

<u>reference</u>	<u>type</u>	<u>sources</u>	<u>comments</u>	<u>pain relief</u>	<u>complications</u>	<u>study design issues</u>	<u>author's conclusions</u>
Neurosurgery. 1995 Dec;37(6):1088-95	SysRev	42 articles on 39 studies	all case series; with multiple methodological problems	<ul style="list-style-type: none"> o 13 studies: 31% (range, 0-50%) of patients who received implants had their stimulators revised. o 20 studies: 14% (range, 0-42%) of patients had their stimulators permanently removed and not replaced. o 29 studies: 59% (range, 15-100%) of patients had >=50% pain relief (back and/or leg). o 9 studies: 23% (range, 0-57%) of patients were taking opioid medications at follow-up. o 2 studies: no patients returned to work; in the other, 25% returned to work. 5 studies: 58% (range, 17-100%) of patients reported that they had improved in their ability to perform activities. o "Success" was defined as a patient using a stimulator with >50% pain reduction at follow-up and was coded for studies reporting follow-up on >=75% of patients who received implants. At 1 year, on average across 14 studies, 62% of patients were successes (range, 15-100%). At 2 years, only five studies could be coded and the range narrowed (success rate, 55-74%; mean, 64%). At 5 years, only three studies could be coded (range, 50-55%; mean, 53%). Only one study r 	<ul style="list-style-type: none"> o 13 studies: 42% (range 20-75%) of patients had some kind of complication. o 20 studies: 5% (range 0-12%) of patients had an infection. o 17 studies: 9% (range 0-42%) of patients had a biological complication other than infection. o 13 studies: 30% (range, 0-75%) of patients had one or more stimulator-related complications. 	A majority of articles reported outcomes of patients with widely varying lengths of follow-up, averaged across all patients in that series. Some articles did separately report outcomes for subgroups of patients available for follow-up at different time periods since implantation, but these follow-up times were not standard (e.g., 6 mo, 1 yr, and 5 yr) across studies, and the number of patients who received follow-up often considerably decreased over time. To draw conclusions based on as many studies as possible, [authors] elected to code 1-year follow-up data whenever possible.	<ul style="list-style-type: none"> o No conclusions may be drawn at this time concerning the efficacy of SCS for failed back surgery syndrome relative to other pain treatments, placebo treatments, or no treatment. o We cannot definitively conclude that the efficacy of stimulators decreased over time. However, these figures suggest that this is the case. o The criteria for selecting patients for a permanent implant after screening with temporary electrodes varied widely. The screening period ranged from 1 day to more than 2 weeks. o Complications were surprisingly frequent but generally minor. o In sum, it seems that approximately 50 to 60% of patients with failed back surgery syndrome report >=50% pain relief with SCS at long-term follow-up visits. However, there is insufficient evidence at present from the literature to draw conclusions about the efficacy of SCS relative to no treatment or to other treatments (e.g., multidisciplinary pain treatment programs) for this patient population or about the effects of SCS on patient work status, functional disability, and health care an

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Spine. 2005 Jan 1;30(1):152-60	SysRev	1 RCT, 1 cohort study, and 72 case series	<p>The overall quality of the RCT was judged to be of good quality.</p> <p>The quality of these case series was in general relatively poor.</p>	<ul style="list-style-type: none"> o <u>RCT</u>: When analyzed by intention to treat, patients in the SCS group experienced significantly more pain relief and required less opiate drug than patients who were reoperated. o <u>Case Series</u>: Most reported pain relief using the threshold cutoff of 50% or more. o When pooled by a random effects model, overall some 62% (95% CI: 56-67%) of patients achieved pain relief of 50% following the implantation of a SCS system. [However], the greater the quality score [of the study], the lower the treatment effect in terms of pain relief. o The pooled relative risk (i.e., probability of taking analgesic post SCS/probability of taking analgesic pre SCS) was not significant (relative risk: 1.03; 95% CI: 0.90-1.18) across studies. o In the five studies that reported return to work, there was a significant increase in the proportion of patients working post SCS compared with before SCS (relative risk: 1.60; 95% CI: 1.10-2.20). 	<ul style="list-style-type: none"> o <u>RCT</u>: Four (17%) and six (26%) patients with FBSS experienced complications at 6 and 12 months post SCS implantation, respectively. o <u>Case Series</u>: Overall, 43% of patients with CBLP/FBSS experienced one or more complications with SCS. The majority of these complications were due to electrode or lead problems (195/722; 27%). Infections (6%), generator problems (6%), extension cable problems (10%), or other issues, such as cerebrospinal fluid leaks (7%), accounted for the remainder. 	<p>A notable aspect of the case series in the present review was the general inadequate reporting, which prevented an appropriate assessment of methodologic quality.</p>	<p>The level of evidence for the efficacy of SCS in patients with CLBP/FBSS remains "moderate." The greatest level of pain relief following SCS appeared to be associated with case series that were of poor quality, short follow-up duration, undertaken in a multicenter setting, and that recruited patients with CLBP or FBSS specifically.</p>

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Neurosurgery. 2005;56(1):98-106	RCT	Patients with surgically remediable nerve root compression and concordant complaints of persistent or recurrent radicular pain, with or without low back pain, after one or more lumbosacral spine surgeries. Excluded patients from the study if they had any: 1) a disabling neurological deficit (e.g., foot drop, neurogenic bladder) in the distribution of a nerve root or roots caused by surgically remediable compression; 2) radiographically demonstrated critical cauda equina compression (1); or 3) radiographic evidence of gross instability necessitating fusion. Also excluded patients who had 1) significant untreated dependency on prescription narcotic analgesics or benzodiazepines; 2) major untreated psychiatric comorbidity; 3) unresolved issues of secondary gain; 4) a concurrent clinically significant or disabling chronic pain problem; or 5) a chief complaint of axial (low back) pain exceeding radicular (hip, buttock, and leg) pain.		<ul style="list-style-type: none"> o Patients randomized to reoperation were significantly more likely ($P_{.02}$) than those randomized to SCS to cross over. o SCS was significantly more successful than reoperation: 9 (47%) of 19 patients randomized to SCS and 3 (12%) of 26 patients randomized to reoperation achieved at least 50% pain relief and were satisfied with treatment. o No significant treatment differences were detected in patients' ability to return to work. 	One SCS patient developed an infection at the receiver site, which was treated by removal of the system followed by specific antibiotic therapy. The system was replaced without further complication. Three SCS patients (9% of permanent implants) underwent hardware revisions because of technical problems (electrode migration or malposition).	N=45 Patients were randomized; all baseline and follow-up data was collected for those participating and for the group of eligible participants who refused randomization. Any patient randomized to SCS who did not have a successful trial could immediately cross over to reoperation. Patients randomized to reoperation could cross over to SCS after a 6-month postoperative period. The patients in all three groups were managed in accordance with a post-spinal surgery physical therapy protocol. Six months after the initial study procedure, a disinterested third party who was aware of which patient had which procedure but was not involved in the treatment assessed outcome using the same test instruments employed at baseline plus scales to rate pain relief and patient satisfaction with treatment. Attempts to obtain long-term follow-up data using the same questionnaires occurred for all patients annually for at least 2 years.	<p>This prospective, randomized trial confirms the inference from previous studies that SCS is superior to reoperation in patients with persistent radicular pain after lumbosacral spine surgery.</p> <p>In patients with persistent radicular pain after lumbosacral spine surgery, therefore, our findings indicate that clinicians should offer SCS as an alternative to repeated operation before exhausting all surgical alternatives.</p>

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<u>Clin J Pain. 2003 Nov-Dec;19(10):371-33</u>	SysRev	1 RCT; 14 case studies or series (12 retrospective, 2 prospective)	RCT of good quality; "unaware" of any method for assessing quality of case studies/series	<ul style="list-style-type: none"> o 12 studies reported that SCS was successful and concluded that SCS was effective therapy for patients with CRPS. o The percentage of patients with CRPS that received successful SCS ranged between 53.7% and 100% in different studies. o In 1 study, SCS was reported to be unsuccessful. In 2 studies, the authors' conclusions regarding SCS for CRPS were unclear 	<ul style="list-style-type: none"> o The proportion of patients with at least one complication ranged from 9% to 50%. o The infection rate ranged from 1.4% to 11.1%. o The rate of complication due to technical problems such as equipment failure, lead migration, or lost coverage ranged from 8.3% to 42.8%. o The rate of reoperation ranged from 11.1% to 50%. 	<p>Studies of adult patients with the clinical diagnosis of CRPS types I and II. Twelve of the 15 studies reported the specific criteria that was used to establish the diagnosis of CRPS.</p> <p>In general, follow-up intervals were variable in length and inconsistent between studies. As a result, we were unable to choose a standard follow-up interval for data pooling. Thus, outcome measures were pooled at the end of the follow-up period regardless of length.</p> <p>Considerable variability existed in the criteria used to determine the success of SCS.</p>	We conclude that available evidence suggests that SCS is effective for the management of pain for patients with CRPS who did not respond to more conservative medical management (grade B/C). Definitive conclusions cannot be made with regard to any of the secondary outcome measures, in part due to poor methodological design and in part due to inadequate reporting by the authors.
<u>Eur J Pain 2006; 10(2): 91-101</u>	SysRev	1 RCT in patients with CRPS I; 25 case series; 1 economic evaluation	RCT appeared to be well conducted The overall quality of the case series was judged to be poor	<ul style="list-style-type: none"> o RCT: SCS therapy lead to a reduction in pain intensity at 12 months of follow-up (mean change in VAS score -2.7), whereas pain increased in the control group (mean change in VAS score +0.4), and this difference was statistically significant ($p < 0.001$). No significant difference in functional capacity was observed between the two treatment groups. A 2-year follow-up of this trial have recently demonstrate that the benefits in pain outcome were maintained. o Case Series: On average, 67% (95% CI 51%, 84%) of implanted patients with CRPS who received SCS achieved pain relief of at least 50%. o Economic Analysis: Based on the included both patient and health service costs at 12 months follow-up and an extrapolation (using decision analysis modeling) of these costs over the lifetime of a patient. The authors reported that although the costs for SCS plus physical therapy, (\$10,200/patient) exceeded those of physical therapy alone (\$6,000/patient) at 12 months, this difference was reversed over a lifetime analysis. Over a lifetime period there was a cost saving of ~US\$ 	<ul style="list-style-type: none"> o RCT: Six of the 36 patients receiving SCS plus physical therapy experienced complications ($n = 11$) at 6 months but only one complication (infection) was reported at 12 months. A total of 9 of the 24 patients (38%) experienced 22 complications needing operation during the 2-years after implantation. o Case Series: Overall, in eight studies, 33.0% (22/66) of patients reported at least one complication with SCS. The majority of complications were related to electrode issues (20% of patients), infections (4% of patients), generator issues (2% of patients) or extension cable issues (1%) of patients. A further 6% of patients had other complications such as hematomas. 	<p>Studies including patients diagnosed with CRPS type I or type II were included in the review.</p> <p>Few studies [case series] provided details of the selection of patients included in their series, potential co-interventions received (e.g. drug therapy), methods of outcome assessment (e.g. blinding, use of validated outcomes) or losses to follow-up.</p>	SCS appears to be an effective therapy in the management of patients with CRPS type I (Level A evidence) and type CRPS II (Level D evidence). Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS type I.

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Ann Neurol. 2004 Jan;55(1):13-8	RCT	<p>Patients meeting IASP criteria for CRPS I.</p> <p>Inclusion criteria were age 18 to 65 years; disease clinically restricted to one extremity, but affecting the whole hand or foot; disease duration of at least 6 months; no lasting success with standard therapy, including 6 months' physical therapy, sympathetic blocks, transcutaneous electrical nerve stimulation, and medication; and a mean pain intensity of at least 5cm, measured on a visual analog scale from 0 to 10cm.</p> <p>Exclusion criteria were presence of Raynaud's disease; presence or previous history of neurological abnormalities not related to RSD; conditions affecting function of diseased or contralateral extremities, other than RSD itself; blood clotting disturbances or anticoagulant drug therapy; cardiac pacemaker use; and a score of 200 or more on the Symptom Check List-90, a standardized psychological test.</p>		<p>o <u>intention to treat</u>: After 2 years, the mean pain intensity with SCS_PT was reduced by 2.1cm, compared with 0cm with PT (p = 0.001).</p> <p>o Changes in other pain measures, health-related quality of life, and functional status were not statistically significant between the treatment groups.</p> <p>o Multivariate regression analysis demonstrated that no baseline factor except treatment group influenced effect size.</p> <p>o <u>adherence to protocol</u>: The mean pain relief of 24 patients with an implanted spinal cord stimulator was 3.0cm, as compared with 0cm change among 16 patients receiving physical therapy.</p>	<p>o 9 of 24 patients (38%) suffered 22 complications needing operation during the 2 years after implantation.</p> <p>o The most frequent complications were electrode displacement and pain from the pulse generator pocket.</p> <p>o Two patients underwent permanent removal of the system on the grounds of recurrent rejection and relapsing ulcerative colitis subscribed to the system, respectively.</p> <p>o Side effects were reported by all 22 patients who still had an implanted system at 2 years.</p>	<p>N = 54</p> <p>Patients were assigned through randomization to a group with SCS and a standardized physical therapy program (SCS_PT group), or to a group with the standardized physical therapy program alone (PT group). Patients who did not have a successful SCS trial continued the study with physical therapy alone. The same physical therapy program was offered to all patients. PT lasted 6 months, with continuation after 6 months being optional. At 2 years, 21 of 51 patients (9 SCS_PT, 12 PT) were still receiving PT.</p>	<p>We conclude that after careful selection and successful test stimulation SCS is safe and has long-term effectiveness in reducing pain.</p>

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<u>Cochrane Database Syst Rev. 2004;(3):CD003783</u>	SysRev	only analyzed RCTs and CCTs; excluded case series	one study of moderate quality, one of poor quality	<ul style="list-style-type: none"> o SCS vs surgery for FBSS: some limited evidence in favor of SCS o SCS plus PT vs PT alone for CRPS type I: limited evidence that SCS improves pain (but not function) in patients with CRPS I. 		The paucity of trials, coupled with the low quality of one of the studies, meant there was insufficient evidence to determine the benefits and harms of this spinal cord stimulation. In the absence of RCT evidence, it is worth noting the findings of other research here. An author of this review, Dr Taylor, has recently performed an extensive literature review of the effects of SCS for Failed Back Surgery Syndrome and CRPS. All levels of evidence (i.e., controlled, non-controlled literature, and unpublished reports) were included. This review concluded that SCS, combined with physical therapy, is a clinically effective alternative to physical therapy alone for patients with CRPS.	At the present time there is limited evidence that spinal cord stimulators are effective for some types of chronic pain (FBSS and CRPS Type 1). It is our opinion that the patient selection has to be thorough, and the indications for SCS need to be clear, before the treatment is given. A trial stimulation period was undertaken in both RCTs included in this review. However, there were no data regarding the benefits of having a trial stimulation period.
<u>J Pain Symptom Manage. 2006 Apr;31(4 Suppl):S13-9</u>	SysRev	1 RCT, 25 case series, and 1 economic evaluation for CRPS. 1 RCT, one cohort study, 72 case series, and 4 cost studies for refractory neuropathic back and leg pain/FBSS		<ul style="list-style-type: none"> o Grade A evidence for efficacy of SCS in CRPS type I. o Grade D evidence for the use of SCS in CRPS type II, since there are only case series studies. o Grade B evidence for efficacy of SCS in refractory neuropathic back and leg pain/FBSS 			

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Pain. 2004 Mar;108(1-2):137-47	SysRev	1 RCT, 6 case series for the review of effectiveness; 15 others met the inclusion criteria for the review of complications	Inclusion criteria: English-language article, ≥75% RSD/CRPS or FBSS or outcomes data reported separately for patients with FBSS or RSD/CRPS, data on pain or disability/work status collected prior to SCS and for ≥75% of implanted patients at ≥6 months follow-up on average.	<ul style="list-style-type: none"> o NNT for SCS in RCT was 3, indicating that among patients with CRPS type I, three people need to be given a trial of SCS for one of them to report "much pain improvement" 6 months later. o 5 case series studies that reported average pain improvement was mild to moderate. The two studies of FBSS patients that reported leg and back pain separately both found greater improvement in leg than in back pain with SCS. 	18 articles: average of 34% (range 0–81%) of the patients who received a permanent stimulator had one or more undesirable outcomes during the study follow-up period. These included superficial and deep infections, local pain in the region of stimulator components, biological complications other than infection or local pain (e.g. dural puncture), equipment failure, a stimulator revision (additional operation to correct an equipment problem; we did not include battery changes in this category), and stimulator removal (most commonly because of infection, equipment failure, or lack of pain relief). Removals included both permanent removals and removals followed by eventual re-implantations (e.g. removal due to infection and stimulator implantation after resolution of the infection).	<p>Could not reach conclusions regarding the effects of SCS on work status because no article systematically reported patient work status before and after SCS and rates of return to work in patients for whom return to work was a goal.</p> <p>The question of whether SCS effects change over time cannot be answered definitively.</p>	We conclude that the literature on SCS for FBSS and CRPS remains inadequate to make definitive statements about efficacy in reducing physical disability, work disability, and medication consumption. Using recently published criteria for levels of evidence, there is moderate evidence (one high-quality RCT) that SCS plus PT is more effective than PT-only for patients with CRPS type I in relieving pain at 6- and 12-month follow-ups. Both the RCT and lower-quality studies suggest a modest pain-relieving effect on average. Less regarding comparisons with placebo controls, other treatments, or the natural history can be gleaned from the literature. Complications leading to the need for additional surgeries have been common.