and 24 months later. Patients were paid $40 each for the baseline and 24-month assessments, and $20 for each of the other assessments. Most assessments were conducted by telephone, but a questionnaire was mailed to patients who could not be reached by telephone.

In each interview, patients were asked to rate the average intensity of their leg pain in the last month on a scale of 0 (no pain) to 10 (pain as bad as could be). Physical functioning was assessed by the Roland-Morris Disability Questionnaire (RDQ) [23]. RDQ scores range from 0 to 24, with higher scores indicating greater disability.

Patients were also asked in each interview about treatments used for pain, and to name every medication they took for back or leg pain more than five times in the past month and the number of days they used it. We considered less than 28 days to be less than daily. We used the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology Anatomical Therapeutic Chemical/Defined Daily Dose (ATC/DDD) Index (http://www.whocc.no/atcddd/) to group medications into seven categories: opioids, sedative-hypnotics (including benzodiazepines and anti-anxiety medications), muscle relaxants, non-opioid analgesics (nonsteroidal anti-inflammatory drugs and acetaminophen), antidepressants, anticonvulsants, and other.

At each interview, patients also completed the SF-36 version 2 [32] Mental Health scale and measures of average back pain intensity in the past month (0–10 scale) and work status. The Mental Health scale is normalized such that a score of 50 equals the mean score in the US population and lower scores indicate worse mental health. At each follow-up, patients who had received a permanent SCS implantation were asked whether they still had the device implanted and, if so, how many days they used it in the past month and for how many hours each day. At 12 and 24 months, patients were asked about their ability to perform everyday tasks compared to 1 year ago.

2.7.2.2. Primary outcome. The primary outcome, specified prior to beginning the study, was a composite measure of therapeutic success, defined as ≥50% reduction (relative to baseline) in leg pain, a 2-point or greater improvement on the RDQ, and less than daily opioid medication use. These outcomes are consistent with the

clinical goals of SCS, which include pain relief, improvement in function, return to work (when possible), and reduction in medication use [18]. At that time, 50% improvement in pain was a common measure of success in studies of SCS and was regarded as a standard for clinically meaningful improvement in chronic pain [9,18]. We added a very modest improvement in function (2-point RDQ improvement) to the definition of success. We added the opioid medication dimension because it would be difficult to interpret the independent benefit of SCS in patients who use opioid medication daily. Furthermore, it could be argued that patients with a successful outcome would not require daily opioid use. We also examined leg pain intensity, RDQ scores, and opioid medication use separately. The primary endpoint was 12 months.

2.7.2.3. Alternate definitions of clinically meaningful improvement. There is a growing consensus that a 2-point change on the RDQ is of dubious clinical importance and that a $\geqslant$30% or $\geqslant$5-point decrease on the RDQ represents the minimal clinically meaningful improvement in physical function [13,20]. Furthermore, recent evidence supports $\geqslant$30% improvement in pain intensity rating as a clinically meaningful difference and $\geqslant$50% as substantial improvement [8,9,20]. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group recommended reporting both the proportion with $\geqslant$30% and the proportion with $\geqslant$50% pain relief in clinical trials of chronic pain treatments [8]. Therefore, we also examined the proportions in each treatment group who achieved improvement by these alternate criteria.

2.7.2.4. Work disability days and status. Workers' compensation administrative data were used to calculate the number of days patients received work time loss compensation, as well as time loss compensation status, 12 and 24 months from study enrollment.

2.7.3. Adverse events

The Department of Labor and Industries keeps copies of all medical records related to assessment and treatment of claimants' work injuries. The Principal Investigator (PI) and a surgeon experienced in SCS surgery trained a research coordinator to review these records for each SCS patient and to record on a structured form information concerning trial and permanent SCS procedures as well as related adverse events and subsequent operations. The medical records of nine (18%) randomly selected SCS patients were abstracted independently by both the PI and the research coordinator; there was excellent agreement. In addition, for each patient identified as having an adverse event or further surgery related to SCS, the PI double-checked the completed abstraction form against the medical records. We did not record adverse events related to other therapies (e.g., medications, non-SCS operations) in any of the three groups.

2.8. Statistical analysis

2.8.1. Analysis sample

Some participants did not receive the anticipated therapy (SCS or Pain Clinic treatment). For analysis, we defined treatment groups by evaluation and treatment received during the year after enrollment, according to billing information provided by the workers' compensation program (confirmed by self-report for all patients and also by medical record review for SCS patients). Fig. 1 provides information concerning crossovers from original study groups. Primary analyses compared the SCS group (patients who received at least a trial of SCS within 1 year of enrollment) to the Pain Clinic group (patients who received multidisciplinary pain clinic evaluation) and Usual Care group (patients who received neither trial SCS nor pain clinic evaluation within 1 year). For patients who crossed over to the SCS

group after enrolling in another group, assessments were rescheduled to take place at the time of SCS referral (before undergoing trial SCS) and 6, 12, and 24 months later. The final analysis sample included 51 patients in the SCS group, 39 patients in the Pain Clinic group, and 68 patients in the Usual Care group.

2.8.2. Group comparisons

Baseline characteristics of the SCS group were compared with those of the Pain Clinic and Usual Care groups using *t*-tests for normally distributed continuous or ordinal measures, Fisher's exact test for categorical variables, and the Kruskal–Wallis *H* test for continuous or ordinal measures with skewed distributions. It is recommended that studies using composite outcomes also report results for each component of the composite [27]. To compare the SCS group with the other groups on each of the individual components of the primary outcome measure, we used a logistic regression analysis with treatment group as an independent variable, adjusting for the baseline value of the criterion. The small number of successes precluded adjustment for baseline measures in logistic regression analyses of the composite outcome.

For analyses of continuous self-report outcome measures, which allowed adjustment for more factors, we conducted a series of regression analyses to identify the most important potential confounders. Our criteria for inclusion as a covariate were either: (1) association ($P < 0.10$) with treatment group and with 12-month (the primary endpoint) RDQ or leg pain score, or (2) addition of the potential covariate to baseline RDQ (or leg pain) and treatment group in the model predicting 12-month RDQ (or leg pain) resulted in >10% change in the coefficient for the treatment effect and a *P*-value < 0.25 for the potential covariate. For one of the identified covariates (legal representation), data were missing for five patients; we multiply imputed 10 values for the missing cases and combined the results using Stata's (StataCorp, College Station, TX) ice command. Sensitivity analyses indicated that the results of models that used imputed values for the missing data were comparable to those of models that did not. The following baseline variables were identified as potential confounders: age, gender, RDQ score (predicting leg pain intensity), leg pain intensity (predicting RDQ), duration of work time loss compensation, disability benefit in addition to workers' compensation (yes or no), unilateral versus bilateral leg pain, legal representation (yes or no), and SF-36 Mental Health. For each continuous outcome measure at each follow-up, we constructed a linear regression model with treatment group as an independent variable, adjusting for these baseline confounding variables and the baseline value of the outcome measure. We compared the groups on the work time loss outcomes using linear regression (for number of days) and logistic regression (for proportions), adjusting for baseline time loss duration.

Whether or not *P*-values should be adjusted for multiple comparisons is controversial [21,24]. We elected not to adjust for multiple comparisons because of the increased likelihood of Type II errors. We considered all statistical tests as significant at a 2-sided $P < 0.05$. In interpreting the findings, we placed emphasis on consistent patterns and on clinically as well as statistically meaningful differences between groups. All statistical analyses were conducted using Microsoft Excel 2000 and Stata/IC 10.0 (StataCorp, College Station, TX).

3. Results

3.1. Baseline characteristics and follow-up completion

The average age of study participants was 44 years and participants were predominantly male (Table 1). At baseline, the three groups were similar on most demographic, work, and pain

Table 1
Baseline characteristics of the three study groups.

	Spinal cord stimulator (n = 51)	Pain Clinic (n = 39)	Usual Care (n = 68)	P-value[*] SCS	
				versus PC	versus UC
Age mean (SD), years[a]	44.7 (7.8)	43.2 (6.5)	44.1(8.7)	0.39	0.70
Male[a]	78%	67%	82%	0.24	0.64
Caucasian[b]	84%	90%	88%	0.54	0.59
Hispanic[b]	6%	10%	6%	0.46	0.99
Some college education or higher[b]	41%	28%	31%	0.27	0.25
Married[b]	63%	62%	56%	0.99	0.57
Job in construction industry[a]	33%	21%	34%	0.24	0.99
Months from claim submission to study enrollment, median (IQR)[a]	46 (30–82)	28 (18–63)	38 (24–62)	0.02	0.22
Lumbar operations in claim, mean (SD)[a]	1.6 (0.8)	1.4 (0.6)	1.5 (0.7)	0.31	0.32
Legal representation[a,c]	49%	26%	29%	<0.01	<0.01
Work time loss compensation duration, months, median (IQR)[a]	39 (20–53)	24 (14–37)	30 (18–51)	0.01	0.26
Disability benefit in addition to DLI (e.g., SSDI, private)[b]	16%	10%	19%	0.54	0.81
Work status[b]					
Not working	98%	97%	93%	0.68	0.45
Working	2%	0%	3%		
Other (e.g., student, retired)	0%	3%	4%		
Leg pain duration, months, median (IQR)[b]	48 (29–74)	31 (14–49)	36 (25–65)	0.02	0.25
Leg pain intensity (0–10), past month, mean (SD)[b]	7.7 (1.0)	7.3 (1.1)	7.2 (1.1)	0.07	0.02
Pain in both legs[b]	47%	41%	41%	0.67	0.58
Back pain intensity (0–10), past month, mean (SD)[b]	6.0 (1.9)	6.3 (1.9)	6.2 (1.8)	0.43	0.56
RDQ (0–24), mean (SD)[b]	21.1 (2.1)	20.1 (2.5)	20.0 (2.4)	0.04	0.01
SF-36v2 Mental Health Scale, mean (SD)[b]	33.6 (12.4)	32.0 (13.1)	35.6 (10.4)	0.53	0.36
Surgeries for back/leg pain, mean (SD)[b]	1.9 (1.0)	1.5 (0.7)	1.8 (0.9)	0.07	0.47
Hospitalization for back/leg pain, mean (SD)[b]	2.5 (2.3)	2.8 (4.0)	2.5 (2.0)	0.59	0.95
Medication taken for back/leg pain, mean (SD) days, past month[b]	27.0 (9.0)	27.0 (8.9)	26.2 (9.3)	0.97	0.66
Medications taken in past month for back/leg pain[b]					
Opioid	86%	77%	78%	0.28	0.34
Benzodiazepine/sedative-hypnotic/anti-anxiety	16%	15%	12%	0.99	0.59
Muscle relaxant	29%	33%	34%	0.82	0.69
Antidepressant	22%	10%	16%	0.25	0.48
Anticonvulsant	31%	21%	25%	0.34	0.54
Non-opioid analgesic	18%	31%	29%	0.21	0.20

DLI = Department of Labor & Industries; IQR = interquartile range; RDQ = Roland Disability Questionnaire; SD = standard deviation; SSDI = Social Security Disability Insurance.
[*] Proportions compared with Fisher's exact test; group means compared with t-tests; group medians compared with the Kruskal–Wallis H test.
[a] Data obtained from DLI.
[b] Data obtained from patient interview.
[c] Legal representation information was obtained from DLI administrative data at the time of study enrollment and reflected notification to DLI that an attorney was involved in the claim. This information was not available for five patients in the SCS group.

characteristics. However, SCS patients were significantly more likely than those in the other groups to have legal representation. In addition, the SCS group had significantly longer work time loss compensation, leg pain, and claim duration as compared with the Pain Clinic, but not the Usual Care, group. Although SCS patients reported significantly greater leg pain intensity than did Usual Care patients and significantly worse physical function than did Pain Clinic or Usual Care patients, the group mean differences were small and well under the threshold for clinically meaningful differences. Patients in all groups reported high levels of physical disability because of their back and leg pain (mean of 20–21 on the 0–24 RDQ scale). The groups did not differ in proportions reporting use of different types of medications for pain. In each group, the majority reported using opioid medication, with substantial minorities also reporting use of sedative-hypnotic, muscle relaxant, antidepressant, anticonvulsant, and non-opioid analgesic medications.

Follow-up interview completion rates were 98% at 6 months, 94% at 12 months, and 87% at 24 months (Fig. 1). No baseline measure was significantly associated with 12-month follow-up completion. Administrative outcome data (time loss compensation days, claim status) were complete for all participants.

3.2. Primary outcomes: SCS versus Pain Clinic and Usual Care

The three groups did not differ on the primary outcome (the composite index of pain, function, and opioid medication use)

and few patients achieved success by this criterion, at any time point (Table 2). The SCS group did not differ significantly from the other groups on the primary outcome or any of its three components at 12 months (the primary endpoint) or 24 months. At 6 months, rates of ⩾50% improvement in leg pain were higher in the SCS group (9 of 51 patients, 18%) than in the Usual Care (2 of 65 patients, 3%) and Pain Clinic (2 of 38 patients, 5%) groups, but fewer SCS patients reported less than daily opioid use (12% SCS versus 34% Pain Clinic [P = 0.04] and 27% Usual Care [non-significant]). Examining the composite outcome without the opioid use criterion (i.e., success defined as ⩾2-point RDQ improvement and ⩾50% leg pain improvement), the success rate was higher in the SCS group (18%) at 6 months (P = 0.01 in comparisons with both the Pain Clinic [0%] and the Usual Care [3%] groups), but comparable among the three groups at 12 and 24 months (all success rates < 17%, P-values 0.23–0.99; all analyses adjusted for baseline leg pain and RDQ).

3.3. Alternate success criteria

At 6 months, more SCS patients showed clinically meaningful improvement on the RDQ using each alternate success criterion (⩾5-point improvement: 22% versus 5% each in the Pain Clinic and Usual Care groups, P = 0.03 and 0.01, respectively; ⩾30% improvement: 16% versus 5% Pain Clinic and 3% Usual Care, P = 0.06 and 0.02, respectively). However, only 4% of SCS patients

Table 2
Rates of successful patient outcomes as indicated by self-reported physical function, leg pain, and opioid medication use at 6, 12, and 24 months.

	Spinal cord stimulator (%)	Pain Clinic (%)	Usual Care (%)	P-value[*] SCS	
				versus PC	versus UC
⩾2-point improvement in RDQ relative to baseline					
6 months	41	29	32	0.38	0.32
12 months	32	36	48	0.69	0.07
24 months	51	41	44	0.50	0.53
⩾50% improvement in leg pain relative to baseline					
6 months	18	5	3	0.09	0.02
12 months	15	8	17	0.46	0.69
24 months	16	15	21	0.66	0.62
Less than daily opioid use					
6 months	12	34	27	0.04	0.17
12 months	19	25	31	0.87	0.43
24 months	21	32	34	0.53	0.24
Primary outcome (all three criteria)					
6 months	4	0	0	0.51	0.19
12 months	4	0	5	0.50	0.99
24 months	5	3	10	0.99	0.47

RDQ = Roland Disability Questionnaire.
See Fig. 1 for n at each follow-up.
[*] P-values from logistic regression models adjusted for the baseline value of the outcome measure (i.e., baseline RDQ for the RDQ analysis, baseline leg pain for the leg pain analysis, baseline opioid use for the opioid analysis) except for the primary outcome, which was calculated using Fisher's exact text.

achieved success on the alternate composite outcome (5-point RDQ improvement, 30% leg pain improvement, less than daily opioid use) at 6 months, and at 12 and 24 months, the SCS group did not differ significantly from either comparison group on any alternate success criterion.

3.4. Physical function and leg pain

The three groups showed modest and similar improvements in RDQ scores over the 24 months of the study (Table 3). At 6 months, the mean score on the 0–24 RDQ scale, adjusted for baseline differences, was 1.2 points (95% CI, 0.0–2.4) lower (better) in the SCS group than in the Usual Care group (P = 0.049). However, the SCS group did not differ significantly on the RDQ from the Pain Clinic group at 6 months or from either comparison group at 12 and 24 months. All three groups also showed modest improvements in leg pain over time, with no differences between groups, adjusting for baseline factors, at any time point.

3.5. Self-reported back pain, mental health, everyday function, and medication use

At 12 and 24 months, adjusting for baseline differences, the SCS group did not differ significantly from the Usual Care or Pain Clinic groups in back pain intensity, Mental Health scores, or opioid medication use (Table 4). As at baseline, the majority of patients in each group reported using opioid medication at 12 and 24 months. There were also no differences between groups in ratings of ability to perform everyday tasks. At 12 months, in each group, substantially more patients said their ability to perform everyday tasks was worse (34–50%) relative to a year ago than said it was better (14–19%).

3.6. Work and claim status

Fewer than 10% of patients in each group were working at 12 months (Table 5). By 24 months, slightly less than one-fourth

Table 3
Observed RDQ and leg pain scores, and adjusted comparisons of treatment groups.

	Spinal cord stimulator Mean[a] (SD)	Pain Clinic Mean[a] (SD)	Adjusted mean difference[b] (95% CI)	Usual Care Mean[a] (SD)	Adjusted mean difference[b] (95% CI)
RDQ (0–24)					
Baseline	21.1 (2.1)	20.1 (2.4)	–	20.0 (2.4)	–
6 months	19.0 (4.1)	19.4 (3.2)	1.1 (−0.2, 2.4)	19.4 (2.9)	1.2 (0.0, 2.4)[*]
12 months	18.9 (4.8)	18.8 (4.0)	0.4 (−1.2, 2.0)	18.4 (3.7)	0.2 (−1.2, 1.6)
24 months	18.1 (4.8)	17.9 (4.7)	0.5 (−1.4, 2.4)	17.5 (5.1)	0.1 (−1.6, 1.7)
Leg pain (0–10)					
Baseline	7.7 (1.0)	7.3 (1.1)	–	7.2 (1.1)	–
6 months	6.3 (2.3)	6.8 (2.1)	0.8 (−0.1, 1.7)	6.2 (1.6)	0.3 (−0.5, 1.0)
12 months	6.8 (1.9)	7.0 (1.7)	0.6 (−0.2, 1.3)	5.8 (2.2)	−0.6 (−1.3, 0.2)
24 months	6.3 (2.0)	6.2 (2.1)	0.4 (−0.6, 1.3)	5.7 (2.1)	−0.2 (−1.0, 0.6)

RDQ = Roland Disability Questionnaire.
[a] Unadjusted mean.
[b] Regression model coefficient comparing treatment groups, adjusted for the following baseline variables: age, gender, RDQ score, leg pain intensity, duration of work time loss compensation, disability benefit in addition to workers' compensation (yes or no), unilateral versus bilateral leg pain, legal representation (yes or no), and SF-36 Mental Health. A mean difference greater than zero (i.e., a positive mean difference) indicates that the treatment group had a worse outcome relative to the SCS group, adjusting for the baseline variables.
[*] P = 0.049; all other adjusted mean differences are not statistically significant.

Table 4
Self-report measures of back pain intensity, mental health, ability to perform everyday tasks, and medication use at 12 and 24 months.

	Spinal cord stimulator (n = 47)	Pain Clinic (n = 36)	Usual Care (n = 65)	P-value[*] SCS	
				versus PC	versus UC
Back pain intensity, mean (SD)					
12 months	6.8 (2.1)	7.2 (2.0)	6.3 (1.9)	0.23	0.88
24 months	6.6 (1.8)	6.6 (1.8)	6.1 (2.3)	0.76	0.76
Mental Health, mean (SD)					
12 months	33.3 (14.2)	31.9 (12.6)	34.7 (11.7)	0.47	0.65
24 months	38.7 (13.7)	36.8 (11.9)	36.3 (12.9)	0.47	0.10
Ability to perform daily tasks (compared to 1 year ago), n (%)					
12 months				0.21	0.89
Much/somewhat better	8 (17%)	7 (19%)	9 (14%)		
About the same	23 (49%)	11 (31%)	32 (49%)		
Much/somewhat worse	16 (34%)	18 (50%)	24 (37%)		
24 months				0.35	0.75
Much/somewhat better	14 (33%)	7 (21%)	16 (26%)		
About the same	15 (34%)	11 (32%)	25 (41%)		
Much/somewhat worse	14 (33%)	16 (47%)	20 (33%)		
Medications taken in past month for back/leg pain					
12 months					
Opioid	40 (85%)	27 (75%)	46 (71%)	0.27	0.11
Benzodiazepine/sedative-hypnotic/anti-anxiety	13 (28%)	7 (19%)	10 (15%)	0.45	0.16
Muscle relaxant	19 (40%)	11 (31%)	17 (26%)	0.49	0.15
Antidepressant	6 (13%)	3 (8%)	8 (12%)	0.73	0.99
Anticonvulsant	10 (21%)	6 (17%)	13 (20%)	0.78	0.99
Non-opioid analgesic	8 (17%)	5 (14%)	15 (23%)	0.77	0.49
24 months					
Opioid	36 (84%)	25 (74%)	43 (71%)	0.40	0.16
Benzodiazepine/sedative-hypnotic/anti-anxiety	8 (19%)	5 (15%)	12 (20%)	0.77	0.99
Muscle relaxant	16 (37%)	9 (27%)	15 (25%)	0.34	0.20
Antidepressant	7 (16%)	4 (12%)	9 (15%)	0.75	0.99
Anticonvulsant	14 (33%)	2 (6%)	10 (16%)	<0.01	0.06
Non-opioid analgesic	10 (23%)	7 (21%)	11 (18%)	0.99	0.62

[*] Comparisons of groups on back pain intensity and mental health in linear regression analyses were adjusted for age, gender, and the following baseline variables: Roland Disability Questionnaire score, leg pain intensity, duration of work time loss compensation, disability benefit in addition to workers' compensation (yes or no), unilateral versus bilateral leg pain, Mental Health score, and legal representation (yes or no). The analysis for back pain intensity also adjusted for back pain intensity at baseline. Ability to perform everyday tasks was compared using Fisher's exact test with a continuity correction for small cell counts, not adjusting for other factors. Medication use was compared using logistic regression and adjusted for use of the medication (yes, no) at baseline.

of patients in each group reported that they were working. The groups did not differ significantly in work status at either time point. Administrative data were consistent with patient-reported data. The majority of patients (71–82% across groups) were still receiving work time loss compensation or on pension at 12 months (Table 5). This rate decreased to 56–73% at 24 months. The groups did not differ significantly in proportion on work time loss compensation or pension, proportion with closed claims, or days of time loss compensation at either 12 or 24 months.

3.7. Permanent stimulator implantation versus pain clinic treatment

Among the 51 patients who had trial SCS, 27 (53%) received a permanent stimulator. Thirteen (25%) of the 51 SCS group patients had a psychological screening for SCS, according to DLI administrative data. Among the 39 Pain Clinic patients, 22 (56%) received at least some pain clinic treatment. Like the full SCS and Pain Clinic groups, fewer than 10% of patients in the SCS permanent stimulator and Pain Clinic treatment subgroups achieved the primary definition of a successful outcome at any time point, with no significant differences between these two subgroups on the composite outcome at any time point (Table 6). Also mirroring results for the entire samples, in the SCS permanent stimulator subgroup as compared with the Pain Clinic treatment subgroup, there were trends towards a higher rate of ⩾50% improvement in leg pain (33% versus 10%, P = 0.06) and a lower rate of less than daily opioid use (15% versus 43%, P = 0.05) at 6 months. There were no signifi-

cant differences on any of the three individual success criteria at 12 or 24 months. Comparisons of the SCS permanent stimulator and Pain Clinic treatment subgroups on RDQ scores and leg pain intensity ratings, adjusted for the baseline covariates, revealed no statistically significant or clinically important difference at 6, 12, or 24 months.

The SCS permanent stimulator subgroup and the Pain Clinic treatment subgroup also did not differ at 12 or 24 months in proportion receiving work time loss or pension benefits or proportion with claim closed (Table 6). At 12 months, only four patients (17%) with permanent stimulators and only one patient in the Pain Clinic treatment group (5%) reported working (P = 0.36); at 24 months, 30% in the permanent stimulator group and 26% in the Pain Clinic treatment group were working (P = 0.99). The two groups did not differ significantly in the number of work time loss compensation days, adjusting for work time loss compensation duration at baseline, at 12 months (SCS mean [SD] = 317 [97] days, Pain Clinic mean [SD] = 302 [94] days, P = 0.77) or 24 months (SCS mean [SD] = 572 [211] days, Pain Clinic mean [SD] 487 [253] days, P = 0.37).

3.8. Subgroup analyses

We conducted post hoc analyses to explore whether there were subgroups within the SCS group that had better or worse pain and function outcomes. We examined two potentially important baseline variables: bilateral versus unilateral leg pain and SF-36v2 Mental Health scores.

Table 5
Work status and disability at 12 and 24 months.

	SCS	Pain Clinic	Usual Care	P-value SCS versus PC	versus UC
Self-reported,[a] 12 months, n (%)	n = 47	n = 36	n = 65		
Work status				0.11	0.99
Working	4 (9%)	2 (6%)	6 (9%)		
Off work, on disability[b]	39 (83%)	24 (67%)	52 (80%)		
Off work, not on disability	4 (9%)	9 (25%)	6 (9%)		
Other	0 (0%)	1 (3%)	1 (2%)		
Self-reported,[a] 24 months, n (%)	n = 43	n = 34	n = 61		
Work status				0.35	0.66
Working	10 (23%)	8 (24%)	14 (23%)		
Off work, on disability[b]	31 (72%)	22 (65%)	39 (64%)		
Off work, not on disability	1 (2%)	4 (12%)	5 (8%)		
Other	1 (2%)	0 (0%)	3 (5%)		
Administrative data[†]	n = 51	n = 39	n = 68		
Time loss days, mean (SD)					
0–12 months	320 (99)	309 (98)	311 (109)	0.95	0.79
0–24 months	589 (215)	526 (235)	532 (245)	0.51	0.29
Time loss or pension, n (%)					
12 months	42 (82%)	28 (71%)	53 (78%)	0.71	0.79
24 months	37 (73%)	22 (56%)	41 (60%)	0.53	0.30
Claim closed, n (%)					
12 months	6 (12%)	8 (21%)	9 (13%)	0.52	0.96
24 months	17 (33%)	17 (43%)	30 (44%)	0.65	0.32

[a] For the self-report measures, proportions were compared using Fisher's exact test with continuity correction for small cell counts.
[b] Workers' compensation or other disability insurance.
[†] Linear or logistic regression analyses comparing groups on mean number of time loss days, proportion on time loss or pension, and closed claim status were adjusted for work time loss compensation duration at baseline.

Table 6
Patients who received a permanent stimulator (n = 27) versus patients who received some Pain Clinic treatment (n = 22).

	Permanent spinal cord stimulator (%)	Pain Clinic treatment %	P-value
⩾2-point improvement in RDQ relative to baseline			
6 months	67	38	0.10[*]
12 months	50	50	0.88[*]
24 months	61	47	0.44[*]
⩾50% improvement in leg pain relative to baseline			
6 months	33	10	0.06[*]
12 months	25	10	0.25[*]
24 months	30	26	0.61[*]
Less than daily opioid use			
6 months	15	43	0.05[*]
12 months	13	20	0.81[*]
24 months	17	42	0.16[*]
All three criteria			
6 months	7	0	0.50[‡]
12 months	4	0	0.99[‡]
24 months	9	5	0.99[‡]
Working			
12 months	17	5	0.36[‡]
24 months	30	26	0.99[‡]
Time loss or pension			
12 months	78	64	0.69[†]
24 months	70	50	0.84[†]
Claim closed			
12 months	11	27	0.18[†]
24 months	30	45	0.50[†]

RDQ = Roland Disability Questionnaire.
[*] P-values calculated from logistic regression models adjusted for the baseline value of the outcome measure.
[‡] P-value calculated using Fisher's exact test.
[†] P-values calculated from logistic regression analyses adjusted for wage replacement compensation duration at baseline.

In each treatment group, patients with unilateral leg pain were more likely than those with bilateral leg pain to show ⩾2-point improvement on the RDQ at 12 months (46%, 52%, and 53% of patients with unilateral leg pain versus 17%, 13%, and 41% of those with bilateral leg pain in SCS, Pain Clinic, and Usual Care, respectively). Patients with unilateral leg pain were also more likely than those with bilateral leg pain to show ⩾50% improvement in leg pain intensity at 12 months in the SCS and Pain Clinic groups (21% and 14% of those with unilateral leg pain versus 9% and none of those with bilateral leg pain in the SCS and Pain Clinic groups, respectively). In the Usual Care group, patients with unilateral leg pain and patients with bilateral leg pain had comparable rates of ⩾50% improvement in leg pain at 12 months (16% and 19%, respectively). The SCS group did not differ significantly from either the Pain Clinic group or the Usual Care group in proportions of unilateral versus bilateral leg pain patients with successful RDQ or leg pain outcomes using these criteria. (Similar patterns, albeit with higher success rates, were observed for the SCS permanent stimulator and Pain Clinic treatment subgroups, with no significant difference between the two treatment groups.) Adjusting for baseline characteristics (age, gender, RDQ, leg pain intensity, work time loss compensation duration, disability benefit in addition to workers' compensation, legal representation, and Mental Health score), there was no significant leg pain laterality × treatment group interaction effect in predicting 12-month RDQ scores (P = 0.66 for SCS versus Pain Clinic and P = 0.80 for SCS versus Usual Care) or leg pain intensity scores (P = 0.28 for SCS versus Pain Clinic and P = 0.19 for SCS versus Usual Care).

In each treatment group, patients whose Mental Health scores were in the highest ("best") third of the sample (>40) were more likely than patients with Mental Health scores in the lowest third (<30) to show ⩾2-point improvement on the RDQ at 12 months (57%, 60%, and 54% of patients with scores in the highest third ver-

Table 7a
Self-reported treatments for back or leg pain: Number and percent of patients in each treatment group who reported having had the treatment between baseline and 12 months.

Treatment	SCS (n = 51)		Pain Clinic (n = 38)		Usual Care (n = 66)	
	n	(%)	n	(%)	n	(%)
Surgery (not SCS)	4	(8)	8	(21)	10	(15)
Spinal injection	14	(27)	12	(32)	22	(33)
Physical therapy	12	(24)	28	(74)	26	(39)
Occupational therapy	5	(10)	20	(53)	9	(14)
Massage	6	(12)	6	(16)	8	(12)
Back brace/corset	16	(31)	6	(16)	23	(35)
Psychological therapy	11	(22)	15	(39)	11	(17)
Ultrasound	2	(4)	2	(5)	14	(21)
Bedrest	17	(33)	9	(24)	17	(26)

sus 16%, 25%, and 39% of those with scores in the lowest third in SCS, Pain Clinic, and Usual Care, respectively). This difference did not vary significantly by treatment group. In the SCS and Usual Care groups, patients with better Mental Health scores were also more likely than those with worse scores to show $\geqslant 50\%$ improvement in leg pain intensity at 12 months (29% and 29% of patients with scores in the highest third versus 11% and 18% of patients with scores in the lowest third in SCS and Usual Care, respectively). In the Pain Clinic group, no patients in either the highest or the lowest third of the sample achieved $\geqslant 50\%$ improvement in leg pain intensity at 12 months, but three patients (30%) in the middle third did. (Similarly, in the SCS permanent stimulator subgroup, 40% [n = 4] of those in the highest third and 13% [n = 1] of those in the lowest third achieved $\geqslant 50\%$ improvement in leg pain at 12 months; in the Pain Clinic treatment subgroup, none in the highest or the lowest third, but 33% [n = 2] in the middle third, did.) Adjusting for baseline characteristics, there was no significant Mental Health × treatment group interaction effect in predicting 12-month RDQ scores (P = 0.66 for SCS versus Pain Clinic and P = 0.80 for SCS versus Usual Care) or leg pain intensity (P = 0.28 for SCS versus Pain Clinic and P = 0.19 for SCS versus Usual Care).

3.9. Treatments received

Table 7a shows the pain treatments received by patients in each group during the first year after enrollment, as reported in the 6-month and 12-month interviews. Patients in each group reported a variety of treatments. Patients in the Pain Clinic group more frequently reported physical therapy, occupational therapy, and psychotherapy, and less frequently reported use of bedrest. Fewer patients in the SCS group reported having had surgery other than SCS, and more patients in the Usual Care group reported having had ultrasound therapy.

Table 7b shows this information for the SCS permanent stimulator subgroup and the Pain Clinic treatment subgroup. As would be expected, patients who received Pain Clinic treatment were sig-

nificantly more likely than patients who received a permanent spinal cord stimulator to have received physical therapy, occupational therapy, and psychological therapy. In addition, four patients in the Pain Clinic treatment group reported some kind of surgery other than SCS, in contrast to no patients who received a permanent stimulators (P = 0.03).

3.10. Permanent SCS implantation: predictors and use

Among all baseline measures, the only significant predictors of receipt of a permanent stimulator in the SCS group were patient age $\leqslant 40$ years (P = 0.04) and high patient expectation of efficacy of SCS. Compared with those whose expectations were <8 on the 0–10 scale, those with ratings $\geqslant 8$ had 3.9 times the odds (95% CI = 1.2–13.1, P = 0.03) of receiving a permanent implant.

Among patients who had a permanent stimulator at the time of assessment, the proportion who used their stimulator every day decreased from 88% at 6 months to 52% at 24 months. The proportion who used the stimulator almost all of the day on a typical day of use decreased from 54% at 6 months to 37% at 24 months.

3.11. Adverse events

Among the 51 patients who had trial SCS, 8 (16%) had an adverse event associated with the trial. Five of these were symptoms of unclear etiology (e.g., dizziness, increased back or leg pain). One patient had fluid leaking from the electrode entry site (no further detail provided) and another experienced a severe post-spinal headache. There was one life-threatening adverse event associated with trial stimulation. This patient developed an extensive epidural abscess diagnosed 1 week after the trial. The patient underwent irrigation and debridement and a T2–L3 hemilaminotomy. The day after surgery, the patient experienced respiratory arrest and required mechanical ventilation.

Permanent implantation was attempted for 28 patients. Table 8 summarizes adverse events noted in medical records over the

Table 7b
Self-reported treatments for back or leg pain: Number and percent of patients in the SCS permanent stimulator and the Pain Clinic treatment subgroups who reported having had the treatment between baseline and 12 months.

Treatment	SCS permanent (n = 27)		PC treatment (n = 21)		P
	n	(%)	n	(%)	
Surgery (not SCS)	0	(0)	4	(19)	0.03
Spinal injection	7	(26)	7	(33)	0.75
Physical therapy	9	(33)	20	(95)	<0.001
Occupational therapy	2	(7)	17	(81)	<0.001
Massage	3	(11)	3	(14)	1.00
Back brace/corset	9	(33)	2	(10)	0.08
Psychological therapy	2	(7)	11	(52)	0.001
Ultrasound	2	(7)	1	(5)	1.00
Bedrest	10	(37)	5	(24)	0.37

P-values calculated from Fisher's exact test.

Table 8
Adverse events associated with attempted permanent SCS implantation ($n = 28$) and documented in medical records in the first 18 months.

Complication	Patients		Comments
	n	%[*]	
Superficial skin/wound infection	3	11	One of these pts underwent surgery for irrigation and debridement at the pulse generator wound site 5 weeks after permanent implantation, but was diagnosed as having only a superficial infection
Deep infection/abscess	1	4	Pt had abscess over signal generator and underwent surgery for wound irrigation, debridement, and stimulator removal. Pt decided not to have equipment replaced
Persistent pain in region of stimulator component	5	19	
Other biological complication	3	11	1. Pt had seizures after permanent implantation which subsided after the stimulator was turned off but resumed after the stimulator was turned on again; pt had stimulator removed 8 months later because of the seizures and insufficient pain relief 2. Pt had discomfort when sitting due to placement of the SCS equipment (>18 months later, pt had 2 revision operations, with second resulting in infection) 3. During attempted placement of a permanent stimulator, there was a dural puncture and CSF leak. The procedure was terminated. The pt was hospitalized for 2 days for neurological monitoring and IV opioid medication. No further attempt was made to implant a stimulator

Stimulator revision (surgical revision, but stimulator not removed)	5	19	1. Pt had 3 revision operations:
			  a. 4 months after permanent implantation, because of pain at generator site, pulse generator was removed then replaced in the same operation in a different site
			  b. 7 months after permanent implantation, pt underwent another surgery because a lead migrated and pt was not obtaining good lower extremity stimulation. During surgery, another lead in the dual lead system migrated, so both leads were removed and replaced with 2 new leads
			  c. 18 months after permanent implantation, due to loss of lower extremity stimulation, electrode was repositioned in another revision operation
			2. Due to lead migration and "SCS malfunction" (no other detail given), revision surgery 17 months after permanent implantation to remove original system and replace with a new system in a different location (same pt described above in comments for superficial infection)
			3. Revision surgery 4 months after permanent implantation due to lead migration (pt had system explanted 20 months after permanent implantation due to ineffectiveness and discomfort)
			4. Pulse generator revision and electrode revision 12 months after permanent implantation due to lead migration
			5. Lead revision surgery 12 months after permanent implantation due to decreased effectiveness of SCS

Stimulator explanted (permanently removed and not replaced)	5	19	1. One of these was the pt with the deep abscess (described above) 2. Removal of equipment 10 months after implantation due to ineffectiveness in relieving pain 3. Explantation 16 months after implantation apparently due to discomfort and ineffectiveness 4. As noted above under "other biological complications," one pt had explantation 8 months after permanent implantation due to seizures and insufficient pain relief 5. 17 months after permanent implantation, system removed due to pain at pulse generator site and decreased effectiveness in relieving pain

Pt = patient, CSF = cerebrospinal fluid, IV = intravenous.
[*] In calculating percents, the denominator was 28 for all events that could be associated with the permanent implantation procedure (infection, other biological complication) and 27 for all events that could only be associated with a completed permanent implantation (pain in region of stimulator component, revision surgery, stimulator explanted).

18 months after permanent implantation. One patient experienced a dural puncture and cerebrospinal fluid leak during attempted permanent implantation, and no further attempt was made for permanent implantation. Among the 27 patients who had a permanent implantation, three (11%) had a superficial infection, one (4%) had a deep infection, five (19%) had persistent pain in the region of the stimulator components that was not due to infection, and three (11%) had a biological complication other than infection or pain at the implant site. Five patients (19%) had revision surgery; one of these had three revision operations in the first 18 months after the permanent implant. Among the seven total revision operations within 18 months, one involved pulse generator revision only (movement of pulse generator due to pain in the region of the original pulse generator site), four were a result of lead migration, and two involved both pulse generator revision and lead revision. Five patients (19%) had the stimulator permanently removed within 18 months after implantation (four due to ineffectiveness in relieving pain; in the fifth case, the equipment was removed due to infection and the patient decided not to have it replaced).

4. Discussion

Workers' compensation claimants with FBSS who received at least a trial of SCS, as compared with those evaluated at a pain clinic and with those who received neither SCS nor pain clinic evaluation, showed modestly greater improvement in leg pain and function at 6 months, but also were more likely to report daily opioid medication use. At baseline, there were indications that the SCS group was at higher risk than the other groups for poor outcomes, but even after adjusting for baseline differences, the SCS group did not differ from the other groups at 12 or 24 months on any outcome, including leg pain intensity, physical function, back pain intensity, and mental health. Outcomes were poor in all groups. At 12 months, in each group, fewer than 6% of patients achieved success on the primary outcome (a composite index of improvement in pain, function, and medication use); fewer than 10% were working; and more than twice as many patients reported a decline as reported improvement in ability to perform everyday tasks.

As in the recent RCT [14], the primary SCS analysis group included all patients who received a trial. Excluding patients who did not respond to trial SCS would introduce bias by weeding out patients unlikely to have good outcomes (not only from SCS but perhaps also from any pain treatment). This approach would suggest only analyzing patients in the other groups who had a favorable initial response to therapy. Although no such screening process exists in usual care, not all patients evaluated at a pain clinic receive treatment.

Comparisons of patients who received permanent SCS to patients who received some pain clinic treatment indicated that, at 6 months, there were trends for patients who received permanent stimulators to be more likely to report clinically meaningful improvement in leg pain but also more likely to report daily opioid

medication use. However, at 12 and 24 months, the groups did not differ in rates of clinically meaningful improvement in leg pain intensity or function, or in work status. At each time point, fewer than 10% in each group achieved success on the primary outcome.

The extent to which the modest benefit of SCS at 6 months reflected active versus nonspecific (placebo) treatment effects, or concomitant opioid use, is unclear. Patients with high expectations of SCS effectiveness had almost four times the odds of a successful trial, consistent with the possibility that expectations played a role.

The trial SCS success rate (53%) was lower than that typically reported (>70%) [14,19,29] and the proportion of SCS patients reporting ⩾50% leg pain improvement was lower than that in the RCTs [14,15,19]. Studies of SCS [16] and of other therapies have found that workers' compensation claimants have worse outcomes [1,3,12]; the extent to which this is somehow related to workers' compensation as opposed to other patient differences (e.g., socioeconomic) is unclear [4].

In addition to the difference in representation of workers' compensation recipients, our study differed from the RCTs in other potentially important ways. Both RCTs were funded by an SCS device manufacturer; in the international RCT, this manufacturer managed all study logistics and collected and analyzed the data. Industry-sponsored studies of drugs and devices yield more favorable results than do non-industry funded studies [5,10,22,25]. Furthermore, in both RCTs, there was a protocol for the SCS procedures, whereas in our study, the physician chose the trial success criteria, surgical procedures, and SCS devices. SCS outcomes may vary according to patient selection criteria, physician technical expertise, and SCS implant techniques and hardware. Therapy benefits and benefit-to-harm ratios in RCTs often exceed those in routine practice due to strict patient selection and use of clinicians, clinical sites, and protocols selected to maximize intervention quality [2,11,33]. Finally, patients who participate in RCTs differ in ways that may affect outcomes [26,30]. Patients in the international RCT [14], as compared with those in our study, had more prognostically favorable characteristics (less severe back pain, better mental health, higher proportion working).

RCTs are regarded as the gold standard for assessing treatment efficacy, but the generalizability of RCT results is often uncertain. Patients, clinicians, payers, and medical policy makers want to know not only *can* a treatment work, but also *does* it work in practice. "Whether it will work in a specific patient population or clinical setting, and whether the benefits will be worth any harms or costs are questions for which evidence from randomized trials is often lacking" [2]. Controlled observational studies are useful for these purposes [2,7]. Thus, this study was designed to evaluate the benefits and risks of SCS for Washington State workers' compensation claimants in actual practice.

We observed higher rates of some SCS-related adverse events as compared with the average rates reported in a systematic review [29]: 11% superficial infection rate versus 4% in the review and 19% rate of persistent pain in the region of the stimulator components versus 6%. However, rates vary across studies and ours were within the range reported in the review. Our 19% rate of stimulator revision surgery by 18 months was similar to the average rate in the review. In the international RCT, 31% of patients who received a stimulator required surgical revision by 24 months [15]. The rate of removal of permanent stimulators in our study (19%) was much higher than the median rate in the review (6%), likely reflecting the lower pain relief in our study.

Information about adverse events associated with trial stimulation is often not reported [29]. In our study, 16% of patients who had trial SCS had a related adverse event, one of which was life-threatening. This underscores the fact that even trial stimulation carries risks and points to the importance of reporting trial-related adverse events in studies of SCS.

Patients with FBSS typically have failed to respond to multiple therapies. Few options remain; these most prominently include reoperation, SCS, and multidisciplinary rehabilitation. The National Institute for Health and Clinical Excellence (NICE) recommended SCS as a treatment option for this group, although they also recommended further observational research to generate evidence regarding the durability of benefits [17]. The NICE report also stated that SCS should be performed only after assessment by a multidisciplinary and experienced team and as part of a multidisciplinary team approach with other therapies aimed at rehabilitation. It would be of interest to evaluate whether SCS for patients with FBSS delivered in combination with a multidisciplinary cognitive-behavioral rehabilitation program after a comprehensive psychological evaluation results in better outcomes than either treatment alone.

Many experts recommend patient psychological evaluation [18], and Medicare and many private US insurers require it, prior to SCS. A recent systematic review [6] concluded that it is unknown whether psychological screening improves outcomes, and empirically-based guidelines for psychological contra-indications are lacking. In our study, patients with better SF-36v2 Mental Health scores had better 12-month pain and function outcomes, suggesting the potential value of screening for and treating psychiatric conditions such as mood and anxiety disorders prior to SCS.

Study limitations include the low enrollment rate in the comparison groups; we do not know how outcomes of participants in those groups compare with those of nonparticipants. We tried to minimize the limitations inherent in a non-randomized study design by enrolling two concurrent comparison groups using the same inclusion criteria as for the SCS group and adjusting analyses for baseline differences. However, we were unable to adjust for multiple baseline factors in the analyses examining the "success" outcomes. Although the sample size was limited, post hoc power calculations indicated >80% power to detect a 2.5-point difference between groups on the RDQ and >95% power to detect a 1.5-point difference in leg pain intensity. Another limitation is that the extent to which opioid medications were used for leg pain (which is more responsive than back pain to SCS) versus other pain problems is unknown.

In summary, we found little evidence for the superiority of SCS over alternative treatments among Washington State workers' compensation claimants with FBSS. A small advantage of SCS in improving leg pain and function at 6 months, albeit accompanied by greater daily use of opioids, disappeared by later follow-ups. Differences in study population, study design, and delivery of care may explain why these results are more disappointing than those of RCTs. The lack of long-term effectiveness of SCS in this study does not necessarily imply ineffectiveness in other settings. The issues associated with involvement in the workers' compensation system may be a stronger influence than pain therapy on patient outcomes. It is possible that no treatment has a substantial impact on average in this patient group. An argument could be made for heightened scrutiny of all therapies applied in this population, especially those that involve substantial costs or risks, and for efforts to provide the most cost-effective care with the least possibility of harm.

Acknowledgements

References

[1] Anderson PA, Schwaegler PE, Cizek D, Leverson G. Work status as a predictor of surgical outcome of discogenic low back pain. Spine 2006;31:2510–5.

[2] Atkins D. Creating and synthesizing evidence with decision makers in mind-integrating evidence from clinical trials and other study designs. Med Care 2007;45:S16–22.

[3] Atlas SJ, Chang Y, Keller RB, Singer DE, Wu YA, Deyo RA. The impact of disability compensation on long-term treatment outcomes of patients with sciatica due to a lumbar disc herniation. Spine 2006;31:3061–9.

[4] Atlas SJ, Tosteson TD, Hanscom B, Blood EA, Pransky G, Abdu WA, Andersson G, Weinstein JN. What is different about worker's compensation patients? Spine 2007;32:2019–26.

[5] Bhandari M, Busse JW, Jackowski D, Montori VM, Schunemann H, Sprague S, Mears D, Schemitsch EH, Heels-Ansdell D, Devereaux PJ. Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. CMAJ 2004;170:477–80.

[6] Celestin J, Edwards RR, Jamison RN. Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. Pain Med 2009;10:639–53.

[7] D'Agostino Jr RB, D'Agostino Sr RB. Estimating treatment effects using observational data. JAMA 2007;297:314–6.

[8] Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite J, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick CG, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 2008;9:105–21.

[9] Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149–58.

[10] Fenton JJ, Mirza SK, Lahad A, Stern BD, Deyo RA. Variation in reported safety of lumbar interbody fusion: influence of industrial sponsorship and other study characteristics. Spine 2007;32:471–80.

[11] Flather M, Delahunty N, Collinson J. Generalizing results of randomized trials to clinical practice: reliability and cautions. Clin Trials 2006;3:508–12.

[12] Harris I, Mulford J, Solomon M, van Gelder JM, Young JP. Association between compensation status and outcome after surgery: a meta-analysis. JAMA 2005;293:1644–52.

[13] Jordan K, Dunn KM, Lewis M, Croft P. A minimal clinically important difference was derived for the Roland-Morris Disability Questionnaire for low back pain. J Clin Epidemiol 2006;59:45–52.

[14] Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O'Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179–88.

[15] Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O'Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery 2008;63:762–70.

[16] Kumar K, Wilson JR. Factors affecting spinal cord stimulation outcome in chronic benign pain with suggestions to improve success rate. Acta Neurochir 2007;97:91–9.

[17] National Institute for Health and Clinical Excellence. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin, NICE technology appraisal guidance 159. London: National Institute for Health and Clinical Excellence; 2008.

[18] North R, Shipley J, Prager J, Barolat G, Barulich M, Bedder M, Calodney A, Daniels A, Deer T, DeLeon O, Drees S, Fautdch M, Fehrenbach W, Hernandez J, Kloth D, Krames E, Lubenow T, Osenbach R, Panchal SJ, Sitzman T, Staats P, Tremmel J, Wetzel T. Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. Pain Med 2007;8:S200–75.

[19] North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005;56:98–107.

[20] Ostelo RWJG, Deyo RA, Stratford P, Waddell G, Croft P, Von Korff M, Bouter LM, de Vet HC. Interpreting change scores for pain and functional status in low back pain. Spine 2008;33:90–4.

[21] Perneger TV. What's wrong with Bonferroni adjustments. Br Med J 1998;316:1236–8.

[22] Ridker PM, Torres J. Reported outcomes in major cardiovascular clinical trials funded by for-profit and not-for-profit organizations: 2000–2005. JAMA 2006;295:2270–4.

[23] Roland M, Morris R. A study of the natural history of back pain. Part 1: Development of a reliable and sensitive measure of disability in low-back pain. Spine 1983;8:141–4.

[24] Rothman KJ. No adjustments are needed for multiple comparisons. Epidemiology 1990;1:43–6.

[25] Shah RV, Albert TJ, Bruegel-Sanchez V, Vaccaro AR, Hilibrand AS, Grauer JN. Industry support and correlation to study outcome for papers published in Spine. Spine 2005;30:1099–104.

[26] Steg PG, Lopez-Sendon J, Lopez de Sa E, Goodman SG, Gore JM, Anderson FA, Himbert D, Allegrone J, Van de Werf F, for the Grace Investigators. External validity of clinical trials in acute myocardial infarction. Arch Intern Med 2007;167:68–73.

[27] Turk DC, Dworkin RH, McDermott MP, Bellamy N, Burke LB, Chandler J, Cleeland CS, Cowan P, Dimitrova R, Farrar JT, Hertz S, Heyse JF, Iyengar S, Jadad AR, Jay GW, Jermano JA, Katz NP, Manning DC, Martin S, Max MB, McGrath P, McQuay HJ, Quessy S, Rappaport BA, Revicki DA, Rothman M, Stauffer JW, Svensson O, White RE, Witter J. Analyzing multiple endpoints in clinical trials of pain treatments: IMMPACT recommendations. Pain 2008;139:485–93.

[28] Turner JA, Deyo RA, Loeser JD. Spinal cord stimulation: stimulating questions. Pain 2007;132:10–1.

[29] Turner JA, Loeser JD, Deyo RA, Sanders SB. Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: a systematic review of effectiveness and complications. Pain 2004;108:137–47.

[30] Uijen AA, Bakx JC, Mokkink HG, van Weel C. Hypertension patients participating in trials differ in many aspects from patients treated in general practices. J Clin Epidemiol 2007;60:330–5.

[31] Vik A, Zwart JA, Hulleberg G, Nygaard O. Eight year outcome after surgery for lumbar disc herniation: a comparison of reoperated and not reoperated patients. Acta Neurochir 2001;143:607–11.

[32] Ware JE, Kosinski M, Dewey JE. How to score version two of the SF-36 health survey. Lincoln (RI): QualityMetric Incorporated; 2000.

[33] Westfall JM, Mold J, Fagnan L. Practice-based research – "blue highways" on the NIH roadmap. JAMA 2007;297:403–6.