

Summary of Selected Spinal Cord Stimulation Studies

Study/Date/ Design	Participants/ Diagnosis*	Interventions or Objectives	Outcomes Measured	Results	Conclusions
Randomized Controlled Trials					
Kemler, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. Neurosurg 2008. RCT	Of initial randomized RSD (CRPS) patients, 24 received SCS, 13 received PT-only	Determine effect of SCS + PT on outcome variables compared to PT alone.	<ul style="list-style-type: none"> • Pain intensity • Global perceived effect • Would patient repeat treatment for same effect • HRQOL • Technical and surgical complications 	<p>Results at 5-years:</p> <ul style="list-style-type: none"> • 20 of 24 implanted patients available for follow-up (2 lost, 2 explanted) vs. 13 PT-only. • Mean pain relief (VAS) was greater in implanted patients ($p = 0.06$; patient groups were too small to detect significant effects). • 7 (35%) implanted patients reported "much improvement" in pain vs. 2 (15%) PT-only patients ($p = 0.02$, a statistically significant difference). • 18 (90%) reported positive global effect of SCS; 19 (95%) would repeat treatment for same result. • Annual SCS complication rate dropped to 5% in last 3 years. 	<p>SCS is a worthwhile treatment for patients with severe pain from CRPS because it achieves cost-effective pain reduction for 2-3 years in patients whose pain has not responded to other therapies.</p> <p>Patient satisfaction at 5 year follow-up remains high.</p>
Kemler, et al. The effect of spinal cord stimulation in patients with chronic reflex sympathetic dystrophy: two years' follow-up of the randomized controlled trial. Ann Neurol 2004. RCT	54 RSD (CRPS) patients (36 PT + SCS, 18 PT only)	Determine effect of SCS + PT on outcome variables compared to PT alone.	<ul style="list-style-type: none"> • Pain intensity • Global perceived effect • Functional status • HRQOL 	<p>Results at 2-year follow-up:</p> <ul style="list-style-type: none"> • 15 of 24 SCS+PT patients (63%) reported "much improvement" in pain compared with one (6%) of 16 PT-only patients. • Changes in health-related quality of life, and functional status were not statistically significant between treatment groups. • Complications occurred in 38% of patients, generally from electrode displacement and pain from the pulse generator pocket. 	<p>Study provides evidence that SCS reduces pain intensity of chronic RSD patients during 2 years of follow-up in a population that did not respond at all to any standard therapy.</p> <p>Complications declined sharply after the first year.</p>
Kemler, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 2000. RCT	54 RSD (CRPS) patients (36 PT + SCS, 18 PT only)	Determine effect of SCS + PT on outcome variables compared to PT alone.	<ul style="list-style-type: none"> • Pain intensity • Global perceived effect • Functional status • HRQOL 	<ul style="list-style-type: none"> • 14 of 24 implanted SCS patients (58%) were much improved after 6 months compared with 1 of 18 (6%) who received PT alone ($p < 0.001$, highly significant). • Pain intensity was significantly improved for SCS patients versus PT alone ($p < 0.001$) • SCS patients had improved pain ratings on McGill Pain Questionnaire ($p < 0.02$) health-related quality of life scores for lower ($p < 0.008$) and upper ($p < 0.02$) extremities. • Functional status not substantially different between groups. • Six of the 24 patients had complications that required additional procedures. 	<p>With careful selection of patients and successful test stimulation, SCS is safe, reduces pain, and improves the health-related quality of life in patients with chronic reflex sympathetic dystrophy. (For longer-term results of this trial, see Kemler, above.)</p>

* See abbreviations on last page

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<p>Kumar et al. 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.</p> <p>PROCESS trial: international, multi-center RCT</p>	<p>100 patients with FBSS and predominant leg pain of neuropathic radicular origin</p>	<p>Assess effectiveness of SCS vs. CMM alone for at least 6 months; crossover permitted after 6 months.</p>	<p>Primary outcome:</p> <ul style="list-style-type: none"> • Proportion of patients achieving 50% or more pain relief in legs at 24 months (VAS) <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Improvement in back, leg pain • HRQOL (SF-36) • Functional capacity • Use of pain medication and non-medication pain treatment • Patient satisfaction <p>Complications and adverse events</p>	<ul style="list-style-type: none"> • At 24 months, 42 patients continuing SCS (of 52 randomized to SCS) reported significantly improved leg pain relief ($p \leq 0.0001$), quality of life ($p \leq 0.01$), and functional capacity ($p \leq 0.0002$) • SCS patients had improved leg and back pain relief, HRQOL, functional capacity, and treatment satisfaction (statistically significant; $p \leq 0.05$ for all). • At 24 months, 46 of 52 patients randomized to SCS and 41 of 48 randomized to CMM who were available, the primary outcome was achieved by 17 (37%) randomized to SCS versus 1 (2%) to CMM ($p \leq 0.003$) and by 34 (47%) of 72 patients who received SCS as final treatment versus 1 (7%) of 15 for CMM ($p \leq 0.02$) 	<p>In selected patients with FBSS, treatment with SCS results in reported pain relief that is sustained at 24 months and is associated with patient satisfaction and clinically important improvements in functional capacity and health-related quality of life.</p>
<p>Kumar, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007.</p> <p>PROCESS trial: international, multi-center RCT</p>	<p>100 patients with FBSS and predominant leg pain of neuropathic radicular origin</p>	<p>Assess effectiveness of SCS vs. CMM alone for at least 6 months; crossover permitted after 6 months.</p>	<p>Primary outcome:</p> <ul style="list-style-type: none"> • Proportion of patients achieving 50% or more pain relief in legs at 6 months (VAS) <p>Secondary outcomes:</p> <ul style="list-style-type: none"> • Improvement in back, leg pain • HRQOL (SF-36) • Functional capacity • Use of pain medication and non-medication pain treatment • Patient satisfaction <p>• Complications and adverse events</p>	<ul style="list-style-type: none"> • At 6 months, 24 SCS patients (48%) and 4 CMM patients (9%) achieved the primary outcome (a statistically significant difference, $p < 0.001$). • SCS patients had improved leg and back pain relief, HRQOL, functional capacity, and treatment satisfaction (statistically significant; $p \leq 0.05$ for all). • At 12 months, 32% of implanted patients had 40 device-related complications (electrode migration (10%), infection (8%), loss of paresthesia (7%)). 	<p>SCS improves pain relief, HRQOL, functional capacity and patient satisfaction compared with CMM alone.</p>

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<p>North, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005.</p> <p>RCT</p>	<p>50 patients with FBSS (45 available for full follow-up)</p>	<p>Re-operation or SCS with crossover allowed</p>	<ul style="list-style-type: none"> • Self-reported pain relief. • Patient satisfaction. • Crossover to other procedure. • Use of analgesics • Improved daily functioning. • Work status. <p>“Success” defined as at least 50% pain relief <i>and</i> patient satisfaction as reported to disinterested third party interviewer.</p>	<ul style="list-style-type: none"> • 9 of 19 (47%) SCS patients vs. 3 of 26 (12%) re-operation patients met success criteria, a statistically significant difference ($p < 0.01$) • Patients initially randomized to SCS were significantly less likely to cross over than those randomized to re-operation (5 of 24 patients versus 14 of 26 patients, $p = 0.02$). • At long-term follow-up, re-operation patients required significantly more opiate analgesics than SCS patients ($p = 0.025$). Other measures of activities of daily living and work status did not differ significantly. • Of 14 patients (37%) who failed re-operation and elected SCS, 6 (43%) were successes. 	<p>SCS was significantly more successful than re-operation in selected patients with FBSS.</p> <p>Clinicians should offer SCS as an alternative to repeated operation to patients with persistent radicular pain after lumbosacral spine surgery.</p>
<p>North, et al. A prospective, randomized study of spinal cord stimulation versus re-operation for failed back surgery syndrome: initial results. Stereotact Funct Neurosurg 1994.</p> <p>RCT</p>	<p>27 FBSS patients</p>	<p>Re-operation or SCS with crossover allowed</p>	<p>Frequency of crossover to alternative procedure after 6 months.</p>	<ul style="list-style-type: none"> • Of 15 patients undergoing re-operation, 10 (67%) opted for crossover to SCS; • Of 12 undergoing SCS initially, 2 (17%) opted for crossover to re-operation. • Of 19 patients who declined study participation and chose re-operation, 8 (42%) opted to have SCS at 6 months. 	<p>Statistically significant advantage for SCS in first 27 patients reaching the 6-month crossover point. Outcome will continue to be assessed by several secondary outcome measures and patients will be enrolled until sample size reaches 50. (For longer-term results of this trial, see North, above.)</p>

* See abbreviations on last page

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Prospective Cohort Studies					
<p>Harke, et al. Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. Eur J Pain 2005.</p> <p>Prospective cohort study</p>	<p>29 patients with CRPS and sympathetically maintained pain (SMP); failure of CMM for at least one year.</p>	<p>Assess long term effect of SCS (+ PT) on functional status (mean follow-up 36 months) in patients with severe disability who responded to placebo-controlled temporary sympathetic block.</p>	<p>Outcomes assessed with SCS on and off:</p> <ul style="list-style-type: none"> • Pain intensity • Allodynia (painful response to usually non-painful stimuli) • Functional impairment • Functional status • Drug use • Back-to-work rate • Technical status of devices 	<p>At 12 months:</p> <ul style="list-style-type: none"> • Median VAS significantly reduced from 10 to 2 (p < 0.01). • Allodynia reduced from 10 to 0. • Multiple measures of functional impairment reduced > 50% (statistically significant for all, p < 0.01). <p>At mean period of 36 months:</p> <ul style="list-style-type: none"> • Median VAS maintained at 2, no allodynia. • 12 of 16 patients (75%) with impaired hand/finger function regained nearly normal movement; grip strength increased significantly (p<0.01). • 8 of 10 patients (80%) with affected leg resumed walking without crutches. • 70% returned to work. • Pain meds significantly reduced; opioids no longer needed. • Beneficial effects cannot be attributed to placebo or spontaneous improvement. • Favorable complication rate 14%/year. 	<p>Study confirms that long term SCS+PT achieves stable pain relief and may significantly restore functional status, improve psychosocial function, and reduce drug consumption in patients with severe disability and long history of disease.</p>
<p>Oakley, et al. A new spinal cord stimulation system effectively relieves chronic, intractable pain: a multi-center prospective clinical study. Neuromod. 2007</p> <p>Prospective multi-center cohort study</p>	<p>65 patients with FBSS, CRPS, other trunk/limb pain; VAS pain score ≥5</p>	<p>Demonstrate safety and efficacy of rechargeable 16-channel SCS system with 1 or 2 percutaneous 8-contact epidural leads (Precision)</p>	<ul style="list-style-type: none"> • Success defined as ≥50% improvement in VAS pain score. • Measured at 2 weeks (n=47), 3 months (n=38), 6 months (n=33), 12 months (n=12); study truncated after FDA device approval. • Complication rates. 	<ul style="list-style-type: none"> • 49 were implanted (75%). • Most CRPS subjects received 1 lead; most FBSS received 2. • All implanted subjects achieved significant pain relief at all time points (p < 0.001). • 32 (67%) obtained success at trial activation. • 37 (75%) success at end of temporary implant trial period. • Pain relief 53% at 6 months, 86% at 18 months for subjects observed. • 6 subjects required 9 revisions, average pain relief = 36%. • Most common adverse event was lead migration (7%). 	<p>SCS is safe and highly effective.</p> <p>The Precision system provides substantial benefits for patients with chronic pain and is likely to provide pain relief for those in whom conventional therapies have failed.</p>

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Long Term Outcomes Studies					
<p>Kumar, et al. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurg 2006.</p> <p>Case series</p>	<p>410 patients with FBSS, CRPS (I & II) and other diagnoses; failure of CMM for at least 6 months; not eligible for remedial surgery; at least 1 year of follow-up data.</p>	<p>Analyze clinical predictors of SCS treatment outcomes for chronic benign pain.</p>	<p>Success defined as > 50% improvement in VAS pain score.</p> <p>Patients assessed at 6-month intervals for 3 years, then annually.</p> <p>56 patients completed instruments measuring functional status and affective response to pain over recent 3 years.</p>	<ul style="list-style-type: none"> • 80% of patients experienced >50% pain relief in trial stimulation and were implanted. • 74% of implanted patients had pain relief at mean follow-up of 97.6 months. • 25.5% of patients with long-term success had > 75% pain relief; 74.5% had > 50% relief. • Overall long term success among screened patients = 59%. • No difference in long-term success for unilateral vs. bilateral pain • No difference based on number of surgeries. • Success rate inversely related to duration of pain before implantation. • Significant improvement in functional and psychological status. • # patients employed increased from 19 to 58. • Multipolar, multichannel electrodes have greater longer-term success. 	<p>SCS provides effective long-term pain control and is a predictable and reproducible outcome when performed by experienced physicians.</p> <p>Trial stimulation should be standard protocol.</p> <p>Multiple leads, new programming holds promise for treatment of predominantly axial back pain.</p>
<p>North et al. Spinal cord stimulation for chronic, intractable pain: experience over two decades. Neurosurgery 1993.</p> <p>Retrospective case series</p>	<p>320 consecutive SCS patients in one center, 1972- 1990 (205 available for follow-up, mean 7 years)</p>	<p>Long-term follow-up (mean 7 years).</p>	<ul style="list-style-type: none"> • Continued pain relief of at least 50% combined w/ patient satisfaction; • Return to work; • Functional gains and losses in activities of daily living (ADL), medication use, and neurological symptoms. 	<ul style="list-style-type: none"> • 52% of 171 patients w/ permanent implants reported > 50% pain relief; 60% would have procedure again for same result; 43% met both criteria. • 54% who were under 65 were working, up from 41% preoperatively. • 58% were taking less pain medicine. • A majority reported improved ADL. • No major morbidities noted. 	<p>Technical improvements in SCS have led to better system reliability and improved clinical results. Multichannel devices have improved ability to deliver relief precisely and improved outcome. This modality compares favorably with other treatments for chronic, intractable pain.</p>
<p>North, et al. Failed back surgery syndrome: 5-year follow -up after spinal cord stimulator implantation. Neurosurgery 1991.</p> <p>Case series</p>	<p>53 FBSS patients who had SCS at one center</p>	<p>Follow-up at average of 2.2 and 5 years postoperatively.</p>	<p>Patient-reported pain intensity and relief. Medication use and ability to perform ADL.</p> <p>Success defined as at least 50% pain relief 2 years post-op and/or at last follow-up, and patient satisfaction with treatment.</p>	<ul style="list-style-type: none"> • Mean estimated pain relief was 61% at 6 weeks, 59% at 6 months, 52% at 6 years, and 47% at 5 years postoperatively. • At 2.2 and 5 years, respectively, 53% and 47% of patients were successes. • After 5 years, 83% continued to use their stimulators. • Only 12% of patients used analgesics at follow-up vs. 74% before SCS. • 25% of previously disabled patients had returned to work. 	<p>SCS was successful in many patients. There were no major treatment complications.</p>

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Cost Effectiveness and Quality of Life Studies					
<p>Bell, et al. Cost effectiveness analysis of spinal cord stimulation in treatment of failed back surgery syndrome. J Pain Symptom Manage 1997.</p> <p>Cost-identification or cost-minimization analysis.</p>	FBSS	Economic analysis of medical costs of treating FBSS; development of model that compares SCS cost with other alternatives.	<ul style="list-style-type: none"> • Estimated annual costs over 5 years for treating two hypothetical, identical FBSS patients, one who opts for SCS and one who is treated with a representative mix of standard therapies. • Payback period. • Sensitivity analysis. 	<ul style="list-style-type: none"> • Over 5 years, both external and internal stimulators would save on total medical costs on either Medicare fees basis or average charge basis. • Cost savings for successful patients who avoid repeated surgery more than offset increased costs of unsuccessful patients even with no allowance for improved QOL, productivity, or mobility. • Payback period would range from 3.3 to 5 years for internal system, depending on cost basis used. Only improved SCS efficacy, perhaps through better patient selection, would significantly change the cost figures. For patients who respond well, payback is 2.1 years or less. 	<p>In reducing demands for medical care by FBSS patients, SCS can lead to medical cost savings, even when factoring in high initial cost, need for periodic replacement or revision, and failure to provide relief in a sizable fraction of implanted patients.</p> <p>Substantially better savings would result from better patient screening or technical improvements in stimulator.</p>
<p>Budd. Spinal cord stimulation: cost-benefit study. Neuromodulation 2002.</p> <p>Retrospective study</p>	20 FBSS patients (19 available for 5-year follow-up).	Find out whether cost neutrality could ever be reached in SCS patients given high cost of implant.	<ul style="list-style-type: none"> • Costs of medical and social care for the year prior to implantation and for five years following. • Pre- and post-implantation pain (VAS), quality of life (patient estimation), mobility and sleep pattern, drug (analgesic) usage. 	Global improvement in clinical parameters after one and 5 years. Prior to SCS implant, costs were £1954 (British) per year, extrapolated to £9770 over 5 years. Post SCS medical care costs over five years were £6250. Including modifications for five years, the post SCS costs were £9782. Cost neutrality was achieved after five years even allowing for a relatively high rate of additional procedures.	<p>Cost neutrality can be reached in five years or less post SCS implant, even allowing for high capital cost of the equipment, any replacements or manipulations of the system for electrode movement, and in-hospital stays of varied length.</p> <p>These results appear to agree with other published data.</p>

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<p>Hornberger, et al. Rechargeable spinal cord stimulation versus non-rechargeable system for patients with failed back surgery syndrome: a cost-consequences analysis. Clin J Pain. 2008</p> <p>Cost analysis</p>	<p>Typical patient with FBSS; characteristics based on literature, e.g. Mekhail, et al., 2004</p>	<p>Estimate average difference in lifetime direct costs between rechargeable and non-rechargeable pulse generators used with SCS for FBSS</p>	<ul style="list-style-type: none"> • Projected # lifetime SCS procedures. • Mean SCS procedures costs (\$ 2006). • Mean lifetime costs per patient. • Projections based on rechargeable battery life of 17.5 years (range 10 to 25 years); non-rechargeable battery life 4.1 years (range 3 to 6 years). 	<ul style="list-style-type: none"> • Projected # SCS procedures = 2.2 for rechargeable vs. 5.9 for non-rechargeable. • Difference is range from 2.6 to 4.2 fewer procedures using rechargeable SCS system. • Mean lifetime costs of \$405,000 for non-rechargeable vs. \$254,000 for rechargeable. • Sensitivity analysis demonstrates results are robust. 	<p>Rechargeable SCS systems result in mean savings of \$150,000 (range \$104,000-\$169,000) for a typical patient compared with non-rechargeable systems.</p> <p>Savings in SCS procedure costs = \$49,000 (\$26,000-\$59,000)</p> <p>Higher upfront costs of rechargeable SCS are offset by 4.1 years.</p> <p>Savings relative to other treatment modalities may be even greater.</p>
<p>Kemler and Furnee. Economic evaluation of spinal cord stimulation for chronic reflex sympathetic dystrophy. Neurology 2002.</p> <p>Economic evaluation based on data from RCT (Kemler 2004, 2000)</p>	<p>54 RSD (CRPS) patients (36 PT + SCS, 18 PT only)</p>	<p>Evaluate the economic aspects of treatment of chronic RSD with SCS, using outcomes and costs of care before and after the start of treatment.</p>	<p>Routine RSD medical costs, SCS costs, out-of-pocket costs. Pain relief by visual analogue scale, and health-related quality of life.</p>	<ul style="list-style-type: none"> • SCS was both more effective and less costly than the standard treatment protocol. • As a result of high initial costs of SCS, the treatment per patient in the first year is \$4,000 more than control therapy. In the lifetime analysis, SCS per patient is \$60,000 cheaper than control therapy. • At 12 months, SCS resulted in superior pain relief and improved health-related quality of life. 	<p>For chronic RSD patients, SCS is both more effective and, after 3 years, less costly than the conventional treatment protocol.</p> <p>SCS can be classified as a grade A technology (compelling evidence for adoption and appropriate utilization).</p>

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<p>Kumar, et al. Treatment of chronic pain with spinal cord stimulation versus alternative therapies: cost effectiveness analysis. Neurosurgery 2002</p> <p>Case series with control group</p>	104 patients with FBSS (60 SCS, 44 controls treated conservatively)	Tabulate and compare costs for a consecutive series of patients treated with SCS in a constant health care delivery environment and a control group treated in the same controlled environment.	Costs of diagnostic imaging, physician fees, implantation (including hardware), nursing visits for maintenance of the stimulators, physiotherapy, chiropractic treatments, massage therapy, and hospitalization for treatment of breakthrough pain. Patient functioning and quality of life (QOL).	<ul style="list-style-type: none"> Actual mean 5-year cost per SCS patient was \$29,123 CDN/patient, compared with \$38,029 for conservative pain treatment (CPT). Cost of SCS treatment was greater than for the CPT group for first 2.5 years but became less after that and remained lower throughout 5-year follow-up. 15% of SCS-treated patients returned to work. No control patients were able to return to employment of any kind. Questionnaire indicated 27% improvement in QOL for the SCS group, compared with 12% for the control group. 88% of SCS patients were satisfied or very satisfied with therapy. 	<p>FBSS patients who respond to SCS can achieve significant cost savings as well as increased rate of return to work, increased pain control, and better QOL.</p> <p>More money could be saved through better patient selection criteria and technological advances.</p> <p>Manufacturers should focus on methods to improve longevity of the pulse generator and durability of the electrode.</p>
<p>Manca, et al. Quality of life, resource consumption and costs of spinal cord stimulation vs. conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). Eur J Pain 2008.</p> <p>Cost and HRQOL analysis based on RCT (Kumar, 2007)</p>	100 patients with FBSS and predominant leg pain of neuropathic radicular origin	Assess HRQOL and cost implications of SCS vs. CMM	<ul style="list-style-type: none"> Resource use related to pre-implant screening, IPG, hospital, drug, non-drug therapy, complications. Costs based on prices in UK and Canada. EQ-5D (0 to 1 scale). <p><i>Note: Implanted patients were hospitalized for screening, average stay = 2.5 days</i></p>	<ul style="list-style-type: none"> 6 month total mean adjusted SCS costs significantly greater than CMM ($p < 0.001$): CAN\$15,400/€10,000 vs. CAN\$3994/€2594. Less drug use in SCS group: <ul style="list-style-type: none"> - 11 days less opioid use - 38 days less NSAID use - Two weeks less antidepressant use - Fewer prescriptions for anticonvulsants Less non-drug treatment use in SCS: <ul style="list-style-type: none"> - Physical therapy 7% SCS vs. 44% CMM - Psychotherapy 4% vs. 14% SCS complications (25%) required inpatient stay, average 2.6 days. Significant HRQOL improvement in SCS ($p < 0.001$) at 3 and 6 months; more improvement among those with recent surgery (≤ 1 year). 	<p>SCS increases HRQOL in FBSS patients by 0.21 on EQ-5D scale (very large effect).</p> <p>SCS costs are upfront; 15% of incremental costs are offset as of 6 months by reducing other treatment costs.</p> <p>PROCESS data alone are not sufficient to assess cost-effectiveness because study was limited to 6 months for ethical reasons.</p>

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<p>North, et al. Spinal cord stimulation versus re-operation for failed back surgery syndrome: a cost effectiveness and cost utility analysis based on a randomized, controlled trial. Neurosurgery 2007.</p> <p>Cost analysis based on RCT (North, et al., Neurosurgery 2005)</p>	<p>40 of 50 FBSS patients in RCT of SCS vs. re-operation</p>	<p>Analyze cost-effectiveness and cost-utility of SCS vs. re-operation for patients with FBSS</p>	<ul style="list-style-type: none"> • Charges for hospital/professional services based on 1) ITT, 2) treated as intended, 3) final treatment. • Utilities for treatment success and failure imputed from prior studies. • Simulation of cost-QALY outcomes displayed on cost-effectiveness plane. 	<ul style="list-style-type: none"> • 62% of patients randomized to re-operation crossed over to SCS; 23% of patients randomized to SCS crossed over to re-operation. • Final treatment → SCS had 12 successes, 15 failures; re-operation had 2 successes, 11 failures. • ITT: No statistically significant differences in ICER, ICUR. • Treated as intended: No significant difference, trend toward SCS. • Final treatment: no mean difference in cost; mean difference in QALYs = 0.18, p = 0.09. • Bootstrapped simulation results of ITT indicate SCS is both less costly and more effective; 72% are < \$40,000/QALY. 	<p>At mean follow-up of 3.1 years, SCS is more cost effective than re-operation in selected FBSS patients and should be the initial therapy of choice. Further validation study is needed.</p>
<p>North, et al. Spinal cord stimulator adjustment to maximize implanted battery longevity: a randomized, controlled trial using a computerized, patient-interactive programmer. Neuromodulation 2004.</p> <p>Cost analysis based on RCT</p>	<p>44 patients in 2 centers who had implanted electrodes and IPGs for low back and lower extremity pain.</p>	<p>Compare battery longevity when IPG is adjusted by manual means vs. interactive, patient controlled, computerized programmer.</p>	<ul style="list-style-type: none"> • Battery longevity. • Pain estimates using VAS. • Estimated cost savings. 	<ul style="list-style-type: none"> • In 95% of patients, the computerized, interactive system identified new settings with improved estimated battery life (and corresponding anticipated cost savings) over manual methods. • Estimated battery life for the setting chosen manually by each patient averaged 25.4 months; longest battery life identified by computerized methods averaged 55.0 months, a 2.2-fold or 29.6 mo. improvement. • 72% of patients achieved better battery life at settings with technical results equal or superior to those achieved by manual methods. • Estimated cost savings averaged just over one-third. • The new system also optimizes pain relief better than traditional, manual methods. 	<p>Computerized IPG stimulator programming is more cost effective than traditional manual methods. Significant potential savings are possible in the majority of patients with implanted spinal cord stimulators. Long-term follow-up will establish full magnitude of the savings.</p> <p>Battery life is a major driver of SCS-related costs. If it can be prolonged, corresponding lifetime savings can exceed \$300,000 for average patient.</p>

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Study/Date/Design	Participants/Diagnosis*	Interventions or Objectives	Outcomes Measured	Results	Conclusions
<p>Taylor and Taylor. Spinal cord stimulation for failed back surgery syndrome: a decision-analytic model and cost-effectiveness analysis. <i>Int J Technol Assess Health Care</i> 2005.</p> <p>Based on 2 RCTs</p>	Average patient with FBSS	Develop a decision-analytic model to assess cost-effectiveness of SCS vs. CMM.	<p>Incremental cost per QALY (ICER; costs in 2003 Euros)</p> <p>Includes sensitivity analysis of SCS screening, complications, effectiveness, and failure rates.</p>	<p>Over lifetime of 36 year-old FBSS patient, SCS reduced costs by €47,000/patient and improved utility by 1.12 QALYs compared with CMM; findings were robust to sensitivity analysis.</p> <p>In 2-year analysis, SCS had higher cost (€3,000) and higher utility gain (+0.07) ICER ranged from “best case” €30,000/QALY to “worst case” €64,000/QALY. Results were highly sensitive to changes in SCS effectiveness and complication rates.</p>	<p>SCS is both more effective and less costly than CMM over a patient’s lifetime. However, short term model results are highly sensitive to choice of input parameters.</p>
<p>Willis. A simple approach to outcomes assessment of the therapeutic and cost benefit success rates for spinal cord stimulation therapy. <i>Anesthes Clin NA</i> 2003.</p> <p>Retrospective study</p>	89 chronic intractable pain patients (60 were available for follow-up an average of 5.8 years post-implant).	Patient satisfaction with results of therapy and reduced medical care cost following therapy.	<p>Therapeutic success: (1) at least 50% reduction in pain while performing usual activities; (2) SCS system providing either good or excellent relief; and (3) patient would repeat procedure for same results.</p> <p>Cost-benefit success: > 50% reduction in average medical care use.</p>	<ul style="list-style-type: none"> • 36 of 55 patients (65.7%) evaluated for therapeutic efficacy met criteria for therapeutic success. 83% reported good-to excellent pain relief; 94% reported improved daily functioning. • 39 of 50 patients (78.7%) evaluated for cost efficacy met criteria for cost benefit success. • 25 of 48 (52.1%) patients met criteria for combined success, indicating that therapy was successful and use of health care resources was significantly reduced. 	<p>SCS was cost-effective and therapeutically effective for a majority of patients who had successful trial screening and were determined to be suitable for SCS. Strikingly, most patients were cost successes.</p> <p>Overall, this study provides continued support that SCS is an effective treatment for pain and reduces costs of treatment of chronic intractable pain patients.</p>

ABBREVIATIONS

ADL	Activities of Daily Living
CLBP	Chronic Limb/Back Pain
CMM	Conventional Medical Management
CRPS	Complex Regional Pain Syndrome (also RSD)
FBSS	Failed Back Surgery Syndrome
HRQOL	Health-Related Quality of Life
ICER	Incremental Cost Effectiveness Ratio
ICUR	Incremental Cost-Utility Ratio
ITT	Intention to Treat
QALY	Quality-Adjusted Life Year
PT	Physical Therapy
RCT	Randomized Clinical Trial
RSD	Reflex Sympathetic Dystrophy (also CRPS)
VAS	Visual Analog Scale

* See abbreviations on last page