WASHINGTON STATE HEALTH CARE AUTHORITY

HTA Appendices: Spinal Cord Stimulation

Supplemental Detailed Data Tables

Health Technology Assessment

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Spinal Cord Stimulation: Supplemental Detailed Data Tables

Provided by:

Spectrum Research, Inc.

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Supplemental Table 1. Demographic Table: Spinal Cord Stimulation Comparative Studies

Author (Year)	Study Type Study Period Study Location	Follow-up (% complete follow-up rate)	No. of patients enrolled Mean age (years) (range) Sex	Preop diagnosis (N, %) Duration of chronic pain	Intervention				Conflict of interest
					Randomized 1	Trial stimulation 2	Last intervention received at follow-up & cross-over 3	Analyses 4	
Efficacy (RCTs)									

Kemler 2000	RCT
	
	Study period NR; recruitment period: March 1997 to July 1998
	
	Maastricht University Hospital; Maastricht, Netherlands
		6 months (100% complete f/u rate)	N = 54
			
			Mean age: 38 years
			
			Age range: NR
			
			Sex: 69% female
				Chronic CRPS I (100%)
				• *affecting the:* hand (n = 33, 61%) foot (n = 21, 39%)
				
				• *caused by:* trauma (n = 26, 48%), surgery (n = 24, 44%), or developed spontaneously (n = 4, 7%)
				
				Duration of chronic pain: 38 months
					• SCS + PT (n = 36)
					• PT alone (n = 18)
						Patients randomized to SCS + PT (n = 36) underwent trial stimulation* for ≥ 7 days:
						
						Successful†:
						• 24/36 patients (67%), went on to receive permanent SCS implant
						
						Unsuccessful†:
						• 12/36 patients, went on to receive PT alone (crossed over)
							SCS + PT group:
							• SCS (permanent implantation)‡
							  • implant: 24/36
							  • no implant: 12/36
							• PT: see below
							
							PT group:
							• 18/18
							• standardized program of graded exercises to improve strength, mobility, and function
							• 30 minutes twice/week for 6 months
							
							Cross-over:
							• Not permitted until 6 months follow-up
								Intention-to-treat analysis:
								• SCS + PT: 36/36
								• PT alone: 18/18
								
								Randomized treatment received analysis:
								• SCS implant: 24/24
								• PT alone: 18/18
									None (study supported by a grant from the Dutch Health Insurance Council)

							(except for SCS patients that failed trial stimulation)		

Kemler 2004		24 month f/u of Kemler 2000 RCT (94% complete f/u rate: 51/54)					SCS + PT group (n = 36):
							• implant: 24/24
							• no implant: 11/12
							  • 1/12 patient excluded (received special implant)
							• 9/24 patients still undergoing PT**
							
							PT group (n = 18):
							• 16/18
							  • 2/18 patients excluded (crossed over)
							• 12/18 patients still undergoing PT**
								Intention-to-treat analysis:
								• SCS + PT: 35/36
								• PT alone: 16/18
								
								Randomized treatment received analysis:
								• SCS implant: 24/24
								• PT alone: 16/18	

Kemler 2008		60 month f/u of Kemler 2000 RCT (81% complete f/u rate: 44/54)					SCS + PT group (n = 36):
							• implant: 22/24
							  • 2/24 lost to f/u
							• no implant: 9/12
							  • 1/12 excluded (received special implant)
							  • 2/12 lost to f/u
							• number of patients still undergoing PT** NR
							
							PT group (n = 18):
								Intention-to-treat:
								• SCS + PT: 31/36
								• PT alone: 13/18
								
								Randomized treatment received analysis:
								• SCS implant: 20/24
								• PT alone: 13/18	

							• 13/18
							  • 4 excluded (crossed over)
							  • 1 lost to f/u
							• number of patients still undergoing PT** NR		

Kumar 2007 (PROCESS trial)	RCT
	
	Study period NR; recruitment period: April 2003 to June 2005
	
	Multicenter study: 12 centers in Europe, Canada, Australia, and Israel
		6 months (primary analysis)††
		
		(94% complete f/u rate: 94/100)
		
		12 months††
		
		(88% complete f/u rate: 88/100)
			N = 100
			
			Mean age: 50.4 years
			
			Age range: NR
			
			Sex: 51% male
				FBSS (100%) with leg pain exceeding back pain
				
				Duration of chronic pain: mean NR (≥ 6 months since surgery)
					SCS + CMM: n = 52
					CMM: n = 48
						Patients randomized to SCS + CMM (n = 52) underwent trial stimulation*:
						
						Successful†:
						• 43/52 patients (83%), went on to receive permanent SCS implant
						
						Unsuccessful†:
						• 9/52 patients
						  • 5/9 went on to receive SCS at patient's request
						  • 4/9 went on to receive CMM alone (crossed over)
							<u>6 months:</u>
							SCS + CMM group:
							• SCS (permanent implantation)‡
							  • 50/52
							  • 2/52 withdrew consent‡‡
							  • implant: (46-48)/52‡‡
							  • no implant: (2-4)/52‡‡
							• CMM***
							
							CMM group:
							• 43/48
							  • 4/48 withdrew consent
							1/48 did not complete 6-month f/u data
							• CMM treatment*** varied and was managed according to local clinical practice
							
							Cross-over:
							• Not permitted until 6 months follow-up
								Intention-to-treat (6 month f/u only):
								• SCS + CMM: 50/52
								• CMM alone: 44/48 (one pt did not complete 6-month f/u data but was included in calculations)
								
								Sensitivity analysis†††
								(primary outcome only ("success")):
								• SCS + CMM: NR/47
								• CMM alone: 43/48 (one pt did not complete 6-month f/u data but was included in calculations)
								
								Worst-case analysis‡‡‡
								(primary outcome only ("success")):
								• SCS + CMM:
									Study managed and funded by Medtronic

(Kumar 2007 continued…)							(except for SCS patients that failed trial stimulation)
							
							<u>12 months:</u>
							SCS + CMM group:
							• SCS (permanent implantation)‡
							  • 47/52
							  • 3/52 withdrew consent‡‡
							  • 2/52 lost to f/u‡‡
							  • SCS: (42-45)/52‡‡
							  • Crossed to CMM: (2-5)/52‡‡
							• CMM***
							
							CMM group:
							• 41/48
							  • 6/48 withdrew consent
							  • 1/48 lost to fu
							• CMM: 16/48 (including 4 pts who requested to crossover but failed trial stimulation)
							• Crossed to SCS: 28/48
								52/52
								• CMM alone: 48/48
								
								Per-protocol analysis (12 month f/u only):
								• SCS: n = 71
								• CMM: n = 17	

Manca 2008 (see Kumar		Manca 2008							

2007) PROCESS trial		(see Kumar 2007) PROCESS trial							

North 2005	RCT
	
	Study period NR
	
	Johns Hopkins University Hospital
		2.9 ± 1.1 years (range: 1.8 – 5.7 years)
		
		(75% complete f/u rate: 45/60††)
			N = 60
			
			Mean age: 50.2 years
			
			Age range: NR
			
			Sex: 50% female
				FBSS (100%) with leg pain exceeding or equal to back pain
				
				Duration of chronic pain: NR
					Randomized:
					• SCS (n = 30)
					• Reoperation (n = 30)
					
					Treated****:
					• SCS: 24/30
					• Reoperation : 26/30
						24/30 patients randomized to SCS underwent trial stimulation* for ≥ 3 days:
						
						Successful†:
						• 17/24 patients (71%), went on to receive permanent SCS implant
						
						Unsuccessful†:
						• 7/24 patients
						• 5/7 went on to receive reoperation (crossed over)
						• 2/7 dropped out of study after failing trial stimulation
							SCS (permanent implantation)‡ group (n = 24 treated):
							• implant: 15/17
							  • 1/17 lost to f/u
							  • 1/17 died
							• no implant (reoperation): 4/7
							  • 2/7 dropped out of the study after failing trial stimulation
							  • 1/7 lost to f/u
							  • 5/7 crossed over immediately due to failed trial stimulation
							
							Reoperation†††† group (n = 26 treated):
							• reoperation: 12/26
							• SCS (crossed-over): 14/26
							
							Cross-over:
							• Permitted after 6 months follow-up (except for SCS patients that failed trial stimulation)
								Intention-to-treat:
								• SCS: 19/24
								• reoperation: 26/26
								
								"Worst case" analysis‡‡‡ ("success" outcome only):
								• SCS: 23/24
								• reoperation: 26/26
								
								Treated as randomized analysis (at long-term f/u):
								• SCS: n = 15
								• reoperation: n = 12
								
								Per protocol analysis (at long-term f/u):
								• SCS: n = 29 (15 as randomized, 14 as cross-over)
								• reoperation: n = 16 (12 as randomized, 4 as cross-over)
									Study funded by Medtronic; Johns Hopkins received profits from a sale of Stimsoft, Inc., which was developing pain stimulator technology, to Medtronic

Effectiveness (cohort studies)								
Author (Year)	**Study Type Study Period Study Location**	**Follow-up Complete f/u rate (%)**	**# Patients (perm. SCS) Age (mean, range) Sex**	**Preop diagnosis (%, N)** **Duration of chronic pain or disease**	**Intervention**			**Conflict of Interest**
					SCS group***	**Pain Clinic (PC) group*****	**Usual Care (UC) group*****	
Turner 2010	Prospective cohort study Patient enrollment: December 2004 to June 2006 Study location: Providers for the WA state workers' comp program; conducted by the Univ. of Washington	Length of f/u: 24 months Complete f/u rate: 87%‡‡‡‡	Total N = 159 Mean age: 44.1 years Age range: NR 77% male	FBSS: 100% All patients had an open workers' compensation claim with the state of Washington Duration of chronic pain (median): 38 months	Enrolled: n = 52 Crossover: from UC: + 3 from PC: + 1 Trial SCS*,†: N = 51 (5 pts did not undergo trial) Crossover: to UC: + 2 to PC: + 3 Permanent SCS‡: N = 27 (52%) (n = 51 included in 24 month analysis, including crossovers)	Enrolled: n = 51 Crossover: to UC: -16 to SCS: -1 from UC: + 4 from SCS: + 2 Pain clinic evaluation: N = 39 Pain clinic treatment: N = 22 (n = 39 included in the 24 month analysis, including crossovers)	Enrolled: n = 56 Crossover: to PC: -4 to SCS: -3 from PC: + 16 from SCS: + 3 Usual care treatment: N = 68 (n = 68 included in the 24 month, including crossovers)	Study funded by Washington State Department of Labor and Industries, which administers the workers' comp provider for the enrolled patients (SCS would be a covered treatment only if patients enrolled in the study)

CRPS I: complex regional pain syndrome type I; previously referred to as reflex sympathetic dystrophy

f/u: follow-up
GPE: global perceived effect: evaluated on a seven-point scale (1 ("worst ever") – 7 ("best ever"))
NR: not reported
PT: physical therapy
SCS: spinal cord stimulation

* Trial stimulation of SCS - devices used:
Kemler 2001, 2004, 2008: temporary electrode (model 3861, Medtronic, Minneapolis, MN): positioned in the in epidural space so the patient experienced paresthesia over the entire region of pain upon stimulation; external stimulator (model 3625, Medtronic).
Kumar 2007: device and length of trial stimulation NR.
North 2005: temporary electrode (3487A Pisces-Quad, Medtronic): placed in the percutaneous space, no other details given.
Turner 2010: device details NR, devices used determined by the treating physician.
† Trial stimulation of SCS – definition of success:
Kemler 2001: trial stimulation was considered successful if patients met either of the following criteria: (1) VAS score for the last four days of test stimulation was ≥ 50% lower than the score prior to randomization, and/or (2) the GPE score was ≥ 6 ("much improved").
Kumar 2007: trial stimulation was considered successful if patients met both of the following criteria: (1) ≥ 50% reduction in leg pain, and (2) ≥ 80% overlap of their pain with stimulation-induced paresthesia.
North 2005: trial stimulation was considered successful if patients met all of the following criteria: (1) ≥ 50% reduction in pain "by standard pain rating methods", (2) did not increase their analgesic medication dosage, and (3) had improved physical activity proportionate to their neurological status and age.
Turner 2010: success criteria NR, determined by the treating physician
‡ Permanent SCS implantation - devices used:
Kemler 2001, 2004, 2008: electrode (model 3487A, Medtronic): placed in thoracic (for hand) or lumbar (for foot) spine so the patient experienced paresthesia over the entire region of pain upon stimulation; pulse generator (Itrell III, model 7425, Medtronic): implanted in the left lower abdominal wall; tunneled extension lead (model 7495-51/66, Medtronic); programmer (model 7434-NL, Medtronic); generator specifications: rate: 85 Hz, pulse width: 210usec, amplitude (adjusted by patient): 0–10 V.
Kumar 2007: implantable neurostimulation system (Synergy System, Medtronic)
North 2005: electrode (3487A-56 or 3587A Resume Electrode, Medtronic): no details given regarding placement; generator (X-trel or Itrel pulse generator, Medtronic): no details given.
Turner 2010: device details NR, devices used determined by the treating physician.
** Kemler 2001, 2004, 2008: continuation of physical therapy past 6 months was optional.
†† Kumar 2007: the primary (intention-to-treat) analysis was performed with data taken at 6 months follow-up due to the high rate of cross-over by 12 months.
‡‡ Kumar 2007: For the SCS group, the authors did not note which treatment patients lost to follow-up had received. At six months follow-up, 2/52 patients in the SCS group had withdrawn consent, however, the authors did not note whether these patients had had successful trial stimulation and received a permanent device or they had failed trial stimulation. At 12 months follow-up, 5/52 patients in the SCS group were lost (2/52 lost to f/u, 3/52 withdrew consent).
*** Kumar 2007: CMM for all patients was reviewed an actively managed at the discretion of the study investigatory and in accordance with local clinical practice and included oral medications (opioid, non-steroidal anti-inflammatory drug, antidepressant, anticonvulsant/antiepileptic and other analgesic

therapies), nerve blocks, epidural corticosteroids, physical and psychological rehabilitative therapy, and/or chiropractic care. No invasive treatments (including spinal surgery or implantation of an intrathecal drug delivery system) were permitted.

††† Sensitivity analysis:

Kumar 2007: excluded five patients in the SCS group who did not meet the screening criteria but requested an implant.

‡‡‡ Worst-case analysis:

Kumar 2007: considered patients unavailable at follow-up in SCS group "failures" and those in CMM group "successes".

North 2005: "worst case" analysis was performed according to intention-to-treat, but patients unavailable at follow-up were considered "failures".

**** North 2005: 10/60 patients (SCS: 6/30; reoperation: 4/30) were randomized but not treated: 9/10 due to failure to obtain insurance authorization and 1/10 due to a stroke; these patients are considered lost to follow-up in the complete follow-up calculation.

†††† North 2005: reoperation patients were treated with laminectomy and/or foraminotomy and/or discectomy with or without instrumentation; cross-over to SCS was permitted six months postoperatively.

‡‡‡‡ Turner 2010: patients paid for each evaluation completed: baseline, 24-months: $40 per visit; 6- and 12-months: $20 per visit.

***** Turner 2010: Patients distributed into treatment groups as follows:

SCS group: only those claimants who were potentially good candidates for SCS, met the study inclusion criteria, and had no contraindications for SCS were considered for trial stimulation. In order to be a candidate for SCS, Washington state workers' compensation claimants must agree to be part of the trial, otherwise, SCS was not a covered treatment. All treatment protocols were determined by the treating physician (details NR). Patients in the SCS group had significantly longer workers' compensation claim duration and work time loss compensation (vs PC only), more likely to have legal representation (vs PC or UC), longer leg pain duration (vs PC only) and greater leg pain intensity (vs UC only), as well as higher (worse) Roland-Morris Disability Questionnaire scores (vs PC and UC). These differences were not controlled for by multivariate analysis.

Pain Clinic group: claimants who met the inclusion criteria and had been approved for pain clinic evaluation were invited to participate in the study. All treatment protocols were determined by the treating physician (details NR).

Usual Care group: claimants who met the inclusion criteria but had not been referred for SCS or pain clinic evaluation were randomly invited (8 patients per week) to participate in the study.

Supplemental Table 2. Inclusion and Exclusion Criteria: Spinal Cord Stimulation Comparative Studies

Author (Year)	Inclusion criteria	Exclusion criteria

Kemler 2001	• 18 – 65 years of age
	• Met the IASP diagnositic criteria for reflex sympathetic dystrophy (CRPS I)
	• Had impaired function and symptoms beyond the region of trauma*
	• Pain restricted to one hand or foot
	• Pain affected entire hand or foot
	• Pain lasting ≥ 6 months that:
	  • did not respond continuously to standard therapy†
	  • had a mean intensity of 5 cm on a scale of 0 cm (no pain) to 10 cm (extreme pain)
	• Consent to randomization to either treatment group
		• Raynaud's disease
		• History of unrelated neurologic abnormalites
		• Unrelated condition that affects the diseased hand or foot
		• Blood-clotting disorder or use of an anticoagulant
		• Cardiac pacemaker
		• Presence of serious psychiatric disorders‡:
		  • did not respond continuously to standard therapy†
		  • had a mean intensity of 5 cm on a scale of 0 cm (no pain) to 10 cm (extreme pain)

Kemler 2004, Kemler 2008	• patients randomized to SCS +PT who crossed over to PT due to failed trial stimulation	• patients randomized to PT who crossed over to SCS (allowed after 6 months)

Author (Year)	Inclusion criteria	Exclusion criteria
Kumar 2007, Manca 2008	• ≥ 18 years of age • Neuropathic pain of radicular origin (predominantly legs) that exceeds back pain • Pain intensity ≥ 50 mm on VAS (0 – 100 mm) • Pain for ≥ 6 months after ≥ 1 anatomically successful surgery for herniated disc • Documented history of nerve injury (root compression by herniated disc) that would explain the radiating pain	• Concurrent clinically significant or disabling chronic pain syndrome • Inability to receive or manage the SCS device • History of coagulation disorder, lupus erythematosus, diabetic neuropathy, rheumatoid arthritis, or ankylosing spondylitis • Active psychiatric disorder, any condition known to affect the perception of pain, or inability to evaluate treatment outcome • Life expectancy < 1 year • Existing or planned pregnancy

Author (Year)	Inclusion criteria	Exclusion criteria

North 2005	• Nerve root compression amenable to surgical treatment
	• Persistent or recurrent radicular pain (with or without low back pain) refractory to conservative care
	• At least one previous lumboscaral spine surgery
	• Consent to randomization to either treatment group
		• Conditions requiring immediate surgical treatment:
		  • Disabling neurological deficit (such as foot drop, neurogenic bladder) in the distribution of a nerve root caused by surgically treatable compression
		  • Critical cauda equina compression
		  • Gross instability (spondylolisthesis or abnormal subluxation) requiring fusion
		• Untreated dependency on prescription narcotic analgesics or benzodiazapines
		• Untreated major psychiatric condition
		• Possibility of secondary gain
		• Concurrent clinically significant or disabling chronic pain condition
		• Primary complaint of axial (low back) pain that exceeds radicular (hip, buttock, leg) pain

Turner 2010	• Open Washington State workers' compensation claim (of any duration) for back injury • Receiving work time loss compensation as a result of temporary total inability to work due to the injury • Age 18–60 years • 1–3 prior open lumbar spine	• Patients who did not meet the inclusion criteria

Author (Year)	Inclusion criteria	Exclusion criteria
	operations during the claim • Pain radiating into one or both legs for > 6 months • Radicular pain greater than axial pain • Average pain in the past mont rated ≥ 6 on 0–10 scale • No prior SCS surgery • Ability to speak English or Spanish SCS patients: • No contraindications for surgery • No progressive motor deficit, bony deformity • SCS would be a covered treatment for the patients by workers' compensation if they participated in the study Pain clinic (PC) patients: • Identified from worker's comp administrative databases when they were approved for PC evaluation Usual care (UC) patients: • Had not been referred for SCS or PC • Eight patients per week were randomly selected	

CRPS I: complex regional pain syndrome type I; previously referred to as reflex sympathetic dystrophy

IASP: International Association for the Study of Pain
SCS: spinal cord stimulation

* These symptoms are not part of the IASP definition of reflex sympathetic dystrophy.
† Standard therapy consists of six months of physical therapy, sympathetic blockade, transcutaneous electrical nerve stimulation, and pain medication.
‡ The psychiatric health of all patients was evaluated using the 90-item Symptom Check List (score range: 90 – 450, higher scores indicate greater psychological distress); psychiatric examination was performed if the patient received a score of ≥ 200 and any patient with major psychiatric illness, substance abuse, or potential secondary gains from the treatment of the disease were excluded.

Supplemental Table 3. Clinical Data: Spinal Cord Stimulation Comparative Studies

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
Efficacy (RCTs)							
Chronic regional pain syndrome type I (CRPS-I)							
Kemler 2000 6 month f/u	*Intention-to-treat analysis:* SCS + PT: 36/36 PT: 18/18 Change in VAS score from baseline (mean ± SD): • SCS+PT: -2.4 ± 2.5 • PT: 0.2 ± 1.6 • *P* < .001 • pain relief similar for pts with affected hand and those with affected foot (data NR) McGill Pain Questionnaire: • NR (continued)	NR	*Intention-to-treat analysis:* SCS + PT: 36/36 PT: 18/18 Percent of patients with GPE score* ≥ 6: • SCS+PT: 39% (14/36) • PT: 6% (1/18) • *P* = .01 (continued)	*Intention-to-treat analysis:* SCS + PT: 36/36 PT: 18/18 Percent change in HR-QoL† from baseline (mean ± SD): • SCS+PT: 6 ± 22% • PT: 3 ± 18 • *P* = .58 (NS) Nottingham Health Profile pain component: • NR EQ-5D (mean ± SD): • NR Self-Rating Depression Scale (mean ± SD): NR (continued…)	NR	NR	"Success": (1) ≤ 50% pain relief (VAS), or (2) GPE ≥ 6 Success (n, %): SCS + PT: 56% (20/36) PT: NR

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2000 continued)	- - - - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 18/18 Change in VAS score from baseline (mean ± SD): • SCS + PT, implant received: -3.6 ± 2.0 • PT: 0.2 ± 1.6 • *P* < .001 McGill Pain Questionnaire pain-rating index: • *P* = .02 in favor of SCS (data NR)		GPE scores* (%, n): SCS+PT: • 1 (worst): 0% (0/36) • 2: 8% (3/36) • 3: 6% (2/36) • 4: 19% (7/36) • 5: 28% (10/36) • 6: 39% (14/36) • 7 (best): 0% (0/36) PT: • 1 (worst): (2/18) • 2: 11% (2/18) • 3: 33% (6/18) • 4: 22% (4/18) • 5: 17% (3/18) • 6: 6% (1/18) • 7 (best): 0% (0/18) (continued)	- - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 18/18 Percent change in HR-QoL† from baseline (mean ± SD): • SCS+PT, implant received: 11 ± 23% • PT: 3 ± 18 • *P* = NR (continued)			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2000 continued)			- - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 18/18 Percent of patients with GPE score* ≥ 6: • SCS+PT, implant received: 58% (14/24) • PT: 6% (1/18) • *P* < .001	Nottingham Health Profile pain component: *Patients with affected hand:* • *P* = .02 in favor of SCS (data NR) *Patients with affected foot:* • *P* = .008 in favor of SCS (data NR) EQ-5D (mean ± SD): • NR Self-Rating Depression Scale (mean ± SD): • NR			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
Kemler 2004 24 month f/u	*Intention-to-treat analysis:* SCS + PT: 35/36 PT: 16/18 Change in VAS score from baseline (mean ± SD): • SCS+PT: -2.1 ± 2.8 • PT: 0 ± 1.5 • *P* = .001 McGill Pain Questionnaire: • NR - - - - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 16/18 Change in VAS score from baseline (mean ± SD): • SCS + PT, implant received: -3 ± 2.7 • PT: 0 ± 1.5 • *P* < .001	NR	*Intention-to-treat analysis:* SCS + PT: 35/36 PT: 16/18 Percent of patients with GPE score* ≥ 6: • SCS+PT: 43% (15/35) • PT: 6% (1/16) • *P* = .001 (continued)	*Intention-to-treat analysis:* SCS + PT: 35/36 PT: 16/18 Percent change in HR-QoL† from baseline (mean ± SD): • SCS+PT: 7 ± 20% • PT: 12 ± 18 • *P* = .41 (NS) Nottingham Health Profile pain component: • NR EQ-5D (mean ± SD): • NR Self-Rating Depression Scale (mean ± SD): • NR (continued)	NR	NR	"Success": (1) ≤ 50% pain relief (VAS), or (2) GPE ≥ 6 Success (n, %): SCS + PT: 57% (20/35) PT: NR

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2004 continued)	(continued) McGill Pain Questionnaire pain-rating index: • *P* = .02 in favor of SCS (data NR)		GPE scores* (%, n): SCS+PT: • 1: 3% (1/35) • 2: 6% (2/35) • 3: 11% (4/35) • 4: 26% (9/35) • 5: 11% (4/35) • 6: 43% (15/35) • 7 (best): 0% (0/35) PT: • 1: 13% (2/16) • 2: 13% (2/16) • 3: 31% (5/16) • 4: 19% (3/16) • 5: 6% (1/16) • 6: 6% (1/16) • 7 (best): 0% (0/16)	- - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 16/18 Percent change in HR-QoL† from baseline (mean ± SD): • SCS+PT, implant received: 12 ± 21% • PT: 12 ± 18 • *P* = NR			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2004 continued)			(continued…) - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 24/24 PT: 16/18 Percent of patients with GPE score* ≥ 6: • SCS+PT, implant received: 63% (15/24) • PT: 6% (1/16) • *P* < .001	(continued) Nottingham Health Profile pain component: *Patients with affected hand (n = NR):* • *P* = .02 in favor of SCS (data NR) *Patients with affected foot (n = NR):* • *P* = .008 in favor of SCS (data NR) EQ-5D (mean ± SD): • NR (continued…) Self-Rating Depression Scale (mean ± SD): • NR			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
Kemler 2008 60 month f/u	*Intention-to-treat analysis:* SCS + PT: 31/36 PT: 13/18 Change in VAS score from baseline (mean ± SD): • SCS+PT: -1.7 ± 2.3 • PT: -1.0 ± 2.9 • *P* = .25 (NS) VAS scores* (mean, cm): SCS+PT (31/36) • 0 years: 6.7 • 1 year: 4.2 • 2 years: 4.3 • 3 years: 5.2 • 4 years: 5.0 • 5 years: 5.0 PT: • 0 years: 6.9 • 1 year: 6.6 • 2 years: 6.6 • 3 years: 6.2	NR	*Intention-to-treat analysis:* SCS + PT: 31/36 PT: 13/18 Percent of patients with GPE score* ≥ 6: • SCS+PT: 23% (7/31) • PT: 15% (2/13) • *P* = .24	*Intention-to-treat analysis:* SCS + PT: 31/36 PT: 13/18 Percent change in HR-QoL† from baseline (mean ± SD): • NR Nottingham Health Profile: SCS + PT (mean ± SD) • mobility: 7 ± 15 • pain: -7 ± 27 • sleep:-15 ± 30 • energy: 5 ± 43 • social isolation: 4 ± 18 • emotional reaction: -2 ± 27 PT (mean ± SD) • mobility: 5 ± 28 • pain: -5 ± 27	NR	NR	"Success": (1) ≤ 50% pain relief (VAS), or (2) GPE ≥ 6 Success (n, %): SCS + PT: 35% (11/31) PT: NR

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2008 continued)	• 4 years: 5.9 • 5 years: 5.9 (continued) McGill Pain Questionnaire: • NR - - - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 20/24 PT: 13/18 Change in VAS score from baseline (mean ± SD): • SCS + PT, implant received: -2.5 ± 2.2 • PT: -1.0 ± 2.9 • *P* = .06 (NS)		(continued) GPE scores* (%, n): SCS+PT: • 1: 3% (1/31) • 2: 26% (8/31) • 3: 6% (2/31) • 4: 10% (3/31) • 5: 32% (10/31) • 6: 23% (7/31) • 7 (best): 0% (0/31) PT: • 1: 8% (1/13) • 2: 23% (3/13) • 3: 23% (3/13) • 4: 23% (3/13) • 5: 8% (1/13) • 6: 15% (2/13) • 7 (best): 0% (0/13)	• sleep: -12 ± 34 • energy: 2 ± 55 • social isolation: 1 ± 20 • emotional reaction: -5 ± 26 *P* = NS for all components EQ-5D (mean ± SD): • SCS + PT: 16 ± 25 • PT: 19 ± 46 • *P* = 0.8 (NS) Self-Rating Depression Scale (mean ± SD): • SCS + PT: 0 ± 9 • PT: -3 ± 11 • *P* = 0.47 (NS) - - - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 20/24 PT: 13/18 Percent change in			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2008 continued)	(continued) VAS scores* (mean, cm): SCS+PT, implant received: • 0 years: 6.6 (estimated from graph) • 1 year: 2.7 (estimated from graph) • 2 years: 2.9 (estimated from graph) • 3 years: 4.2 (estimated from graph) • 4 years: 4.4 (estimated from graph) • 5 years: 4.1 (estimated from graph) PT: see above McGill Pain Questionnaire:		(continued) - - - - - - - - - - - *Randomized treatment received analysis:* SCS + PT, implant received: 20/24 PT: 13/18 Percent of patients with GPE score* ≥ 6: • SCS+PT, implant received: 35% (7/20) • PT: 15% (2/13) • *P* = .02	HR-QoL† from baseline (mean ± SD): • NR (continued) Nottingham Health Profile: SCS + PT, implant received) (mean ± SD): • mobility: 6 ± 15 • pain: -15 ± 25 • sleep: -22 ± 35 • energy: 12 ± 35 • social isolation: 5 ± 18 • emotional reaction: -6 ±26 *P* = NS for all components (comparing SCS to PT) EQ-5D (mean ± SD): • SCS + PT, implant received: 24 ± 26 • PT: 19 ± 46			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kemler 2008 continued)	• NR			• *P* = 0.73 (NS) (continued) Self-Rating Depression Scale (mean ± SD): • SCS + PT, implant received: -1 ± 8 • PT: -3 ± 11 • *P* = 0.66 (NS)			

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
Failed back surgery syndrome (FBSS)							
Kumar 2007 (& Manca 2008 where indicated) **PROCESS trial** 6 month f/u: ITT analysis 12 month f/u: PP analysis	**PRIMARY OUTCOME: 6 month follow-up** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 ≥50% leg pain relief (%, n) (primary outcome) at 6 months: • SCS + CMM: 48% (24/50) • CMM: 9% (4/44) • Risk difference (99% CI): 39% (18, 60%) • Odds ratio (99% CI): 9.23 (1.99, 42.84) • $P < .001$‡	**6 month follow-up** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 Satisfied with pain relief (%, n): • SCS + CMM: 66% (33/50) • CMM: 18% (8/44) • Difference in means (99% CI): 48% (25, 71%) • Odds ratio (99% CI): 8.73 (2.46, 31.01)	NR	**6 month follow-up** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 **SF-36 (mean ± SD):** Physical function: • SCS + CMM: 38.1 ± 23.0 ($P < .001$ vs baseline) • CMM: 21.8 ± 16.2 (P = NS vs baseline) • Difference in means (99% CI):	**6 month follow-up** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 **Oswestry disability index** (mean ± SD): • SCS + CMM: 44.9 ± 18.8 ($P < .001$ vs baseline) • CMM: 56.1 ± 17.9 (P = NS vs baseline) • Difference in means (99% CI): -11.2 (-21.2, -1.3) • $P < .001$	**6 month follow-up** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 **Morphine** (oral equivalent daily mg)*** (mean ± SD): Low end of range: • SCS + CMM: 68.3 ± 139 (P = NS vs baseline) • CMM: 96.9 ± 214 (P = NS vs baseline) • Difference in means (99% CI): -28.6 (-125.5,	NR

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
		• $P < .001$		16.3 (5.3, 27.2) • $P < .001$		68.3) • $P = 0.21$ (NS)	
(Kumar 2007 continued)	(continued) - - - - - - - - - - - - - - *Sensitivity analysis**:* SCS + CMM: NR/47 CMM: 44/48 ≥50% leg pain relief (%, n) (primary outcome) at 6 months: • SCS + CMM: 51% (NR) • CMM: 9% (4/44) • $P < .001$ - - - - - - - - - - - - - - *Worst-case analysis††:* SCS + CMM: 52/52 CMM: 48/48 ≥50% leg pain relief (%, n) (primary outcome) at 6 months:	(continued) Agree with treatment (%, n): • SCS + CMM: 86% (43/50) • CMM: 50% (22/44) • Difference in means (99% CI): 36% (13, 59%) • Odds ratio (99% CI): 6.14 (1.66, 22.67) • $P < .001$ Return to work‡‡ (%, n): • SCS + CMM: 11% (4/36) • CMM: 3% (1/33) • Difference in means (99%		(continued) Role-physical: • SCS + CMM: 17.5 ± (32.4) ($P = .006$ vs baseline) • CMM: 8.0 ± 22.7 • (P = NS vs baseline) • Difference in means (99% CI): 9.5 (-5.9, 24.9) • $P = .12$ (NS) Bodily pain: • SCS + CMM: 33.0 ± 20.9 ($P < .001$ vs baseline) • CMM: 19.5 ± 12.9 ($P < .001$ vs baseline) • Difference in		(continued) High end of range: • SCS + CMM: 76.8 ± 146 (P = NS vs baseline) • CMM: 125 ± 281 (P = NS vs baseline) • Difference in means (99% CI): -48.4 (-167.8, 71.1) • $P = 0.20$ (NS) **Drug therapy** (%, n) Opioids: • SCS + CMM: 56% (28/50) (P = NS vs baseline) • CMM: 70% (31/44) (P = NS vs	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kumar 2007 continued)	• SCS + CMM: 46% • CMM: 17% • *P* = .002 (continued) - - - - - - - - - - - - - - - **SECONDARY OUTCOMES:** **6 month follow-up only** *Intention-to-treat analysis:* SCS + CMM: 50/52 CMM: 44/48 Leg pain relief ≥ 30% (%, n): • SCS+CMM: 64% (32/50) • CMM: 18% (8/44) • Risk difference (99% CI): 46% (23, 69%) • Odds ratio (99% CI): 8.00 (2.27, 28.22)	CI): 8% (-7, 22%) • Odds ratio (99% CI): 4.00 (0.21, 76.18) • *P* = 0.36 (NS)		means (99% CI): 13.4 (3.9, 23.0) • *P* < .001 (continued) General health: • SCS + CMM: 52.8 ± 22.3 (*P* = .004 vs baseline) • CMM: 41.3 ±24.4 (*P* = .007 vs baseline) • Difference in means (99% CI): 11.5 (-1.2, 24.1) • *P* < .001 Vitality: • SCS + CMM: 41.3 ± 21.5 (*P* = .002 vs baseline) • CMM: 31.1 ± 20.9 (*P* = NS vs		baseline) • Difference in means (99% CI): -15 (-40, 11)% • *P* = 0.20 (NS) (continued) NSAIDs: • SCS + CMM: 34% (17/50) (*P* = NS vs baseline) • CMM: 50% (22/44) (*P* = NS vs baseline) • Difference in means (99% CI): -16 (-42, 10)% • *P* = 0.14 (NS) Antidepressants: • SCS + CMM: 34% (17/50) (*P* = NS vs baseline) • CMM: 55% (24/44) (*P* = NS vs baseline) • Difference in	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kumar 2007 continued)	• *P* < .0001 (continued) Leg pain relief ≥ 80% (%, n): • SCS+CMM: 22% (11/50) • CMM: 7% (3/44) • Risk difference (99% CI): 15% (-3, 33%) • Odds ratio (99% CI): 3.85 (0.65, 22.71) • *P* = .05 (NS) Leg pain VAS (mean ± SD) • SCS+CMM: 39.9 ± 26.3 (*P* < .0001 vs baseline) • CMM: 66.6 ± 24.0 (*P* = .03 vs			baseline) • Difference in means (99% CI): 10.2 (-1.4, 21.7) • *P* = .01 (continued) Social functioning: • SCS + CMM: 49.3 ± 29.7 (*P* = .001 vs baseline) • CMM: 33.5 ± 18.4 (*P* = NS vs baseline) • Difference in means (99% CI): 15.7 (2.1, 29.4) • *P* = .002 • (99% CI): Role-emotional: • SCS + CMM: 51.3 ± 44.3 (*P* = NS vs baseline) • CMM: 29.5 ± 40.8		means (99% CI): -21 (-47, 5)% • *P* = 0.06 (NS) (continued) Anticonvulsants: • SCS + CMM: 26% (13/50) (*P* = NS vs baseline) • CMM: 50% (22/44) (*P* = NS vs baseline) • Difference in means (99% CI): 0.35 (0.11, 1.10)% • *P* = 0.02 **Non-drug therapy** (%, n) Physical rehabilitation: • SCS + CMM: 6% (3/50)	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kumar 2007 continued)	baseline) • Difference in means (99% CI): -26.7 (-40.4, -13.0) • *P* < .0001 (continued) Back pain VAS (mean ± SD) • SCS+CMM: 40.6 ± 24.9 (*P* = .007 vs baseline) • CMM: 51.6 ± 26.7 (*P* = NS vs baseline) • Difference in means (99% CI): -11.0 (-25.0, 3.0) • *P* = .008 - - - - - - - - - - - - - - - **PRIMARY OUTCOME: 12 month follow-up** *Intention-to-treat*			(*P* = NS vs baseline) • Difference in means (99% CI): 21.8 (-1.4, 45.0) • *P* = .02 (continued) Mental health: • SCS + CMM: 62.6 ± 22.2 (*P* = .004 vs baseline) • CMM: 50.1 ± 23.3 (*P* = NS vs baseline) • Difference in means (99% CI): 12.5 (0.1, 24.8) • *P* = .002		(*P* = NS vs baseline) • CMM: 18% (8/44) (*P* = NS vs baseline) • Difference in means (99% CI): 0.29 (0.05, 1.80) • *P* = 0.11 (NS) (continued) Psychological rehabilitation: • SCS + CMM: 2% (1/50) (*P* = NS vs baseline) • CMM: 11% (5/44) (*P* = NS vs baseline) • Difference in means (99% CI): 0.16 (0.01, 2.82) • *P* = 0.09 (NS) Acupuncture: • SCS + CMM: 0% (0/50) • CMM: 7% (3/44) (*P* = NS vs baseline)	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Kumar 2007 continued)	*analysis:* NR due to high number of cross-over at 6 months *Per protocol analysis:* SCS + CMM: n = 71 CMM: n = 17 (continued) ≥50% leg pain relief (%, n) (primary outcome) at 12 months: • SCS+CMM: 48% (34/71) • CMM: 18% (3/17) • *P* = .03 *Post-hoc modified intention-to-treat analysis (crossover = failure):* SCS + CMM: n = 47 CMM: n = 41 ≥50% leg pain relief (%, n) (primary outcome) at			(continued) **EQ-5D** (reported in Manca 2008) EQ-5D weighted index score (mean ± SD): 6 months: • SCS + CMM: 0.47 ± 0.32 • CMM: 0.25 ± 0.30 • Difference in adjusted means††† 0.23 (0.12, 0.35) • *P* < .001††† (adjusted) *[Unadjusted difference:*		• Difference in means (99% CI): -7 (-17, 3)% • *P* = 0.10 (NS) (continued) Massage: • SCS + CMM: 0% (0/50) • CMM: 9% (4/44) (*P* = NS vs baseline) • Difference in means (99% CI): -9 (-20, 2)% • *P* = 0.05 (NS) TENS: • SCS + CMM: 0% (0/50) • CMM: 11% (5/44) (*P* = NS vs baseline) • Difference in means (99% CI):	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
	12 months: • SCS+CMM: 34% (16/47) • CMM: 7% (3/41) • *P* = .005			*0.22 (0.09, 0.35), p-value NR]*		-11 (-24, 1)% • *P* = 0.02 Manca 2008 gives a detailed report of the number of treatment episodes and prescriptions.	
Kumar 2008 **(PROCESS trial, continued…)** 24 month follow-up per-protocol and modified intention-to-treat analysis only (where cross-over = failure) only	**PRIMARY OUTCOME: 24 month follow-up** *Per protocol analysis:* SCS + CMM: n = 72 CMM: n = 15 ≥50% leg pain relief (%, n): • SCS+CMM: 47% (34/72) • CMM: 7% (1/15) • *P* = .02 • Relative Risk (RR) = 7.08 (95% CI, 1.05,	NR	NR	NR	NR	NR	NR

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
	47.80) *Modified intention-to-treat analysis (cross-over = failure):* SCS + CMM: n = 46 CMM: n = 41						
(Kumar 2008 continued)	(continued) ≥50% leg pain relief (%, n): • SCS+CMM: 37% (17/46) • CMM: 2% (1/41) • *P* = .003 • RR = 18.48 (95% CI, 2.56, 133.38) *Worst-case analysis††:* SCS + CMM: n = 52 CMM: n = 48 ≥50% leg pain relief (%, n): • SCS + CMM: 33% (17/52)						

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
	• CMM: 17% (8/48) • *P* = .07 • RR = 1.96 (95% CI, 0.93, 4.1)						
North 2005 2.9 ±1.1 years follow-up	NR, see "success": ≥ 50% pain relief and patient satisfaction	NR, see "success": ≥ 50% pain relief and patient satisfaction	NR	NR	*Intention to treat:* SCS: 19/24 CMM: 26/26 Data could only be crudely estimated from graphs so is not reported here. Authors claim NS difference between groups in any of the following patient-reported outcomes: Activity : • Work	*Intention to treat:* SCS: 19/24‡‡‡ CMM: 26/26 Opioid use increased: • SCS: 13% (3/23‡‡‡) • Reoperation: 42% (11/26) • *P* = .025 Opioid use stable or decreased: • SCS: 87% (20/23‡‡‡) • Reoperation: 58% (15/26)	**"Success": ≥ 50% pain relief and patient satisfaction** *Intention to treat:* SCS: 19/24 CMM: 26/26 "Success": • SCS: 47% (9/19) • Reoperation: 12% (3/26) • *P* < .01 - - - - - - - - - - - - *Worst-case*

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(North 2005 continued)					• Walk • Climb stairs • Sleep • Engage in sex • Drive a car • Sit at a table to eat Neurological function: • Lower extremity strength and coordination • Sensation • Bladder/bowel function	• *P* = NR	*analysis††:* SCS: 23/24 CMM: 26/26 "Success": • SCS: 39% (9/23) • Reoperation: 12% (3/26) • *P* = .04 (continued) - - - - - - - - - - - - - *Per-protocol analysis (of patients available at long-term f/u):* SCS: n = 29 CMM: n = 16 "Success": • SCS: 52% (15/29) (15 as randomized, 14 as crossovers) • Reoperation: 19% (3/16) (12 as randomized,

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(North 2005 continued)							4 as crossovers) • $P < .05$ - - - - - - - - - - - - - *Treated as randomized (of patients available at long-term f/u, excludes crossovers)* SCS: n = 15 CMM: n = 12 (continued) "Success": • SCS: 60% (9/15) • Reoperation: 25% (3/12) • P = NR - - - - - - - - - - - - - *Crossovers to:* SCS: n = 14 Reoperation: n = 4 "Success": • SCS: 43% (6/14)

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
							• Reoperation: 0% (0/4) • *P* < .01
Effectiveness (cohort studies)							
Turner 2010 **24 month data unless otherwise indicated** *Modified per-protocol analysis****:* SCS: n = 43 PC: n = 34	*Modified per-protocol analysis****:* ≥50% leg pain relief†††† (%): • SCS: 16% (7/43) • PC: 15% (5/34) • UC: 21% (13/61) • *P* = .66 (NS) (SCS vs PC) • *P* = .62 (NS)	NR	NR	*Modified per-protocol analysis****:* SF-36 Mental Health (mean ± SD): • SCS: 38.7 ± 13.7 • PC: 36.8 ± 11.9 • UC: 36.3 ± 12.9	*Modified per-protocol analysis****:* ≥2-point improvement in RDQ score (%, n): • SCS: 51% (22/43) • PC: 41% (14/34) • UC: 44% (27/61) • *P* = .50 (NS) (SCS vs PC) • *P* = .53 (NS) (SCS vs UC)	*Modified per-protocol analysis****:* Less than daily opioid usage (%, n): • SCS: 21% (9/43) • PC: 32% (11/34) • UC: 34% (21/61) • *P* = .53 (NS) (SCS vs PC) • *P* = .24 (NS)	**PRIMARY OUTCOME:** "Success": (1) ≤ 50% reduction in leg pain; (2) RDQ improvement of ≥2 points; and (3) less than daily opioid usage

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
UC: n = 61 *Per-protocol analysis****:* SCS: n = 27 PC: n = 22 *(Turner 2010 continued)*	(SCS vs UC) VAS leg pain score†††† (mean ± SD): • SCS: 6.3 ± 2.0 • PC: 6.2 ± 2.1 • UC: 5.7 ± 2.1 • *Adjusted‡‡‡‡ mean difference (SCS vs PC):* 0.4 (95% CI, -0.6, 1.3) (NS) • *Adjusted‡‡‡‡ mean difference (SCS vs UC):* -0.2 (95% CI, -1.0, 0.6) (NS) (continued) VAS back pain score†††† (mean ± SD): • SCS: 6.6 ± 1.8 • PC: 6.6 ± 1.8 • UC: 6.3 ± 2.3 • *P* = .76‡‡‡‡ (NS) (SCS vs PC) • *P* = .76‡‡‡‡ (NS) (SCS vs UC) - - - - - - - - - - - *Per-protocol*			• *P* = .47‡‡‡‡ (NS) (SCS vs PC) • *P* = .10‡‡‡‡ (NS) (SCS vs UC)	RDQ score (mean ± SD): • SCS: 18.1 ± 4.8 • PC: 17.9 ± 4.7 • UC: 17.5 ± 5.1 • *Adjusted‡‡‡‡ mean difference (SCS vs PC):* 0.5 (95% CI, -1.4, 2.4) (NS) • *Adjusted‡‡‡‡ mean difference (SCS vs UC):* 0.1 (95% CI, -1.6, 1.7) (NS) (continued) Ability to perform daily tasks (%, n): <u>Much/somewhat better:</u> • SCS: 33% (14/43) • PC: 21% (7/34) • UC: 26% (16/61) <u>About the same:</u> • SCS: 34% (15/43) • PC: 32% (11/34) • UC: 41% (25/61) <u>Much/somewhat worse:</u>	(SCS vs UC) Medications taken in past month for leg/back pain (%, n)*****: <u>Opioid:</u> • SCS: 84% (36/47) • PC: 74% (25/34) • UC: 71% (43/61) • *P* = .40 (NS) (SCS vs PC) • P = .16 (NS) (SCS vs UC) (continued) <u>Benzodiazepine/sedative-hypnotic/anti-anxiety:</u> • SCS: 19% (8/47) • PC: 15% (5/34) • UC: 20% (12/61) • *P* = .77 (NS) (SCS vs PC) • P = .99 (NS) (SCS vs UC) <u>Muscle relaxant:</u> • SCS: 37% (16/47)	*Modified per-protocol analysis****:* Success (n, %): • SCS: 5% (2/43) • PPC: 3% (1/34) • UUC: 10% (6/61) • *P* = 0.99 (NS) (SCS vs PC) • *P* = .47 (NS) (SCS vs UC) (continued) - - - - - - - - - - - *Per-protocol analysis****:* Success (%, n): • SCS: 9% (2/27) • PC: 5% (1/22) • *P* = .99***** (NS)

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Turner 2010 continued)	*analysis***** ≥50% leg pain relief†††† (%, n): • SCS: 30% (8/27) • PC: 26% (6/22) • *P* = .61***** (NS)				• SCS: 33% (14/43) • PC: 47% (16/34) • UC: 33% (20/61) *P* = .35 (NS) (SCS vs PC) *P* = .75 (NS) (SCS vs UC) Work status/disability (%, n): <u>Working:</u> • SCS: 23% (10/43) • PC: 24% (8/34) • UC: 23% (14/61) <u>Off work, on disability:</u> • SCS: 72% (31/43) • PC: 65% (22/34) • UC: 64% (39/61) (continued) <u>Off work, not on disability:</u> • SCS: 2% (1/43) • PC: 12% (4/34) • UC: 8% (5/61) <u>Other:</u> • SCS: 2% (1/43) • PC: 0% (0/34) • UC: 5% (3/61) *P* = .35 (NS) (SCS vs PC)	• PC: 27% (9/34) • UC: 25% (15/61) • *P* = .34 (NS) (SCS vs PC) • P = .20 (NS) (SCS vs UC) <u>Antidepressant:</u> • SCS: 16% (7/47) • PC: 12% (4/34) • UC: 15% (9/61) • *P* = .75 (NS) (SCS vs PC) • P = .99 (NS) (SCS vs UC) (continued) <u>Anticonvulsant:</u> • SCS: 33% (14/47) • PC: 6% (2/34) • UC: 16% (10/61) • *P* < .01 (SCS vs PC) • P = .06 (NS) (SCS vs UC) <u>Non-opioid analgesic:</u>	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Turner 2010 continued)					*P* = .66 (NS) (SCS vs UC) Work-related administrative data†††††† (%, n): <u>Time loss days (mean ± SD):</u> • SCS: 589 ± 215 • PC: 526 ± 235 • UC: 532 ± 245 • *P* = .51 (NS) (SCS vs PC) • *P* = .29 (NS) (SCS vs UC) (continued) <u>Time loss or pension (%, n):</u> • SCS: 73% (37/51) • PC: 56% (22/39) • UC: 60% (41/68) • *P* = .53 (NS) (SCS vs PC) • *P* = .30 (NS) (SCS vs UC) <u>Claim closed (%, n):</u>	• SCS: 23% (10/47) • PC: 21% (7/34) • UC: 18% (11/61) • *P* = .99 (NS) (SCS vs PC) • P = .62 (NS) (SCS vs UC) - - - - - - - - - - - - - *Per-protocol analysis****:* Less than daily opioid usage (%, n): • SCS: 17% (5/27) • PC: 42% (9/22) • *P* = .16***** (NS) (SCS vs PC) (continued) Treatments for pain at 12 months: <u>Surgery (not SCS):</u> • SCS: 0% (0/27) • PC: 19% (4/21) • *P* = .03 <u>Spinal injection:</u> • SCS: 26% (7/27) • PC: 33% (7/21)	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
(Turner 2010 continued)					• SCS: 33% (17/51) • PC: 43% (17/36) • UC: 44% (30/65) • *P* = .65 (NS) (SCS vs PC) • *P* = .32 (NS) (SCS vs UC) - - - - - - - - - - - - - - - *Per-protocol analysis***** ≥2-point improvement in RDQ score (%, n): • SCS: 61% (16/27) • PC: 47% (10/22) • *P* = .44***** (NS) Working (%, n): • SCS: 30% (8/27) • PC: 26% (6/22) • *P* = .99***** (NS) (continued) Claim closed (%, n): • SCS: 30% (8/27) • PC: 45% (10/22) • *P* = .50***** (NS)	• *P* = .75 (NS) <u>Physical therapy:</u> • SCS: 33% (9/27) • PC: 95% (20/21) • *P* < .001 <u>Occupational therapy</u> • SCS: 7% (2/27) • PC: 81% (17/21) • *P* < .001 <u>Massage:</u> • SCS: 11% (3/27) • PC: 13% (3/21) • *P* = 1.00 (NS) <u>Back brace/corset:</u> • SCS: 33% (9/27) • PC: 10% (2/21) • *P* = .08 (NS) <u>Psychological therapy:</u> • SCS: 7% (2/27) • PC: 52% (11/21) • *P* = .001 (continued) <u>Ultrasound:</u> • SCS: 7% (2/27) • PC: 5% (1/21) • *P* = 1.00 (NS) <u>Bedrest:</u> • SCS: 37% (10/27)	

Author (Year)	Pain	Patient satisfaction	Global perceived effect (GPE)	Health-related quality of life (HR-QoL)	Function	Medication usage	"Success"
						• PC: 24% (5/21) • *P* = .37	

EQ: EuroQol (European quality of life scoring tool)
GPE: Global Perceived Effect
NR: not reported
NRS: numerical rating scale
NS: not statistically significant
NSAID: non-steroidal anti-inflammatory drug
PC: pain clinic group
RDQ: Roland-Morris Disability Questionnaire
SCS: spinal cord stimulation
SD: standard deviation
TENS: transcutaneous electrical nerve stimulation
UC: usual care group
VAS: visual analogue scale
WCB: Worker's Compensation Board

*GPE scores range from 1 to 7 and are defined as follows:
1 = worst ever
2 = much worse
3 = worse
4 = not improved and not worse
5 = improved
6 = much improved
7 = best ever

† Kemler 2000: HR-QoL measured using a VAS where 0 = death and 100 = perfect health.
‡ Kumar 2007: p-value adjusted for location of leg pain and may not exactly correspond to the unadjusted confidence intervals.
** Sensitivity analysis:
Kumar 2007: excluded five patients in the SCS group who did not meet the screening criteria but requested an implant.
†† Worst-case analysis:
Kumar 2007, 2008: considered patients unavailable at follow-up in SCS group "failures" and those in CMM group "successes".

North 2005: "worst case" analysis categorized patients lost to follow-up (but presumably excluding the one patient in the SCS group who died) as "failures".

‡‡ Kumar 2007: return to work analysis based on the number of people not working at baseline.

*** Kumar 2007: standard conversion tables were used to convert opioid dosages to morphine equivalents. Because a range was provided for some drugs, the authors calculated the "low" and "high" end of the range of morphine equivalent scores.

††† Manca 2008: using EQ-5D scores adjusted for differences in baseline EQ-5 scores between the groups.

‡‡‡ North 2005: The total number of available patients reported the SCS group for opiate use (n = 23 reported) does not correlate with the number of patients available for follow-up (SCS: 19/24 available for follow-up). No explanation was given in the text.

**** Modified per-protocol analysis was defined by the treatment received during the first year of the study: SCS (only trial stimulation was required); PC (pain clinic evaluation performed), and UC (patients did not undergo SCS trial or PC evaluation). Per-protocol analysis was used to compare SCS (patients underwent permanent implantation of SCS device) vs PC (some pain clinic treatment was received).

†††† Pain measured on a VAS (0 (no pain) to 10 (worst pain)).

‡‡‡‡ Adjusted for baseline differences between groups in the following characteristics: age, gender, RDQ score, leg pain intensity, duration of work time loss compensation, disability benefit other than workers' compensation, unilateral vs bilateral leg pain, legal representation, and SF-36 mental health scores.

***** Adjusted for baseline value of the outcome measure being assessed

††††† Adjusted for work-related time loss compensation at baseline.

Supplemental Table 4. Safety Data: Spinal Cord Stimulation Comparative Studies

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality

Kemler 2000	6 months	**SCS group, permanent implant received* (24/24 available):**
		
		Summary:
		11 total complications requiring revision occurred in 25% of patients (6/24)
		
		Complications include:
		Revision of electrode:
		• Repositioning of electrode: 21% (5/24)
		  • successful in 4/5 in one procedure
		  • 1/5 required three procedures
		• Replacement of electrode: 4% (1/24)
		  • due to defective electrode
		
		Revision of pulse generator: 8% (2/24)
		• due to painful pulse generator pocket
		
		Total removal and reimplantation of system: 4% (1/24)
		• due to clinical signs of infection (implant removed, antibiotics given, reimplantation perfomed when patient recovered)
			SCS group, implant received* (24/24 available):
			
			Complications (not leading to revision) include:
			Dural puncture: 8% (2/24)
			• associated headache: 1/2
				SCS group, implant received* (24/24 available):
				No data reported
				
				PT (n = 18):
				No data reported
					SCS group: 0% (0/36)
					
					PT group: 0% (0/18)

Kemler 2004	24 months	**SCS group, permanent implant received* (22/24 available):**	**SCS group, implant received* (22/24 available):**	**SCS group, implant received* (22/24**	SCS group: 0% (0/35)

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality

		Summary:
		22 total complications requiring revision occurred in 38% of patients (9/24); number of complications per year:
		• year 1: 82% of complications (18/22)
		• year 2: 18% of complications (4/22)
		
		Complications include:
		Revision of electrode:
		• Repositioning of electrode: 8 procedures (number of patients NR)
		  • year 1: 8/8
		  • year 2: 0/8
		• Replacement of electrode: 2 procedures (number of patients NR)
		  • year 1: 1/2
		  • year 2: 1/2
		
		Revision of pulse generator:
		• Revision of pulse generator pocket: 7 procedures (number of patients NR)
		  • year 1: 7/7
		  • year 2: 0/7
		• Replacement of pulse generator: 1 procedure (in 1 patient, 4%)
		  • year 1: 0/1
		  • year 2: 1/1
			Summary: 100% of patients (22/22) available for follow-up with systems still implanted reported side effects. Note that these could not be separated from those requiring revision:
			
			Change in amplitude by bodily movements: 86% of patients
			
			Paresthesia in other body parts: 59% of patients (13/22)
			
			Pain/irritation from extension lead or plug: 50% of patients (11/22)
			
			Pain/irritation from pulse generator: 45% of patients (10/22)
			
			More pain in other body parts: 32% of patients (7/22)
			
			Disturbed urination: 18% of patients (4/22)
			
			Movements or cramps resulting from elevated amplitude: 14% of patients (3/22)
				available):
				No data reported
				
				PT (n = 18):
				No data reported
					PT group: 0% (0/16)

(Kemler 2004		(continued…) Total removal and replacement of system:			

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality

continued)		• Explantation of system: 3 procedures (number of patients NR
		  • year 1: 1/3
		  • year 2: 2/3
		  • Permanent explantation performed in two patients (8%):
		  • due to recurrent rejection in one patient
		  • due to relapsing ulcerative colitis subscribed to the SCS system in one patient
		• Reimplantation of system: 1 procedure (in 1 patient, 4%)
		  • year 1: 1/1
		  • year 2: 0/1			

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
Kemler 2008	60 months	**SCS group, permanent implant received* (20/24 available at 5 years):** **Summary:** 29 total complications (not including pulse generator replacements) requiring revision occurred in 42% of patients (10/24); Number of complications per year: • year 0–2: 72% of complications (21/29) • year 3: 7% of complications (2/29) • year 4: 10% of complications (3/29) • year 5: 10% of complications (3/29) **Complications include:** Replacement of generator: 17 procedures in 54% of patients (13/24), 54% [# procedures per patient: 4x (n = 1), 2x (n = 1), 1x (n = 11)] • year 0–2: 1/17 • year 3: 4/17 • year 4: 4/17 • year 5: 8/17 • 42 total pulse generators needed for 36 patients randomized; mean battery life = 4 years) Revision of generator: • Revision of pulse generator pocket: 28% of revisions (8/29) (number of patients NR) • year 0–2: 7/8 • year 3: 1/8 • year 4: 0/8 • year 5: 0/8	**SCS group, implant received* (20/24 available at 5 years):** No complications reported (that weren't associated with revision)	**SCS group, implant received* (20/24 available):** No data reported **PT (n = 18):** No data reported	SCS group: 0% (0/31) PT group: 0% (0/13)

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality

(Kemler 2008 continued)		(continued…)
		Revision of electrode: 59% of revisions (17/29)
		• Repositioning of electrode: 11 procedures (number of patients NR):
		  • year 0–2: 8/11
		  • year 3: 0/11
		  • year 4: 1/11
		  • year 5: 2/11
		• Replacement of electrode: 6 procedures (number of patients NR)
		  • year 0–2: 2/6
		  • year 3: 1/6
		  • year 4: 2/6
		  • year 5: 1/6
		
		Total removal (and replacement) of system:
		  • Permanent explantation performed in 8% of patients (2/24) (7% of revisions (2/29)
		  • due to recurrent rejection in one patient (year 0-2)
		  • due to relapsing ulcerative colitis subscribed to the SCS system in one patient (year 0-2)
		• Explantation and reimplantation of system: 4% of patients (1/24) (3% of revisions) (1/29)) (year 0-2)			

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
Kumar 2007 PROCESS trial	12 months	**SCS (all), any implant received (including trial stimulation): n = 84** (including 28 crossover and 4 attempted crossover patients) (71/84 available at 12-month follow-up) **Summary:** Reoperation was required in 24% of patients who received SCS (20/84). **Revision due to†:** Hardware-related: 12% (10/84) of patients, including: • Electrode migration: 10% (8/84) of patients • Electrode/extension fracture/torqued contacts: 1% (1/84) of patients • IPG migration: 1% (1/84) of patients Loss of therapeutic effect, loss of paresthesia, or unpleasant paresthesia: 1% (1/84) of patients • details of revision NR Technique‡: 5% (4/84) of patients (5 events)	**SCS, implants received (including trial stimulation): n = 84** (including 28 crossover and 4 attempted crossover patients) (71/84 available at 12-month follow-up) **Summary: NR** **Complications (not leading to revision) include:** Hardware-related: 1% (1/84) of patients, including: • Lead/extension fracture/torqued contacts: 1% (1/84) of patients Loss of therapeutic effect, loss of paresthesia, or unpleasant paresthesia: 6% (5/84) of patients Total biological: 12% (10/84) of patients including: • Infection/wound breakdown: 2% (2/84) of patients • Pain at IPG/incision site: 5% (4/84) of patients • Fluid collection at neurostimulator pocket: 5% (4/84) of patients	*Complications reported by randomized group:* SCS + CMM: (47/52 available at 12-month follow-up) CMM: (41/48 available at 12-month follow-up) **Summary:** Non-device-related complications occurred in a total of: • SCS group: 35% (18/52) of patients (25 events) • CMM group: 52% (25/48) of patients (37 events)	SCS group: 0% (0/47) CMM group: 0% (0/41)

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
(Kumar 2007 continued)		(continued)… Total biological: 7% (6/84) of patients, including: • Infection/wound breakdown: 6% (5/84) of patients • Pain at IPG/incision site: 1% (1/84) of patients • Fluid collection at neurostimulator pocket: 0% (0/84) of patients		(continued…) **Complications include:** Drug adverse events: • SCS group: 4% (2/52) (2 events) • CMM group: 21% (10/48) (12 events) Extra pain events: • SCS group: 0% (0/52) (0 events) • CMM group: 4% (2/48) (2 events) New illness/injury/condition: • SCS group: 25% (13/52) (16 events) • CMM group: 23% (11/48) (13 events, including 1 back reoperation) • Worsening of pre-existing condition: • SCS group: 13% (7/52) (7 events) • CMM group: 15% (7/48) (10 events, 1 patient required back reoperation)	

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
Kumar 2008 PROCESS trial	24 months	**SCS group**, any implant received (including trial stimulation): n = 52** (42/52 available at 24-month follow-up) **Summary:** Revision occurred in a total of: • SCS group: 31% (13/42) of patients (number of events NR) **Reoperation due to†:** Hardware-related: • Electrode migration: 14% (6/42) of patients • Lead/extension fracture/torqued contacts: 2% (1/42) of patients • IPG migration: 2% (1/42) of patients Loss of therapeutic effect, loss of paresthesia, or unpleasant paresthesia: 5% (2/42) of patients Technique††: 5% (2/42) of patients (continued…) Total biological: 7% (3/42) of patients (number of events NR), including: • Infection/wound breakdown: 5% (2/42) • Pain at IPG/incision site: 2% (1/42) • Fluid collection at neurostimulator pocket: 0% of patients	**SCS group**, implant received (including trial stimulation): n = 52** (42/52 available at 24-month follow-up) **Summary: 14% (6/42) had complications not leading to revision** **Complications (not leading to revision) include:** Hardware-related: 5% (2/42) of patients including: • Lead/extension fracture/torqued contacts: 5% (2/42) of patients Loss of therapeutic effect, loss of paresthesia, or unpleasant paresthesia: 7% (3/42) of patients Total biological: 14% (6/42) of patients (12 events), including: • Infection/wound breakdown: 5% (2/42) of patients • Pain at IPG/incision site: 10% (4/42) of patients • Fluid collection at neurostimulator pocket: 5% (2/42) of patients	**SCS group**, implant received (including trial stimulation): n = 52** (42/52 available at 24-month follow-up) **CMM**: NR **Summary:** Non-device-related complications occurred in a total of: • SCS group: 31% (13/42) of patients (15 events) **Complications include:** New illness/injury/condition: • SCS group: 17% (7/42) (8 events) Worsening of pre-existing condition: • SCS group: 17% (7/42) (7 events)	SCS group: 0% (0/42) PT group: NR

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
(Kumar 2008 continued					
North 2005	2.9 ±1.1 years	**SCS (all), permanent implant received: n = 31** (29/31 available at long-term follow-up)‡‡ Repositioning of lead due to electrode migration or malposition: 10% (3/31)‡‡ Total removal and replacement of system: 3% (1/31)‡‡ • due to clinical signs of infection at the receiver site (implant removed, antibiotics given, reimplantation perfomed when patient recovered)	**SCS (all), permanent implant received: n = 31** (29/31 available at long-term follow-up)‡‡ No complications reported (that weren't associated with revision)	NR	SCS group: 5% (1/20) (due to heart attack) Reoperation group: 0% (0/26)

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
Turner 2010	2.0 years	**N = 27 patients underwent permanent device implantation** **Revision of electrode/lead: 15% of patients (4/27)** • Lead migration or malpositioning/ineffective or decreased pain relief **Revision of generator: 11% of patients (3/27)** • Pain/discomfort at generator site **Revision of connecting cable/lead: NR** **Total removal and replacement of system: 4% (1/27), due to:** • Lead migration and "SCS malfunction" **Total removal of system: 22% of patients** (6/27), due to:** • ineffectiveness and discomfort (20 months post-implantation)** • deep abscess over generator; device had to be removed and patient did not have re-implantation • ineffectiveness of pain relief (10 months post-implantation) • discomfort and ineffectiveness (16	**N = 28 patients underwent attempted implantation of a permanent device** **Summary: NR** • Implantation terminated due to dural puncture and CSF leak: 4% of patients (1/28) • Superficial skin/wound infection: 11% of patients (3/28) • Persistent pain over SCS components: 18% of patients (5/28) (not clear whether this lead to revision in any patients) - **N = 51 patients underwent at least trial stimulation** **16% of patients had an adverse event associated with trial stimulation (8/51):** • Symptoms of unknown etiology (ie., dizziness, increased back or leg pain): 5 patients • Fluid leaking at electrode entry site: 1 patient • Severe post-spinal headache: 1 patient • Extensive epidural abscess that necessitated irrigation, debridement,	None reported	2% of patients (1/51) in the SCS group died (cause NR) between the 6 and 12 month follow-ups 0% of patients in the usual care and pain clinic groups died (0/39 & 0/68, respectively)

Author (Year)	Length of f/u	Revisions	Other SCS device-related complications or side effects	Complications unrelated to SCS	Mortality
		months post-implantation) • seizures and ineffective pain relief (8 months post-implantation) • pain at pulse generator site and decreased effectiveness (17 months post-implantation)	and a T2-L3 hemilaminotomy; one day following surgery, the patient had respiratory arrest and was placed on mechanical ventilation: 1 patient		

NR: not reported
SCS: spinal cord stimulation
IPG: implantable pulse generator

* Kemler (2000, 2004, 2008): Reported complications only for patients randomized to receive SCS. Thus, the final follow-up (60 months) excluded the 4 patients randomized to CMM alone who crossed over and received permanent implants; similarly, 2 CMM patients who had crossed over by 24 months were excluded.
† Kumar 2007, 2008: The number of revisions performed for each SCS component were not reported; many complications occurred requiring revision but the details of the procedure were not provided.
‡ Kumar 2007: Technique-related complications include: IPG cap not installed when only one lead was implanted; intermittent stimulation due to improper connection of extension to IPG; shocks caused by anteriorly implanted electrode; lead cut during implantation; and dural tear during implantation.
** Kumar 2008: Reported complications only for patients randomized to receive SCS. Thus, 32 CMM patients were excluded (28 crossed over, 4 underwent trial stimulation only).
†† Kumar 2008: Technique-related complications included intermittent stimulation due to improper connection of extension to IPG; shocks caused by anteriorly implanted electrode; and lead cut during implantation.
‡‡ North 2005: The authors did not report the denominator used for complication rates; we inferred it to be 31 based on one statement: "three SCS (9% of permanent implants) underwent hardware revisions…". A total of 31 patients underwent permanent implantation, and 3/31 gives a rate of 9.6%. 29/31 patients were available for final follow-up, but we report the data using n = 31 as the denominator in accordance with the study.
** Turner 2010: study reported that 19% (5/27) of patients underwent total explantation of system, but another patient was apparently not included in this total and had explantation 20 months after the original implantation; our rate includes this additional patient.

Supplemental Table 5. Demographic Table: Spinal Cord Stimulation Case Series

Author (Year)	Study Type Study Period Study Location	Follow-up (% complete follow-up rate)	# patients permanent SCS Mean age (range) Sex	Preop diagnosis (N, %) Duration of chronic pain	Intervention: permanent SCS device*,†	Conflict of interest
Kay 2001	Case-series 1984 – 1997 Dundee Royal Infirmary; Dundee, UK	Mean f/u: 5.4 years Range: 1–13 years Complete f/u rate: NR	N = 70* Mean age: 47 years Age range: 21 – 76 years 59% female	*Neuropathic pain:* FBSS: 51% (36/70) Postsurgical pain syndrome: 14% (10/70) Atypical facial pain: 9% (6/70) CRPS I: 4% (3/70) Peripheral nerve injury: 4% (3/70) Phantom limb pain: 3% (2/70) Diabetic neuropathy: 3% (2/70) *Ischemic pain:* Angina pectoris: 4% (3/70) Reynaud's syndrome: 1% (1/70) *Other/unknown:* Pain syndrome of unknown etiology: 6% (4/70) Duration of chronic pain: mean NR (≥ 5 years)	N = 70* Permanent SCS devices† varied.	none‡

Author (Year)	Study Type Study Period Study Location	Follow-up (% complete follow-up rate)	# patients permanent SCS Mean age (range) Sex	Preop diagnosis (N, %) Duration of chronic pain	Intervention: permanent SCS device*,†	Conflict of interest
Kumar & Wilson 2007	Case-series 1982–2007 Regina General Hospital; Regina, Saskatchewan, Canada	Mean f/u: 8.1 years Range: NR Complete f/u rate: ≥ 88%**	N = 338* Mean age: †† 54 years (21–87 years) 61% male††	Of the 338 patients that received permanent SCS implantation: *Neuropathic pain:* FBSS: 55.9% (189/338) CRPS I and II: 8.6% (29/338) Peripheral neuropathy: 4.7% (16/338) Phantom limb/stump pain: 0.3% (1/338) Multiple sclerosis: 5.0% (17/338) Spinal cord injury/lesion/cauda quina syndrome/paraplegic pain: 2.1% (7/338) Post-herpetic/intercostal neuralgia: 3.0% (10/338) *Ischemic pain:* Peripheral vascular disease: 12.4% (42/338) Angina: 3.3% (11/338) *Other:* Bone and joint pain syndromes: 2.4% (8/338) Perirectal pain: 1.2% (4/338) Miscellaneous pain syndromes or upper limb pain secondary to disc surgery: 1.2% (4/338) Duration of chronic pain: NR	N = 338* Permanent SCS devices† varied.	Authors had access to and cited results of bench tests (designed to evaluate complications) that were conducted by Medtronic[1]. No financial interest was disclosed.

Author (Year)	Study Type Study Period Study Location	Follow-up (% complete follow-up rate)	# patients permanent SCS Mean age (range) Sex	Preop diagnosis (N, %) Duration of chronic pain	Intervention: permanent SCS device*,†	Conflict of interest
Kumar & Toth 1998	Case-series	Mean follow-up: 8.8 ± 4.5 years Range: (0.67 – 17 years) Complete f/u rate: 80%*	N = 165* Mean age‡‡: 51.6 years 84% male‡‡	FBSS (referred to as postlaminectomy pain): 100% Duration of disease (mean ± SD): 8.3 ± 6.7 years (range, 0.67 – 47 years)	N = 165*†	NR
Lanner 2007	Case-series 1999–2005 Clinic of Neurosurgery, Klagenfurt, Austria	Mean f/u: 5.0 years Range: 1.25–6.25 years Complete f/u rate: NR	N = 88*** Mean age: 45 years 55% male	FBSS (referred to as postdiscotomy syndrome): 38% (33/88) Posttraumatic pain: 26% (23/88) CRPS: 11% (10/88) Phantom limb pain: 8% (7/88) Stump pain: 7% (6/88) Low back pain: 3% (3/88) Posttraumatic intercostal neuralgia, polyneuropathia: 5% (4/88) Unreported: 2% (2/88) Duration of chronic pain (mean): 8 years	N = 88* Permanent SCS devices NR.	NR

Author (Year)	Study Type Study Period Study Location	Follow-up (% complete follow-up rate)	# patients permanent SCS Mean age (range) Sex	Preop diagnosis (N, %) Duration of chronic pain	Intervention: permanent SCS device*,†	Conflict of interest
North 1993	Case-series Implantation between 1971–1990 Johns Hopkins Hospital, Baltimore, Maryland	Mean f/u: 7.1± 4.5 years Range: 1.5 – 20.4 years Complete f/u rate: 69%	N = 249* Mean age†††: 47.3 ± 12.0 years (20.3 – 84.2 years) 54% male†††	Diagnosis (of the 171/249 patients available at follow-up): FBSS: 77.8% (133/171) Spinal cord injury: 5.8% (10/171) Pain syndromes of peripheral origin: 16.4% (28/171) Duration of chronic pain (mean ± SD): 11.8 ± 8.2 years (range, 0.33 – 44.4 years)	N = 249* Permanent SCS devices† varied.	The study was supported by a grant from Medtronic, and Medtronic was not involved in data collection or analysis. None of the authors had any financial interest in Medtronic or Neuromed.
Sanchez-Ledesma 1989	Case-series Study period NR Hospital Universitario, Salamanca, Spain	Mean f/u: 5.5 years Range: NR Complete f/u: 100%	N = 36* Mean age: 47.3 years‡‡‡ 76% male‡‡‡	Deafferentation pain (100%), including‡‡‡: CRPS (causalgia or reflex sympathetic dystrophy): 49% (24/49) Plexus and nerve root avulsion: 16% (8/49) Phantom limb pain: 12% (6/49) Postherpetic neuralgia: 12% (6/49) Stump pain: 10% (5/49) Duration of chronic pain (mean): 14.5 months‡‡‡	N = 36* Permanent SCS devices† varied.	"Stimulation equipment was provided by Medtronic"

f/u: follow-up
NR: not reported
SCS: spinal cord stimulation

* Trial stimulation device details for case-series are beyond the scope of this report. All patients reported here received a permanent SCS device; the number of patients reported that underwent trial stimulation is as follows:
Kay 2001: NR
Kumar & Wilson 2007: 424 patients enrolled; trial stimulation was successful in 80% (338/424) and a failure (not internalized) in 20% (86/424).
Kumar & Toth 1998: 221 patients enrolled, 39 either died or were lost to follow-up; 165 of the remaining 182 patients had successful trial stimulation and recieved permanent devices and an additional 5 who failed trial stimulation either died or were lost to follow-up.
Lanner 2007: NR
North 1993: 249 of 320 consecutive patients had successful trial SCS and received a permanent implant.
Sanchez-Ledesma 1989: 36 of 49 patients had successful trial SCS and received a permanent implant.

† Permanent SCS devices:
Kay 2001: Unipolar or quadripolar plate electrodes in the thoracic or cervical spine; stimulators included radiofrequency-coupled receiver transducer (14%) or total intracorporal pulse generators. Manufacturer information NR.
Kumar & Wilson 2007: Device details reported in Kumar 2006[1]: Electrode systems (Medtronic); cylindrical electrodes (percutaneous implantation) (Pisces-Sigma, quadripolar Pisces, and octapolar Pisces elctrodes) or paddle electrodes (small laminotomy required) (Resume and Specify electrodes).
Kumar & Toth 1998: electrodes placed percutaneously (Pisces-Sigma and Pisces-Quadripolar, Medtronic) or via small laminotomy (Resume, Medtronic); pulse generators with internal batteries and external programmers (Itrel I, II, III;X-trel, Medtronic).
Lanner 2007: devices NR.
North 1993: Of the 298 total devices implanted in 249 patients, 76% (226/298) were implanted percutaneously and 24% (72/298) were implanted by laminectomy; 44% (131/298) were either monopolar or bipolar, and 56% were multipolar (4 or 8 contacts). The generators were single-channel randofrequency-coupled in 48% (144/298) and multichannel programmable randofrequency-coupled in 52% (154/298). Device manufacturers were Medtronic and Neuromed, Inc. (Ft. Lauderdale, Florida).
Sanchez-Ledesma 1989: Electrodes implanted percutaneously and connected to a subcutaneous radiofrequency receiver (Medtronic) or to a total implantable system (Medtronic).

‡ Kay 2001: authors explicitly stated that they received no financial contribution from Medtronic for the study.

** Kumar & Wilson 2007: although the study suggests a complete follow-up rate of 99.4% (336/338), Kumar 2006[1] (which is an earlier follow-up of a subset of patients) noted that 42 patients had been excluded with < 1 year follow-up available; whether these patients had undergone permanent SCS implantation was not noted. Kumar & Wilson 2007 did not provide any additional information, though it is clear that at least 42 patients were excluded.

†† Kumar & Wilson 2007: patient demographics are for the total number of patients enrolled, only 338/424 underwent permanent SCS implantation.

‡‡ Kumar & Toth 1998: patient demographics are for the 182 patients enrolled and available for follow-up; only 165 underwent permanent SCS implantation.

*** Lanner 2007: In the period between 1999–2005, 145 patients with chronic pain were treated with SCS, yet only 88/145 (61%) were included in the study. No information was provided regarding the selection of these 88 patients from the larger pool.

††† North 1993: It is not clear which subset of patients the demographic data pertains to (ie., all 320 patients; the 249 that underwent implantation, or the 171 of the latter group available at follow-up).

‡‡‡ Sanchez-Ledesma 1989: patient demographics are for the total number of patients enrolled, only 36/49 underwent permanent SCS implantation.

Supplemental Table 6. Safety Data: Spinal Cord Stimulation Case Series

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality

Kay 2001	Mean f/u: 5.2 (1–13) years	**SCS: n = 70**
		
		Summary:
		72 total revisions were performed in 60% of patients (42/70):
		• 1 – 6 revisions performed per patient
		• median time to first revision: 36 months (95% CI, 24–60 months)
		• 40% (28/70) patients required no revision during f/u
		
		Reason for revision:
		Revision of electrode: 44% (32/72 revisions)
		• inappropriate area of paraesthesia: 14% (10/72)
		  • revision successful in all patients; 2 patients required 3 revisions
		• inadequate paraesthesia due to migration: 11% (8/72)
		  • axial and lateral shifts
		  • revision successful in 5/8
		• inadequate paraesthesia due to fibrosis: 11% (8/72)
		  • revision successful in 5/8
		• inadequate paraesthesia – cause unknown: 7% (5/72)
		  • revision successful in 2/5
		• infection: 1% (1/72)
			SCS-related complications not leading to revision:
			Infection: 6% (4/70)
				NR	Death: 3% (2/70)
					• cerebrovascular accident: 1% (1/70)
					  • occurred in patient treated with SCS for angina
					• suicide: 1% (1/70)

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality

(Kay 2001 continued)		(continued…)
		Revision of generator: 30% (22/72 revisions)
		• battery depletion: 22% (16/72)
		  • mean battery life: 4.5 years (median 3.3 years)
		• discomfort/new pain: 6% (4/72)
		• defective: 1% (1/72)
		• displacement (pregnancy): 1% (1/72)
		
		Revision of connecting cable/lead: 8% (6/72 revisions)
		• fracture: 7% (5/72)
		• discomfort/new pain: 1% (1/72)
		
		Total removal of system: 17% (12/72 revisions)
		• new intolerable pain: 8% (6/72)
		  • pain from neurostimulation or laminotomy-related wound pain
		• infection: 4% (3/72)
		• no pain relief: 1% (1/72)
		• for MRI: 1% (1/72)
		• defective transmitter: 1% (1/72)			

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality

Kumar & Wilson 2007	Mean f/u: 8.1 years	**SCS: n = 336 (of 338) underwent permanent SCS implantation and were available for long-term f/u**
		
		Summary: NR
		
		Reason for revision†:
		Revision of electrode due to†:
		• displaced electrode: 26.7% (90/336)
		  • 42/90 were repositioned, 48/90 were replaced
		• fractured electrode: 6.4% (27/336)
		  • all electrodes replaced
		• due to hardware malfunction (increased impedance): 6.0% (20/336)
		  • all electrodes replaced
		
		Revision of generator, due to†:
		• electrical leak: 1.2% of patients (4/336)
		• displacement (90° rotation due to improper placement): 1.2% of patients (4/336)
		• discomfort over pulse generator requiring repositioning: 1.5% (5/336)
		
		Revision of connecting cable/lead: revisions), due to†:
		• insulation damage: 2.7% (9/336)
		  • all leads replaced
			SCS-related complications:
			Discomfort over pulse generator: 6.5% (22/336)
			
			CSF leak: 0.6% (2/336)
			• resolved spontaneously
			
			Subcutaneous hematoma: 5.7% (19/336)
			• 10/19 resolved spontaneously
			• 1/19 required surgical evaculation
			• 8/19 required aspiration
			
			Infection: 1.5% (5/336)
				NR	NR
					(none reported, but as many as 42 patients with < 1 year follow-up were excluded, so can't assume morbidity rate is 0%)

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality
		Total removal and replacement of system, due to: • infection: 3.0% (10/336)			

Kumar & Toth 1998	Mean f/u: 8.8 ± 4.5 years	**SCS: n = 164**
		
		Summary: NR
		
		Reason for revision:
		Revision of electrode due to:
		• displaced electrode: 33.5% of patients (55/164)
		  • 37 were repositioned, 20 electrodes were replaced
		• fractured electrode: 3.6% (6/164)
		  • all replaced
		  • fractured typically occurred at point of fixation to deep fascia
		• hardware malfunction: 3.6% (6/164)
		  • all repaired
		  • no details provided
		
		Revision of generator, due to:
		• electrical leak: 1.2% (2/164)
		• all receivers replaced; problem was generally the site where the connector cord met the pulse receiver
		
		Total removal and replacement of system, due to:
		• infection: 4.9% (8/164)
			Infection: 0.6% (1/164)
			
			CSF leak: 0.6% (1/164)
			• Resolved spontaneously
			
			Neurological injuries: 0% (0/164)
			
			Other anatomic complications: 0% (0/164)
				NR	NR
					(2 deaths occurred in total patient population, not clear whether the patients received permanent implants)

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality
Lanner 2007	Mean f/u: 60 months	**SCS: n = 88** **Summary:** NR **Reason for revision:** Revision of electrode due to: • dislocation occurred in "very few cases" Revision of generator, due to†: • dislocation occurred in "very few cases" Total removal and replacement of system, due to: • wound infection: 6% (7/88) • reimplantation successful	None reported that did not require revision	NR	0% (0/88)

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality
North 1993	Mean f/u: 7.1± 4.5 years Range: 1.5 – 20.4 years	298 devices implanted total in 249 patients; 171/249 patients available at follow-up **Summary:** NR **Reason for revision:** Total removal and replacement of system, due to: • infection (wound): 5% of patients (patient N NR) Failure of electrode/lead‡ due to: • electromechanical failure (ie., fatique fracture of conductors and/or failure of insulation): 7.4% of systems (22/298) • not stated whether or not the components were revised Failure of generator (radiofrequency receiver): 5.4% of systems (16/298) • not stated whether or not the components were revised Revision of connecting cable/lead: NR	None reported that did not require revision	NR	NR (13 of the original 320 patients had died, 205 were available for follow-up but not all received permanent implants)

Author (Year)	Length of follow-up	Revisions	Other SCS device-related complications	Complications unrelated to SCS	Mortality
Sanchez-Ledesma 1989	Mean f/u: 5.5 years	SCS: n = 36 **Summary:** NR **Reason for revision:** Revision of electrode, due to: • dislodgment of electrode: 3% (1/36) • required replacement Revision due to: • infection with wire extrusion through the skin at the receiver connector: 3% (1/36) • required replacement	None reported that did not require revision	NR	0% (0/36)

f/u: follow-up
NR: not reported
SCS: spinal cord stimulation
* Kumar & Wilson 2007: complete f/u rate was not explicitly stated; we obtained a 99% f/u based on the data provided.
† Kumar & Wilson 2007: the authors used all 424 patients to calculate the complication rates even though only 338/424 underwent permanent implantation of SCS. For our reported complication rates, we used the 336/338 patients who underwent permanent implantation of SCS and were available at long-term follow-up.
‡ North 1993: data not reported separately for electrode and lead failures.

Supplemental Table 7. Demographic Table: Spinal Cord Stimulation Prognostic Studies

Author (Year)	Study Type Study Period Study Location	Follow-up Complete f/u rate (%)	# Patients (perm. SCS) Age (mean, range) Sex	Preop diagnosis (%, N) Duration of chronic pain or disease	Intervention	Conflict of Interest
Burchiel 1995	Prospective cohort 1990–1993 Oregon Health Sciences University	Length of f/u: 3 months Complete f/u rate: 60%*	N = 40† Mean age: 51.6 years Age range: 22–82 years 50% female	Pain confined to back and/or legs, including: • FBSS: 85% (34/40) • Peripheral neuropathy: 8% (3/40) • Chronic leg pain: 5% (2/40) • Arachnoiditis: 3% (1/40) Back and leg pain: 83% (33/40) Leg pain only: 18% (7/40) Duration of chronic pain (mean): 5.6 years	Enrolled: N = 79 consecutive patients; Received permanent SCS device*: N = 57 (72%) 45 available for 3 month f/u data†; of these, 40/45 had pain confined to the back and/or legs; 34/40 included in the final analysis	Medtronic provided a portion of the funding for the project; one or more of the authors is associated with Medtronic.
Lamé 2009	Prospective cohort 2000–2006 Maastricht University Hosptial, Maastricht, The Netherlands	Length of f/u: 9 months Complete f/u rate: 91% (32/35)	N = 35 Mean age: 38.9 years‡ Age range: 15–58 years‡ 79% female‡	Chronic CRPS (100%) (limited to one hand or foot) Arm pain: 47% Leg pain: 53% Duration of chronic pain (mean): 4.5 years (range, 0.5–16 years)	Enrolled: N = 58 Received permanent SCS device*: N = 35 (60%) 32/35 included in the analysis	NR

Author (Year)	Study Type Study Period Study Location	Follow-up Complete f/u rate (%)	# Patients (perm. SCS) Age (mean, range) Sex	Preop diagnosis (%, N) Duration of chronic pain or disease	Intervention	Conflict of Interest
North 1991	Retrospective cohort Study period: NR Johns Hopkins Hospital, Baltimore, Maryland	Length of f/u: 5.0 years Complete f/u rate: 85%	N = 53 Mean age: 50 ± 10 years** Age range: 28–72 years** 54% male**	FBSS: 100% Duration of chronic pain (mean ± SD): 11.7 ± 8.7 years (range, 1–40 years)	Enrolled: N = 57 Received permanent SCS device*: N = 53** (93%) (45/53 included in the final analysis)	NR

Author (Year)	Study Type Study Period Study Location	Follow-up Complete f/u rate (%)	# Patients (perm. SCS) Age (mean, range) Sex	Preop diagnosis (%, N) Duration of chronic pain or disease	Intervention	Conflict of Interest
North 1996	Prospective cohort Study period: NR Johns Hopkins Hospital, Baltimore, Maryland	Mean length of f/u: 3.5 years†† Range of f/u: 2–13.5 years†† Complete f/u rate: NR	N = 35 Mean age: 48 years†† Age range: 20–65 years†† 55% female††	FBSS: 72% (42/58)†† Spinal cord injury: 3% (2/58)†† Peripheral neuropathic pain syndromes: 24% (14/58)†† Duration of chronic pain (mean): NR	<u>Enrolled</u>: N = 58‡‡ <u>Received permanent SCS device*:</u> N = 35‡‡ (51%)	Supported by Medtronic***. None of the authors had a financial interest in Medtronic or Neuromed.
Turner 2010	See Table 1					

Author (Year)	Study Type Study Period Study Location	Follow-up Complete f/u rate (%)	# Patients (perm. SCS) Age (mean, range) Sex	Preop diagnosis (%, N) Duration of chronic pain or disease	Intervention	Conflict of Interest
Van Eijs 2010	Retrospective cohort Study period NR; recruitment period: March 1997 to July 1998 Maastricht University Hospital; Maastricht, Netherlands	Length of f/u: 12 months Complete f/u rate: 94%††† (35/36)	N = 36‡‡‡, but only 24/36 underwent permanent SCS implantation Mean age: 40 years**** Age range: 21–65 years**** 61% female****	Chronic CRPS type I: 100%, affecting the: • hand: 61% (22/36)**** • foot: 39% (14/36)**** Duration of chronic pain (mean): 3.33 years (range, 0.75–10 years****	<u>Enrolled</u>: N = 36 <u>Received permanent SCS device*:</u> N = 24 (51%) (see Kemler 2000 in Table 1 for details)	None (study supported by a grant from the Dutch Health Insurance Council)

CRPS: complex regional pain syndrome
FBSS: failed back surgery syndrome
f/u: follow-up
NR: not reported
SCS: spinal cord stimulation
SD: standard deviation

* Permanent SCS devices:

Burchiel 1995: 37/40 patients had implantation of a quadripolar electrode (PISCES-Quad Model 3487A or PISCES-Quad Plus Model 3888, Medtronic) via the epidural space; 3/40 had a laminectomy and implantation of the RESUME electrode (Medtronic); pulse generators (ITREL I or II, Medtronic) were implanted in patients who had successful trial stimulation with a handheld programmer for 2 days.

Lame 2009: device details NR.

North 1991: electrodes were placed percutaneously in 64% of patients (Model 1980 JF, Neuromed, Inc.; Pisces Quad, Medtronic) and by laminectomy in 36% of patients (Medtronic Myelostat and Resume). Quadruple electrode arrays used in 76% of patients (Medtronic Pisces Quad or Resume; Neuromed 1980

JF) which utilized implanted radiofrequency-coupled programmable stimulators (Medtronic SE-4; Neuromed MNR-4); bipolar electrodes were used in 24% of patients and were connected to single-channel radiofrequency coupled stimulators (Medtronic Pisces). Electrodes were typically placed within T9–T12 segments to achieve the most overlap of parasthesias with pain.

North 1996: device details NR.

Van Eijs 2010: electrode (model 3487A, Medtronic): placed in thoracic (for hand) or lumbar (for foot) spine so the patient experienced paresthesia over the entire region of pain upon stimulation; pulse generator (Itrell III, model 7425, Medtronic): implanted in the left lower abdominal wall; tunneled extension lead (model 7495-51/66, Medtronic); programmer (model 7434-NL, Medtronic); generator specifications: rate: 85 Hz, pulse width: 210usec, amplitude (adjusted by patient): 0–10 V.

† Burchiel 1995: N = 79 enrolled; 57/79 had successful trial stimulation and received permanent device, 45/57 available at 3 months (2/57 excluded after explantation of SCS system (hardware malfunction, ineffective stimulation); 1/57 discontinued use (ineffective stimulation); 9/57 lost to f/u or did not provide f/u data); 40/45 met the diagnostic inclusion criteria. Complete follow-up rate determined by the number of patients included at follow-up who underwent permanent SCS implantation (34/57).

‡ Lame 2009: Demographic information provided for 32/35 patients who received permanent implantation of SCS that were available for follow-up.

** North 1991: Demographic information provided for 50/53 patients available at follow-up.

†† North 1996: Demographic information provided for the 58 patients enrolled in the study, only 35 of whom underwent permanent SCS implantation.

‡‡ North 1996: 42 of the 58 patients were also reported in North 1993

*** North 1996: No conflict of interest was reported, however, North 1993 (which included 42/58 patients included here) was supported by a grant from Medtronic, and Medtronic was not involved in data collection or analysis. None of the authors had any financial interest in Medtronic or Neuromed.

††† Van Eijs 2010: complete f/u rate NR in this study, but the complete f/u rate for these patients (the 36 patients in the SCS group) was 94% (35/36) in Kemler 2004.

‡‡‡ Van Eijs 2010: patient population was taken from an RCT (Kemler 2000) in which the authors participated.

**** Van Eijs: demographic data provided for the 36 patients included in the study; only 24/36 underwent permanent device implantation.

Supplemental Table 8. Special Populations Data: Spinal Cord Stimulation Prognostic Studies

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
Burchiel 1995 f/u: 3 months N = 34 (of the 40 patients available at follow-up) were included in analysis	NR	**Outcome: pain relief* > 50%:** • Univariate analysis: *P* = .004 (data NR) favoring younger patients • Multivariate predictive model: *P* = .0002 (data NR); favoring younger patients; • Age significantly associated with MMPI (D) and MPQe in a predictive equation†	**Outcome: pain relief *> 50%:** • *P* = .3 (NS) (data NR) (univariate analysis) - - - - - - - - - - - - - - - - - - - **Outcome: pain relief* (%):** • females: 56% relief • males: 35% relief • *P* = .06 (NS) (univariate analysis) - - - - - - - - - - - - - - - - - - - **Outcome: change in VAS score (from baseline):** • *P* = .1 (NS) (data NR) (univariate analysis)	***<u>Prognostic factor:</u> receiving worker's compensation or other disability payments*** **Outcome: pain relief* > 50%:** • *P* = .5 (NS) (data NR) (univariate analysis)	***<u>Prognostic factor:</u> MMPI*** **Outcome: pain relief > 50%*:** Univariate analysis: • Hypochondriasis: *P* = 1.0 (NS) (data NR) • Depression: *P* = .08 (NS) (data NR) • Hysteria: *P* = .9 (NS) (data NR) • Mania: *P* = .46 (NS) (data NR) • Psychasthenia: *P* = .2 (NS) (data NR) • D, age: *P* = .006 (data NR) • D, MPQe: *P* = .7 (NS) (data NR) • Age, MPQe *P* = .2 (NS) (data NR) Multivariate predictive model: • Depression (D): *P* = .002 (data NR); significantly associated with age and MPQe in a predictive equation† - ***<u>Prognostic factor:</u> Education*** *(no details provided)* **Outcome: pain relief > 50%*:** • *P* = .3 (NS) (data NR) (univariate analysis) - ***<u>Prognostic factor:</u> Pain location*** *(back & legs or legs alone)* **Outcome: pain relief > 50%*:** • *P* = .2 (NS) (data NR) (univariate analysis) - ***<u>Prognostic factor:</u> Prior operations for pain*** **Outcome: pain relief > 50%*:** • *P* = .1 (NS) (data NR) (univariate analysis)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Burchiel 1995 continued)					(continued…) - ***Prognostic factor:* Duration of pain** **Outcome: pain relief > 50%*:** • *P* = .6 (NS) (data NR) (univariate analysis) - ***Prognostic factor:* Oswestry Disability Questionnaire** **Outcome: pain relief > 50%*:** • *P* = .1 (NS) (data NR) (univariate analysis) - ***Prognostic factor:* Beck Depression Inventory** **Outcome: pain relief > 50%*:** • *P* = .5 (NS) (data NR) (univariate analysis) - ***Prognostic factor:* McGill Pain Questionnaire** **Outcome: pain relief > 50%*:** Univariate analysis: • Pain Rating Index: *P* = .8 (NS) (data NR) • Affective: *P* = .2 (NS) (data NR) • Evaluative: *P* = .3 (NS) (data NR) • Sensory: *P* = .7 (NS) (data NR) Multivariate predictive model: • Evaluative: *P* = .0002 (data NR); significantly associated with age and MMPI (D) in a predictive equation† - ***Prognostic factor:* Sickness Impact Profile** **Outcome: pain relief > 50%*:** Univariate analysis: • Total: *P* = .5 (NS) (data NR) • Physical subscale: *P* = .3 (NS) (data NR) • Psychosocial subscale: *P* = .3 (NS) (data NR) • Sensory: *P* = .7 (NS) (data NR)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
Lamé 2009 N = 32 (for analysis) f/u: 9 months	NR	**Outcome: pain relief* (mean age ± SD):** • pain relief ≥ 50%: 40.5 ± 9.9 years • pain relief < 50%: 38.2 ± 10.6 years • *P* = .54 (NS) (univariate analysis) **Outcome: GPE score (mean age ± SD):** • GPE score 6–7: 40.8 ± 9.8 years • GPE score ≤ 5: 37.1 ± 10.7 years • *P* = .32 (NS) (univariate analysis) **Outcome: SF-36 scores:** • *P* = NS for all domains (data NR) (multivariate analysis performed *post hoc*‡)	**Outcome: pain relief ≥ 50%*:** • Male: 29% (2/7) • Female: 40% (10/25) • *P* = .68 (NS) (univariate analysis) **Outcome: GPE score of 6 or 7:** • Male: 57% (4/7) • Female: 52% (13/25) • *P* = 1.00 (NS) (univariate analysis) **Outcome: SF-36 scores:** • *P* = NS for all domains (data NR) (multivariate analysis performed *post hoc*‡)	NR	***Prognostic factor:* Pain catastrophizing** **Outcome: pain relief* (mean PCS ± SD):** • pain relief ≥ 50%: 34.4 ± 4.9 • pain relief < 50%: 29.0 ± 12.0 • *P* = .15 (NS) (univariate analysis) • *P* = NS (value NR) (multivariate regression analysis) **Outcome: GPE score (mean PCS ± SD):** • GPE score 6–7: 30.1 ± 10.4 • GPE score ≤ 5: 32.1 ± 10.2 • *P* = .59 (NS) (univariate analysis) • *P* = NS (value NR) (multivariate regression analysis) **Outcome: SF-36 domain scores at follow-up** Multivariate regression analysis‡: • Physical functioning: *P* = .55 (NS) • Social functioning: *P* = .94 (NS) • Role limitations- physical: *P* = .29 (NS) • Role limiations-emotional: *P* = .81 (NS) • Mental health: *P* = .29 (NS) • Vitality: *P* = .68 (NS) • Bodily pain: *P* = .72 (NS) • General health: *P* = .93 (NS)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Lamé 2009 continued)					(continued…) - ***<u>Prognostic factor:</u> Education*** **Outcome: pain relief ≥ 50%*** • High education level**: 24% (4/17) • Low education level**: 53% (8/15) • *P* = .14 (NS) (univariate analysis) **Outcome: GPE score of 6 or 7:** • High education level††: 53% (9/17) • Low education level††: 53% (8/15) • *P* = 1.00 (NS) (univariate analysis) **Outcome: SF-36 scores:** Multivariate regression analysis performed *post hoc*‡: • General health: *P* = .04 (favoring higher education) • *P* = NS for the remaining domains (data NR)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Lamé 2009 continued)					(continued…) - ***<u>Prognostic factor:</u> Localization of pain:*** **Outcome: pain relief ≥ 50%*:** • Hand: 40% (6/15) • Foot: 35% (6/17) • *P* = 1.00 (NS) (univariate analysis) **Outcome: GPE score of 6 or 7:** • Hand: 60% (9/15) • Foot: 47% (8/17) • *P* = .50 (NS) (univariate analysis) **Outcome: SF-36 scores:** • *P* = NS for all domains (data NR) • (multivariate analysis performed *post hoc*‡) - ***<u>Prognostic factor</u>: Duration of pain:*** **Outcome: pain relief* (mean length of pain duration ± SD):** • pain relief ≥ 50%: 5.3 ± 4.6 years • pain relief < 50%: 4.0 ± 2.2 years • *P* = .29 (NS) (univariate analysis) • *P* = NS (data NR) (multivariate regression analysis) **Outcome: GPE score (mean length of pain duration ± SD):**

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Lamé 2009 continued)					• GPE score 6–7: 5.4 ± 4.0 years • GPE score ≤ 5: 3.5 ± 2.0 years • *P* = .09 (NS) (univariate analysis) • *P* = NS (data NR) (multivariate regression analysis) (continued…) *(prognostic factor: duration of pain, continued)* **Outcome: SF-36 scores:** Multivariate regression analysis‡ (*P* < .05 indciates longer duration of pain is significantly associated with better outcome) (data NR): • Physical functioning: *P* = .96 (NS) • Social functioning: *P* = .03 • Role limitations- physical: *P* = .07 (NS) • Role limiations-emotional: *P* = .55 (NS) • Mental health: *P* = .19 (NS) • Vitality: *P* = .09 (NS) • Bodily pain: *P* = .01 • General health: *P* = .09 (NS)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
North 1991 N = 50 mean f/u: 5.0 years	NR	NR	**Outcome: "success"*:** • *P* = .003 (favoring females) (coefficient of -1.71) (univariate analysis) • *P* < .05 (favoring females) (multivariate analysis) **Outcome: combination of everyday activities, medication use, or neurological function:** • *P* = .009 (favoring females) (multivariate analysis)	NR	***<u>Prognostic factor</u>: McGill Pain Questionnaire*** **Outcome: "success"*:** • Affective: *P* = NS (data NR) (univariate and multivariate analysis) • Evaluative: *P* = NS (data NR) (univariate and multivariate analysis) • Sensory: *P* = .052 (NS) (coefficient, -0.31) (data NR) (univariate analysis; NR for multivariate analysis) • Total number of adjectives chosen from affective, evaluative, and sensory lists: *P* = .067 (coefficent, -0.17) (univariate analysis • Choice of adjective "pressing": *P* = .082 (favoring poor outcome) (univariate analysis) • Choice of adjective "terrifying": *P* = .09 (favoring poor outcome) (univariate analysis) • Choice of any of the adjectives "aching", "burning", "cramping", "dull", exhausting", "frightening", "pounding", "punishing", "sharp", "shooting", "sickening", or "wretched": *P* = NS (values NR) (univariate and multivariate analysis) - ***<u>Prognostic factor</u>: Time since first operation*** **Outcome: "success"*, everyday activities, medication use, or neurological function:**

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(North 1991 continued)					• *P* = NS (values NR) for either outcome (univariate and multivariate analysis) (continued…) - ***<u>Prognostic factor</u>: Number of previous operations*** **Outcome: "success"*, everyday activities, medication use, or neurological function:** • *P* = NS (values NR) for any of the domains (univariate and multivariate analysis) - ***<u>Prognostic factor</u>: Pain location (percentage of axial vs radicular pain)*** **Outcome: "success"*, everyday activities, medication use, or neurological function:** • *P* = NS (values NR) for any of the domains (univariate and multivariate analysis)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
North 1996 N = 35 mean f/u: 3.5 years	NR	NR	NR	NR	***Prognostic factor*: Psychological testing****:** **Outcome: "success"*:** MMPI: Clinical Scales Univariate analysis: • "schizophrenia" (Sc) score: *P* = .05-.10 (NS) (favoring elevated scores) • *P* = NS (values NR) for any of the other domains Multivariate analysis: • *P* = NS (values NR) for any of the domains MMPI: Content Scales: • *P* = NS (values NR) for any of the domains (univariate and multivariate analysis) DABS (Deogatis Affects Balance Scale) Univariate analysis: • "vigor" score: *P* = .05-.10 (NS) (favoring elevated scores) • " affection" score: *P* = .05-.10 (NS) (favoring elevated scores) • total score: *P* = .05-.10 (NS) (favoring positive scores) • multivariate analysis:

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
					• "affection" score: *P* = .05-.10 (NS) (favoring elevated scores) • *P* = NS (values NR) for any of the domains Symptom Check List–90–Revised • *P* = NS (values NR) for any of the domains (univariate and multivariate analysis)
Turner 2010 f/u: 12 months	NR	NR	NR	NR	***Prognostic factor:*** ***Unilateral versus bilateral leg pain*** **Outcome: leg pain relief ≥ 50%** SCS: • Unilateral, pain relief ≥ 50%: 21% • Bilateral, pain relief ≥ 50%: 9% Pain Clinic: • Unilateral, pain relief ≥ 50%: 14% • Bilateral, pain relief ≥ 50%: 0% *P* = .28 (NS)†† (SCS vs pain clinic) Usual Care: • Unilateral, pain relief ≥ 50%: 16% • Bilateral, pain relief ≥ 50%: 19% *P* = .19 (NS)†† (SCS vs usual care) **Outcome: RDQ improvement ≥ 2 points** SCS: • Unilateral, RDQ ≥ 2 pts: 46% • Bilateral, RDQ ≥ 2 pts: 17% Pain Clinic: • Unilateral, RDQ ≥ 2 pts: 52%

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Turner 2010 continued					• Bilateral, RDQ ≥ 2 pts: 13% *P* = .66 (NS)†† (SCS vs pain clinic) Usual Care: • Unilateral, RDQ ≥ 2 pts: 53% • Bilateral, RDQ ≥ 2 pts: 41% *P* = .80 (NS)†† (SCS vs usual care) (continued…) ***Prognostic factor:* SF-36v2 Mental Health Scores:*** *"highest" – patients with SF-36 Mental Health scores in the highest third* *"lowest" – as above, but the lowest third* **Outcome: leg pain relief ≥ 50%** SCS: • "highest", pain relief ≥ 50%: 29% • "lowest", pain relief ≥ 50%: 11% Pain Clinic: • "highest", pain relief ≥ 50%: 0% • "lowest", pain relief ≥ 50%: 0% *P* = .28 (NS)†† (SCS vs pain clinic) Usual Care: • "highest", pain relief ≥ 50%: 29% • "lowest", pain relief ≥ 50%: 18% *P* = .19 (NS)†† (SCS vs usual care) **Outcome: RDQ improvement ≥ 2 points** SCS: • "highest", RDQ ≥ 2 pts: 57%

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
					• "lowest", RDQ ≥ 2 pts: 16% Pain Clinic: • "highest", RDQ ≥ 2 pts: 60% • "lowest", RDQ ≥ 2 pts: 25% *P* = .66 (NS)†† (SCS vs pain clinic) Usual Care: • "highest", RDQ ≥ 2 pts: 54% • "lowest", RDQ ≥ 2 pts: 39% *P* = .80 (NS)†† (SCS vs usual care)
Van Eijs 2010 Length of f/u: 12 months **NOTE: only 24 (of the 36 patients included in the analysis) received permanent implants††**	NR	**Outcome: "success"*** • Age ≤ 40 years, "successful": 65% (13/20)‡‡ • Age ≤ 40 years, "unsuccessful": 35% (7/20)‡‡ • Age > 40 years, "successful": 44% (7/16)‡‡ • Age > 40 years, "unsuccessful": 56% (9/16)‡‡ • *P* = .20 (NS) (univariate analysis)	**Outcome: "success"*** • Male, "successful": 43% (6/14)‡‡ • Male, "unsuccessful": 57% (8/14)‡‡ • Female, "successful": 64% (14/22)‡‡ • Female, "unsuccessful": 36% (8/22)‡‡ • *P* = .22 (NS) (univariate analysis)	NR	***Prognostic factor:* Localization** **Outcome: "success"*** • Upper limb, "successful": 55% (12/22) • Upper limb, "unsuccessful": 45% (10/22) • Lower limb, "successful": 57% (8/14) • Lower limb, "unsuccessful": 43% (6/14) • *P* = .88 (NS) (univariate analysis) - - - - - - - - - - ***Prognostic factor:* Duration of chronic pain:** **Outcome: "success"*** • < 40 months, "successful": 62% (13/21) • < 40 months, "unsuccessful": 38% (8/21) • ≥ 40 months, "successful": 47% (7/15) • ≥ 40 months, "unsuccessful": 53% (8/15) • *P* = .36 (NS) (univariate analysis) - - - - - - - - - - ***Prognostic factor:* Pain intensity at baseline:** **Outcome: "success"*** • VAS ≤ 7.1, "successful": 57% (12/21) • VAS ≤ 7.1, "unsuccessful": 45% (9/21) • VAS > 7.1, "successful": 53% (8/15)

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
(Van Eijs 2010 continued)					• VAS > 7.1, "unsuccessful": 47% (7/15) • *P* = .20 (NS) (univariate analysis) - ***Prognostic factor*: Presence of allodynia at baseline:** **Outcome: "success"*** • Absent, "successful": 81% (13/16) • Absent, "unsuccessful": 19% (3/16) • Moderate, "successful": 50% (2/4) • Moderate, "unsuccessful": 50% (2/4) • Severe, "successful": 31% (5/16) • Severe, "unsuccessful": 69% (11/16) • *P* = .017 (univariate analysis) (continued) - ***Prognostic factor*: Presence of allodynia at baseline:** **Outcome: "success"*** • Absent, "successful": 81% (13/16) • Absent, "unsuccessful": 19% (3/16) • Moderate, "successful": 50% (2/4) • Moderate, "unsuccessful": 50% (2/4) • Severe, "successful": 31% (5/16) • Severe, "unsuccessful": 69% (11/16) • *P* = .017 (univariate analysis) ***Multivariate logistic regression model*** (used to calculate a ROC curve and calculate an area under the curve (AUC)): • Found that the cutoff point for the brush-evoked allodynia pain intensity NRS score is 2.5 (sensitivity: 0.75, specificity: 0.81). -

Author (Year)	Diagnosis	Age	Gender	Third-party coverage	Other
					Prognostic factor*: Presence of hypoesthesia *at baseline:* **Outcome: "success"*** • Absent/light, "successful": 50% (8/16) • Absent'light, "unsuccessful": 50% (8/16) • Severe, "successful": 60% (12/20) • Severe, "unsuccessful": 40% (8/20) • *P* = .55 (NS) (univariate analysis)

CRPS: complex regional pain syndrome
DABS: Derogatis Affects Balance Scale
FBSS: failed back surgery syndrome
f/u: follow-up
GPE: global perceived effect
MMPI: Minnesota Multiphasic Personality Inventory
NR: not reported
NRS: numerical rating scale
PCS: pain catastrophizing score
PGIC: patients global impression of change
RDQ: Roland-Morris Disability Questionnaire
RSD: reflex sympathetic dystrophy
SCS: spinal cord stimulation
SD: standard deviation
SF-36: Short-Form 36
WCB: Worker's Compensation Board
* Pain outcome measures:
Burchiel 1995: 10-cm VAS scale used.
Lamé 2009: the VAS was recorded three times a day for four days and the mean score was used to determine pain intensity and compared to the VAS at baseline.
North 1991: "success" was achieved if a patient had ≥ 50% pain relief at last available follow-up and patient satisfaction (patient would repeat treatment for the result obtained).
North 1996: "success" was defined as continuous pain relief of ≥ 50% by VAS and patient satisfaction (patient would repeat treatment for the result obtained).

Van Eijs 2010: "success": patients with SCS were considered successful at the 12-month f/u if they had sustained pain reduction, as defined by a reduction in their VAS by ≥ 2.5 and/or a PGIC score of "much improved" or "very much improved" at 3 of the 4 follow-up visits.

† Burchiel 1995: A prediction equation was generated using forward, stepwise linear regression analysis of all the prognostic variables listed above; age, the McGill Pain Questionnaire evaluative subscale (MPQe), and depression (D) subscale scores were found to be significant predictors of outcome. The predictive equation generated is: %ΔVAS = 112.57 – 1.98(D) – 1.68(Age) + 35.54(MPQe).

‡ Lame 2009: Multivariate regression analysis done for the domains of the SF-36; pain duration and the corresponding baseline score of each SF-36 domain were both used as control variables; pain catastrophizing was used as the crucial variable. *Post hoc* analysis was additionally performed by substituting the remaining variables for pain catastrophizing.

** Lame 2009: Education classified as "low" (lower vocational education) or "high" (secondary education).

†† Turner 2010: Adjusted for baseline differences between groups in the following characteristics: age, gender, RDQ score, leg pain intensity, duration of work time loss compensation, disability benefit other than workers' compensation, unilateral vs bilateral leg pain, legal representation, and SF-36 mental health scores.

‡‡ Van Eijs 2010: Although only 24/36 of the patients had a successful trial stimulation and received permanent SCS implants, prognostic data was reported for all 36 patients. "Successful" patients consisted of 20/24 of those who underwent permanent implantation, while "unsuccessful" patients consisted of 4/24 of those with permanent implants as well as the 12 who did not receive permanent implants (failed trial stimulation).

*** Van Eijs 2010: Absent or light hypoesthesia was defined as normal or diminished sensibility to light touch; severe hypoesthesia was defined as diminished sensibility or loss of protective sensation.

1. Kumar, K., Hunter, G., Demeria, D.: Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. Neurosurgery, 58: 481, 2006