

Spinal Cord Stimulation for Complex Regional Pain Syndrome Type I: A Prospective Cohort Study With Long-Term Follow-Up

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Objectives: Spinal cord stimulation (SCS) is an effective treatment for intractable complex regional pain syndrome type I pain. Long-term data are scarce on effectiveness, degree of pain relief, predictors, and complications.

Materials and methods: From 1997 to 2008, 84 consecutive patients who received an implanted SCS system after positive test stimulation were included in the prospective study. Treatment effectiveness was assessed annually as measured by mean visual analog scale pain scores and with the Patients Global Impression of Change scale. Treatment success was defined as at least 30% mean pain relief at end point and treatment failure as explantation of the system. A Cox regression determined if baseline factors were associated with both these outcomes.

Results: During 11 years, 41% (95% CI: 27–55) of the patients experience at least 30% pain relief at assessment end point. During 12 years of follow-up 63% (95% CI: 41–85) of the implanted patients still use their SCS device at measured end point. Pain relief of at least 50% one week following test stimulation is associated with a higher probability of long-term treatment success. In 51 patients, 122 reinterventions were performed over 12 years; 13 were due to complications, 44 to battery changes, and 65 reinterventions were equipment related.

Conclusion: SCS provides an effective long-term pain treatment for 63% (95% CI: 41–85) of implanted patients. Forty-one percent (95% CI: 27–55) of SCS treated patients have at least 30% pain reduction at measurement end point. The number of reinterventions after implantation due to equipment-related problems, battery changes, and complications is 122 over 12 years of follow-up. Sixty-one percent ($N = 51$) of the patients had at least one reintervention. Mean pain relief of at least 50% (visual analog scale) one week after the test stimulation is associated with long-term treatment success.

Keywords: Complex regional pain syndrome type I (CRPS-1), complications, follow-up study, mixed model, pain, spinal cord stimulation (SCS)

Conflict of Interest: None for any of the authors.

INTRODUCTION

Complex regional pain syndrome type I (CRPS-1) is a painful and debilitating disorder that is highly refractory to conventional pain therapy. CRPS is a progressive disease and after one year of the diagnosis the majority of the signs and symptoms are well developed (1). A population-based cohort study of 102 patients with CRPS showed that two years after the diagnosis 31% remained incapable of working (2). Spinal cord stimulation (SCS) has shown to be successful in 56% of the patients with CRPS-1 (3). The long-term efficacy of therapeutic interventions in CRPS-1 is thus of major clinical importance. Information on the effects of SCS in CRPS-1 patients after five years of treatment is limited (4). Due to the chronic and debilitating character of CRPS-1, data on the outcomes, side-effects, and complications of SCS treatment for CRPS-1 are very important for the continued use and development of this treatment modality. Therefore, we examined the long-term effects of SCS in CRPS-1 patients on reduction of pain intensity, nature and number of complications, and treatment failure. Furthermore, factors associated

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with attaining more than 30% pain relief, and treatment failure resulting in explantation, were assessed.

MATERIALS AND METHODS

The study was prospective in design. Eighty-four patients who underwent SCS implantation during the period from 1997 to 2008 gave their informed consent for follow-up assessment. The patients prospectively received each year a questionnaire booklet and pain diary asking for information about pain, reinterventions, Patient Global Impression of Change scale (PGIC), complications and side-effects. Data on number and nature of complications were each year checked against information the patients provided.

Patient Selection

Patients were eligible for inclusion in the study if the following CRPS-1 criteria according to the International Association for the Study of Pain (5) were met: 1) presence of an initiating noxious event or a cause of immobilization; 2) continuing pain, allodynia, or hyperalgesia disproportionate to the inciting event; 3) evidence at some time of edema, changes in skin blood flow, or abnormal sudomotor activity in the area of pain; 4) the diagnosis is excluded by the existence of any conditions that would otherwise account for the degree of pain and dysfunction. Additional inclusion criteria were age from 18 to 65; disease clinically restricted to one extremity; disease duration of at least six months; no lasting success with standard therapy over the last six months including physiotherapy, medication, transcutaneous electrical nerve stimulation, or sympathetic blocks. Furthermore, patients had to have a pain intensity of mean 50 mm, scored on the visual analog scale (VAS), which rates pain from 0 mm for no pain to 100 mm for "the worst pain you can imagine" (6,7).

Exclusion criteria were the presence of Raynaud's disease; presence and history of neurological abnormalities unrelated to CRPS-1 (e.g., polyneuropathy); conditions other than CRPS-1 affecting the function of diseased or contralateral extremities (e.g., diabetes mellitus); blood clotting disturbances or anticoagulation therapy or cardiac pacemaker use. The study protocol complied with the declaration of Helsinki regarding investigations in humans and was approved by the medical ethics committee of the University Hospital Maastricht.

Procedure of SCS Treatment

Patients meeting the inclusion criteria received a test SCS for at least one week. The operative procedures concerning the implantation of a test or permanent SCS system have previously been described in detail (3). Patients received a permanent SCS stimulator if test stimulation was successful. Success was defined as having at least 50% mean pain reduction in the last four days of the testing period (VAS pain was marked by the patient three times a day for four days) or at least a score of "much improved" on the PGIC. The PGIC is recommended by IMMPACT for use in chronic pain clinical trials as a core outcome measure of individual patients' global improvement with treatment. The PGIC (8) provides a responsive and readily interpretable assessment of participants' evaluations of the importance of their improvement or worsening. This single-item rating by participants of their response during a clinical trial uses a 7-point rating scale with the options "very much improved (7)," "much improved (6)," "minimally improved (5)," "no change (4)," "minimally worse (3)," "much worse (2)," and "very much worse (1)."

Patients who did not meet these criteria did not receive a permanent SCS system and were excluded from this study.

Physical Therapy Program

All patients received a physical therapy program that consisted of exercise using a graded activity approach, aimed to improve endurance, mobility, and function of the affected extremity. Pain increase during exercise was considered acceptable, but pain had to return to its normal level within 24 hours, otherwise the intensity of the exercise was reduced. The frequency of therapy was twice a week for 30 min, with a minimum of two days between sessions. Total duration was at least six months. To ensure standardization, therapy was performed by a selected physical therapist who had received pain treatment training, and were visited on a regular basis by the coordinating physical therapist and movement scientist from our institute.

Data Collection

Before trial stimulation, gender, age, baseline VAS pain scores, pain localization, and the initiating event were recorded. After one week of trial stimulation, mean VAS pain scores marked by the patient three times a day for four consecutive days, and the PGIC were assessed. Each year following the definitive implantation of the SCS system, patients received a booklet with questionnaires that included questions about side-effects and complications, reasons for reintervention, PGIC, and a VAS pain diary in which pain had to be scored three times a day for four consecutive days. Patients returned these questionnaires to the research team in a special prepaid envelope. Questionnaires that had not been returned within 14 days were followed up by contacting the patient by telephone.

All SCS-related side-effects that required reintervention, registered by the physician as well as by the patient, were later divided in the following categories: lead migration, hardware malfunction, fractured electrode, pulse generator discomfort, pain, superficial infection, deep infection, and inadequate stimulation not further specified. Furthermore, replacement of empty batteries was recorded.

Clinical Follow-Up

We defined the SCS therapy as successful (responder) when the patient's pain achieved a significant mean VAS pain reduction of at least 30% compared with baseline (9,10). According to the IMMPACT guidelines, a 30% reduction in pain is considered moderately important change and is equal to "much improved" as measured by the PGIC (9). Failure (nonresponder) was defined as a pain reduction of less than 30% compared with baseline (pre-SCS). A once-only value of less than 30% pain relief was not considered as a failure of SCS. Only if the value of pain relief—less than 30%—occurred in two consecutive years, the first year of failure was considered the failure year. If the last observation showed less than 30% pain relief, it was considered failure in the year of the last observation.

For assessment of the duration of SCS treatment, failure was defined by ceasing to use the SCS system and ultimately explantation.

Reduction in Pain Scores

The time curve of absolute reduction in mean VAS pain scores at each consecutive year following baseline was analyzed using a

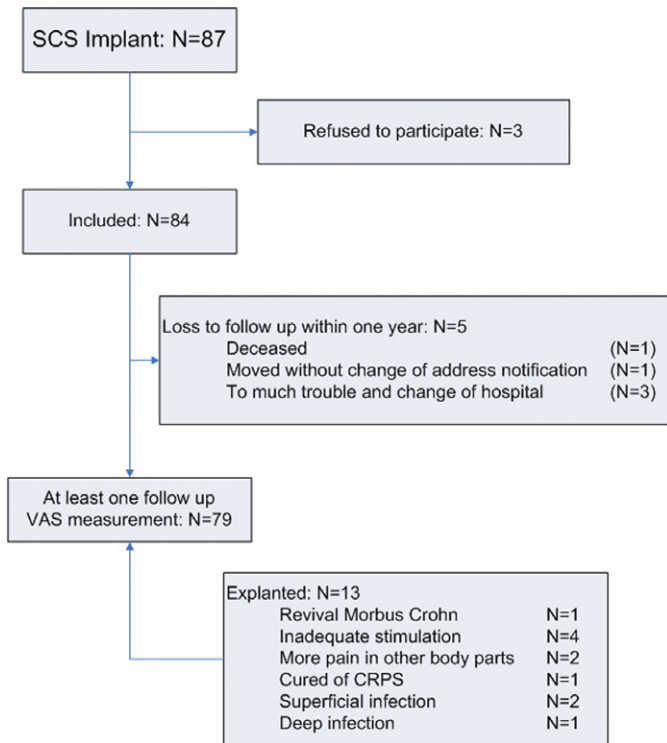


Figure 1. Flowchart of SCS implanted CRPS-1 patients.

mixed linear regression model. To take into account that the outcomes are correlated within the pain scores of one patient, a general linear mixed model was used to examine the trend in time (11,12). The patients' entrance and exit point in the study differed; therefore Kaplan–Meier failure analyses were used to evaluate success and duration of the treatment. Strength of association between the outcome and the baseline characteristics (i.e., gender, age, education, initiating event, localization of CRPS-1), disease duration, and test stimulation results were evaluated with univariate Cox proportional hazard regression analyses. *p*-Values of less than 0.05 were considered significant.

Analyses were performed with the Statistical Package for the Social Sciences, version 18 (SPSS Inc., Chicago, IL, USA) and STATA/SE version 11.1 (StataCorp LP, College Station, TX, USA).

RESULTS

From 1997 to 2008, a total of 84 patients were included in the study. The duration of follow-up ranged from 0.2 to 11.9 years with a median of 5.2 years. All patients who consecutively received an implant at the Maastricht University Medical Centre were included in this follow-up study (Fig. 1). A summary of the population characteristics is presented in Table 1.

Effects on Pain and Treatment Success

Figure 2 shows the time curve of changes in mean VAS pain scores at each consecutive year following baseline. The regression line of the means shows a stable trend between the first and eleventh year of follow-up.

Treatment success and failure—failure is defined as pain decrease of less than 30% as measured with the mean VAS for pain—is rep-

Table 1. Baseline characteristics of included SCS patients.

Gender	N (%) [#]
Male	22 (26%)
Female	62 (74%)
Age median (IQR)	35 (32–46)
Education	
Primary	15 (19%)
Secondary	49 (51%)
Tertiary	16 (29%)
Initiating event	
Surgery	29 (35%)
Trauma	46 (55%)
Spontaneous	9 (11%)
Localization	
Arm affected	45 (54%)
Leg affected	39 (46%)
Pain VAS score median (IRQ)	77 (65–87)
Disease duration until SCS	
Median years(IQR)	2.7 (1.7–4.9)
[#] N (%) if not mentioned otherwise.	
IQR, InterQuartile Range.	

resented in the Kaplan–Meier curve (Fig. 3). It shows that 41% (95% CI: 27–55) of the patients experience at least 30% pain reduction at measurement end point over 11 years.

Figure 4 shows the time until explantation of the system in years, i.e., duration of SCS treatment. At measurement end point, 63% (95%CI: 41–85) of the patients still use their SCS system for pain relief.

PGIC

All SCS implanted patients (*N* = 84) originally had a PGIC pain score of at least “much improved” after one week of trial stimulation. Of the 84 patients, 64 patients (76%) scored their pain at least as minimally improved at assessment end point, 54% (*N* = 42) scored “much improved”, and three patients considered their pain “very much improved.”

Complications and Battery Changes

Reinterventions were mostly performed because of equipment-related problems. Thirteen complications occurred in 11 of the 84 patients (13%) (Table 2). Lead migration was noted in 23 patients; in 11 patients this was a recurrent problem. The mean failure time of lead migration was 1.9 years after the start of the SCS treatment. Hardware malfunction requiring surgical replacement was reported in seven patients (11%). Deep or superficial infection occurred in seven patients, and in three patients the SCS system was removed for this reason. However, bacterial cultures remained negative in all cases.

Forty-four battery changes were performed over 11 years. This occurred once in 12 patients and more than once in 11 patients (Table 2). The mean lifetime of a battery in this study was 4.4 years.

Predictors for Treatment Failure and SCS Explantation

The baseline demographics and characteristics shown in Table 1, disease duration, and test stimulation results were used in univari-

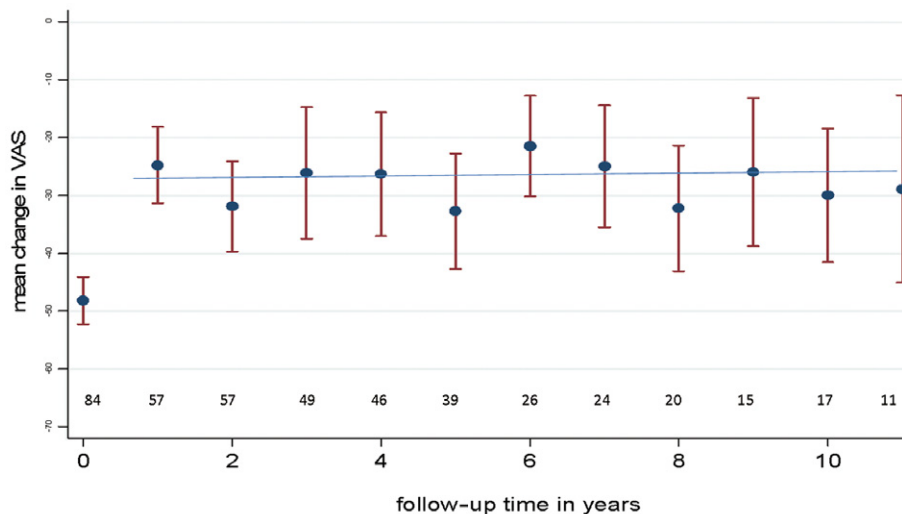


Figure 2. Changes in mean VAS pain score after SCS implantation at baseline and each consecutive year. Time-point zero shows change in mean VAS pain score one week after SCS implant. The linear regression line of the last 11 time points is depicted (mean_change = $-28 + 0.18 \times \text{follow_up_time}$). The numbers at the bottom of the figure shows the numbers of observations of varying subsets of patients at baseline and the follow-up years.

ate Cox regression analyses to explore correlations between baseline characteristics and success of SCS treatment. Patient and disease characteristics were not associated with SCS treatment failure. Having less than 50% pain relief after one week of trial SCS was highly associated with “long-term” treatment failure: $p < 0.001$.

The Kaplan–Meier curves showed that in patients with 50% pain relief after trial stimulation, 47% (95%CI: 31–63) were treated successfully, i.e., had at least 30% pain relief at end point. In contrast 36% (95%CI: 11–61) of the patients who did not have 50% pain relief after trial stimulation were successfully treated.

DISCUSSION

This study shows that SCS provides an effective long-term pain treatment for at least 63% of CRPS-1 patients and results in long-term pain relief of 30% or more in 41%. The mean VAS score for pain as compared with the baseline pain stabilizes at 25% to 30% reduction during follow-up. The PGIC showed that 59% of patients in this study rated their CRPS-1 induced pain change as “much” and “very much” improved. The overall longevity of SCS treatment was rather good for 60% of patients used the SCS system during 12 years. Major complications like epidural hematomas or infections that were confirmed by bacterial cultures did not occur in our study population.

The number of reinterventions in this study requiring minimal invasive procedures were substantial ($N = 122$) and most were equipment related or related to the lifetime of batteries. These reinterventions happened over 11 years; the annual mean total complication rate was 30%. However, in the last four years the annual mean complication rate was 22%. The technical development of SCS hardware is likely the cause of this decrease. Before 2004, lead fracture occurred more with Medtronic Pisces Quad® lead (Medtronic, Inc., Minneapolis, MN, USA), and since the introduction of Medtronic Octad® leads (Medtronic, Inc., Minneapolis, MN, USA) in 2006 interventions to restore lead migration occurred less. The annual mean intervention rate due to lead migration was 13% in 2005; this was even reduced to 7% in 2007 and 2008.

As far as we know this is the first prospective long-term follow-up study about SCS in CRPS-1 patients. This prospective design increases the level of evidence of this study by preventing selection-bias and recall-bias. This could also explain the amount of reinterventions in this study as compared with the smaller numbers of reported reinterventions in two retrospective studies (13,14).

A limitation of this study is that this study was designed in 1997 and at that time medication use and functional improvement were not included as outcome measures. Although studies have proven that SCS treatment improves mental health and quality of life, there is currently no evidence that SCS improves function in CRPS-1 patients (15,16).

To the best of our knowledge, the database used for this study is presently one of the largest ($N = 84$ included patients) and describes the longest follow-up period of SCS for CRPS-1 pain. The results of this study, however, may be an overestimation due to the fact that it has no control group to adjust for the natural course of CRPS-1.

Our observation that the mean VAS pain score stabilizes over time is in line with a recent retrospective follow-up study of SCS in CRPS-1 patients by Kumar et al. ($N = 25$ patients) who also described long-term benefit of this therapy (4). The failure time curve of the SCS implantation indicates that SCS treatment in most CRPS-1 patients is successful during at least 11 years.

Responding to treatment (success) was defined as pain relief of at least 30% compared with baseline. This is in line with the IMMPACT recommendations in which a decrease of 30% is considered clinically important improvement to chronic pain patients (9,17).

SCS for intractable CRPS-1 pain proves to be a valuable therapy with long-term efficacy in about 41% of patients. Test stimulation is successful in 56% of patients (3). A fair number of patients do not respond to this invasive and costly treatment. Clinical predictors of success or failure may improve patient selection and reduce failure rates (18).

Test stimulation is performed to assess whether patients will respond to SCS positively. In general, the decision to implant the permanent SCS system is made when mean pain intensity during the testing period is at least 50% lower as compared with the original (baseline) mean VAS pain score or if at least “much improvement” (6 points) is reported by the patient on a 7-point PGIC. The

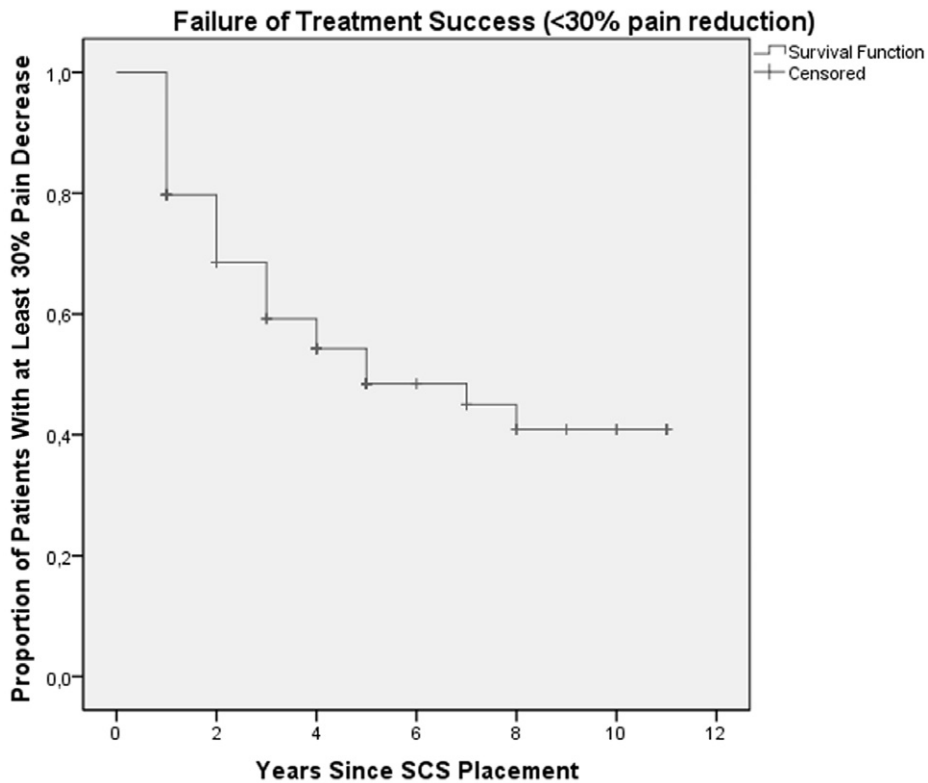


Figure 3. Failure curve of SCS treatment. Failure is defined by less than 30% decrease of the original mean pain VAS score.

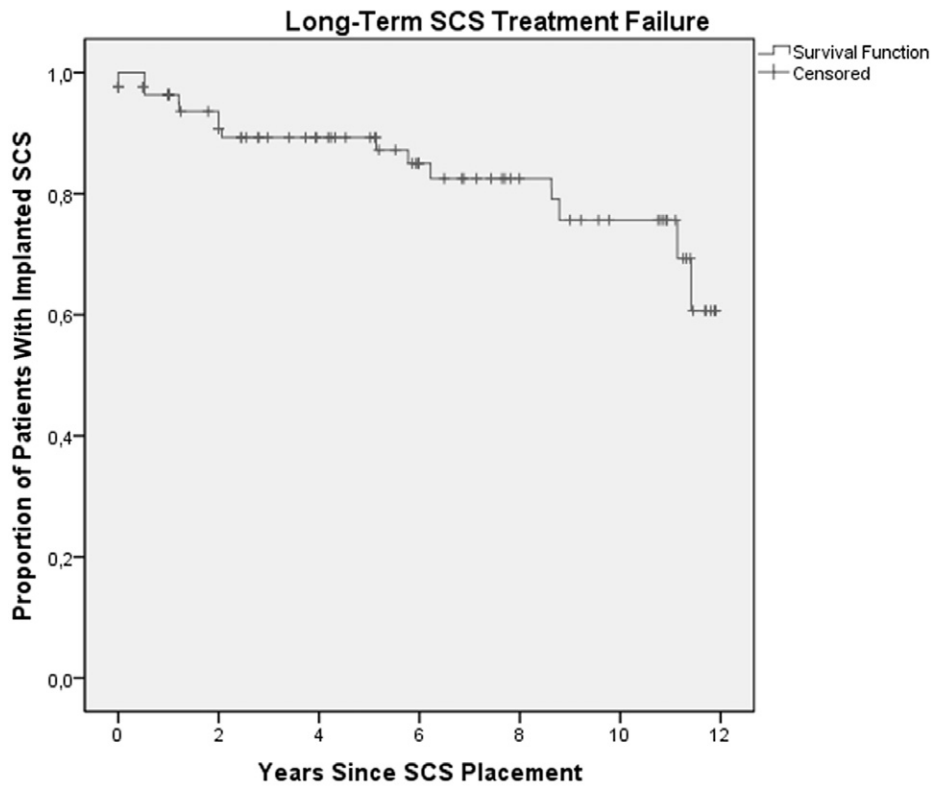


Figure 4. Duration of SCS treatment. Failure curve of SCS implantation in CRPS-1 patients. Failure is defined by explantation of the SCS system.

Table 2. Reasons for reintervention in CRPS-1 patients treated with SCS.

	Number of reinterventions	Number of patients
Battery replacements		
One replacement		12
Two replacements		7
Three replacements		2
Four replacements		1
Five replacements		
	44	22
Equipment-related problems		
Lead migration	34	23
Hardware malfunction	10	7
Fractured electrode	9	7
Pulse generator discomfort	8	7
Inadequate stimulation	4	4
	65	48
Complications and side-effects		
Pain	6	5
Superficial infection	6	5
Deep infection	1	1
13	11	
Reinterventions total	122	51

simultaneous use of these outcome measures is common practice (16,19). The PGIC is used as an anchor in determining the clinical importance of improvement in pain ratings (10,20,21). Our finding that a $\leq 50\%$ decrease of mean pain after the test period is associated with success of SCS treatment (success of 47% vs. 36%), independently of the PGIC, is therefore clinically important. It indicates that after test stimulation, the PGIC results might be overrated.

The nature of the complications and side-effects in this study was relatively mild, although, any procedure to correct hardware failure can increase the risk for infections (22,23). The superficial (skin) infection rate of 7% is larger compared with other studies. This could be due to meticulous registration of minor side-effects in this study. The deep infection rate was low (1%). Severe complication rates in this study are in line with other larger studies, these also reported no severe complications (e.g., epidural abscesses or hematomas) of SCS treatment in CRPS-1 and Failed Back Surgery Syndrome, and of SCS treatment in severe angina pectoris (24–27). The most frequently reported complication, in 24% to 37% of the patients, is lead migration. This is in line with our findings. Lead migration is most frequently reported in percutaneously placed leads, and several studies indicate that lead migration may be one of the main reasons for failure to maintain long-term pain control with SCS (28–30). It has to be taken into account that, for the most part, the hardware that was used over the years is currently outdated; this is an inherent problem of long-term follow-up studies. Technological innovation improved the hardware and the lifetime of batteries over the years and may reduce the number of reintervention in the future. In order to further decrease the frequency of equipment-related reinterventions and battery replacements, technological development of SCS hardware and batteries should continue, i.e., recharging by electric field induction or use of batteries with a longer life. Furthermore, further innovations that prevent lead migration are needed, especially for percutaneous leads, to establish long-term effectiveness of SCS.

CONCLUSION

SCS in CRPS-1 patients provides an effective long-term pain treatment for 63% of implanted patients. During 11 years of follow-up, the percentage of patients who have at least 30% pain reduction with SCS was reduced from 100% to 41%. The number of reinterventions due to equipment-related problems and battery changes was substantial. This study showed that patients who have at least 50% pain relief after the test intervention have a better chance of long-term SCS treatment success. In patients who did not achieve at least 50% pain reduction after trial stimulation still 36% were successfully treated with SCS. In clinical practice, indications for a permanent SCS device and potential for long-term treatment success should be carefully balanced against possible complications and side-effects. Treatment results might be further improved by advancements and research in device-related technical aspects and by patient selection.

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Authorship Statement

José Geurts, Helwin Smits, Maarten van Kleef, and Alfons Kessels participated in the conduction of the study and acquisition of the data. Analyses were performed by José Geurts and Alfons Kessels. All authors substantially contributed to the interpretation of the data and helped to write the manuscript. José Geurts, Alfons Kessels, and Maarten van Kleef oversaw and contributed to the overall execution of the project. All authors reviewed the article for important intellectual content, commented on the manuscript, and gave their final approval of this version to be published.

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