Neurostimulation
Übersicht,Beschreibung des Verfahren, Indikation,Patientenselektion

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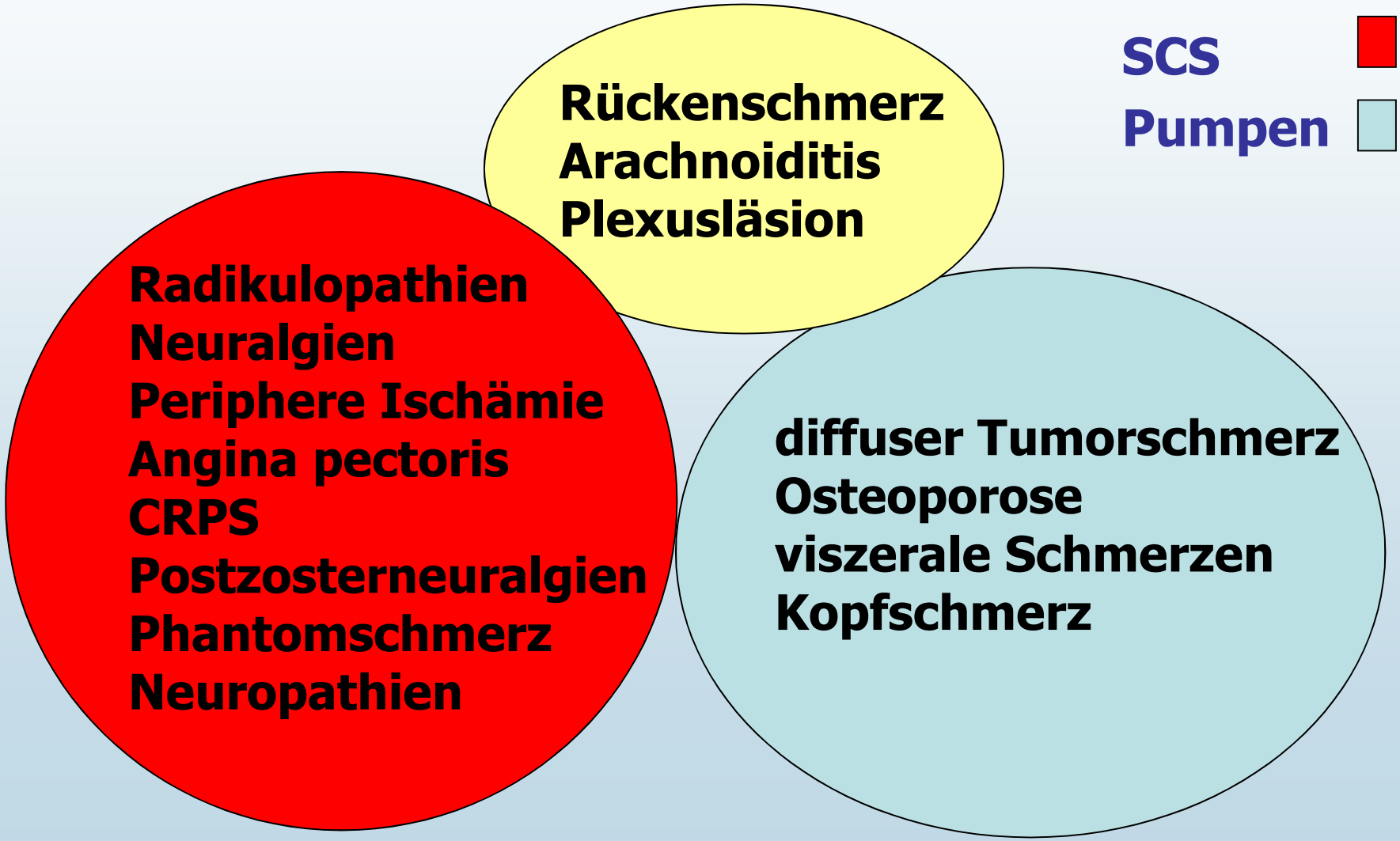
Indikationen für SCS



Absolute criteria for the consideration of SCS, selected by the expert panel

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Inclusion criteria	Exclusion criteria

• Age ≥ 18 years
• Chronic pain with a duration of least 6 months
• One of the following primary indications:
  • Chronic low back/leg pain
  • Complex regional pain syndrome
  • Neuropathic pain syndrome
  • Ischaemic pain syndrome
• Pain severity at least moderate (VAS ≥ 5) having a substantial impact on daily functioning and quality of life
• Insufficiently responding to appropriate trials of medication and/or minimally invasive treatments (such as local anaesthetic nerve blocks) and/or experiencing intolerable side effects of these treatments
• No clear benefits of surgery expected
	• Unwilling to have an implant
	• Unable to manage the device
	• Absolute contra-indications for active treatment (e.g. unfit for undergoing SCS, pregnancy, spine infection, coagulation disorder)
	• Uncontrolled disruptive psychological or psychiatric disorder
	• Ongoing alcohol and drug misuse
	• Widespread pain

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

Table 2. Commercially Available Neurostimulators and Leads.

Company	Device	Device type	Target	Approvals
BioControl Medical	CardioFit	Responsive stimulation of right vagus nerve	Right vagus nerve	EU
Bioness	H200 Wireless	Noninvasive prosthesis for functional electrical stimulation	Arm flexor, extensor muscles	EU, US
Bioness	L300	Noninvasive prosthesis for functional electrical stimulation	Peroneal nerve, anterior tibialis	EU, US
Bioness	L300 Plus	Noninvasive prosthesis for functional electrical stimulation	Quadriceps or hamstring	US
Bioness	StimRouter	External pulse transmitter, implanted lead	Median nerve	Pending US
Boston Scientific	Artisan 2 × 8 Surgical Lead	Paddle lead with 16 electrodes	Spinal cord	AU, CA, EU, US
Boston Scientific	Infinion 16 Lead	Cylindrical lead with 16 electrodes	Spinal cord	AU, CA, EU, US
Boston Scientific	Linear 8 Contact Lead	Cylindrical lead with 8 electrodes; 6-, 4-, or 1-mm spacing	Spinal cord	AU, CA, EU, US
Boston Scientific	Precision Plus	Rechargeable, constant-current IPG	Spinal cord	AU, CA, EU, US
Boston Scientific	Precision Spectra	IPG	Spinal cord	EU
Boston Scientific	Vercise	IPG	Brain	AU, EU
Cerbomed	NEMOS	Transcutaneous vagus nerve stimulator	Vagus nerve	EU
CerebralRx	FitNeS	IPG	Left vagus nerve	EU
CVRx	Barostim Neo	IPG	Right carotid artery	EU
CVRx	Rheos	IPG	Carotid arteries	EU
Cyberonics	VNS Therapy Generators	IPG	Left vagus nerve	CA, EU, US
Cyberonics	VNS Therapy Leads	Leads	Left vagus nerve	CA, EU, US
EndoStim	EndoStim	IPG	Lower esophageal sphincter	EU
EnteroMedics	Maestro RC	Rechargeable high-frequency IPG	Vagus nerve	AU, EU
EnteroMedics	Maestro RC leads	Anterior and posterior leads	Vagus nerve	AU, EU
ImThera	aura6000	Rechargeable IPG	Hypoglossal nerve	EU
IntraPace	abiliti	IPG	Stomach	EU
Medtronic	1 × 4 Percutaneous Leads	Cylindrical lead with four electrodes; 12-, 6- or 4-mm spacing	Spinal cord	AU, CA, EU, US
Medtronic	1 × 8 Percutaneous Leads	Cylindrical lead with eight electrodes; 6-, 4- or 1.5-mm spacing	Spinal cord	AU, CA, EU, US
Medtronic	4-Electrode Surgical Leads	Paddle lead with four electrodes	Spinal cord	AU, CA, EU, US
Medtronic	8-Electrode Surgical Leads	Paddle lead with eight electrodes	Spinal cord	AU, CA, EU, US
Medtronic	16-Electrode Surgical Leads	Paddle lead with 16 electrodes	Spinal cord	AU, CA, EU, US
Medtronic	Activa PC	Dual-channel, nonrechargeable, constant-current/voltage IPG	Brain	AU, CA, EU, US
Medtronic	Activa RC	Dual-channel, rechargeable, constant-current/voltage IPG	Brain	AU, CA, EU, US
Medtronic	Activa SC	Single-channel, nonrechargeable, constant-current/voltage IPG	Brain	AU, CA, EU, US
Medtronic	DBS Lead 3387	Cylindrical lead with four electrodes, 1.5-mm spacing	Brain	AU, CA, EU, US
Medtronic	DBS Lead 3389	Cylindrical lead with four electrodes, 0.5 mm spacing	Brain	AU, CA, EU, US
Medtronic	Enterra	Nonrechargeable IPG	Stomach muscle	CA, EU, US
Medtronic	InterStim & InterStim II	Nonrechargeable IPG	Sacral nerve	AU, CA, EU, US
Medtronic	Itrel 4	Nonrechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	PrimeAdvanced	Nonrechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	RestoreAdvanced	Rechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	RestorePrime	Nonrechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	RestoreSensor	Rechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	RestoreUltra	Rechargeable constant-voltage IPG	Spinal cord	AU, CA, EU, US
Medtronic	Tined Leads 3889 & 3093	Cylindrical lead with four electrodes; 1.5- or 3.0-mm spacing	Sacral nerve	AU, CA, EU, US
Medtronic	Unipolar Intramuscular Lead	10-mm electrode	Stomach muscle	CA, EU, US
NeuroPace	RNS System	Responsive neurostimulator	Cortex	US
Neurostream	Neurostep	IPG	Leg peripheral nerves	EU
Nevro	8-Contact Percutaneous Leads	Cylindrical lead with eight electrodes	Spinal cord	EU
Nevro	Senza HF-SCS	Rechargeable high-frequency IPG	Spinal cord	EU

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Deer TR, Krames E, Mekhail N. et al.The Appropriate Use of Neurostimulation: New and Evolving Neurostimulation Therapies and Applicable Treatment for Chronic Pain andSelected Disease States. Neuromodulation 2014; 17: 599–615

Second Sight	Argus II	Epiretinal prosthesis	Retina	EU
Spinal Modulation	Axium	Constant-voltage IPG	Spinal cord, dorsal root ganglion	AU, EU
Spinal Modulation	Axium Leads	Cylindrical leads	Spinal cord, dorsal root ganglion	AU, EU
St. Jude Medical	1-Column Paddle Lead	Paddle lead	Spinal cord	AU, EU, US
St. Jude Medical	2-Column Paddle Lead	Paddle lead	Spinal cord	AU, EU, US
St. Jude Medical	3-Column Paddle Lead	Paddle lead	Spinal cord	AU, EU, US
St. Jude Medical	5-Column Paddle Lead	Paddle lead	Spinal cord	AU, EU, US
St. Jude Medical	Brio	Rechargeable, dual-channel, constant-current IPG	Brain	AU, EU
St. Jude Medical	DBS Leads	Cylindrical lead with four electrodes; 1.5- or 0.5-mm spacing	Brain	AU, EU
St. Jude Medical	Eon	Rechargeable constant-current IPG	Spinal cord	AU, EU, US
St. Jude Medical	Eon	Rechargeable constant-current IPG	Peripheral nerves	AU, EU
St. Jude Medical	EonC	Nonrechargeable constant-current IPG	Spinal cord	AU, EU, US
St. Jude Medical	EonC	Nonrechargeable constant-current IPG	Peripheral nerves	AU, EU
St. Jude Medical	Eon Mini	Rechargeable constant-current IPG	Spinal cord	AU, EU, US
St. Jude Medical	Eon Mini	Rechargeable constant-current IPG	Peripheral nerves	AU, EU
St. Jude Medical	Genesis	Nonrechargeable IPG	Spinal cord	AU, EU, US
St. Jude Medical	Genesis	Nonrechargeable IPG	Peripheral nerves	AU, EU
St. Jude Medical	Libra	Single-channel, constant-current, nonrechargeable IPG	Brain	AU, EU
St. Jude Medical	Libra XP	Dual-channel, constant-current, nonrechargeable IPG	Brain	AU, EU
St. Jude Medical	Percutaneous Leads	Cylindrical lead	Spinal cord	AU, EU, US
St. Jude Medical	Percutaneous Leads	Cylindrical lead	Peripheral nerves	AU, EU

AU, Australia, CA, Canada; DBS, deep brain stimulation; EU, European Union; IPG, implantable pulse generator; US, United States.

Deer TR, Krames E, Mekhail N. et al.The Appropriate Use of Neurostimulation: New and Evolving Neurostimulation Therapies and Applicable Treatment for Chronic Pain andSelected Disease States. Neuromodulation 2014; 17: 599–615


Das Stufenschema der Schmerztherapie
Körperliches Training
Meditation und Entspannungstechniken
Nichtopioide Analgetika
Adjuvante Medikation (Antidepressiva, Antikonvulsiva)
Physikalische Rehabilitation
Somatische und sympathische Nervenblockade
Kognitive und Verhaltens-Therapien
Orale Opioidmedikation
Epidurale Elektrostimulation (SCS)
Intrathekale Analgesie
Neurodestruktive Verfahren

Table 3. Alternative Methods of Current Delivery in Neurostimulation Devices.

Method	Device description	Potential advantages
High frequency	Neurostimulation devices that utilize higher pulse rates than conventional stimulators are being developed and tested for alleviating chronic pain (154,156). For example, one such device delivers pulses at a rate of 10,000 Hz to the spinal cord (155) and peripheral nerve neuromas (157). Due to the high pulse rate, this type of stimulation does not produce paresthesia.	-Patients do not experience paresthesia. -May produce greater pain reduction than conventional stimulation in the back.
Burst	Delivers stimulating pulses in bursts (158,159) of 5 spikes lasting 1 msec each (with a 1 msec interspike interval) 40 times per second. This pattern of stimulation does not produce paresthesia.	-Patients do not experience paresthesia. -May salvage patients who have failed conventional SCS.
Microwave powered	Microwave neurostimulation device consists of a 1 cm long dipole platinum wire antenna and Schottky diode contained within 0.8 mm diameter polyimide tubing (160). Both ends of the tubing terminate in 1 mm platinum balls that function as stimulating electrodes. Current delivery must be limited to levels of microwave radiation that can be safely absorbed.	-Will eliminate the need for an IPG -The microwave transmitter can be up to 7 cm from body surface, providing wireless stimulation. -May be ideal for PNS and PNfS
Waveforms	Alternative waveforms have been developed for neurostimulation devices such as deep brain stimulation devices (161). For example, replacing standard rectangular waveforms (mono- or biphasic) with alternative waveforms (e.g., triangular or Gaussian or "randomly modulated" or mimicking normal neural activity from the target; i.e., other novel waveforms) may produce positive effects and even be energy saving.	-More energy efficient waveforms have the potential to increase neurostimulator device lifetime, reducing or delaying the need for additional surgeries.
Closed loop	Involves neural sensors and stimulating electrodes. The sensors provide data to adjust stimulation parameters dynamically, for example, localizing stimulation in the epileptogenic brain region during an epileptic seizure (162).	-Faster adjustments in stimulation than manual patient adjustment -May alleviate the need for accelerometers and similar sensors
Sensing	SCS device that detects changes in body position (163). The patient's desired stimulation levels in a position are programmed into the stimulator and that setting is automatically applied as body position changes.	-Automatic adjustments may result in better satisfaction. -Fewer manual adjustments in stimulation are required by patients.

IPG, implantable pulse generator; PNfS, peripheral nerve field stimulation; PNS, peripheral nerve stimulation.

Deer TR, Krames E, Mekhail N. et al.The Appropriate Use of Neurostimulation: New and Evolving Neurostimulation Therapies and Applicable Treatment for Chronic Pain andSelected Disease States. Neuromodulation 2014; 17: 599–615

Table 1. Hierarchy of Studies by the Type of Design (U.S. Preventive Services Task Force, Ref [7]).

Evidence level	Study type
I	At least one controlled and randomized clinical trial, properly designed
II-1	Well-designed, controlled, nonrandomized clinical trials
II-2	Cohort or case studies and well designed-controls, preferably multicenter
II-3	Multiple series compared over time, with or without intervention, and surprising results in noncontrolled experiences
III	Clinical experience-based opinions, descriptive studies, clinical observations or reports of expert committees.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

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Table 2. Meaning of Recommendation Degrees (U.S. Preventive Services Task Force, Ref [7]).

Degree of recommendation	Meaning
A	Highly recommended (good evidence that the measure is effective and benefits outweigh the harms)
B	Recommended (at least, moderate evidence that the measure is effective and benefits exceed harms)
C	Neither recommend nor advise (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified)
D	Not advisable (at least moderate evidence that the measure is ineffective or that the harms exceed the benefits)
I	Insufficient, low quality, or contradictory evidence; the balance between benefit and harms cannot be determined.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

Table 3. Strength of Consensus.

Strength of consensus	Definition*
Strong	>80% consensus
Moderate	50–79% consensus
Weak	<50% consensus

*Quorum defined as 80% of participants available for vote.

Deer et al., The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks, International Neuromodulation Society, 2017, 20:155-176.

Table 1. Classification of the Quality of Evidence, Strength of Recommendation, and Description of the Recommendation

Quality of Evidence	Strength of Recommendation	Recommendation
High	Strong	Must (not) be used
Moderate	Moderate	Should (not) be used
Low	Weak	Could (not) be used
Very low	Very weak	Could (not) be considered

Huygen F. et al.; „Evidence-Based Interventional Pain Medicine According to Clinical Diagnoses“: Update 2018: Pain Practice, Volume 19, Issue 6, 2019 664-675.

Tab. 1	Empfehlungen der Leitlinie	
CRPS I	A	Bleiben alle Versuche einer multimodalen konservativen Therapie des CRPS I ohne dauerhaften Erfolg, sollte eine Therapie mit epiduraler Rückenmarkstimulation unter Beibehaltung einer intensiven physikalischen Behandlung angeboten werden.
CRPS II	O	Ein individueller Behandlungsversuch kann bei CRPS II bei Wirkungslosigkeit konservativer Maßnahmen erwogen werden.
FBSS	B	Die SCS sollte beim FBSS mit prädominantem neuropathischem Beinschmerz bei Erfolglosigkeit konservativer Verfahren und Ausschluss psychologischer Kontraindikationen eingesetzt werden.
FBSS	O	Ein individueller Behandlungsversuch kann bei überwiegendem Kreuzschmerz bei Wirkungslosigkeit konservativer Maßnahmen erwogen werden.
Angina pectoris	A	SCS soll bei refraktärer Angina pectoris bei KHK nach Ausschöpfung aller konservativen und interventiven Therapiemaßnahmen eingesetzt werden.
PAVK	A	SCS soll bei pAVK Stadium IIb–III nach erfolgloser konservativer, interventiver Therapie eingesetzt werden.
PAVK	O	Ein Behandlungsversuch kann bei anderen vasokonstriktorischen Erkrankungen wie Morbus Raynaud, Thrombangiitis obliterans nach erfolgloser konservativer Therapie erwogen werden.

Kemler MA, Barends GA, Kleef M van et al (2000) Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 343:618-643Tronnier V. et al Epidurale Rückenmarkstimulation zur Therapie chronischer Schmerzen S3 Leitlinie Der Schmerz 2012 CRPS I Empfehlung B

Table 7. Selected and Chronologically Presented SCS Guideline or Consensus Statements.

Study date/ author	Society affiliation	Sponsorship/ funding	Indications	Level of evidence (if identified)	Recommendations	Recommendation strength (if identified)
Stanton Hicks et al. 1998 (3)	Expert panel report	Not reported	CRPS		SCS should be used with a multimodal strategy to treat CRPS early	
Stanton-Hicks et al. 2002 (5)	Expert panel report	Medtronic	CRPS		SCS should be used with a multimodal strategy to treat CRPS early	
Kirkpatrick 2003 (6)	International Research Foundation for RSD/CRPS	Not-for-profit organization	CRPS		Reserved for patients with severe CRPS	
Airaksinen et al. 2006 (7)	European guidelines for the management of chronic nonspecific low back pain	Not reported	Chronic low back pain	Level D	SCS is not recommended in the treatment of chronic low back pain	
Boswell et al. 2005 (8)	ASIPP	ASIPP	CRPS; FBSS		SCS is recommended for FBSS and CRPS; Strong for short-term management, moderate for long term	
Netherlands Society of Rehabilitation Specialists and Netherland Society of Anesthesiologists 2006 (9)	Netherlands Society of Rehabilitation Specialists and Netherland Society of Anesthesiologists (VRA)	Order of Medical Specialists in the context of the evidence-based guidelines development program	CRPS	Level 3: A2 and C[††]	SCS in patients with CRPS-1 that are carefully selected patients causes long-term pain reduction and improves the quality of life, not function.	
Boswell et al. 2007 (10)	ASIPP	None	CRPS; FBSS; with positive results for angina		SCS is recommended for FBSS and CRPS; Strong for short-term management, moderate for long term	
North and Shipley 2007 (11)	Expert panel	NTAC, NANS	FBSS, CRPS I, CRPSII, "other"[§]		SCS is recommended in treating FBSS, CRPS, and "other"	Level A for FBSS and CRPS I and II; B for "other"[‡]
Cruccu et al. 2007 (13)	EFNS	Not reported	CRPS, FBSS	Class II	SCS is efficacious in FBSS and CRPS	Level B
Hegmann 2008 (14)	ACOEM Guidelines (2008 version)		CRPS; FBSS	I	SCS is not recommended for acute, subacute, or chronic low back pain, lower extremity radicular pain, or failed back surgery syndrome; SCS is recommended for CRPS for short to intermediate durations, not long term (more than three years)	FBSS: Insufficient Evidence CRPS: Limited C for short term/intermediate; insufficient evidence for long term; Level C Not recommended for long term

Deer TR, Thomson S, Pope JE et al.International Neuromodulation Society Critical Assessment: Guideline Review of Implantable Neurostimulation Devices. Neuromodulation 2014; 17: 678–685

Table 7. Selected and Chronologically Presented SCS Guideline or Consensus Statements.

Ades et al. 2008 (15)	NICE	Non-departmental public body	Chronic pain of neuropathic origin (and ischemic pain if research trial)		Recommended for chronic neuropathic pain with 5/10 on VAS, >6 mo pain, s/p successful trial, ischemic pain in the context of an experimental trial	
Manchikanti et al. 2009 (16)	ASIPP	Not reported	CRPS, FBSS	II-1 or II-2 for long-term relief in managing patients with FBSS	SCS is recommended for FBSS and CRPS	FBSS and CRPS: 1B or 1C/strong†
Simpson et al. 2009 (17)	BPS	Sponsorship was BPS and SBNS and endorsed by NSUKI	Chronic neuropathic pain		SCS is effective in treating FBSS and CRPS and recommends for these and refractory neuropathic pain; SCS is recommended for selected patients with CCLI and RA only as part of robust clinical trial	
Chou R et al. 2009 (18)	APS	APS	Nonspecific low back pain, radiculopathy from FBSS, radiculopathy from prolapsed disc	SCS for FBSS with persistent radiculopathy: Fair** SCS for nonspecific low back pain; persistent radiculopathy with herniated disc no trials or evidence	SCS provides moderate benefit for patients with FBSS with persistent radiculopathy **SCS for treatment of nonspecific low back pain or radiculopathy from prolapsed disc: unable to estimate	SCS for FBSS with persistent radiculopathy: B; SCS for nonspecific low back pain or from prolapsed disc with persistent radiculopathy: I

Deer TR, Thomson S, Pope JE et al.International Neuromodulation Society Critical Assessment: Guideline Review of Implantable Neurostimulation Devices. Neuromodulation 2014; 17: 678–685

Table 7. *Continued*

Study date/ author	Society affiliation	Sponsorship/ funding	Indications	Level of evidence (if identified)	Recommendations	Recommendation strength (if identified)
Rosenquist et al. 2010 (19)	ASA and the ASRA and Pain Medicine	Not reported	CRPS; FBSS; "other conditions" (peripheral neuropathic pain, peripheral vascular disease, postherpetic neuralgia)	CRPS: Category A3; FBSS: A3; "other conditions": B2	SCS should be used for persistent radicular pain, other conditions, CRPS, PHN, visceral pain, PVD, with demonstrated efficacious trial	
Hunter Integrated Pain Service 2010 (20)	HIPS	Hunter New England	CRPS, FBSS, ischemic pain		SCS has limited evidence for sustainable treatment for FBSS or CRPS type 1. SCS can improve tissue perfusion and should be considered when bypass surgery is not feasible	
Mailis and Taenzer 2012 (21)	CPS	CPS	CRPS, FBSS, traumatic neuropathy, or brachial plexopathy; other neuopathic pain syndromes	FBSS and CRPS: Good; traumatic neuropathy/brachial plexopathy: fair; other neuropathic pain syndromes: poor	In patients with FBSS or CRPS who are not candidates for corrective surgery and have failed conservative therapy, trial should be considered; B; neuropathy/brachial plexopathy: consider trial if no corrective surgery and conservative therapies failed; other neuropathic pain syndromes: SCS trial not recommended because of lack of evidence	FBSS and CRPS: Grade B; neuropathy/brachial plexopathy: Grade C; other neuropathic pain syndromes: Grade I
Tronnier et al. 2010 (22)	Summary S3 Guidelines		CRPS type I and FBSS radiculaopathy; peripheral arterial occlusive disease; refractory angina pectoris		SCS is effective in treating CRPS type I, FBSS radiculopathy; peripheral arterial occlusive disease and refractory angina pectoris	
Neuromodulation Therapy Access Coalition 2010 (23)	NTAC	Device company sponsorship	Chronic neuropathic pain		SCS is effective in treating chronic neuropathic pain	
Dworkin et al. 2013 (24)	Neuropathic Pain Special Interest Group	International association for the study of Pain	FBSS; CRPS type I		SCS is effective in treating FBSS and CRPS type I	Weak

*Based on USPSTF (1).
†Based on Guyatt et al. 2006 (25).
‡Based on grading system (11).
§Other: peripheral neuropathic pain, phantom limb pain/postamputation syndrome, postherpetic neuralgia, root injury pain, spinal cord injury/lesion.
¶Based on level of evidence as defined by Rosenquist et al. (19).
**Based on definitions of magnitude of estimating effects (18).
††Based on literature quality assessment and strength of evidence (9).
ACOEM, American College of Occupational and Environmental Medicine; APS, American Pain Society; ASA, American Society of Anesthesiologists; ASIPP, American Society of Interventional Pain Physicians; ASRA, American Society of Regional Anesthesia; BPS, British Pain Society; CPS, Canadian Pain Society; CRPS, complex regional pain syndrome; EFNS, European Federation of Neurological Societies; FBSS, Failed Back Surgery Syndrome; HIPS, Hunter Integrated Pain Service; NICE, National Institute for Health and Clinical Excellence; NTAC, Neuromodulation Therapy Access Coalition; RSD, reflex sympathetic dystrophy; SCS, spinal cord stimulation; USPSTF, US Preventative Services Task Force.

Deer TR, Thomson S, Pope JE et al.International Neuromodulation Society Critical Assessment: Guideline Review of Implantable Neurostimulation Devices. Neuromodulation 2014; 17: 678–685

Table 1 Summary of GRADE results in neurostimulation studies of neuropathic pain, CRPS I and fibromyalgia

Procedure	Neuropathic pain				Complex regional pain syndrome type I				Fibromyalgia			
Assessment	Final quality of evidence	Effect size	Tolerability/ safety	Values and preferences	Final quality of evidence	Effect size	Tolerability/safety	Values and preferences	Final quality of evidence	Effect size	Tolerability/ safety	Values and preferences
SCS[a]	Low	Low	Moderate	ND	Low	Low	Moderate	ND				
DBS	Very low	Very low	Moderate	ND								
MCS	Very low	Low	Moderate	High[b]								
rTMS of M1	Low	Low	High	ND	Very low	Low	High	ND	Low	Low	High	ND
rTMS of DLPFC	Very low	Low	High	ND					Very low	Low	High	ND
tDCS of M1	Low	Low	High	ND					Low	Low	High	ND
tDCS of DLPFC	Very low	Low	High	ND					Very low	Low	High	ND

CRPS I, complex regional pain syndrome type I; DBS, deep brain stimulation; DLPFC, dorsolateral prefrontal cortex; M1, primary motor cortex; MCS, epidural motor cortex stimulation; ND, not determined; rTMS, repetitive transcranial magnetic stimulation; SCS, spinal cord stimulation; tDCS, transcranial direct current stimulation.

[a]SCS is the only procedure that was studied specifically in post-surgical chronic back and leg pain (two randomized controlled studies): final quality of evidence was low, effect size was moderate, tolerability/safety was moderate and patients' preferences compared to reoperation or standard of care were high; [b]in one study, a number of patients with insignificant pain relief were willing to be reoperated for the same outcome [14].

Cruccu G, Garcia-Larrea L; Hansson P et al.EAN guidelines on central neurostimulation therapy in chronic painconditions. European Journal ofNeurology 2016, 23: 1489–1499

North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005; 56: 98–106.

Table 2 Summary of GRADE recommendations for neurostimulation in chronic pain

Procedure	Neuropathic pain	Post-surgical chronic back and leg pain	CRPS I	Fibromyalgia
Spinal cord stimulation				
SCS versus conventional management	Weak for	Weak for	Weak for	
SCS versus reoperation		Weak for		
Deep brain stimulation	Inconclusive			
Epidural motor cortex stimulation	Weak for			
Repetitive transcranial magnetic stimulation				
rTMS of M1	Weak for		Inconclusive	Weak for
rTMS of DLPFC	Inconclusive			Inconclusive
Transcranial direct current stimulation				
tDCS of M1	Weak for (inconclusive in SCI)			Inconclusive
tDCS of DLPFC	Inconclusive			Inconclusive

CRPS I, complex regional pain syndrome type I; DLPFC, dorsolateral prefrontal cortex; M1, primary motor cortex; rTMS, repetitive transcranial magnetic stimulation; SCI, spinal cord injury; SCS, spinal cord stimulation; tDCS, transcranial direct current stimulation.

Cruccu G, Garcia-Larrea L; Hansson P et al.EAN guidelines on central neurostimulation therapy in chronic painconditions. European Journal ofNeurology 2016, 23: 1489–1499

Bleiben alle Versuche einer multimodalen konservativen Therapie des CRPS I ohne dauerhaften Erfolg, sollte eine Therapie mit epiduraler Rückenmarkstimulation unter Beibehaltung einer intensiven physikalischen Behandlung angeboten werden.

Kemler MA, Barends GA, Kleef M van et al (2000) Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. N Engl J Med 343:618-643

Tronnier V. et al Epidurale Rückenmarkstimulation zur Therapie chronischer Schmerzen S3 Leitlinie Der Schmerz 2012

Die SCS sollte beim FBSS mit prädominantem neuropathischem Beinschmerz bei Erfolglosigkeit konservativer Verfahren und Ausschluss psychologischer Kontraindikationen eingesetzt werden.

Kumar K, Taylor RS, Jacques L et al (2007) Spinal cord stimulation versus conventional medical management for neuropathic pan: A multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 132:179-188

Taylor RJ, Taylor RS (2005) Spinal Cord stimulation for failed back surgery syndrome: a decision analytic model and cost-effectiveness analysis. Int J Technol Assess Health 21:351-358

Ein individueller Behandlungsversuch kann bei überwiegendem Kreuzschmerz bei Wirkungslosigkeit konservativer Maßnahmen erwogen werden.

Taylor RS (2006) Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: results of a systematic review and metaanalysis. J Pain Symptom Manage 32:S13-S19

Turner JA, Loeser JD, Bell KG (1995) Spinal cord stimulation for chronic low back pain: a sytematic literature review synthesis. Neurosurgery 37:1088-1096

Die SCS ist bei therapierefraktärer Angina pectoris effektiv und senkt die kardiovaskuläre Morbidität, die Häufigkeit und Intensität der Anginaattacken; sie reduziert den Nitratverbrauch und die Häufigkeit Angina-bedingter Krankenhausaufenthalte. SCS soll bei refraktärer Angina pectoris bei KHK nach Ausschöpfung aller konservativen und interventiven Therapiemaßnahmen eingesetzt werden.

Andrell P, Ekre O, Eliasson T et al (2003) Cost-effectiveness of spinal cord stimulation versus coronary artery bypass grafting in patients with severe angina pectoris – long-term results from the ESBY study. Cardiology 99:20-24

Die SCS ist bei peripherer arterieller Verschlusskrankheit über einen Zeitraum von 12 Monaten effektiv und kann zu einem Erhalt der betroffenen Extremitäten beitragen. SCS soll bei pAVK Stadium IIb-III nach erfolgloser konservativer, interventiver Therapie eingesetzt werden.

Donas KP, Schulte S, Ktenidis K et al (2005) The role of epidural spinal cord stimulation in the treatment of Buerger's disease. J Vasc Surg 41:830-836

Pace AV, Saratzis N, Karokis D et al (2002) Spinal cord stimulation in Buerger's disease. Ann Rheum Dis 61:1114

Bei anderen vasokonstriktorischen Erkrankungen wie Morbus Raynaud oder Thrombangiitis obliterans liegen positive Fallberichte vor. Ein Behandlungsversuch kann bei anderen vasokonstriktorischen Erkrankungen wie Morbus Raynaud, Thrombangiitis obliterans nach erfolgloser konservativer Therapie erwogen werden.

Donas KP, Schulte S, Ktenidis K et al (2005) The role of epidural spinal cord stimulation in the treatment of Buerger's disease. J Vasc Surg 41:830-836

Pace AV, Saratzis N, Karokis D et al (2002) Spinal cord stimulation in Buerger's disease. Ann Rheum Dis 61:1114

Bei chronischen Schmerzen durch Nervenverletzungen oder Gefäßleiden steht die epidurale Rückenmarkstimulation für medikamentös nicht ausreichend therapierbare Fälle zur Verfügung. Vor der Überweisung solcher Patienten an Schmerztherapiezentren sollte die Indikation genau überprüft werden. Weniger invasive medikamentöse und physikalische Maßnahmen sollten ausgeschöpft sein oder wegen intolerabler Nebenwirkungen nicht in Betracht kommen. Die Patienten müssen informiert sein, dass die epidurale Rückenmarkstimulation Teil eines Gesamtschmerztherapiekonzepts ist.

V Tronnier, R Baron, F Birklein, S Eckert, H harke, D Horstkotte, P Hügler, M Hüppe, B Kniesel, C Maier, G Schütze, R Thoma, R D Treede, V Vadokas; Epidurale Rückenmarkstimulation zur Therapie chronischer Schmerzen; Der Schmerz 2011 25:484-492

KABEG
KLINIKUM KLAGENFURT
AM WÖRTHERSEE

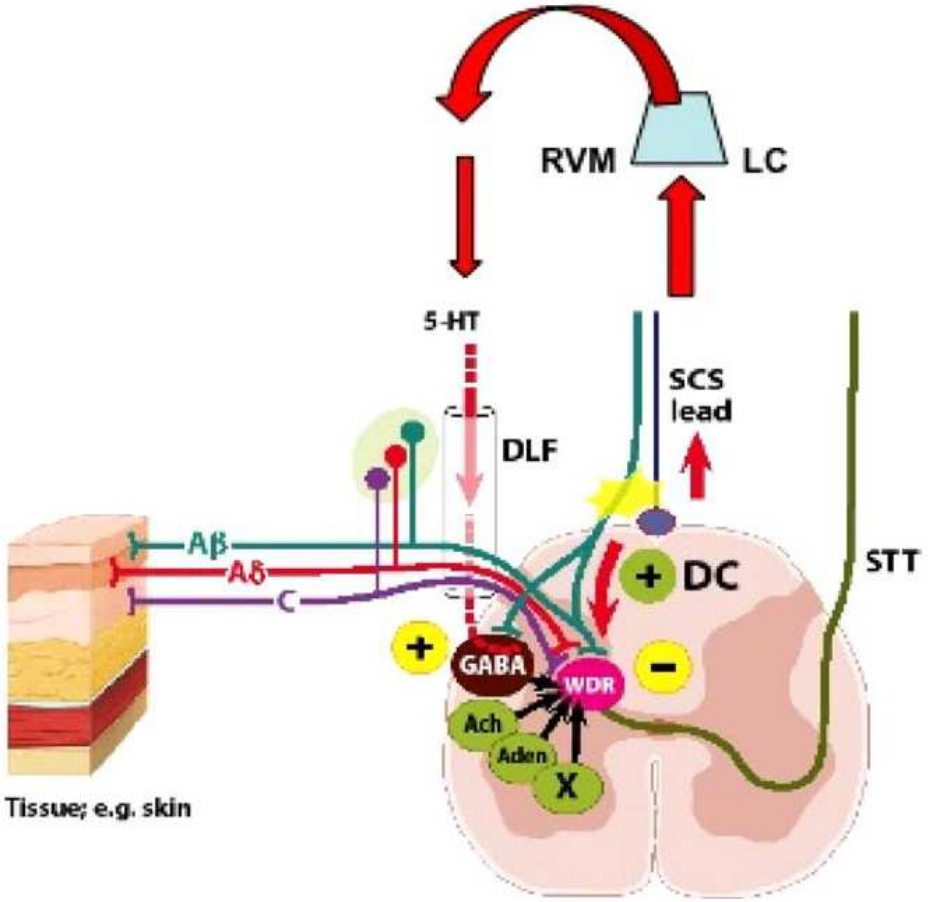
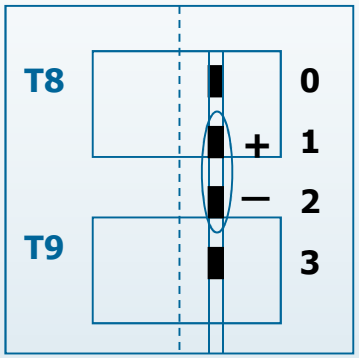


Figure 1. Schematic summary of the known segmental and supraspinal mechanisms involved in conventional SCS when applied for neuropathic pain. Antidromic stimulation of DC afferents induces activation of inhibitory interneurons in the dorsal horns and the ortodromic impulses in the DCs activate neurons in the RVM and the locus coeruleus (LC) in the brainstem, leading to descending inhibition further strengthening the segmental inhibitory mechanisms (adapted from Linderoth and Meyerson, Anesthesiology 2010 (38)).

Linderoth et al., Conventional and Novel Spinal Stimulation Algorithms: Hypothetical Mechanisms of Action and Comments on Outcomes. Neurostimulation. 2017.

PARAMETERWAHL

Zentraler Bipol

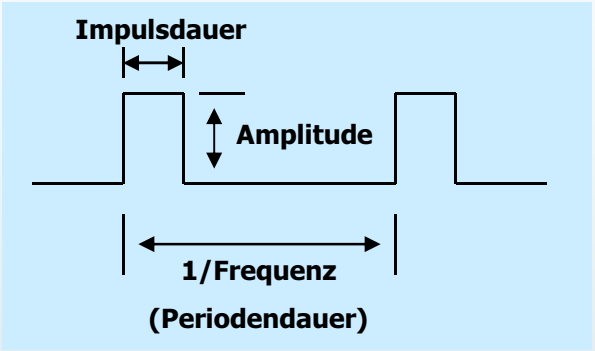


Erhöhung der Effizienz oft noch durch sog. „Guarded Cathode"

1 +

2 –

3 +



Parameter	empf. Anfangswert	Bereich	Werte aus der Praxis	Effekt der Anpassung
Pulsbreite	210 µs	60 - 450 µs	60 - 450 µs	Änderung der relativen Ausdehnung
Frequenz	50 Hz	2,1 - 130 Hz	35 - 50 Hz	Änderung der Art der Parästhesien
Amplitude	0 V	0 - 10,5 V	1,0 - 8,0 V	Stärke der Parästhesien

Vorsicht: Vor Erhöhung von Impulsdauer oder Frequenz auf jeden Fall Amplitude reduzieren, da es sonst durch überhöhte „Energiezufuhr" für den Patienten zu einer schmerzhaften Stimulation führen kann !

KABEG
KLINIKUM KLAGENFURT
AM WÖRTHERSEE

Current SCS Options

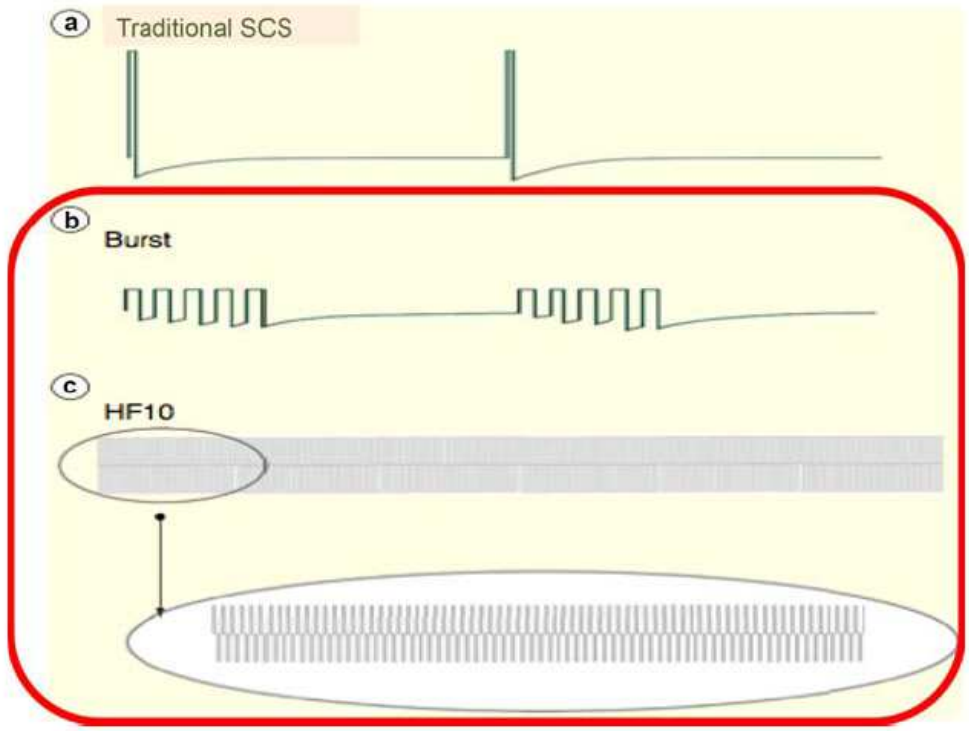


Figure 2. Current SCS options: the new algoritms are framed by a red rectangle. a. Conventional SCS freq. about 30–80 Hz; b. Burst SCS with internal pulse freq. 500 Hz and burst repetition rate 40 Hz; c. High frequency stimulation—usually 10 kHz (adapted from Pope, Falowski, and Deer 2015 (49)).

Linderoth et al., Conventional and Novel Spinal Stimulation Algorithms: Hypothetical Mechanisms of Action and Comments on Outcomes. Neurostimulation. 2017.

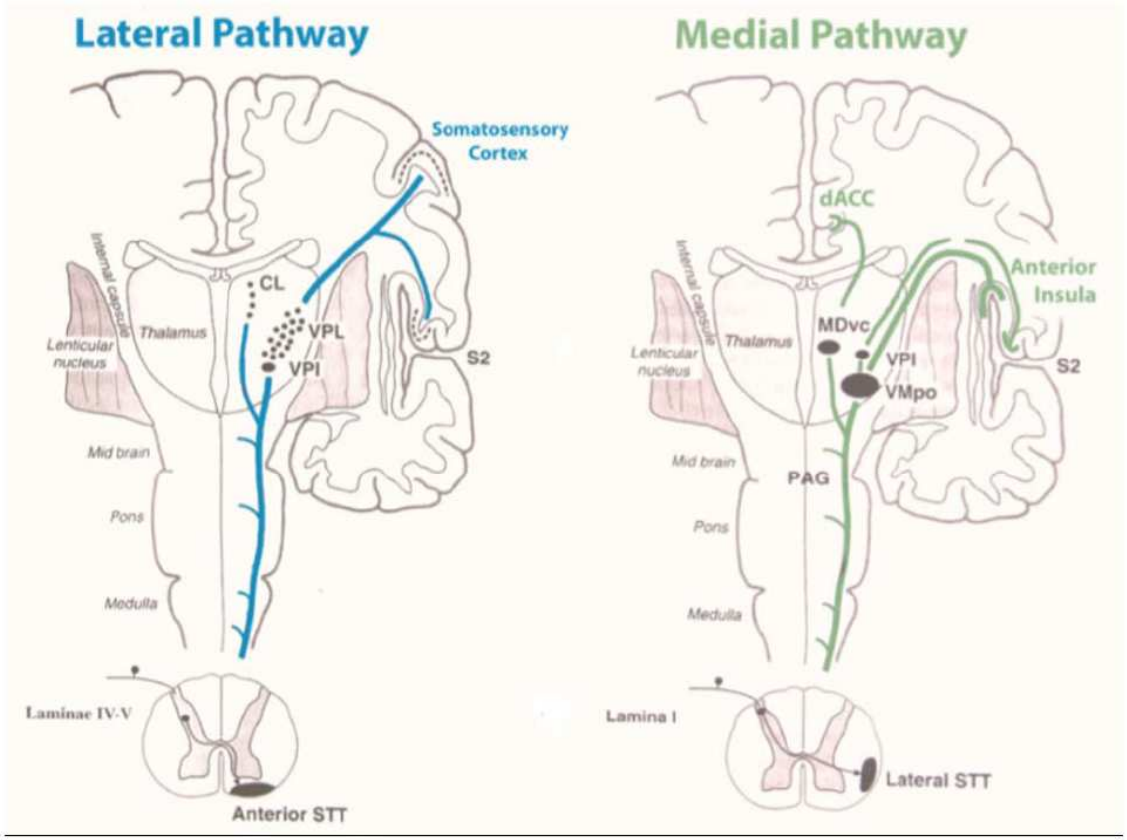


Figure 3. Present "working hypotheses" for mechanisms behind effects of burst stimulation of the spinal cord (adapted from De Ridder and Vanneste 2015 (76)). Burst SCS is hypothesized to especially modulate the activation of the medial (affective/attentional) pathway (on the right in the figure).

Linderoth et al., Conventional and Novel Spinal Stimulation Algorithms: Hypothetical Mechanisms of Action and Comments on Outcomes. Neurostimulation. 2017.

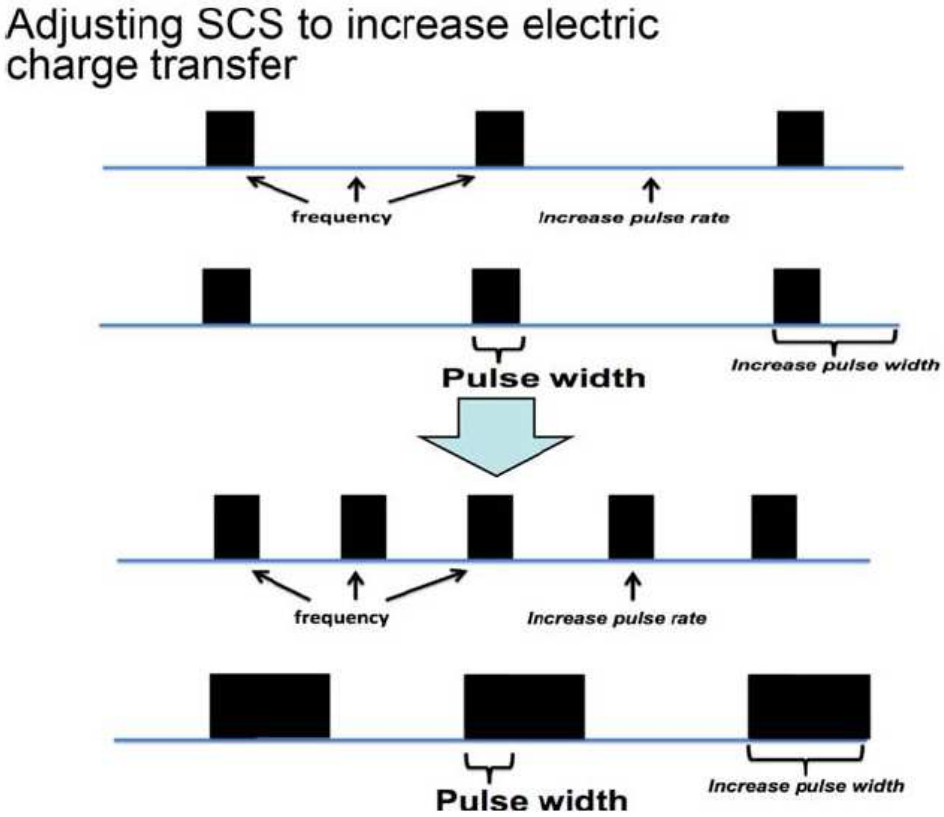


Figure 4. Illustrates how merely increasing stimulation frequency and/or pulse duration can increase the amount or electric charge transmitted. [Color figure can be viewed at wileyonlinelibrary.com]

Linderoth et al., Conventional and Novel Spinal Stimulation Algorithms: Hypothetical Mechanisms of Action and Comments on Outcomes. Neurostimulation. 2017.

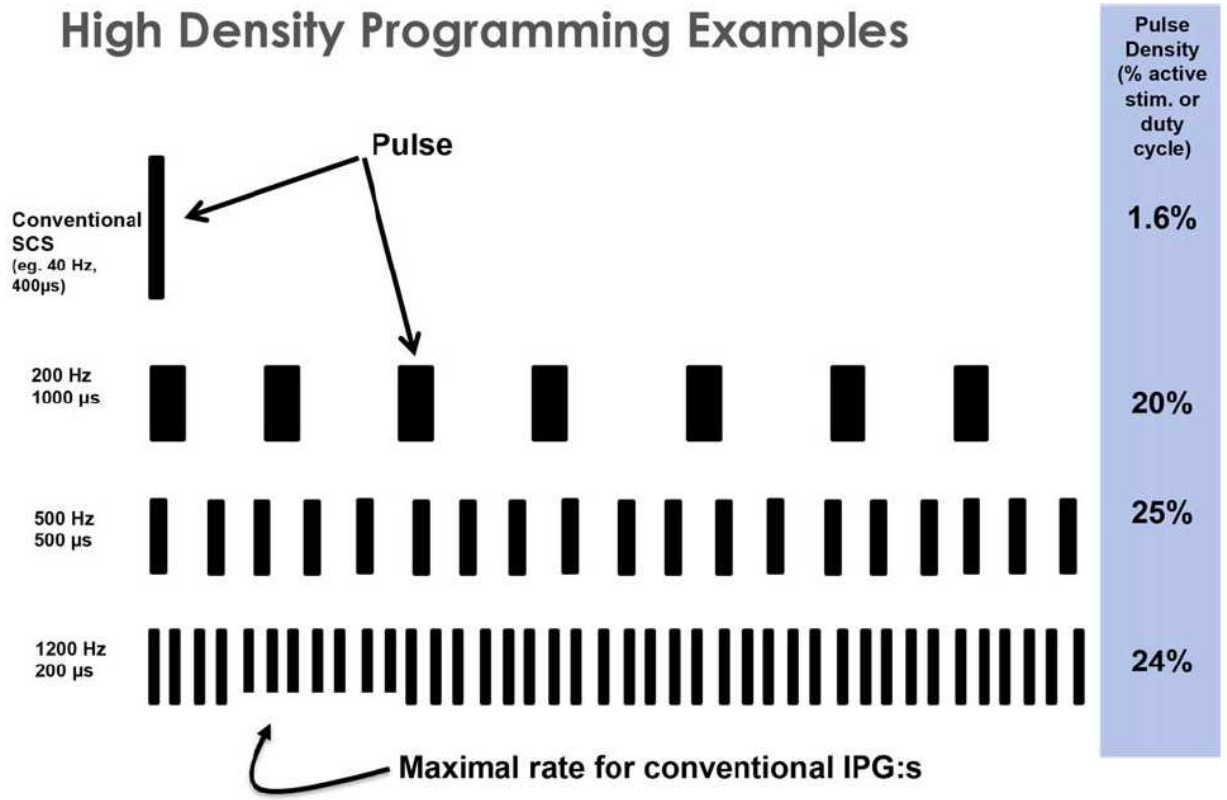


Figure 5. The figure illustrates how increases of the stimulation frequency result in higher pulse densities. It is evident that the conventional SCS settings produce a low pulse density while the lower parts of the picture with settings of 500 Hz/500 μsec or 1200 Hz and 200 μsec can produce pulse densities between 24 and 25% even with subparestetic amplitudes. IPG, Implantable Pulse Generator. [Color figure can be viewed at wileyonlinelibrary.com]

Linderoth et al., Conventional and Novel Spinal Stimulation Algorithms: Hypothetical Mechanisms of Action and Comments on Outcomes. Neurostimulation. 2017.

Stimulationsmöglichkeiten

- **Spinal Cord Stimulation (SCS)**
- **Dorsal Root Stimulation (DRS)**
- **Periphere Nervenstimulation (PNS)**
- **Subkutane Nervenstimulation (s.c.NS)**
- **Motorcortex Stimulation**

Stimulation options

- **Spinal Cord Stimulation (SCS)**

  HF –Stimulation – Adaptive Stimulation - High Density Stimulation

- **Nerve Root Stimulation (NRS)**

  Dorsal Root ganglion stimulation

- **Peripheral Nerve Stimulation (PNS)**

- **Subcutaneous Peripheral (Nerve)Field Stimulation (s.c.NS)**

- **Motor Cortex Stimulation**

Recommendations of the PACC to reduce morbidity and mortality

1. **The use of IDDS** (intrathecal drug delivery systems) to treat chronic pain **should be part of a treatment algorithm** that involves the failure of more conservative attempts at treatment. IDDS should be considered prior to other options when unacceptable side-effects or lack of efficacy is established.

2. **The use of IDDS should be based on** an analysis of safety, efficacy, a goal of economic neutrality and appropriateness for **the individual patient**. These factors have been described as the S.A.F.E. principles.(safety,approppriateness,fiscal neutrality,efficacy)

3. Spinal cord stimulation (SCS), peripheral nerve stimulation (PNS), and hybrids of both SCS and PNS should be considered inappropriate candidates prior to considering an IDDS.

4. Psychological evaluation and stability should be confirmed prior to proceeding with an IDDS in noncancer patients.

Portenoy RK, Hassenbusch SJ. Polyanalgesic Consensus Conference 2000. J Pain Symptom Manage 2000;20:S3; Krames E, Poree L, Deer T, Levy R. Implementing the SAFE principles for the development of pain medicine therapeutic algorithms that include neuromodulation techniques. Neuromodulation 2009;12:104–113;Deer TR.A critical time for practice change in the treatment continuum:we need to reconsider the role of pumps in the patient care algorithm. Pain Med 2010;11:987– 989; Deer TR, Smith HS, Cousins M et al. Consensus guidelines for the selection and implantation of patients with non-cancer pain for intrathecal drug delivery. Pain Physician 2010; 13:E175–E213.

Indikationsstellung zur neurostimulativen Therapie

- **chronischer Schmerz**
- **unzureichende Schmerzreduktion nach Ausschöpfung konservativer Therapieformen (erfahrenen Schmerztherapeuten)**
- **Ausschluss von somatoformen Schmerzsyndromen (Evaluation durch erfahrenen Psychologen/Psychiater)**
- **Compliance des Patienten**
- **endgültige Indikationsstellung in spezialisierten Zentren**
- **Ausschluss von Kontraindikationen**

Kontraindikationen für Neurostimulation

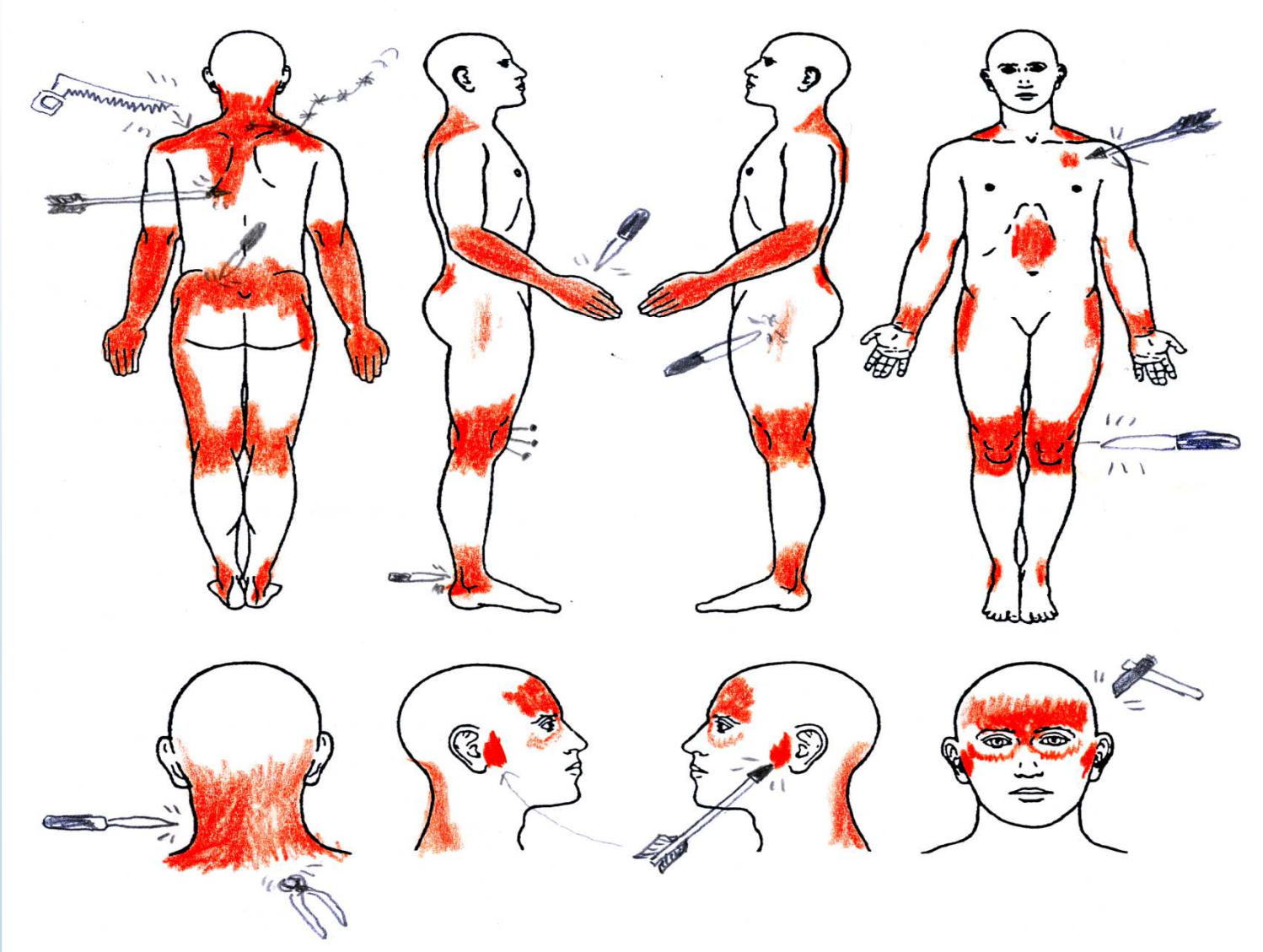
- **somatoforme Schmerzen**
- **Psychose**
- **endogene Depression**
- **mangelnde Compliance, Verständnis**

Alkohol- und Drogenabusus sind keine Kontraindikation

Kontraindikation für SCS

- **Komplexe Rückenmarksdurchtrennung**
- **Nervenwurzelausriss**
- **nozizeptiver Schmerz**

Krames, Neuromodulation 2004, 7: 82 - 88

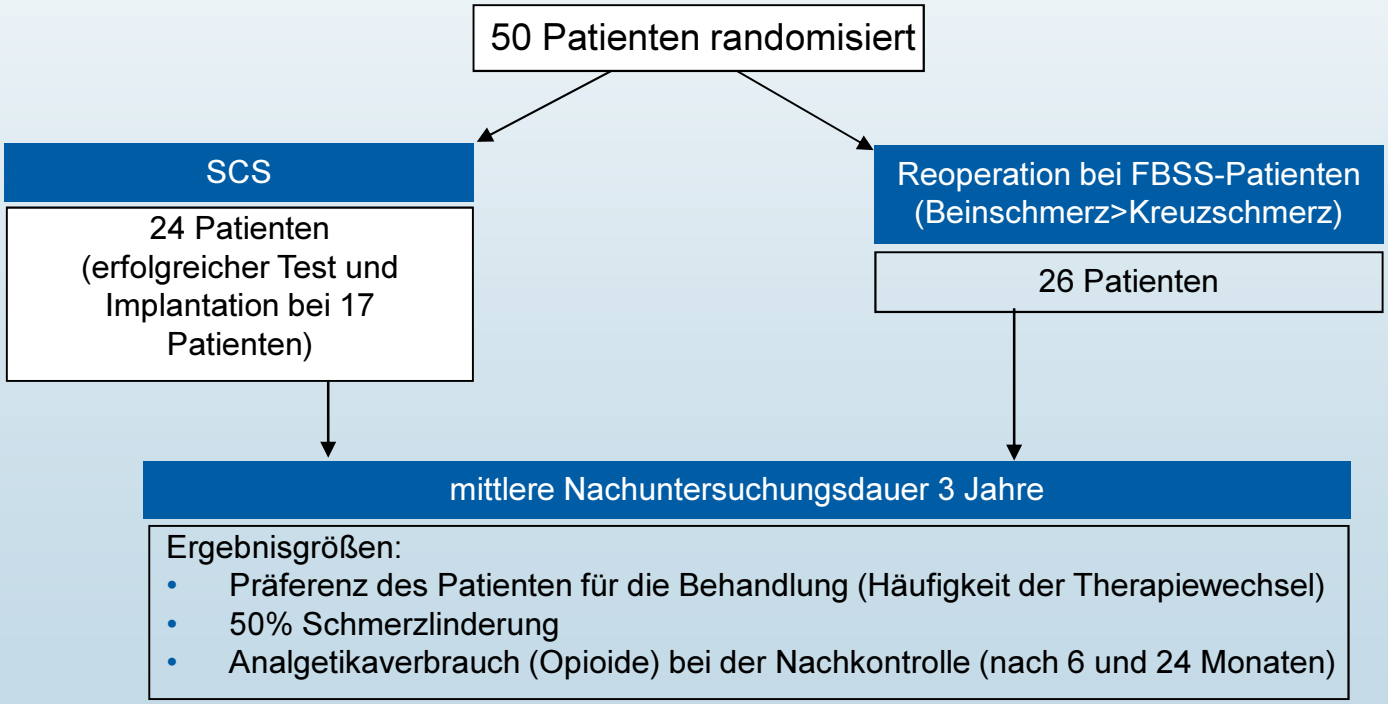


- **Beim Failed back Surgery gibt es Einfluss von Alter.**
- **Bei Patienten über 50 ist der Erfolg größer.**
- **Je früher der Behandlungsbeginn desto besser der Therapieerfolg.**

Kumar K, Malik S, Demeria D, Treatment of chronic pain with spinal cord stimulation versus alternative therapies: cost-effectiveness analysis, Neurosurgery.2002 Jul;51(1):106-15

RCT: SCS vs. Reoperation bei FBSS-Patienten

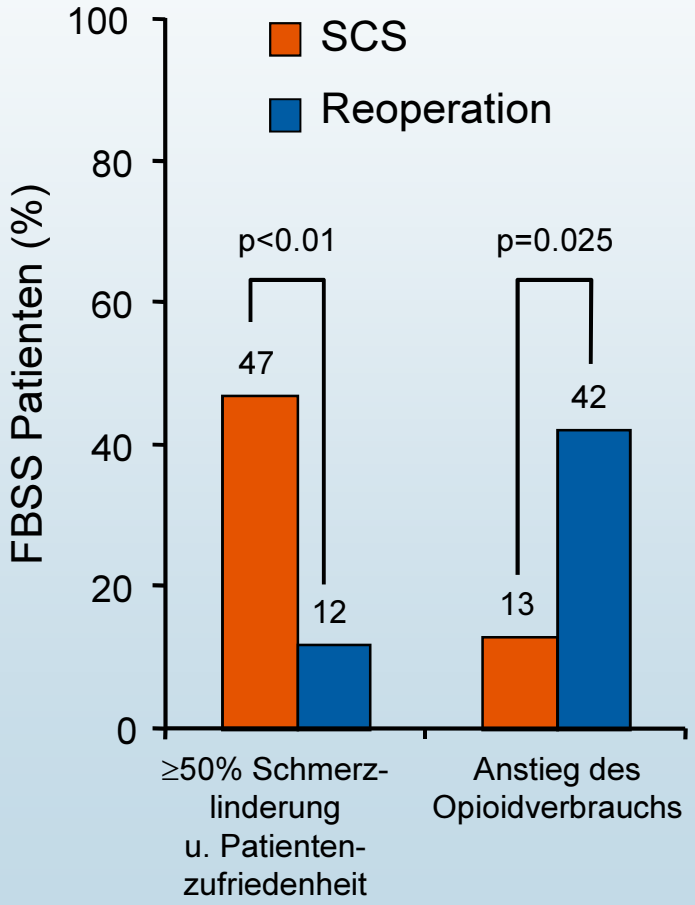
- **prospektive, kontrolliert randomisierte Studie[1]**
  - erhielt 4 von 5 Punkten auf der Jadad-Skala für methodische Qualität[2]



Evidenz der SCS bei schmerzhafter Radikulopathie

North et al. Neurosurg 2005
Jadad et al. Controlled Clin Trials 1996

SCS erfolgreicher als Reoperation bei FBSS – Ergebnisse einer 3-Jahres-RCT



RCT von North *et al.* ergab:

- **verbesserte Schmerzlinderung**
  - SCS wirksamer als Reoperation (p<0,01)
- **geringerer Anstieg der Opioiddosen**
  - Dosisreduktion bei SCS stärker als bei Reoperation (p=0,025)

North et al. Neurosurg 2005

SCS erfolgreicher als Reoperation bei FBSS – Ergebnisse einer RCT

Die RCT von North *et al*. hat ergeben:

- **SCS wurde von den Patienten bevorzugt**
  - die Rate der Therapiewechsel von Reoperation zu SCS war durchgehend höher als die Rate der Therapiewechsel von SCS zu Reoperation
    - 54% der Reoperationspatienten entschieden sich für einen Therapiewechsel zu SCS
    - nur 21% der SCS-Patienten entschieden sich für einen Therapiewechsel zur Reoperation

North et al. Neurosurg 2005

Austestung - Implantation

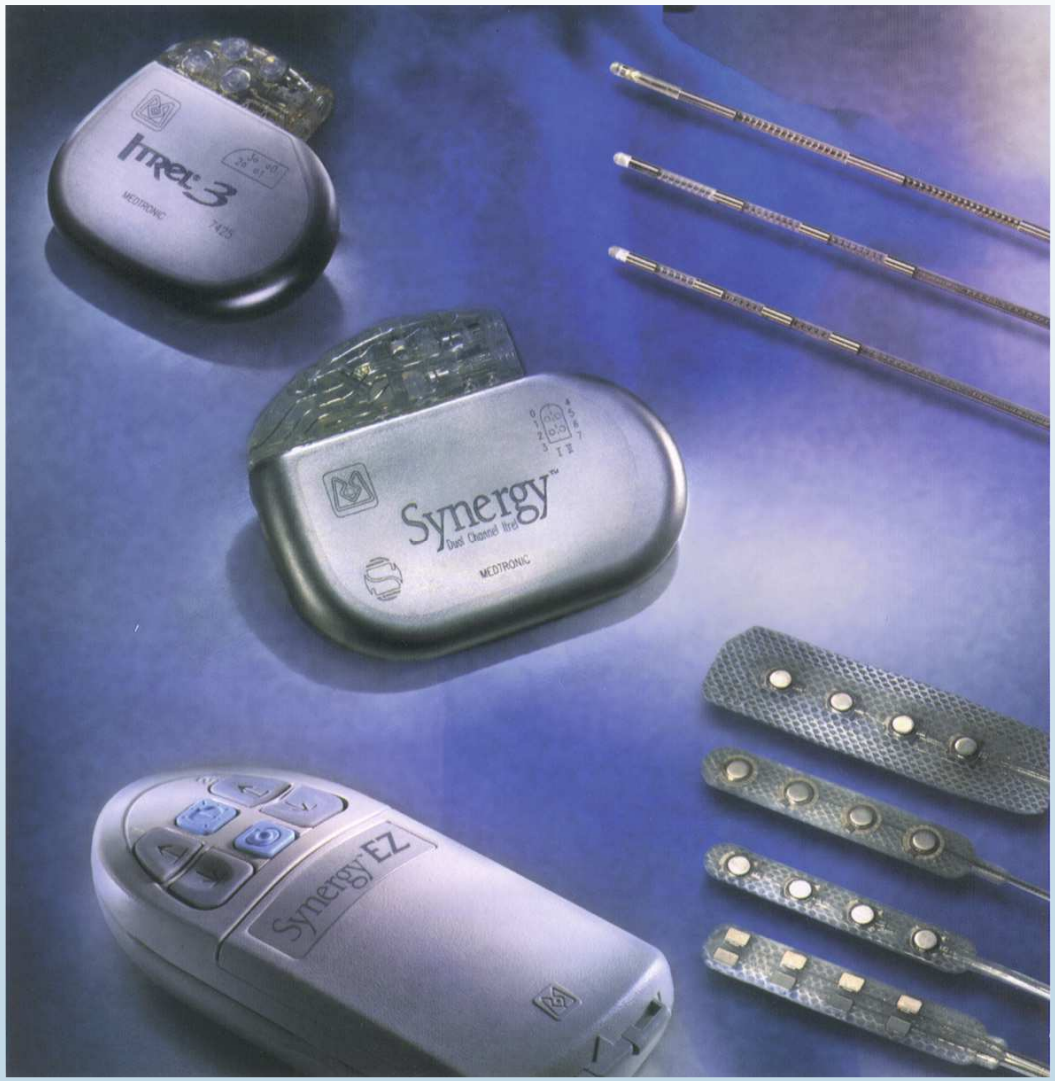
- **Stationäre Aufnahme**
- **Epidurale Platzierung der Sonden durch Anästhesist bzw. Neurochirurg, Patient nicht in Narkose**
- **Parästhesieausbreitung muss genau angegeben werden können.**
- **Probephase ca. 7 bis 14 Tage mit externem Stimulator.**
- **Fiximplantation in Allgemeinnarkose.**

Test-Stimulation	Erfolg
Bei richtiger Indikation	mehr als 70 %
Bei Angina pectoris	über 90 %
Bei peripheren Durchblutungsstörungen	79 %
Failed back Surgery	60 %
Komplex regionales Schmerzsyndrom	72 %

50 % Schmerzlinderung ist der goldene Standard
30 % ist klinisch relevant

Kumar K, Toth C, Nath RK, Laing P, Epidural spinal cord stimulation for treatment of chronic pain—some predictors of success. A 15-year experience. Surg Neurol. 1998 Aug;50(2):110-20

Technik Neurostimulation

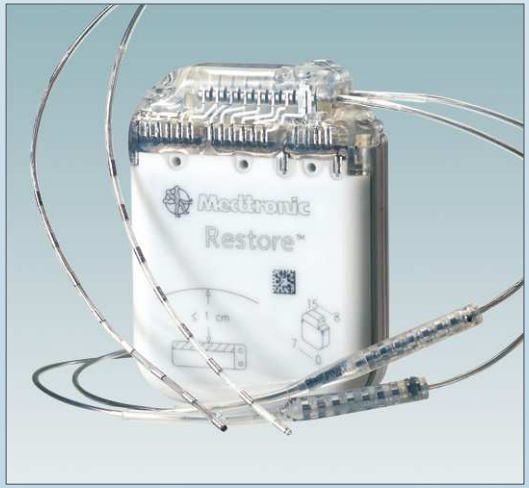


Teststimulation - Screening Kabel

- **Multi-Channel Design**
  - **ein od. zwei 4-polige Elektroden**
  - **ein od. zwei 8-polige Elektroden**

Das Restore™-System

- **Wiederaufladbar**
- **Zum Anschluss von zwei 8-poligen Elektroden**
- **wesentlich kleiner als Synergy (39cc vs. 51cc)**
- **32 verschiedene Programme**
- **Lebensdauer: 9 Jahre**
- **Ladezyklen: 6 Tage bis 3 Monate**
- **Ladezeiten: 2 bis 6 Stunden**



Höhe der Elektroden:

- **Hals C2/C3**
- **Schulter C4**
- **Arm, Hand, Finger C4-C5**
- **LWS-Bereich , Gesäß Th9 – Th10**
- **Beine Th10-Th11**
- **Füße Th12**
- **ilioinguinal + genitofermoralis Versorgungsgebiet L3/L4 Punktion**

  Sonde lateral L1/L2

Höhe der Elektroden:

- **perinealer Schmerz**
  - → **sacrale Nervenwurzel**
- **Knieschmerz**
  - → **L3/L4 Nervenwurzel**
- **Fußschmerz**
  - → **L5/S1 Nervenwurzel L5 – Fußrücken, Fußsohle S1**
- **Coccygodynie**
  - → **Eingang L2/L3 (retrograd) oder Hiatus sacralis**
  - **S4 Bereich – Sonde**

ELEKTRODENLAGE

Die optimale Elektrodenposition ist abhängig vom Schmerzareal.

Rostrokaudale Position:

- **Nicht höher als Th 8 schieben**
- **(Dead Zone ⟷ breiter Liquorraum)**
- **Für Kreuz in aller Regel Th 8 bis Th 10 !**
- **Nur die Unterschenkel: Th 11 bis Th 12**

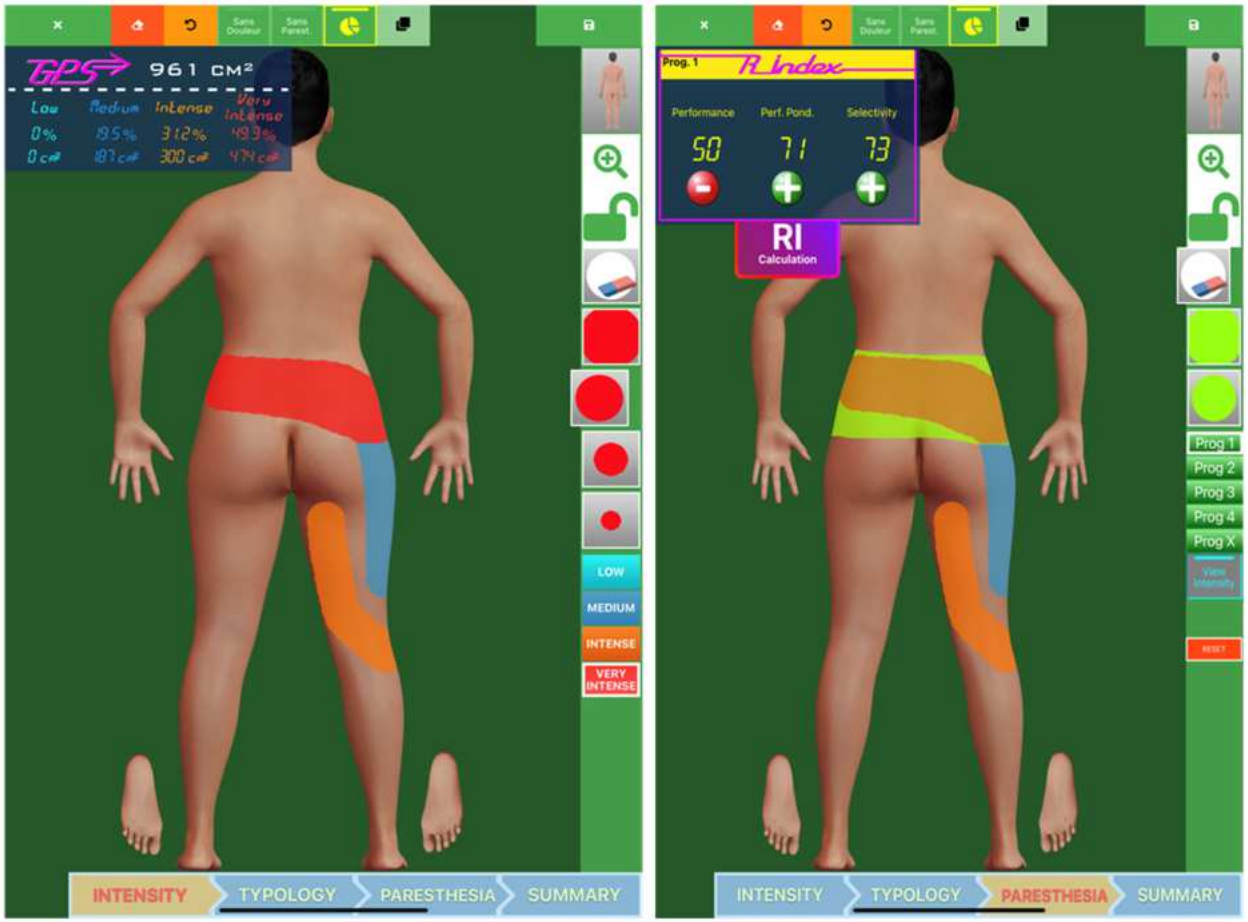
Dorsolaterale Position:

- **Für beide Beine (ohne Kreuzschmerzkomponenten !) recht theoretisch eine mediale Elektrode – allerdings mit der Gefahr der leichten Dislokation aus der Mitte und somit Verlust adäquater Schmerzlinderung.**

- **Konsequenz: Mit 2 Elektroden erzielt man generell maximale Flexibilität.**

- **Um zusätzlich zur radikulären Schmerzkomponente auch den Kreuzschmerz zu behandeln, unbedingt (möglichst !) laterale Positionierung der Elektrode(n).**

- **Konsequenz: Bei Kreuzschmerz unbedingt 2 Elektroden verwenden!**

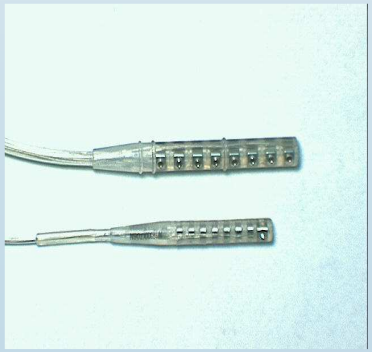


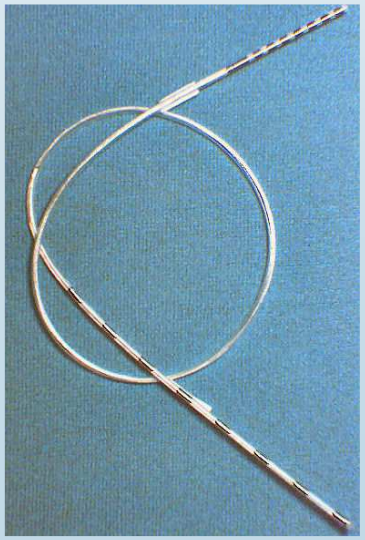
Pain mapping software used to assess pain surface and pain coverage where the patient could draw different painful zones. The pixels in the patient drawing are then converted into cm2, using several anatomical landmarks, patient morphology and morphometry. Four colors are available for patients to represent the different pain intensities. Pain coverage can then be obtained by drawing paresthesia (in green), which is converted to a percentage of pain coverage (performance).

Rigoard P., Ounajim A., Goudman L., et al. The Challenge of Converting „Failed Spinal Cord Stimulation Syndrome“ Back to Clinical Success, Using SCS Reprogramming as Salvage Therapy, through Neurostimulation Adapters Combined with 3D-Computerized Pain Mapping Assessment: A Real Life Retrospective Study. J Clin. Med. 2022, 11, 272.

Elektroden und Verlängerung

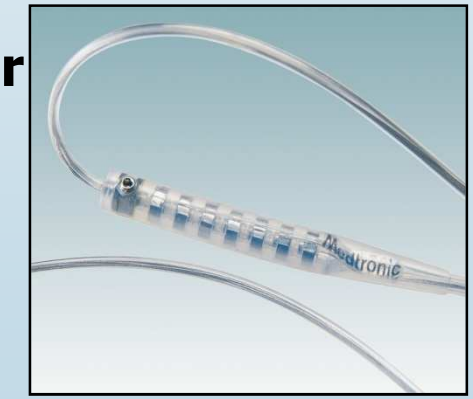
- **8-polige Elektroden**
  - **Impedanz <= 15 Ohm**
  - **Modelle: Sandard (3/6mm), Compact(3/4mm), Sub Compact (3/1,5mm)**
  - **3 Längen: 45, 60 u. 75 cm**
  - **über Verlängerung oder direkt an Restore anzuschließen**





Verlängerung:

- **Kürzerer Konnektor**
- **Kleinerer Durchmesser**
- **Nur 1 Fixierschraube**
- **3 Längen: 20, 40 und 60cm**

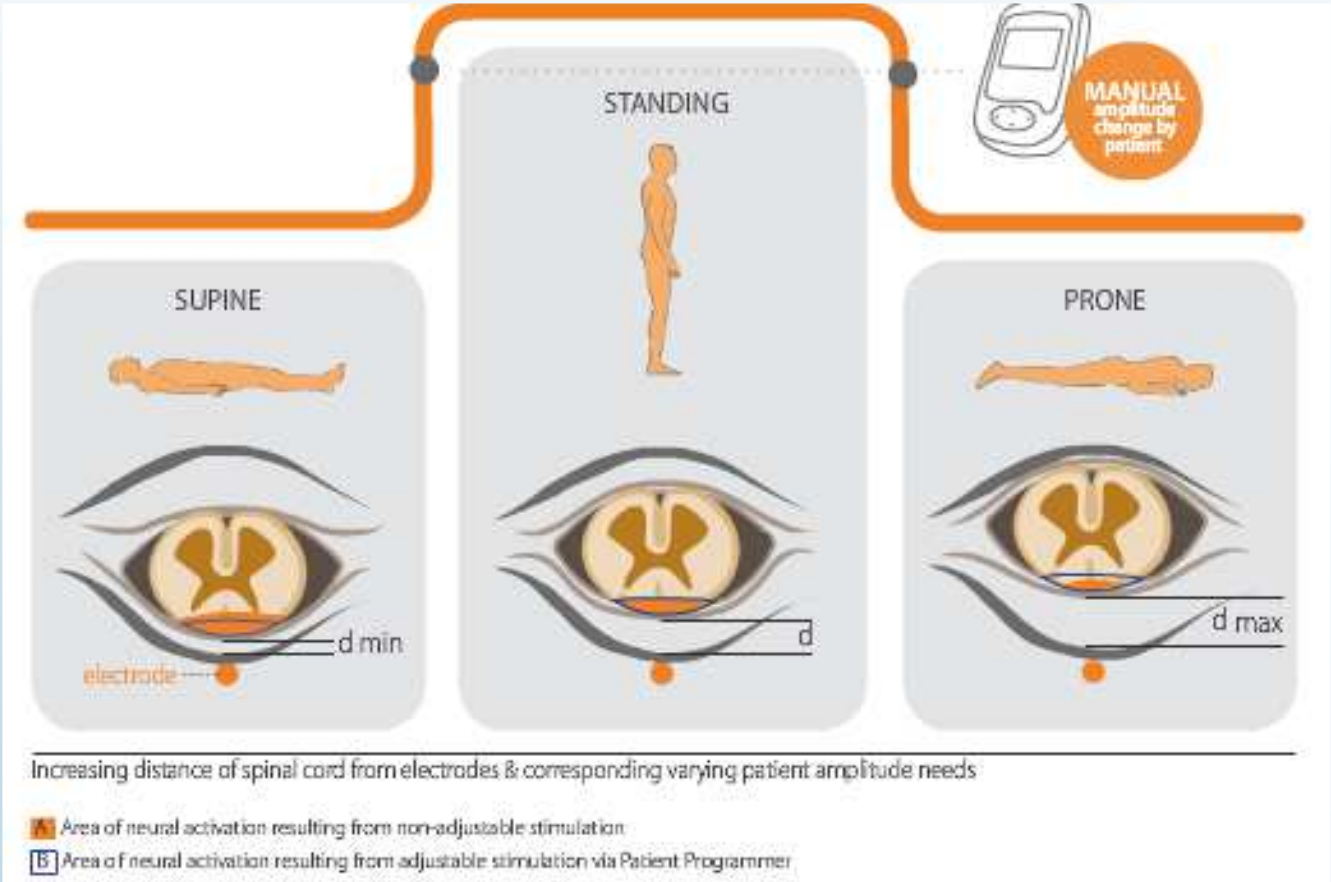


Das Restore ADVANCED™-System

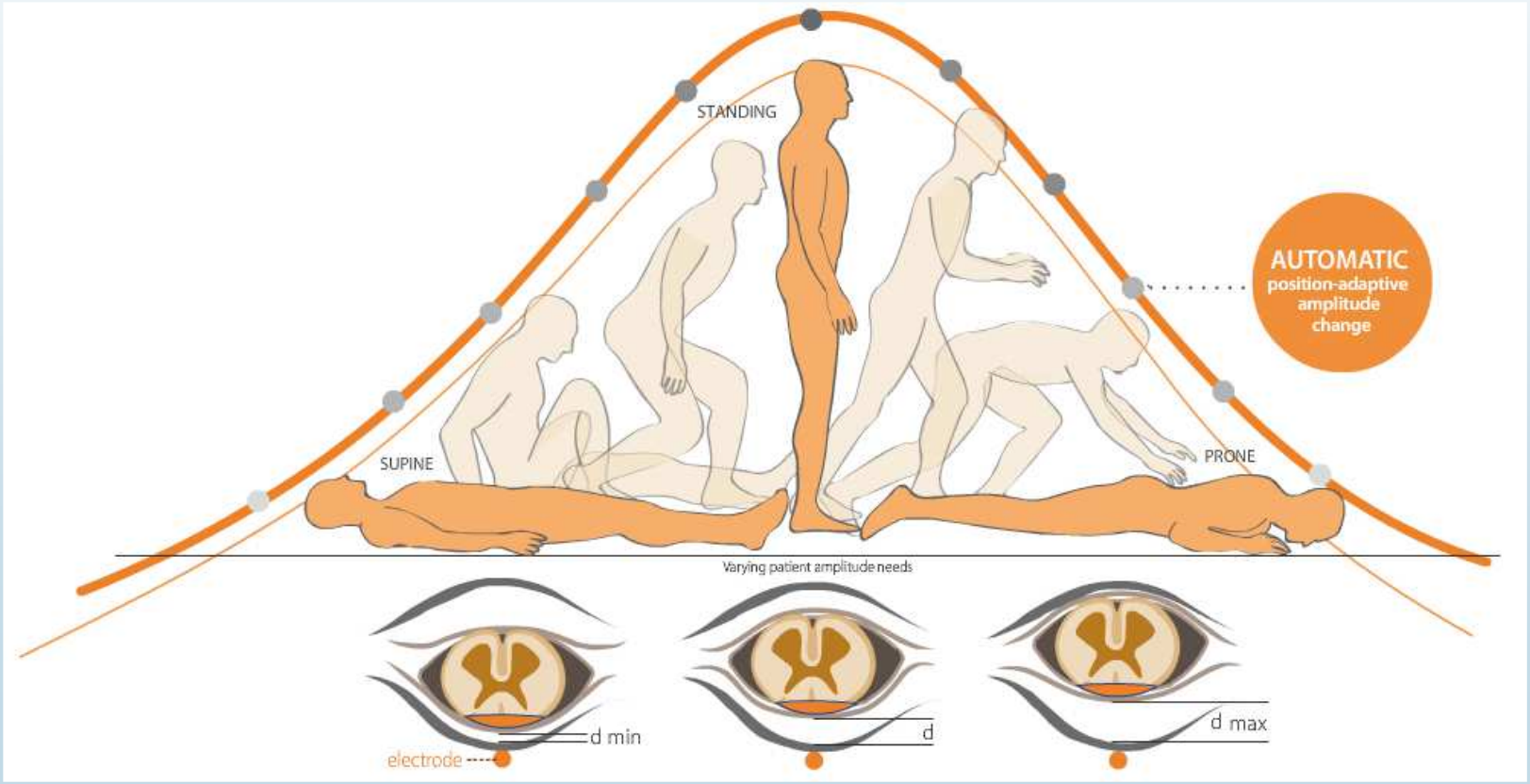
Der Restore ADVANCED™ ist

- **Vollständig kompatibel mit dem Restore™-System**
- **Verbessertes User Interface**
- **Wesentlich eindeutiger in der Bedienung**
  - **Mehr Text, weniger Icons**
  - **Klarer strukturiert**
  - **damit viel einfacher!**
- **Komplett neue Software-Features ... um ein Optimales Ergebnis für den Patienten möglichst rasch zu erreichen**
- **Multiple Delete**
- **Größerer Speicher für bis zu 200 Sitzungen**

Most current neurostimulators require manual adjustment of settings in order to keep stim activation constant



Introducing RestoreSensor™: The Worlds First and Only Neurostimulator to automatically adapt stim settings for position change



The first neurostimulator to offer objective functional data

Amplitude Trend

Min/Max V used by patient.

Group A

	A1	A2	A3	
☑ Upright				
Min V	2.7	2.9	2.8	
Max V	3.1	3.3	3.2	
☑ Upright+Mobile				
Min V	3.5	3.6	3.4	
Max V	3.9	3.8	3.7	
☑ Lying Back				
Min V	1.0	1.1	0.9	
Max V	1.2	1.3	1.1	
☑ Lying Front				
Min V	--	--	--	
Max V	--	--	--	
☑ Lying Right				
Min V	1.8	1.9	1.7	
Max V	2.0	2.1	1.9	
☑ Lying Left				
Min V	1.8	1.9	1.7	
Max V	2.0	2.1	1.9	

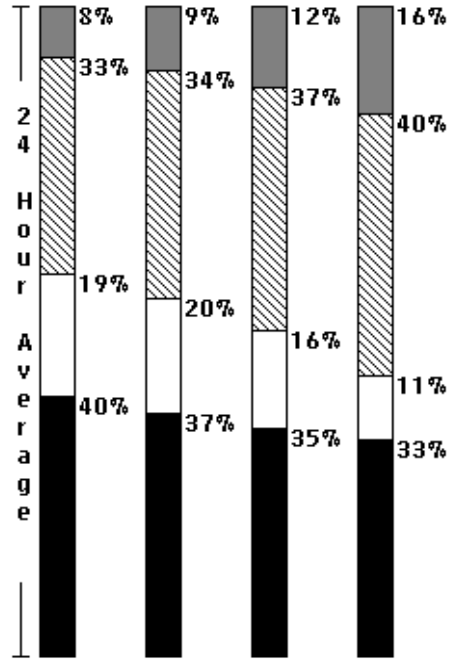
-- Patient did not adjust.

Ⓟ enables AdaptiveStim with the Min V for selected positions.

Ⓟ

NKS****** 37714 John Doe

Position Trend

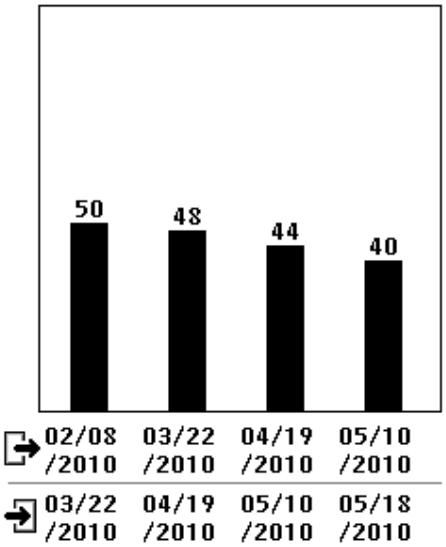


ⓘ View Details

NKS****** 37714 John Doe

Resting Trend

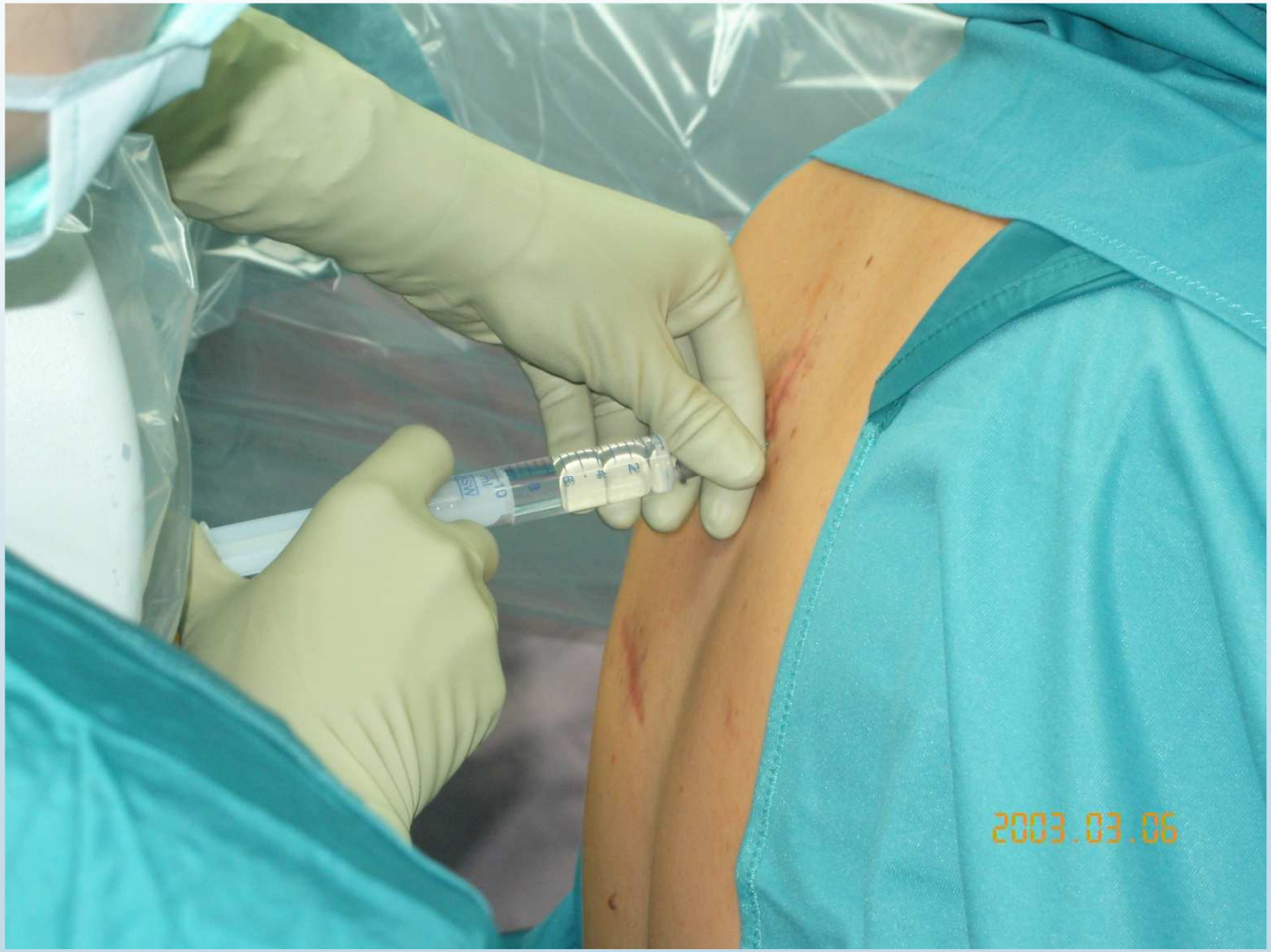
Average number of position changes when lying/day:



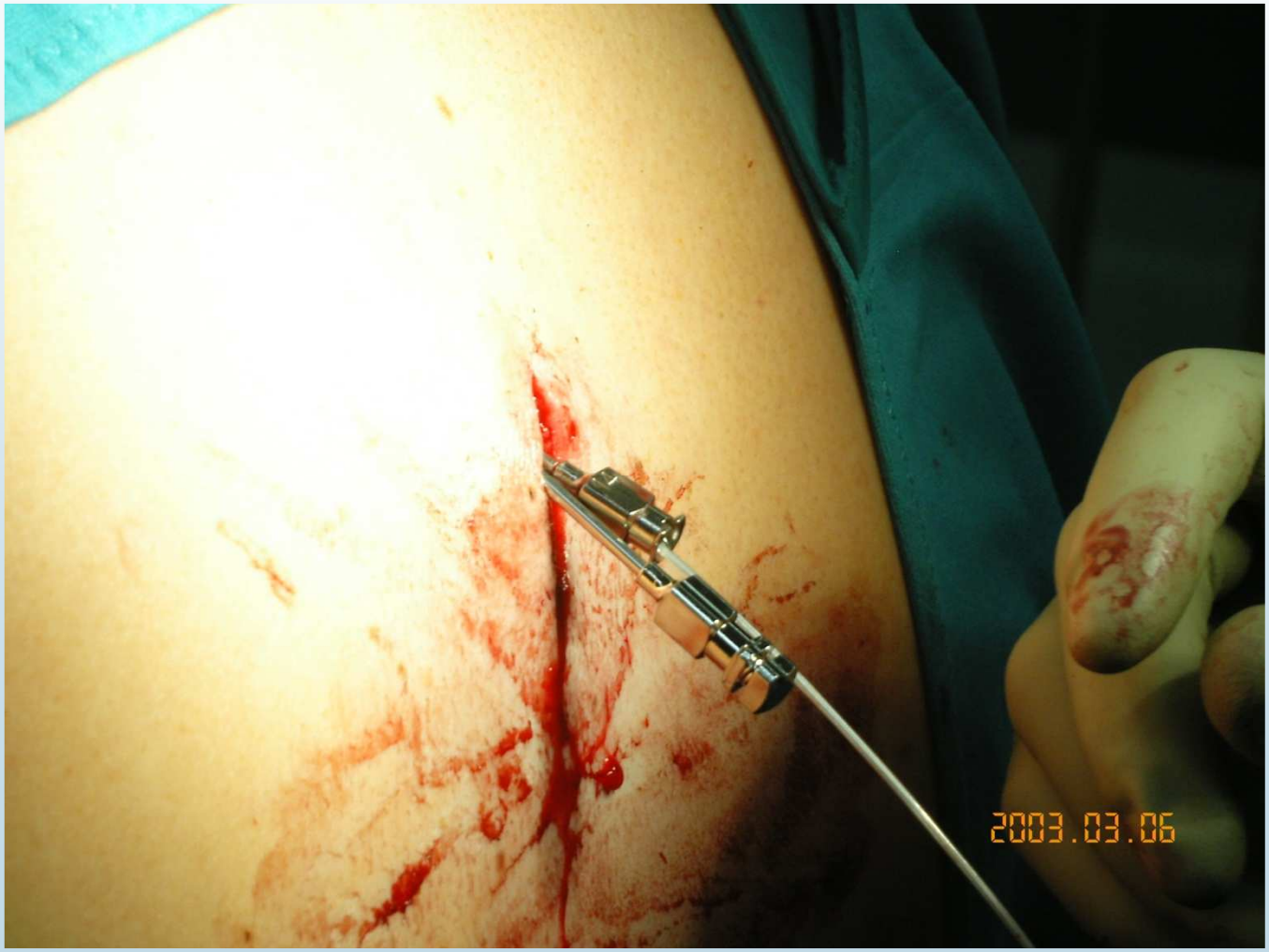
ⓘ

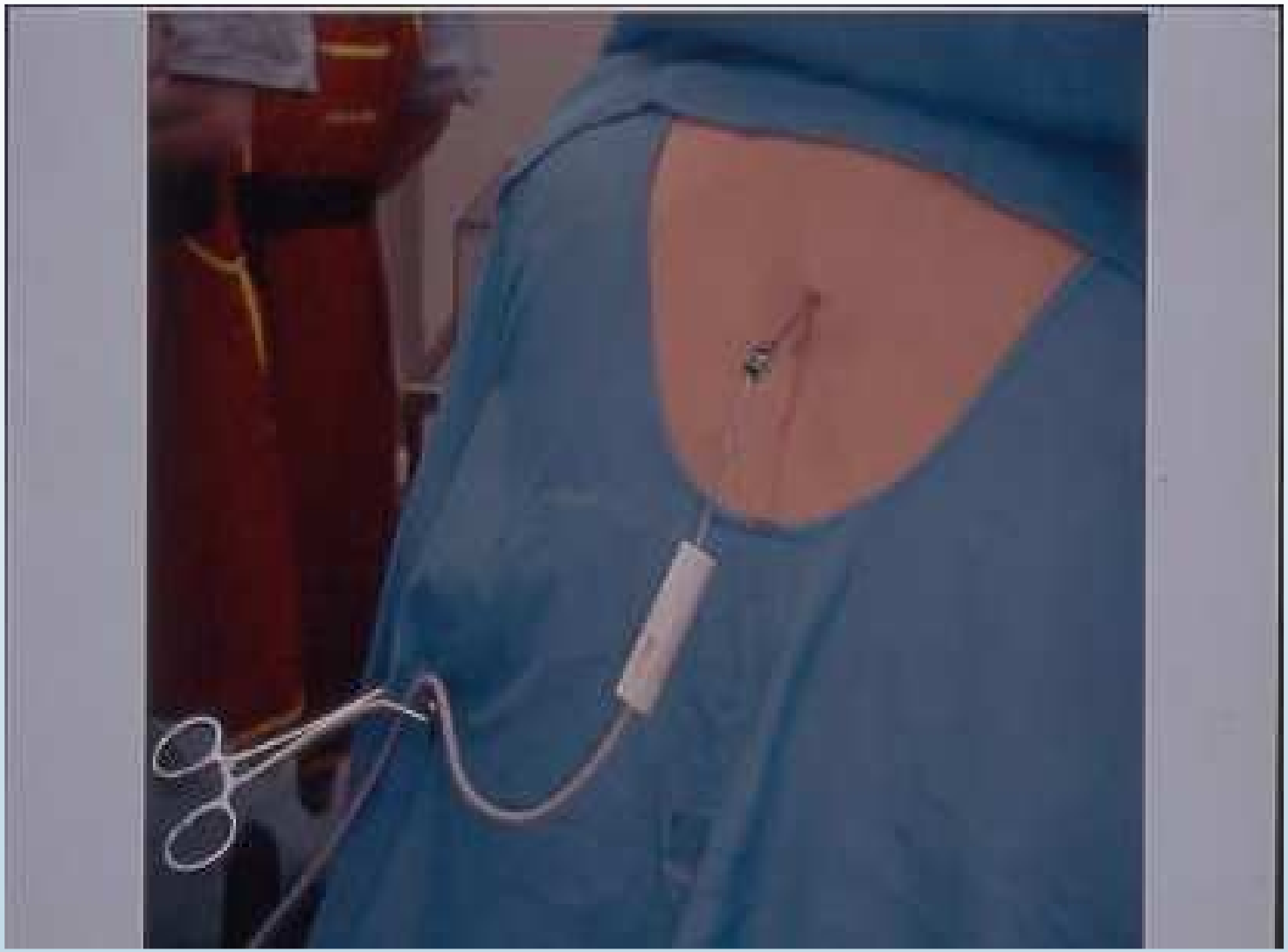
NKS****** 37714 John Doe

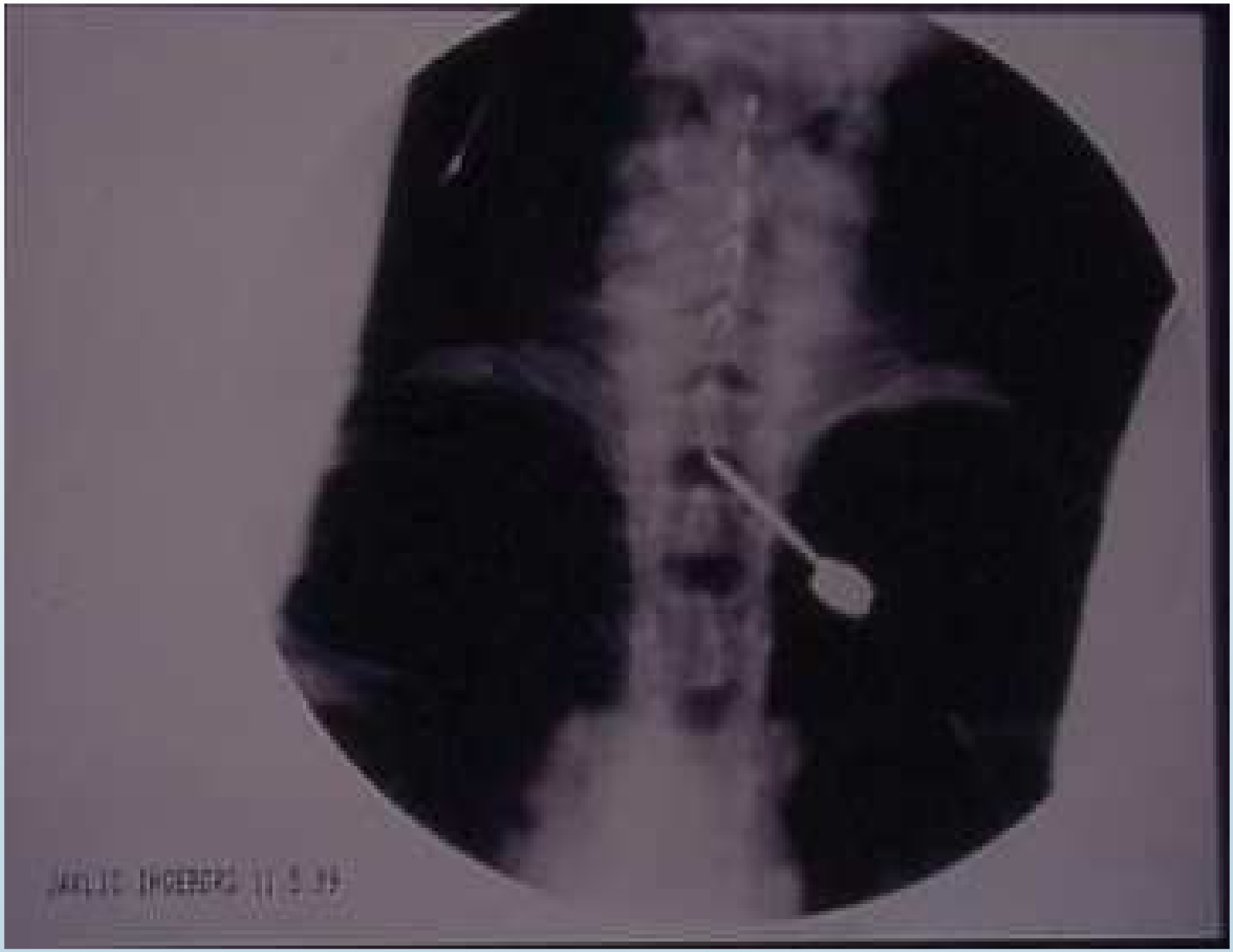
Neurostimulation - SCS



Neurostimulation - SCS

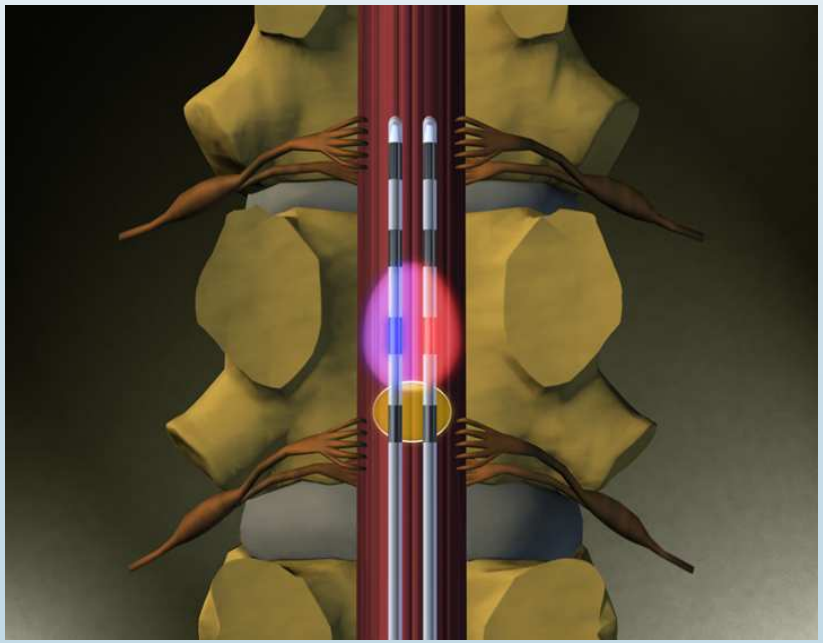


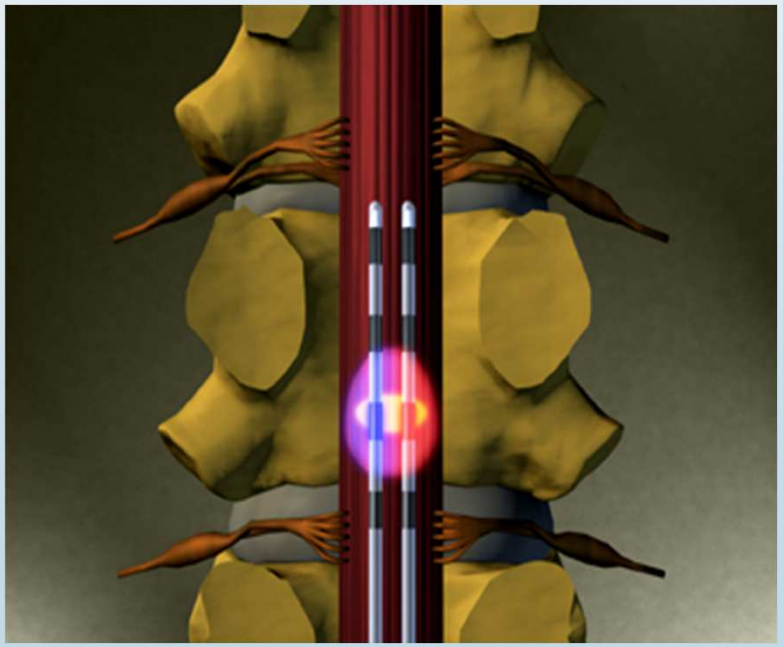


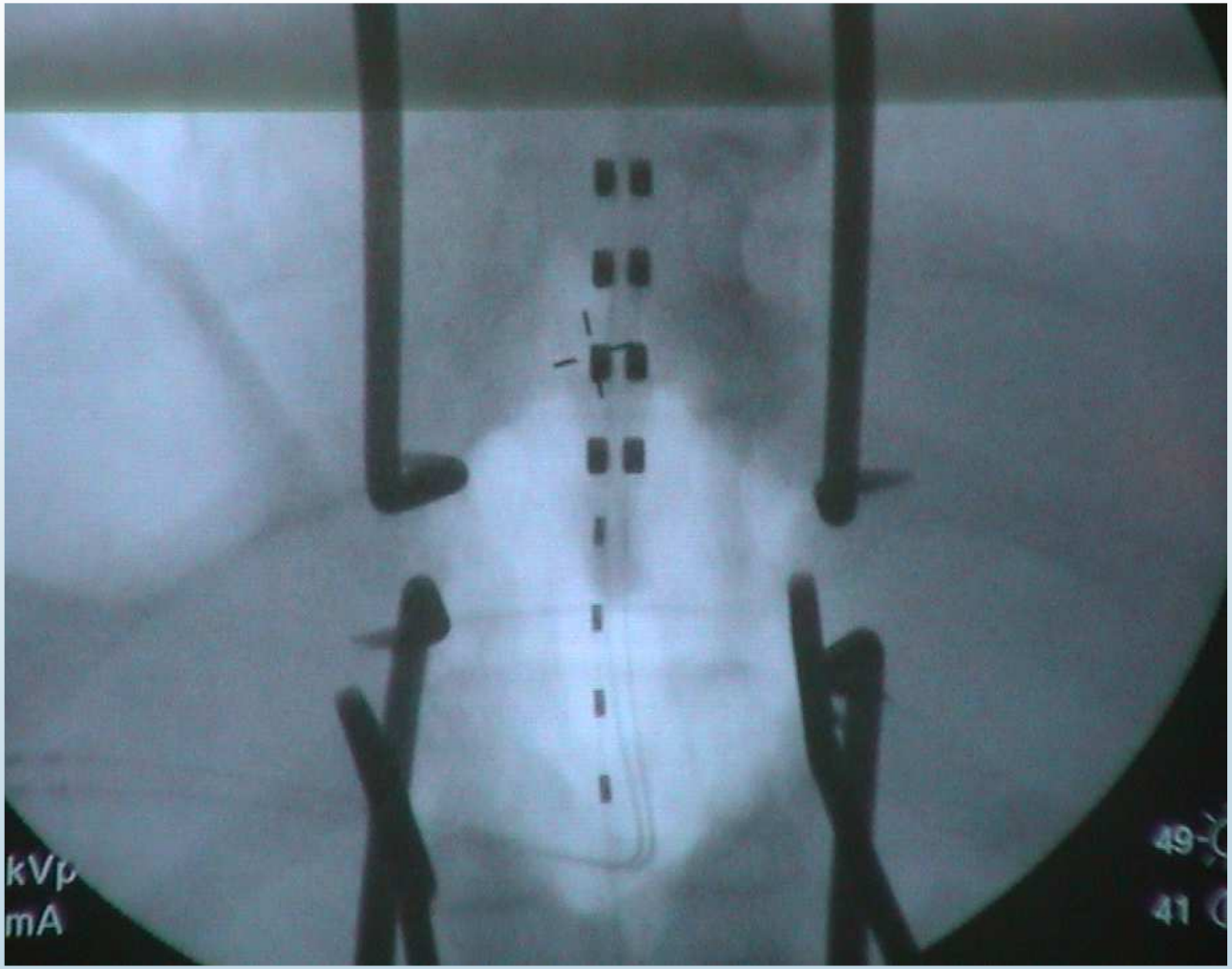


„Trolling" - Technik

- **Opt. Elektrodenposition**
- **Reduziert Fehlversuche**
- **Zeitoptimierung im OP**
- **Stromersparnis d. IPG's**






kVp
mA
49
41

KABEG
KLINIKUM KLAGENFURT
AM WÖRTHERSEE

Preoperative planning. Patient morphology can influence the choice of IPG implantation site and should be considered before the implantation procedure. Photo courtesy of Philippe Rigoard and used with permission.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:1-34.

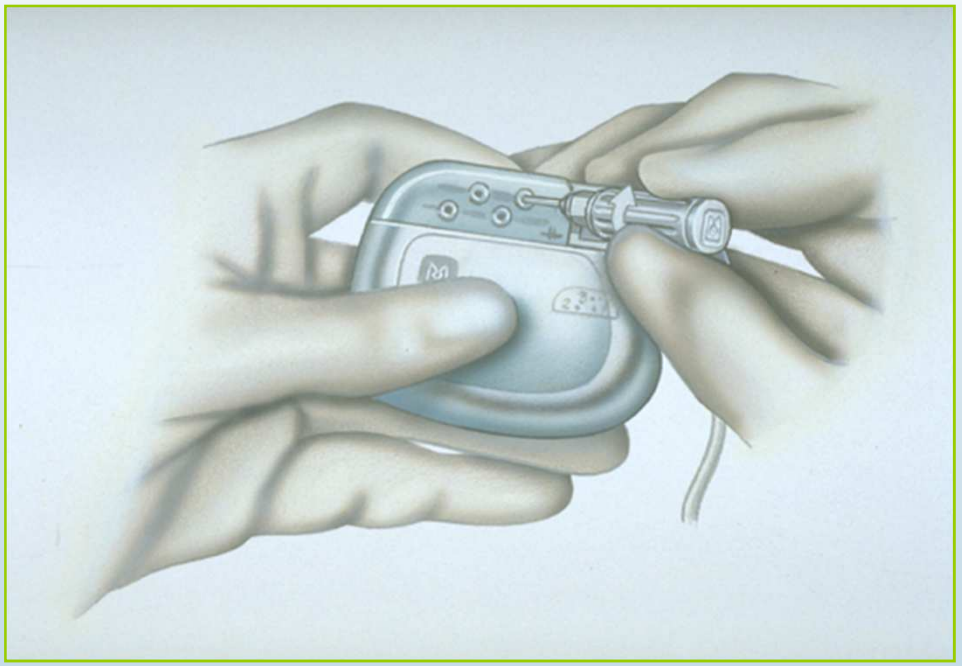
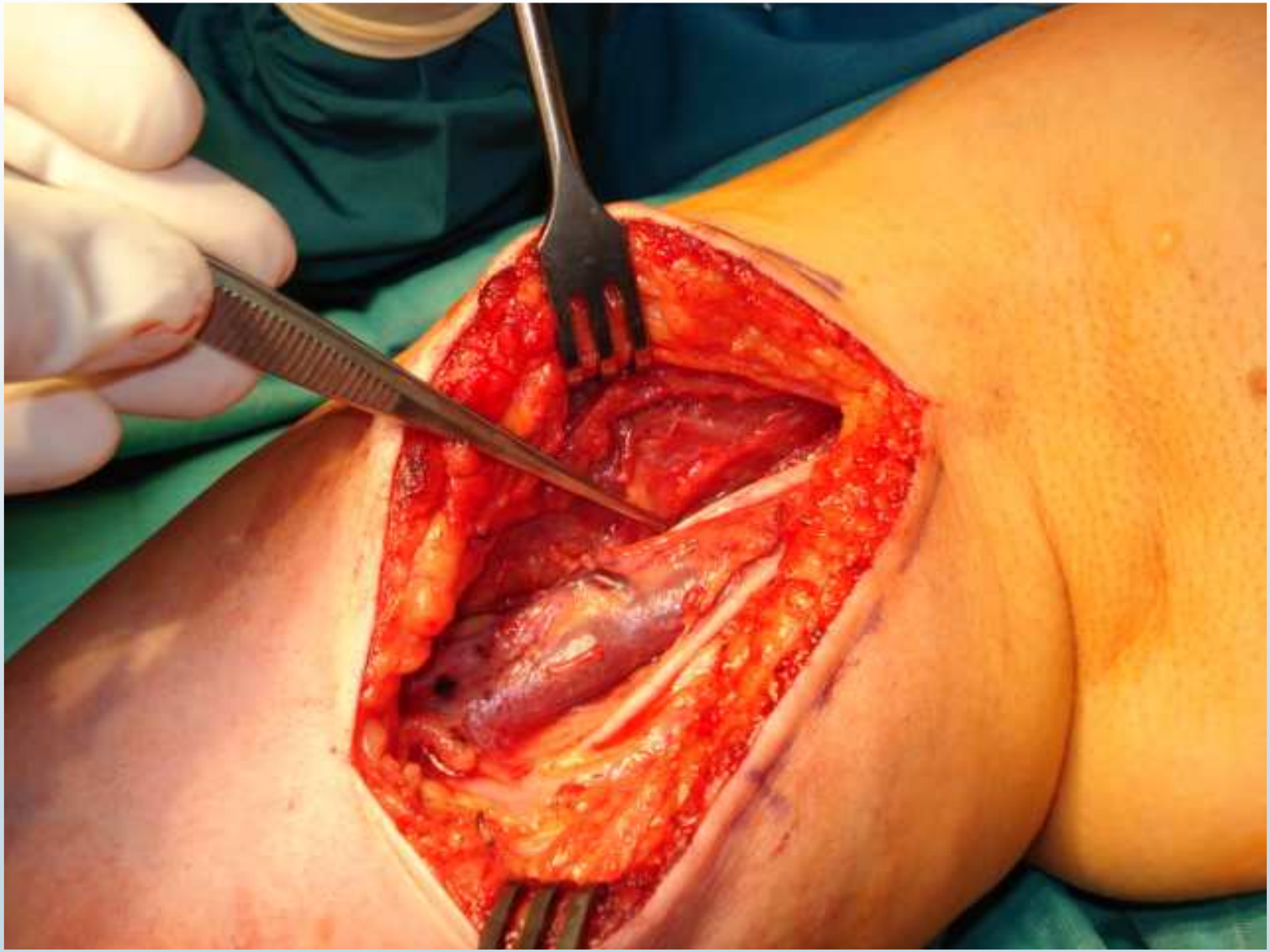


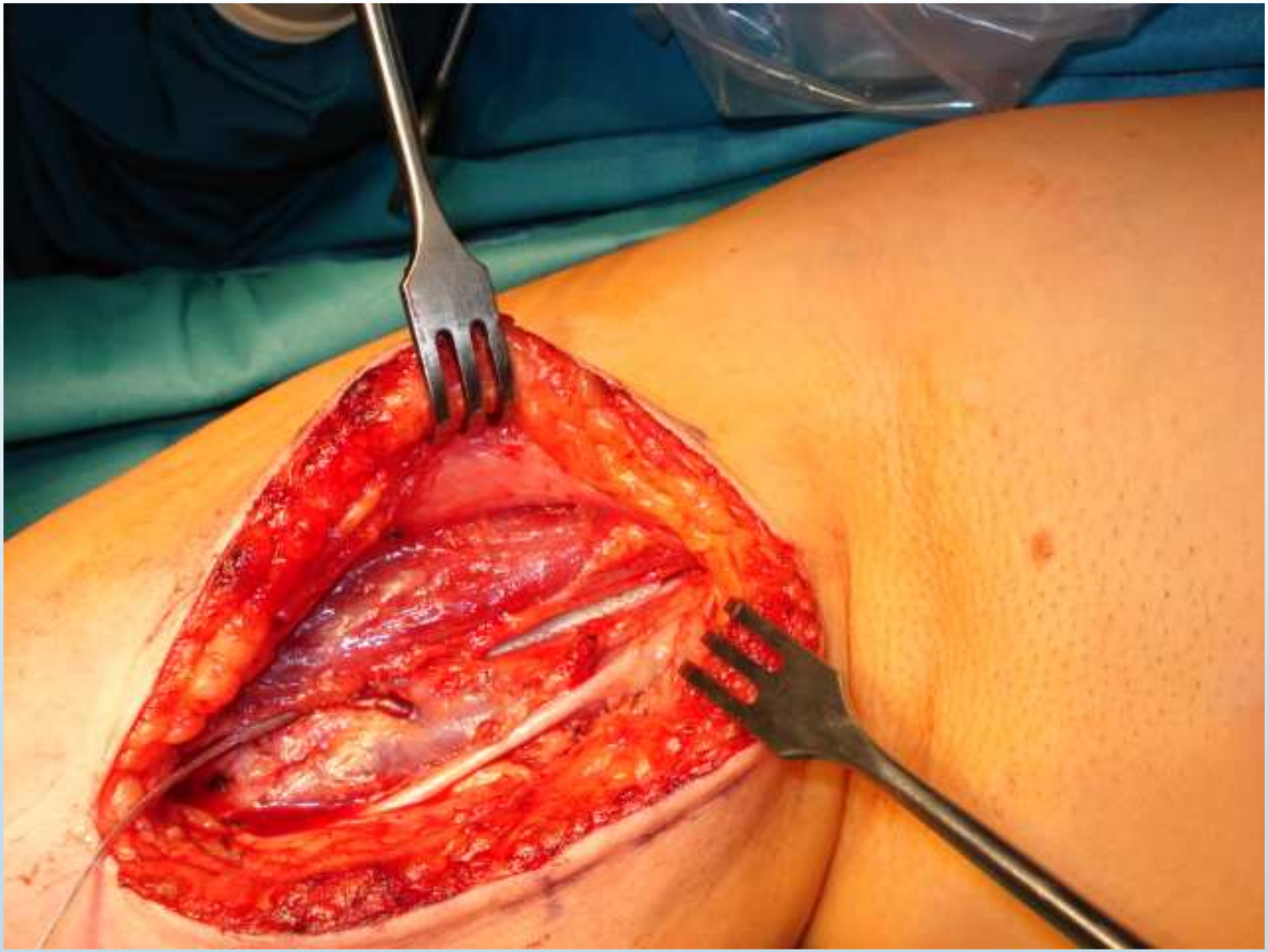
Table 10. Selected and Chronologically Presented Peripheral Nerve Stimulation Guideline Statements.

Study	Society Affiliation	Sponsorship/ Funding	Indications	Level of evidence (if identified)	Recommendations	Recommendation Strength (if identified)
Stanton-Hicks et al. 2002 (5)	Expert panel report	Medtronic	CRPS		PNS is good for treatment of CRPS with limited pain distribution around named nerves, although limited by technology at the time	
Cruccu et al. 2007 (13)	EFNS	Not reported	Chronic neuropathic pain		No conclusions	
Rosenquist et al. 2010 (19)	ASA and the ASRA and Pain Medicine	Not reported	Pain peripheral nerve injuries	Category B2 evidence*	Subcutaneous peripheral nerve stimulation should be used for painful peripheral nerve injuries	

*Based on evidence assessment (19). ASA, American Society of Anesthesiologists; ASRA, American Society of Regional Anesthesia; CRPS, complex regional pain syndrome; EFNS, European Federation of Neurological Societies; PNS, peripheral nerve stimulation.

Deer TR, Thomson S, Pope JE et al.International Neuromodulation Society Critical Assessment: Guideline Review of Implantable Neurostimulation Devices. Neuromodulation 2014; 17: 678–685





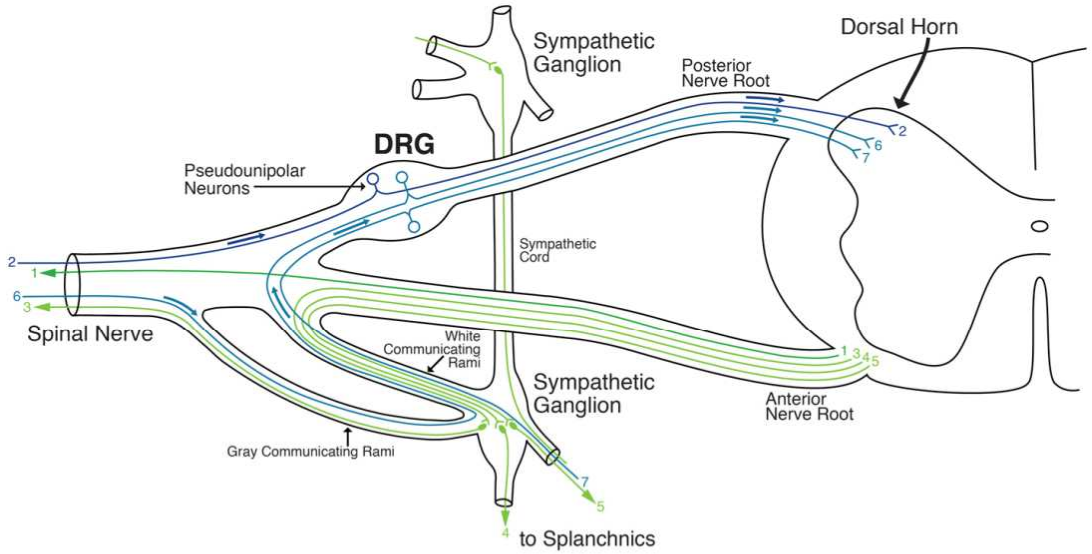
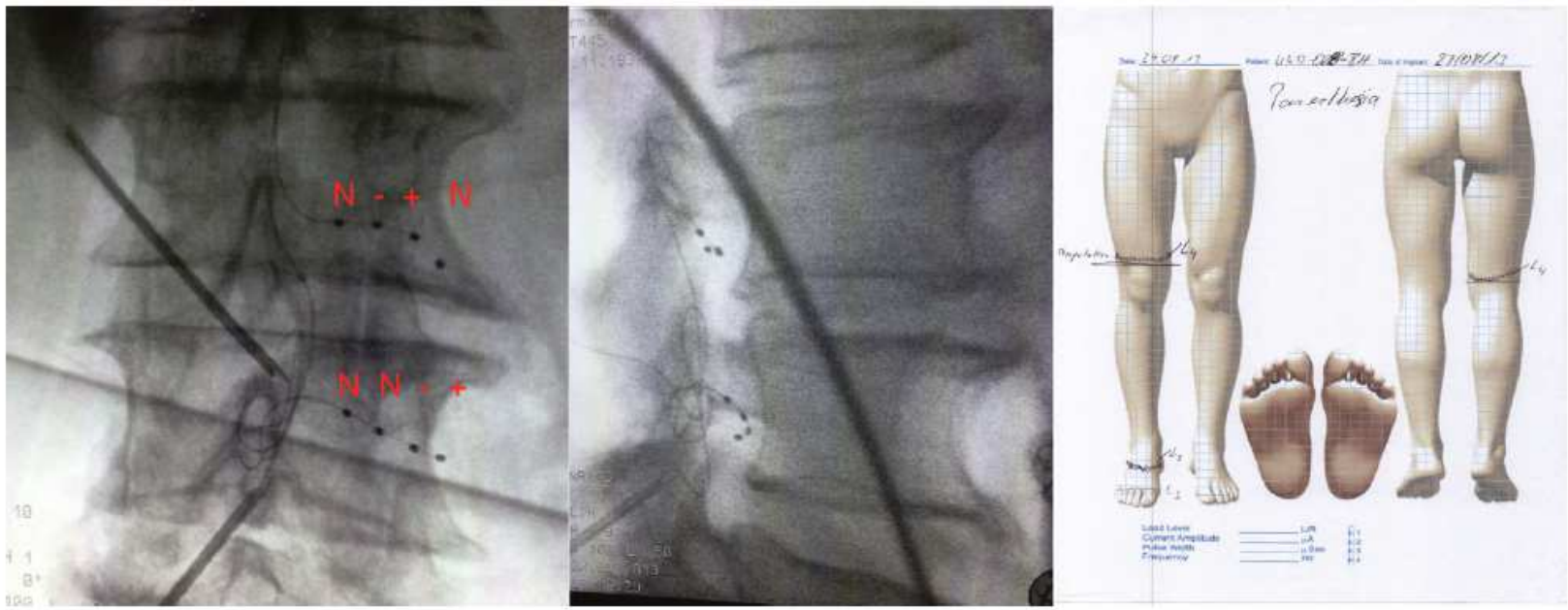


Figure 3. Control of electrical impulses that reach the dorsal horn. The dorsal root ganglion (DRG) acts to either block, propagate, or filter potentials from the periphery. 1) Somatic efferent fibers; 2) Somatic afferent fibers; 3,4,5) Sympathetic efferent fibers; 6,7) Sympathetic afferent fibers. [Color figure can be viewed at wileyonlinelibrary.com]

Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35



Fluoroscopic image of lead placement at L3 and L4 DRGs (left, middle) along with the polarities and the paresthesia map (right) for one patient. Stimulation of the L3 DRG created paresthesia at the top of the phantom foot while that of the L4 DRG elicited paresthesia in the stump. At follow-up, the patient reported complete cessation of stump pain and overall residual VAS rating of pain as only 10 mm.

Eldabe S, Burger K, Moser H. Dorsal Root Ganglion (DRG) Stimulation in the Treatment of Phantom Limb Pain (PLP). Neuromodulation 2015; 18: 610–617

Table 15. Effective DRG-Lead Combinations for Various Pain Locations (64).

Pain location	Sample size	Most impactful DRG	Optimal lead combination(s)
Foot	106	S1	L5/S1 (include L4 if ankle pain is present)
Knee	23	L4	L3/4
Groin	25	T11	T12/L1/2 > T11/12/L1 = T11/12
Buttock	12	L2	T12/L1/L2 > T12/S1
Back	28	T12	T12/L1/2 > L5/S1
Pelvic	6	S2	L1/S2 (bilateral leads for bilateral pain)

Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35

Table 10. Evidence for DRG in Treating CRPS.

Key statements	Supporting references	Levels of evidence	Recommendation strength	Consensus strength
DRG was effective in treating CRPS type I or type II of the lower extremity.	Deer et al. 2017 (23)	I	A	Strong
DRG stimulation of the upper extremity for CRPS type I or type II requires more study.	Deer et al. 2017 (23)	II-2	A	Strong
DRG achieved improved results for patients with CRPS compared to SCS.	Deer et al. 2017 (23)	I	A	Strong

Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35

Table 11. Evidence for DRG in Treating Peripheral Neuropathies.

Key statements	Supporting references	Levels of evidence	Recommendation strength	Consensus strength
DRG stimulation may be effective for the pain of diabetic peripheral neuropathy.	Schu et al. 2015 (86) Eldabe et al. 2017 (87)	III	C	Strong
No recommendations can be made for other forms of peripheral neuropathy, but considering the orientation of the pain, patients should be implanted on a case-by-case basis.	Falowski et al. 2017 (88)	III	B	Moderate

Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35

Table 12. Evidence for Chronic Postsurgical Pain.

Key statements	Supporting references	Levels of evidence	Recommendation strength	Consensus strength
In a small prospective, noncontrolled study, DRG stimulation demonstrated relief of CPSP.	Espinet 2015 (91)	III	B	Moderate
Preliminary data from this prospective study suggests that stimulation of the DRG may be an effective intervention for CPSP.	Liem et al. 2014 (92)	III	B	Strong
After six months, VAS and BPI scores decreased significantly. The median satisfaction rating with the overall therapy was 8.0 out of 10.0.	Breel et al. 2016 (93)	III	B	Strong

Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35

Table 13. Evidence for Phantom Limb Pain.

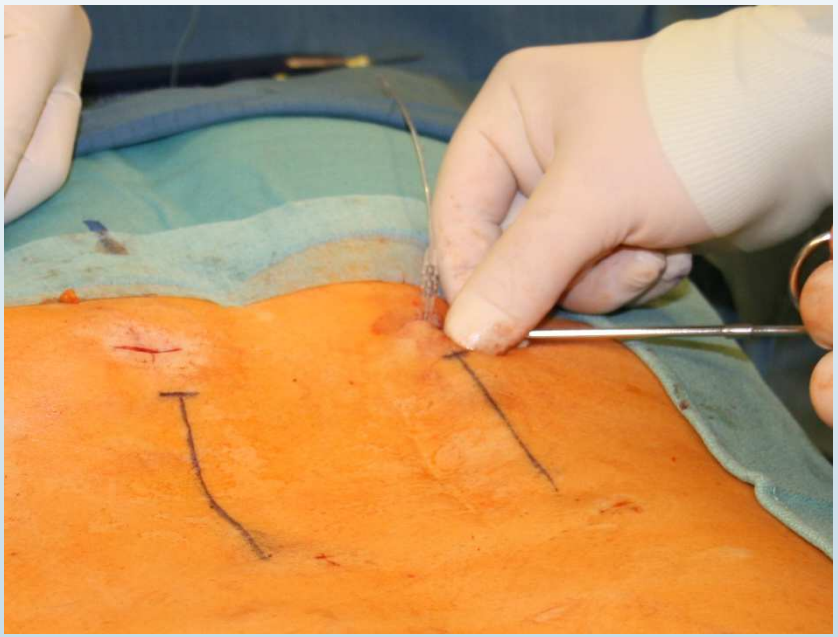
Key statements	Supporting references	Levels of evidence	Recommendation strength	Consensus strength
DRG stimulation may be effective for phantom limb pain.	Eldabe et al. 2015 (22) Hunter et al. 2017 (64)	III	I	Moderate

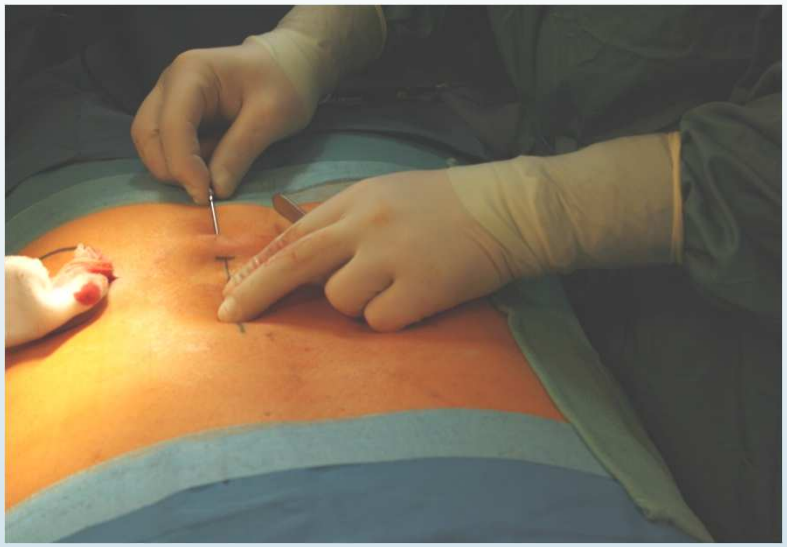
Deer TR, Pope JE, Lamer TJ et al.The Neuromodulation AppropriatenessConsensus Committee on Best Practices forDorsal Root Ganglion Stimulation. Neuromodulation 2019; 22: 1–35

Table 14. Evidence for Postherpetic Neuralgia.

Key statements	Supporting references	Levels of evidence	Recommendation strength	Consensus strength
DRG is efficacious for postherpetic neuralgia.	Vesper et al. 2016 (104)	II-2	I	Moderate
	Sullivan et al. 2015 (105)	II-2	B	
	Yang et al. 2013 (106)	II-2	C	
	Yanamoto et al. 2012 (107)	III	B	
DRG stimulation is safe for postherpetic neuralgia.	Vesper et al. 2016 (104)	II-2	I	Strong
	Sullivan et al. 2015 (105)	II-2	B	

What is Subcutaneous Stimulation?

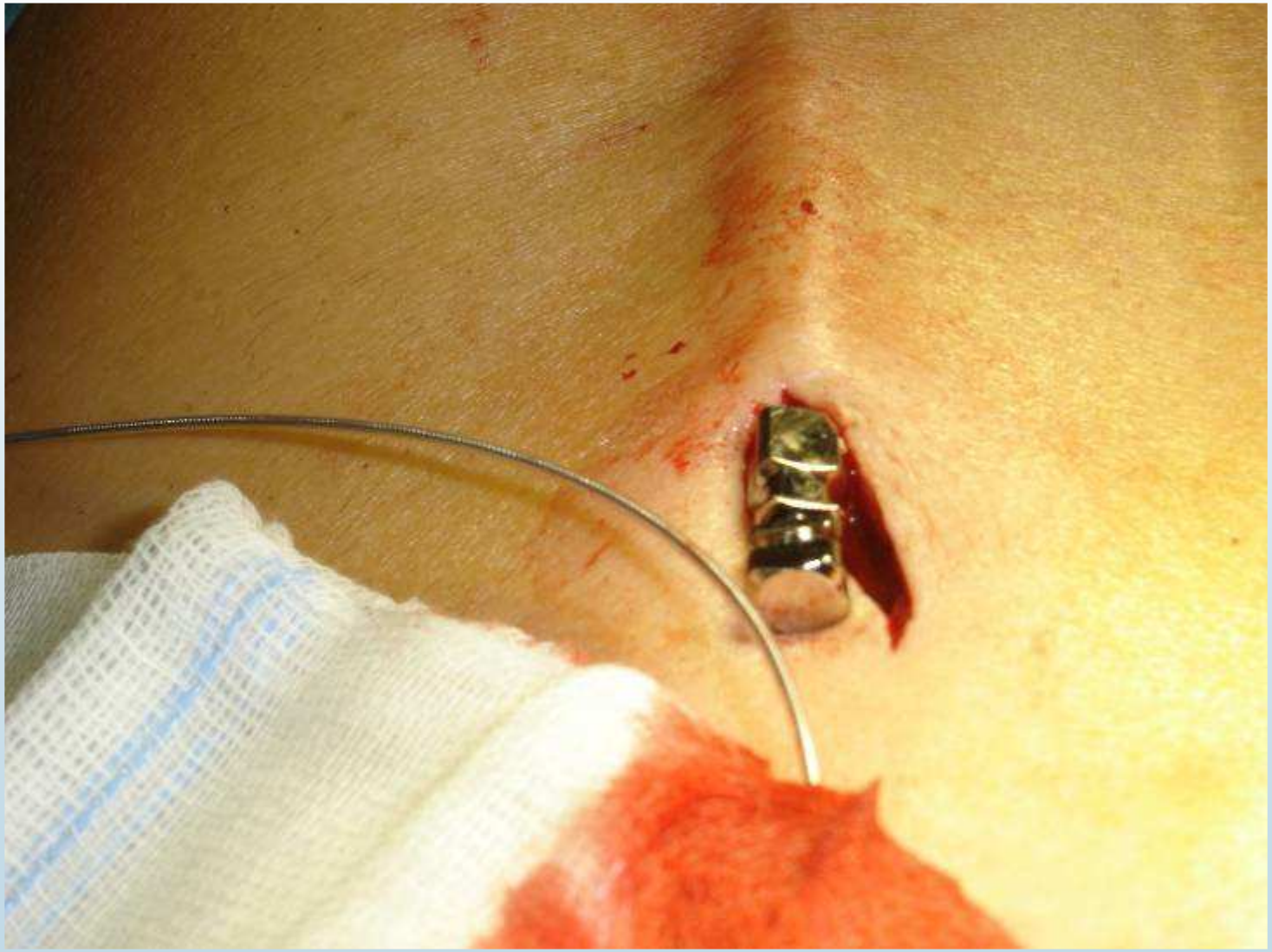


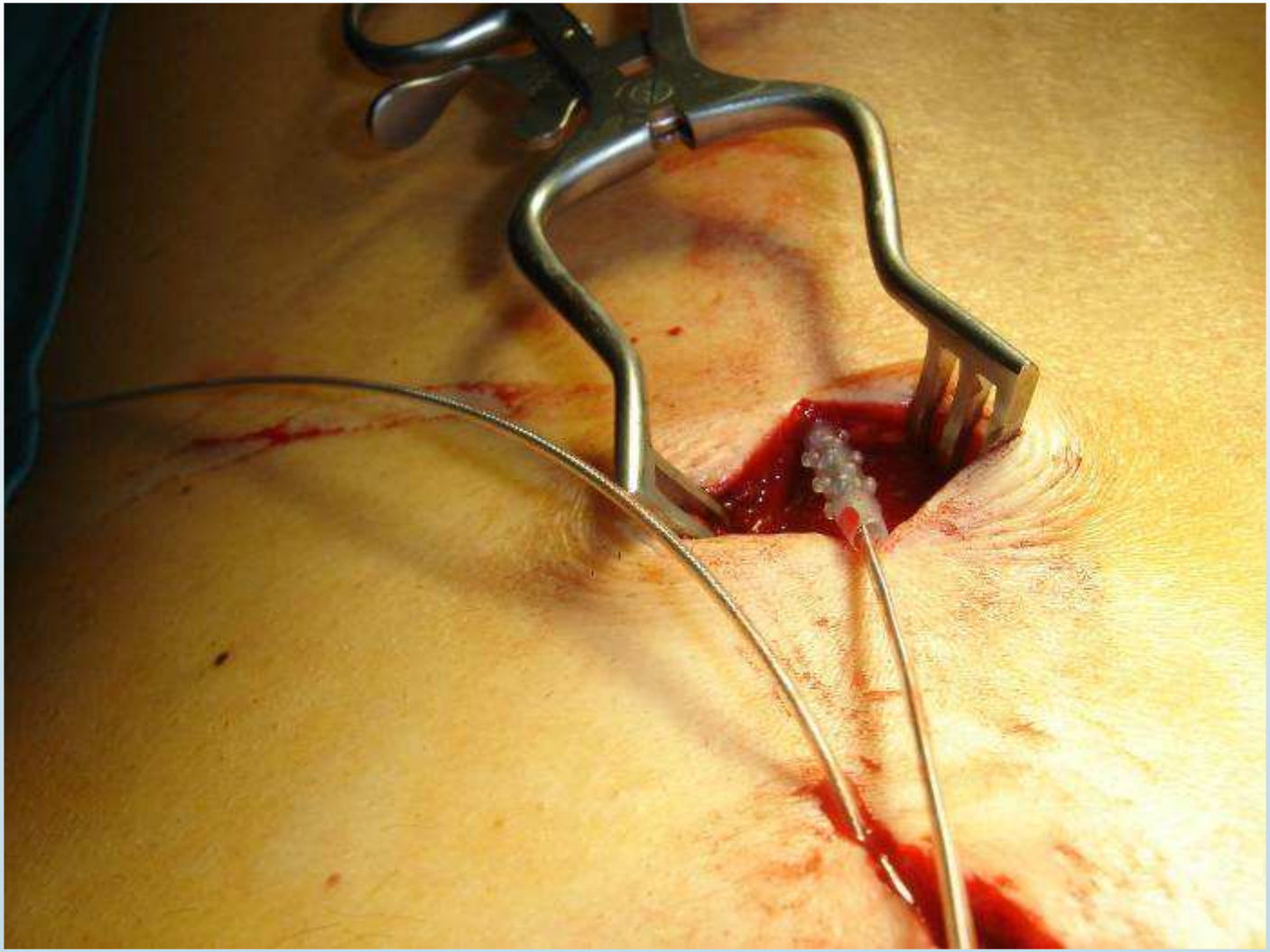


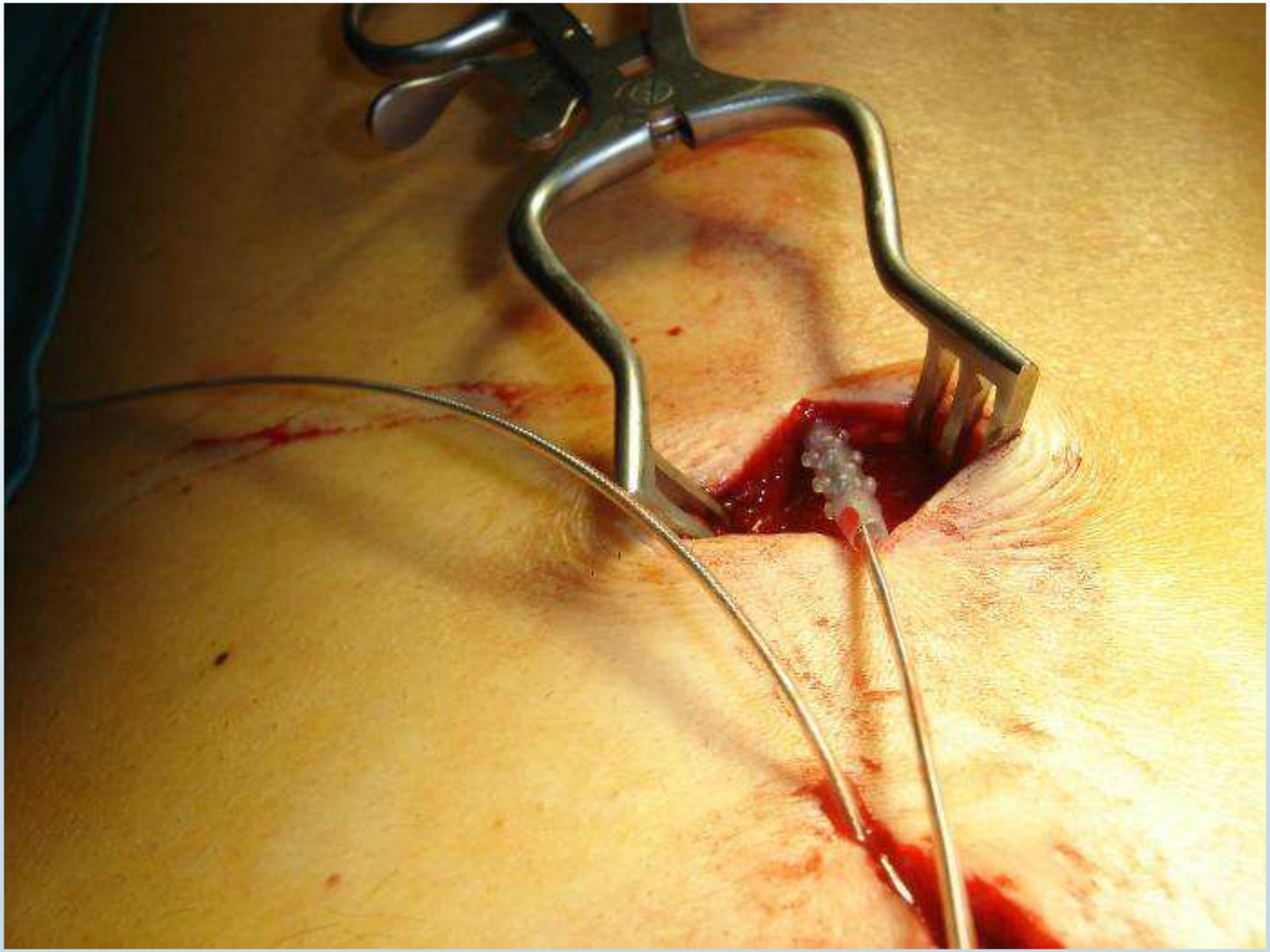
- ⇨ leads placed in the area of pain
- ⇨ right in the subcutaneous tissue
- ⇨ Cave: not too deep!
- ⇨ you should feel the Tuohy needle

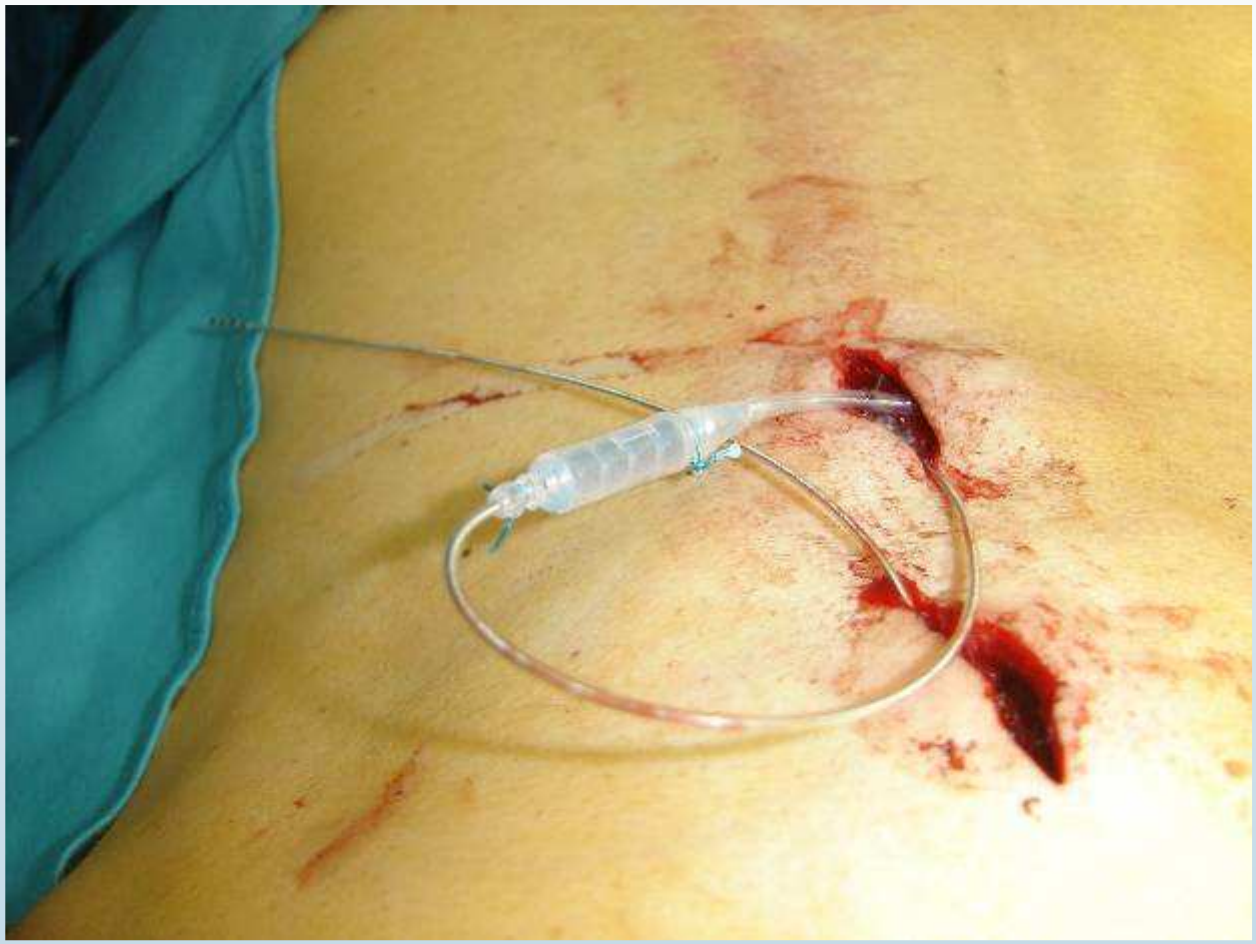
Subkutane Stimulation

- **Evaluierung,TENS Therapie?**
- **Welche Elektroden vorzugsweise für welche Indikation?**
- **Wohin und wie tief sollen die Elektroden gelegt werden?**
- **Welche Befestigungstechniken werden empfohlen?**
- **Soll intraoperativ getestet werden? Wenn ja, welche Vorgangsweise wird empfohlen – ohne Lokalanästhetika, mit wenig Lokalanästhetika?**
- **Schmerzlinderung mehr als 50% ?**
- **Paresthesieabdeckung mehr als 80% ?**
- **Verwendung von Antibiotika?**
- **Sollte postoperativ getestet werden? Wenn ja, wie lange – zu Hause?**



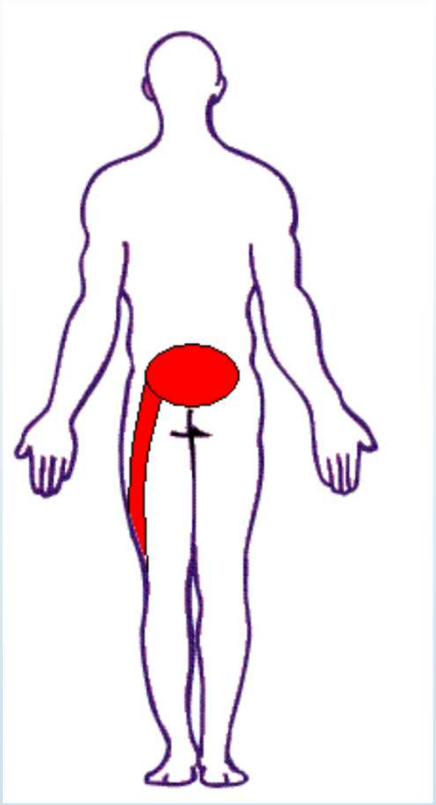




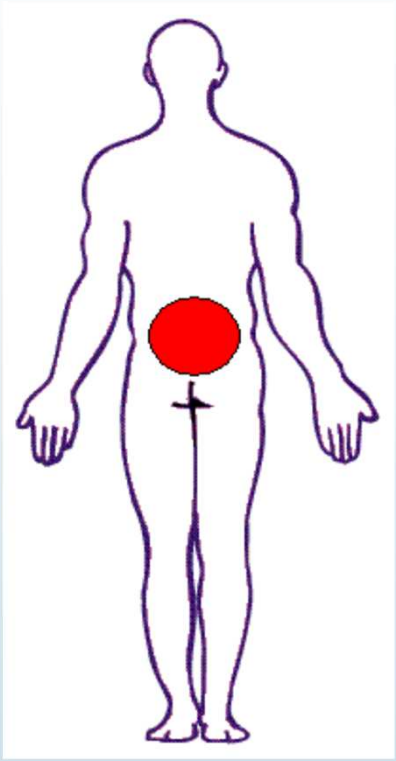


111 Patienten mit fokalen chronischen nicht Tumorschmerz wurden in die retrospektive Analyse eingeschlossen.
Indikation für subcutane Feldstimulation war low back pain n = 29, failed back surgery n = 37, Schmerzen in der HWS-Region n = 15, postherpetischen Neuralgie n = 12.
Nach der Implantation war die Schmerzreduktion mehr als 50 %, von 8.2 auf 4.0.
Elektrodendislokation in 14 Patienten (13 %), Infektion in 7 (6 %) und in 6 Fälle (5 %) kam es zum Elektrodenbruch.

Subcutaneous Target Stimulation in chronic non-cancer pain: A nation-wide retrospective study; Sabine Sator-Katzenschlager, Katharina Fiala, Hans G. Kress, Alexandra Kofler, Josef Neuhold, Herwig Kloimstein, Wilfried Ilias, Eva-Maria Mozes-Balla, Michaela Pinter, Nadja Loining, Wolfgang Fuchs, Georg Heinze, Rudolf Likar; publiziert in Pain Practice, 2010

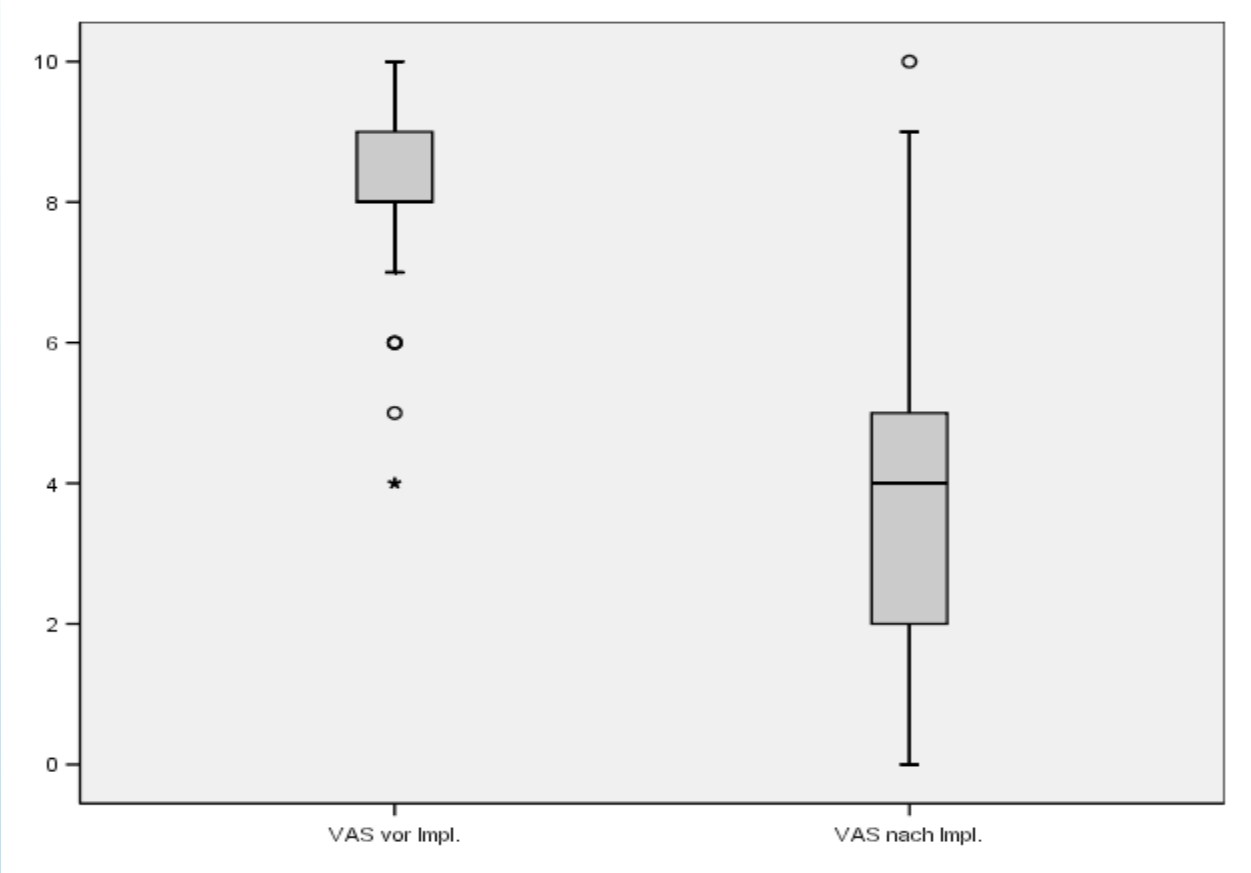


(a)

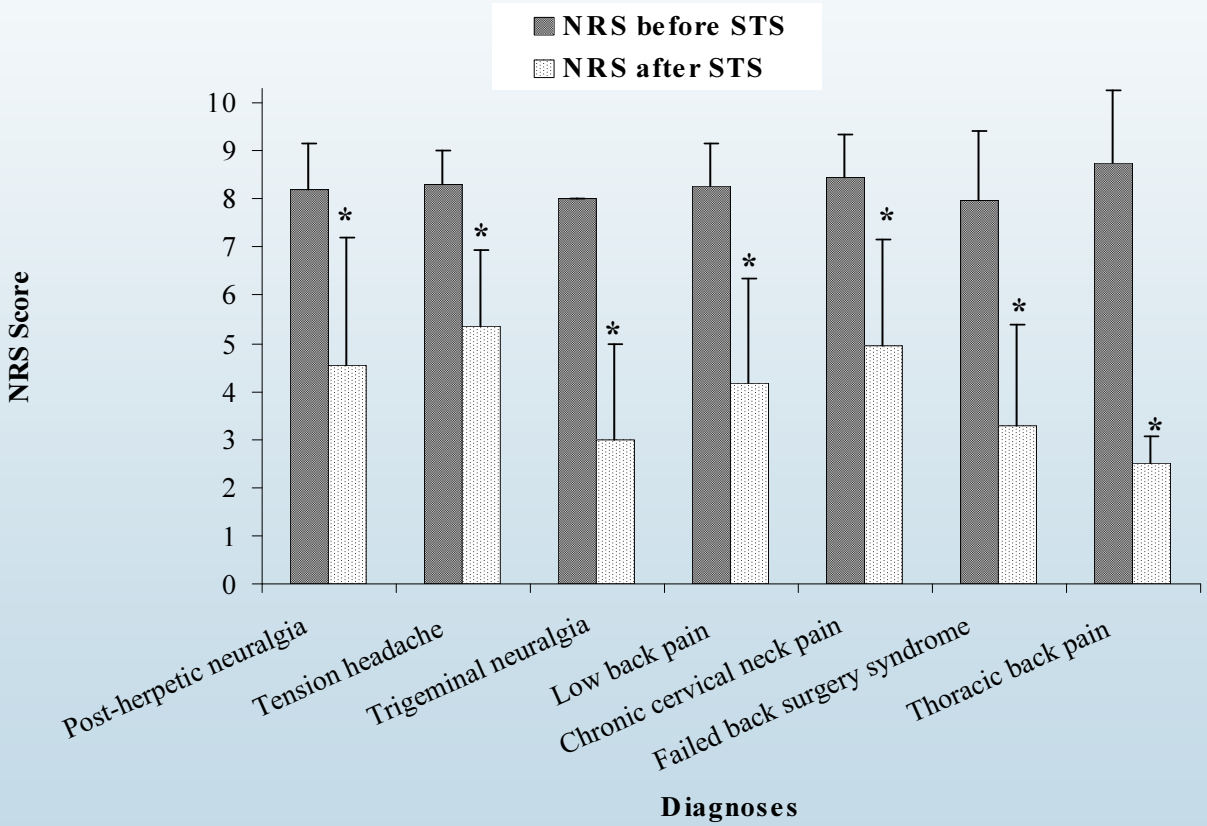


(b)

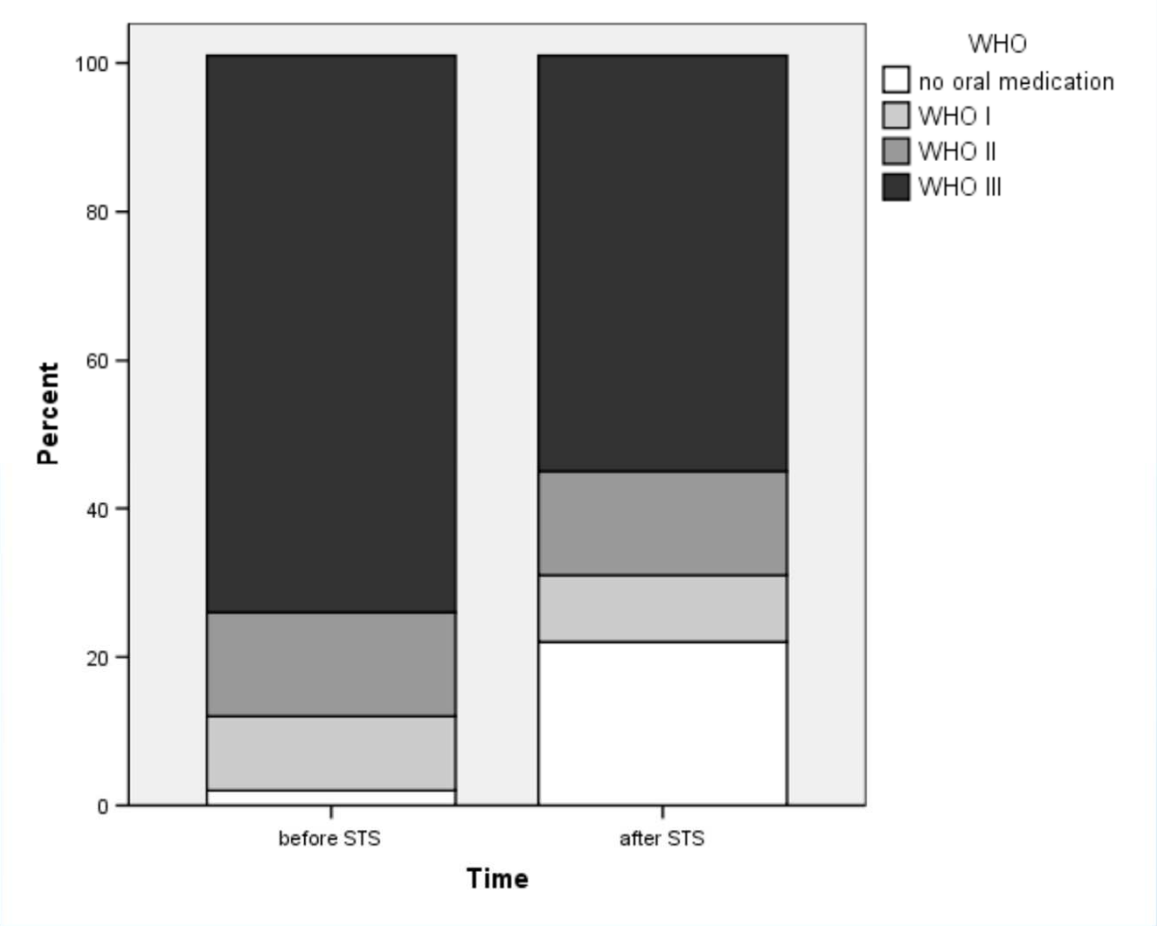
Subcutaneous Target Stimulation in chronic non-cancer pain: A nation-wide retrospective study; Sabine Sator-Katzenschlager, Katharina Fiala, Hans G. Kress, Alexandra Kofler, Josef Neuhold, Herwig Kloimstein, Wilfried Ilias, Eva-Maria Mozes-Balla, Michaela Pinter, Nadja Loining, Wolfgang Fuchs, Georg Heinze, Rudolf Likar; publiziert in Pain Practice, 2010



Pain intensity score before and after STS stimulation for all 111 patients (Numerical rating scale; 0= no pain, 10= unbearable pain), (median; 8 before STS, 4 after STS), percentile 25 (8 before STS, 2 after STS), percentile 75 (9 before STS, 5 after STS) *P<0.001


NRS before STS
NRS after STS
NRS Score
0
1
2
3
4
5
6
7
8
9
10
*
Post-herpetic neuralgia
Tension headache
Trigeminal neuralgia
Low back pain
Chronic cervical neck pain
Failed back surgery syndrome
Thoracic back pain
Diagnoses

Analgesic medication according to WHO 3 steps (I-III) before and 3 months after implantation
percent of patients; WHOI (non-opioids), WHOII (weak opioids), WHO III (strong opioids)



"Austrian Subcutaneous Registry"

- **Design:**
  - ⇨ Physician initiated trial
  - ⇨ Prospective Registry
  - ⇨ Multi-center
  - ⇨ Started: 03/2008
  - ⇨ End of patient enrollment: 03/2011
  - ⇨ Follow-Up: 1, 3, 6 and 12 months after lead implant
    - ⇨ extended to 5 years, 6 months interval

- **Inclusion Criteria:**
  - ⇨ Medically refractory patients
  - ⇨ Chronic pain for more than 6 months
  - ⇨ Patients that did not have subcutaneous stimulation yet

"Austrian Subcutaneous Registry"

- **Study objectives:**

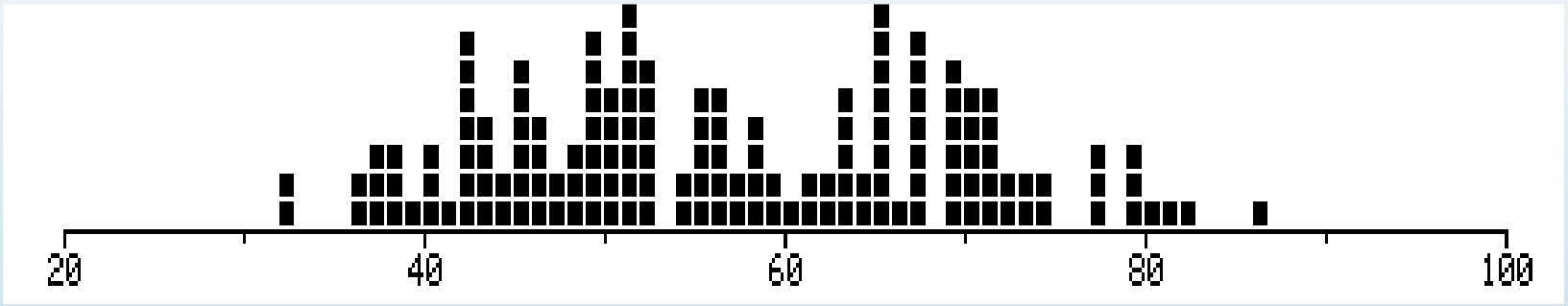
  ⇨ Aim: to assess the efficacy of Subcutaneous Stimulation for chronic pain of different origin, such as

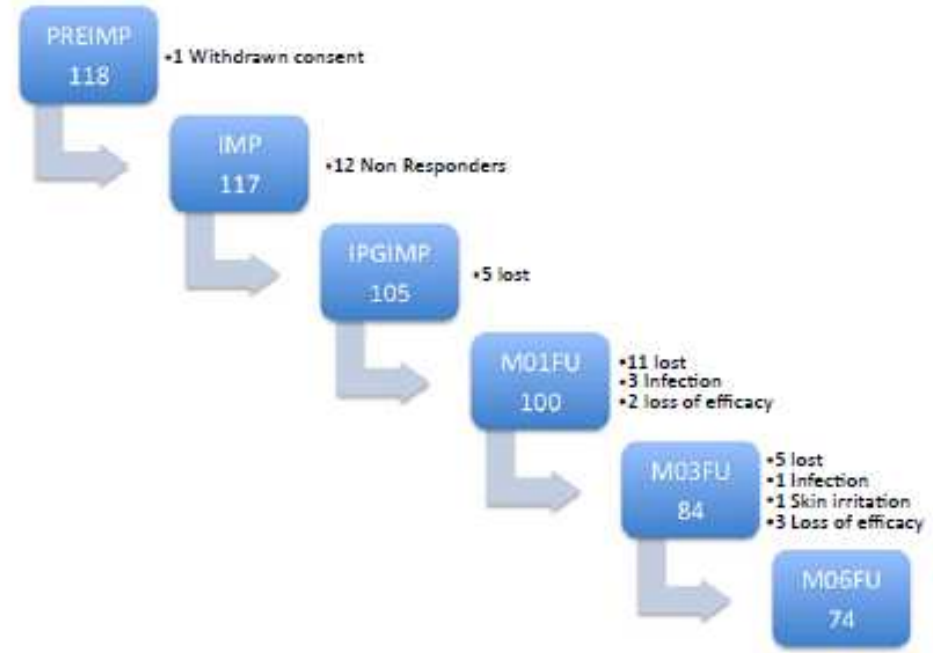
  - Low Back Pain
  - Post Zoster Neuralgia
  - Tension Headache
  - Trigeminal Neuropathy
  - Upper Cervical Syndrome
  - Occipital Neuralgia
  - Cluster Headache
  - Migraine

  ⇨ Endpoints:

  - effect on pain and QoL (VAS, SF12, Oswestry, BDI, …)
  - effect on medication

Age Distribution Patients





Patients' flow chart: PREIMP, screening visit; IMP, test electrodes implanted; IPGIMP, implantation of permanent stimulation device; M01FU, one month follow-up; M03FU, three months follow-up; M06FU, six months follow-up.

Kloimstein H., Likar R., Kern M. et al 2013. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. Neuromodulation 2013

Patients characteristics at inclusion

		Low back pain			Other indications* * Only indications with more than 1 patients are presented here				
		PNS alone	**PNS+SCS**	**All PNS**	Tension headache	Trigemina lneuro-pathy	Upper cervical syndrome	Occipital neuralgia	*Other indications
Number of implanted patients		**N=49**	**N=69**	**N=118**	N=4	N=3	N=6	N=5	N=17
Gender	**Female**	**31(63.3%)**	**41(59.4%)**	**72(61.0%)**	2	0	3	2	5
	Male	**18(36.7%)**	**28(40.6%)**	**46(39.0%)**	2	3	3	3	12
Age	**n**	**49**	**69**	**118**	4	3	6	5	17
	Min-Max	**37-81**	**32-86**	**32-86**	38-80	44-69	43-73	44-79	32-77
	Mean	**60.2**	**56.6**	**56.6**	55.2	59.3	57.3	56.6	53.6
	Std	**11,7**	**12,1**	**12,1**	17,9	13,4	12,3	13,8	13,1

*4 patients with two indications included, cf p.5.

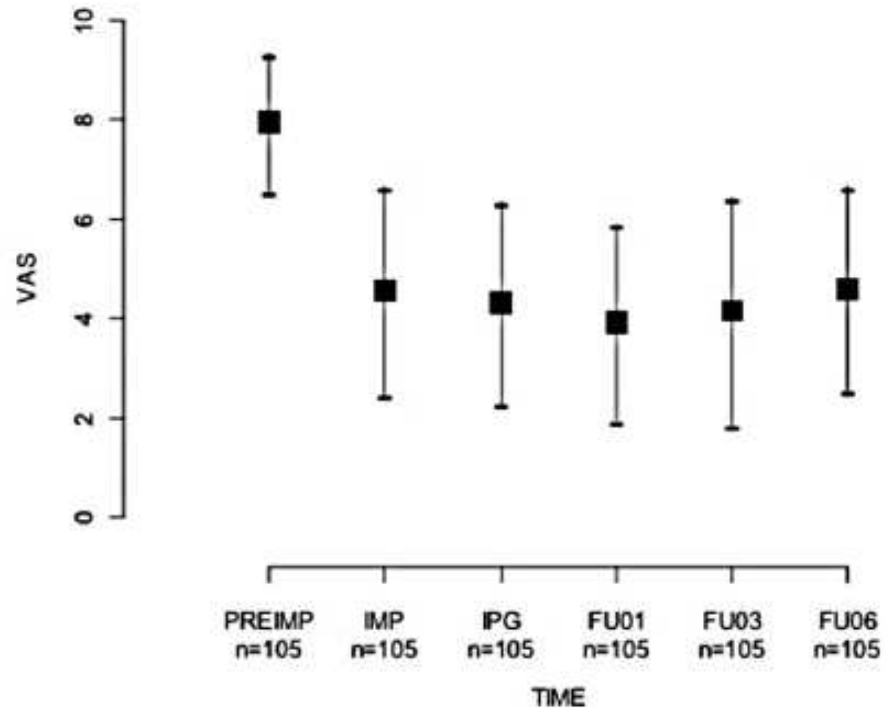
Implant Data

- **Number of Leads**
  - 10 x 1 lead
  - 56 x 2 leads
  - 2 x 3 leads
  - 3 x 4 leads
- **Lead models**
  - 1 x Quad
  - 128 x Quad Plus
  - 7 x Resume TL
- **IPGs**
  - 1 x Versitrel
  - 4 x Synergy
  - 39 x Prime Advanced
  - 11 x Restore Advanced
  - 14 x Restore Ultra
  - 2 x Restore Sensor
- **Lead(s) fixed?**
  - Yes: 59 patients
  - No: 12 patients
- **Screening duration**
  - Mean: 10,3 days (7-21)
- **Paresthesia coverage**
  - Mean: 83,1%
  - 43 out of 71 patients: 100%
- **Anesthesia type**
  - Local 57
  - General 14
- **Antibiotic regime**
  - No 4
  - Single-Shot 15
  - Continuous 52
  - Mean: 9,9 days (1-21)

Coverage of painful area

Nr	Min	Med	Max	Mean	SDev	SEM	n
1	0	100	100	80.58	27.01	2.5	117
2	28	100	100	83.46	23.52	2.3	105
3	0	62.5	100	55.31	41.07	11.85	12

1: Responders and Non-responders
2: Responders
3: Non-responders



VAS score over the six-month period; continuation scenario (intention-to-treat analysis). M01FU, (Follow-up 1 month); M03FU, (Follow-up 3 months); M06FU, (Follow-up 6 months); IMP, test electrodes implanted; IPG, impulse generator; PREIMP, screening visit; VAS, visual analog scale.

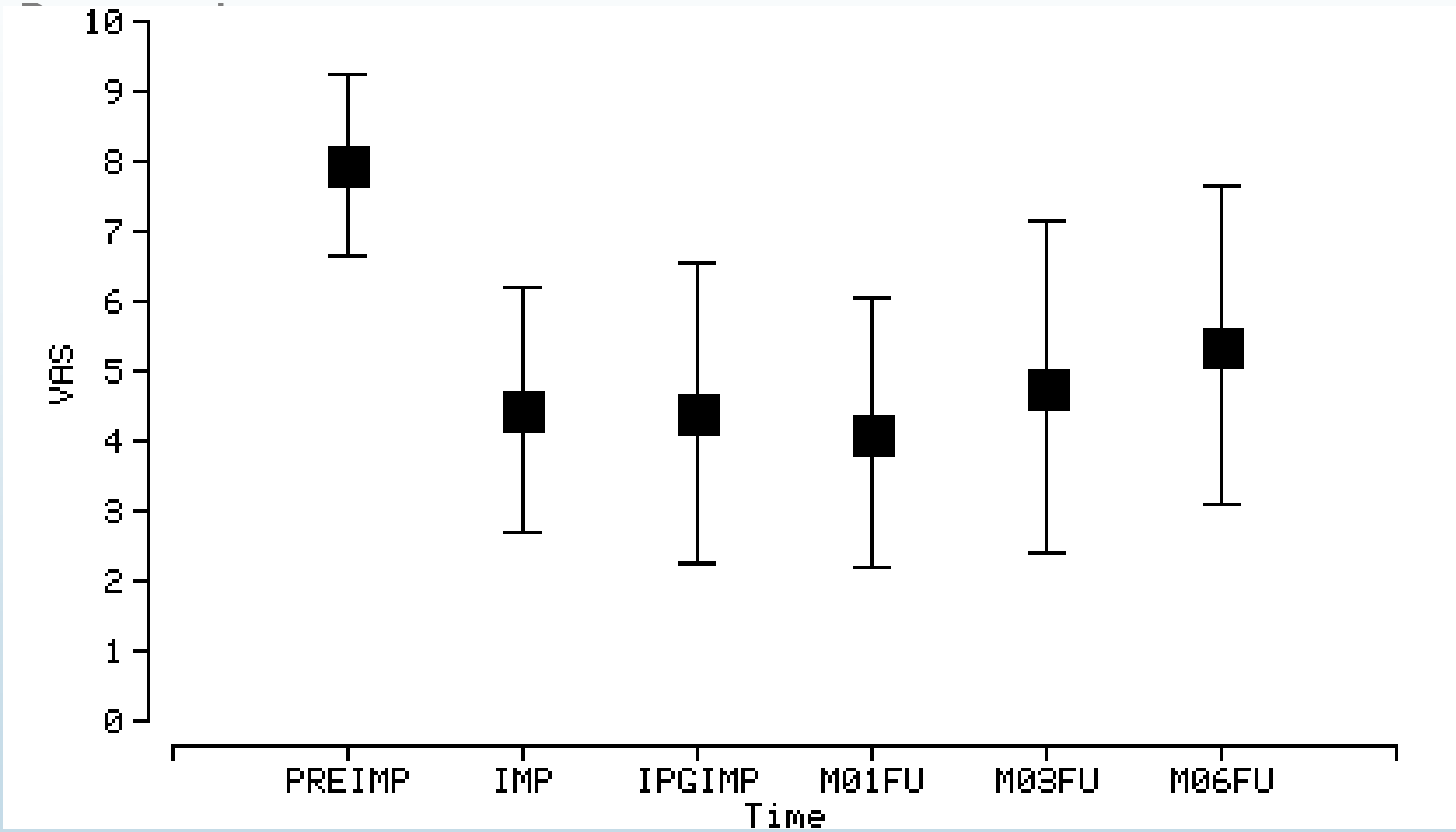
Kloimstein H., Likar R., Kern M. et al 2013. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. Neuromodulation 2013

Status Quo – Data Collection

- TENS:
  - 8 x not applicable
  - 63 x Yes
    - 23 – no effect
    - 23 – moderate effect
    - 16 – good effect

  ⇨ TENS is no predictor!

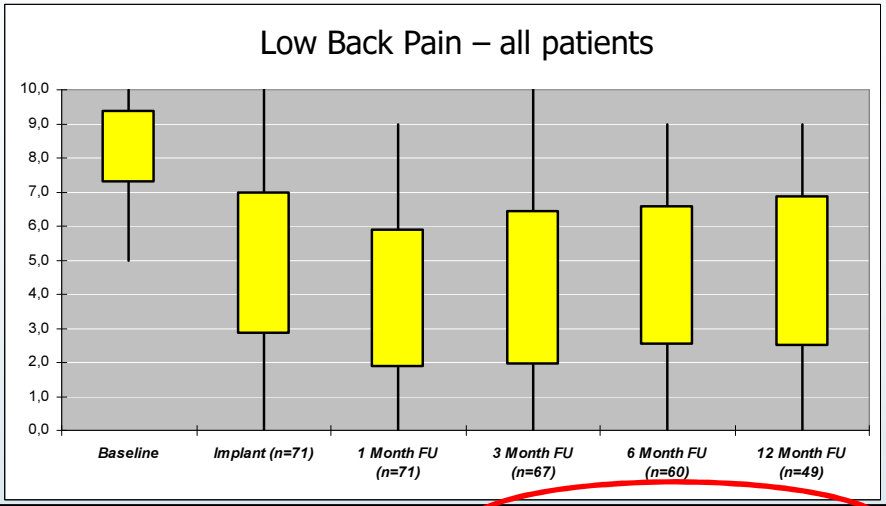
Pain reduction and TENS



VAS reduction in patients with NO TENS effect

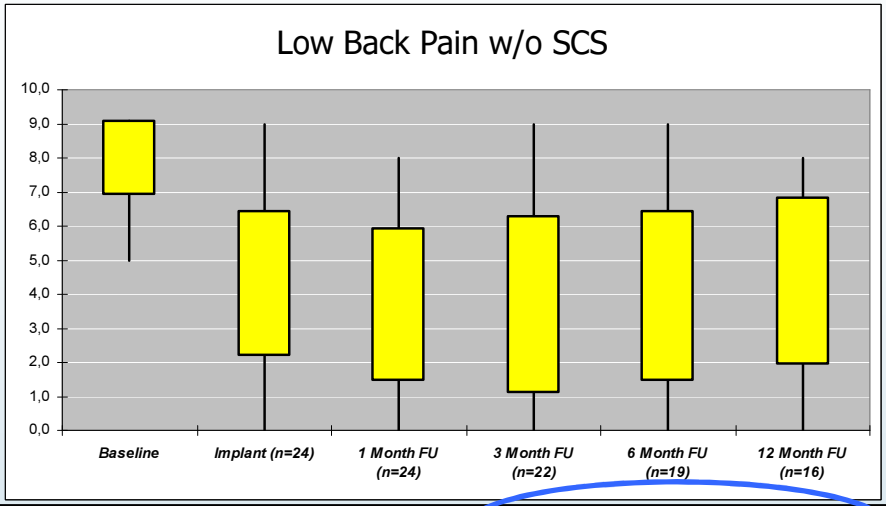
VAS – Low Back Pain

Low Back Pain – all patients



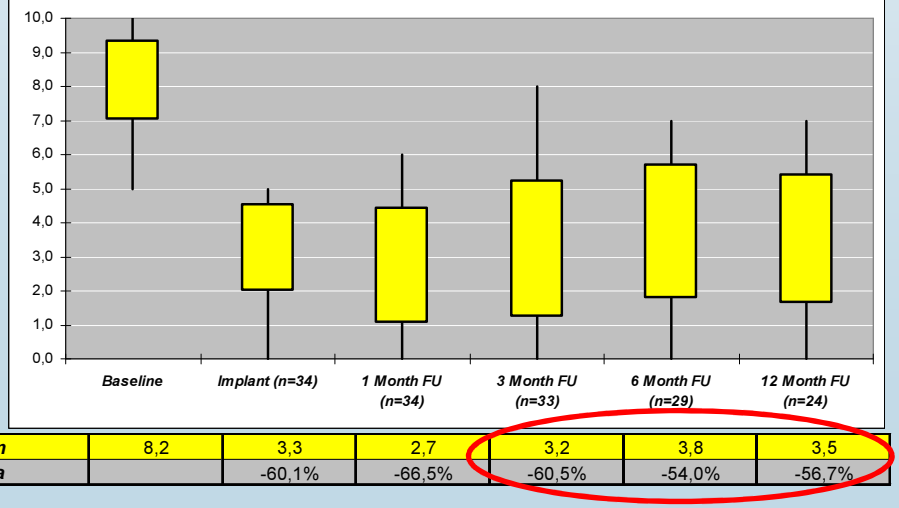
Mean	8,3	4,9	3,9	4,2	4,6	4,7
Delta		-41,0%	-53,3%	-49,8%	-45,3%	-43,9%

Low Back Pain w/o SCS



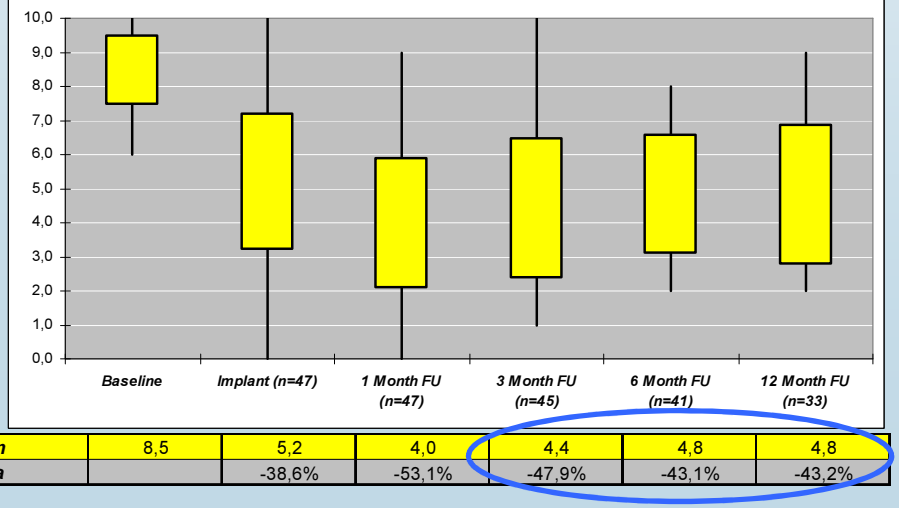
Mean	8,0	4,3	3,7	3,7	3,9	4,4
Delta		-46,1%	-53,6%	-54,0%	-50,7%	-45,3%

Low Back Pain – all patients, ≥50%



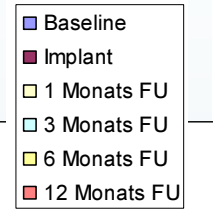
Mean	8,2	3,3	2,7	3,2	3,8	3,5
Delta		-60,1%	-66,5%	-60,5%	-54,0%	-56,7%

Low Back Pain with SCS

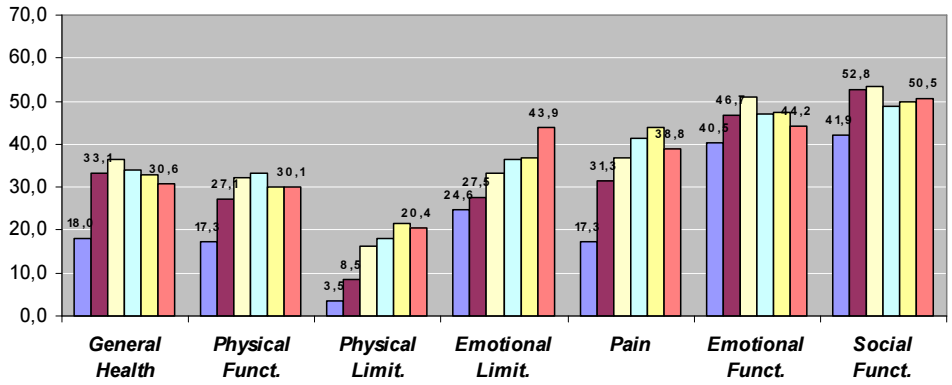


Mean	8,5	5,2	4,0	4,4	4,8	4,8
Delta		-38,6%	-53,1%	-47,9%	-43,1%	-43,2%

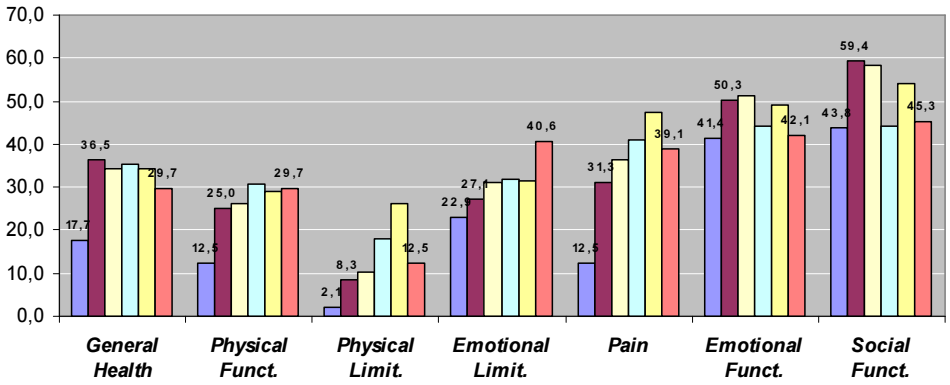
SF 12 – Low Back Pain



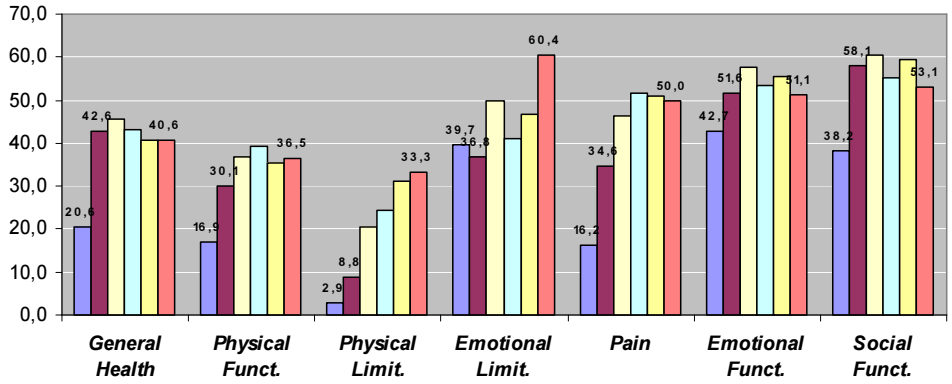
Low Back Pain - all patients



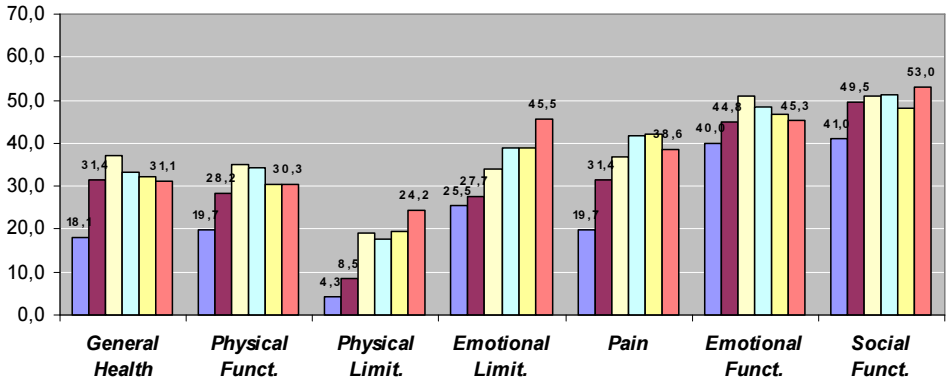
Low Back Pain w/o SCS



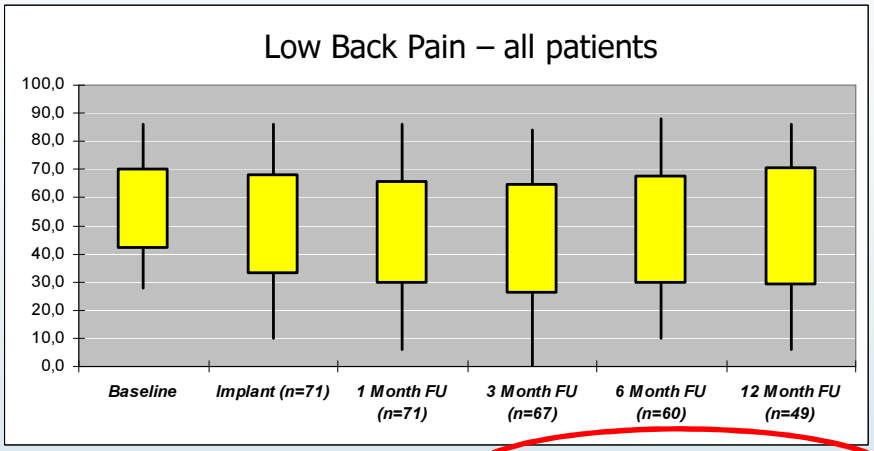
Low Back Pain - all patients, ≥50%



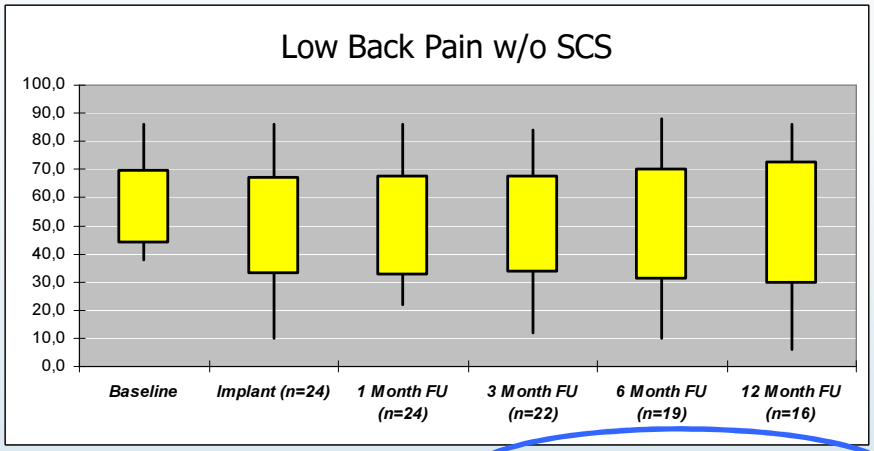
Low Back Pain with SCS



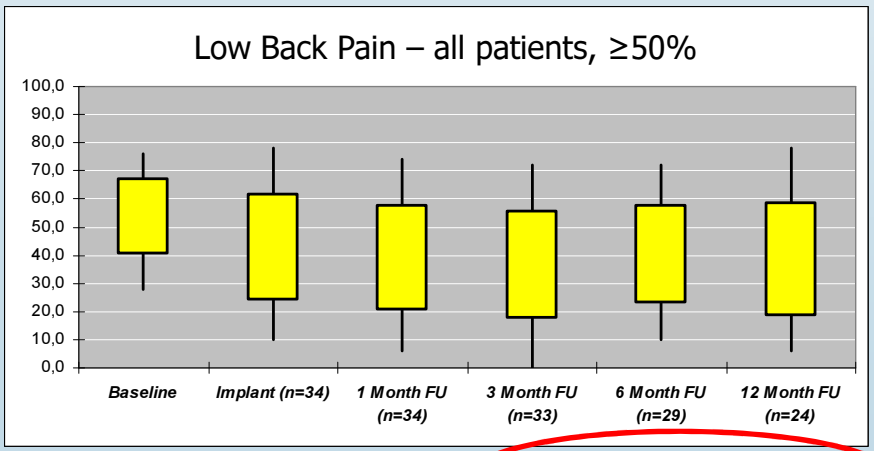
Oswestry – Low Back Pain



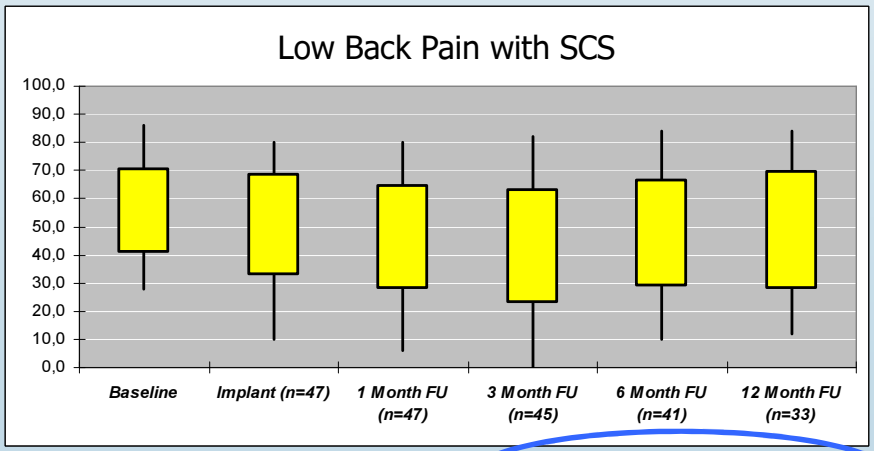
Mean	55,9	50,5	47,4	45,3	48,6	49,6
Delta		-9,8%	-15,2%	-18,9%	-13,2%	-11,4%



Mean	56,6	50,2	49,9	50,5	50,6	51,1
Delta		-11,4%	-11,8%	-10,8%	-10,7%	-9,8%

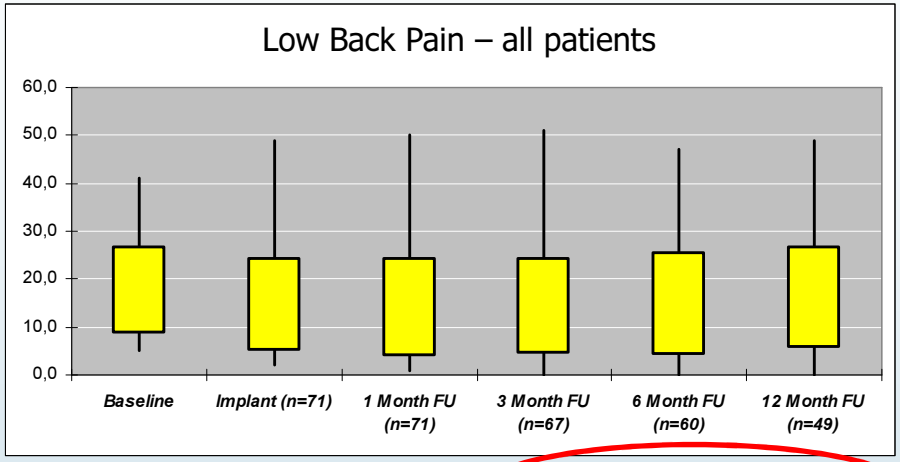


Mean	53,9	42,8	38,9	36,5	40,2	38,6
Delta		-20,6%	-27,8%	-32,2%	-25,5%	-28,3%

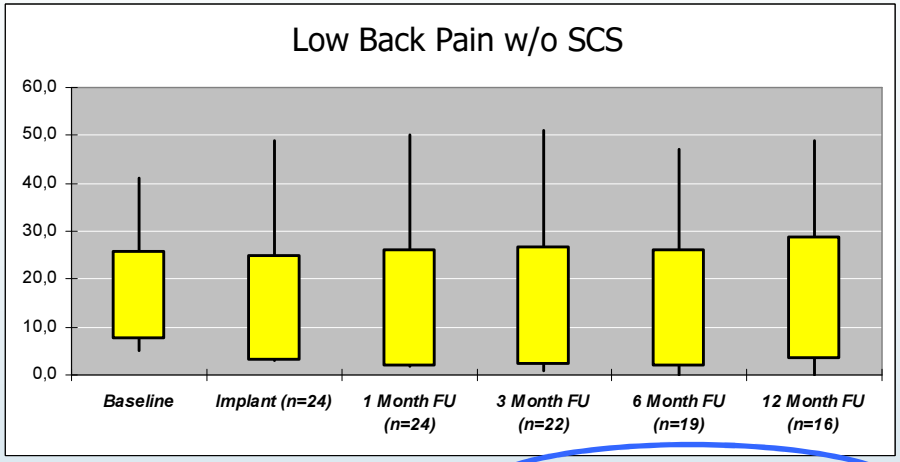


Mean	55,6	50,6	46,1	42,8	47,6	48,9
Delta		-9,0%	-17,0%	-23,0%	-14,3%	-12,1%

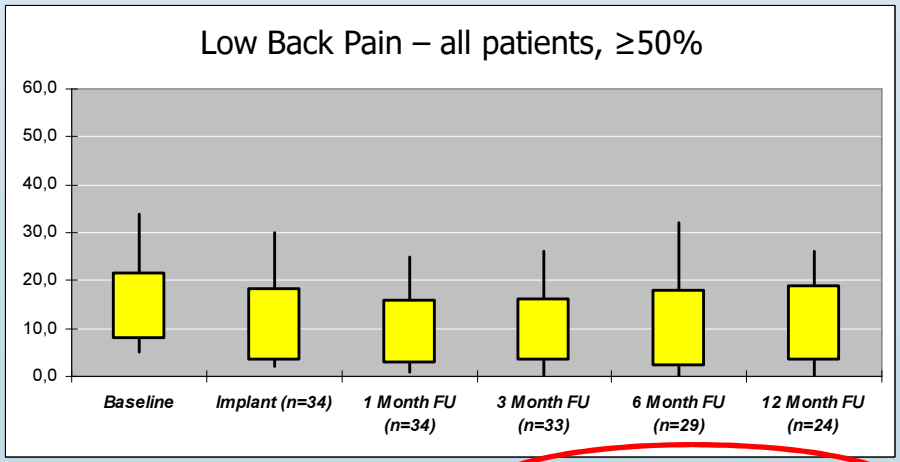
BDI – Low Back Pain



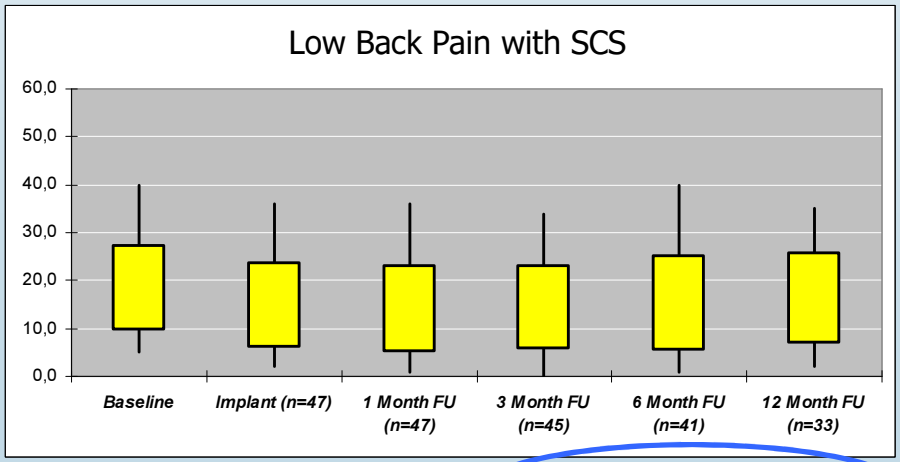
Mean	17,8	14,6	14,0	14,4	14,9	16,2
Delta		-18,2%	-21,3%	-19,1%	-16,5%	-8,9%



Mean	16,7	14,0	14,0	14,4	13,8	16,1
Delta		-16,2%	-16,0%	-14,0%	-17,2%	-3,5%



Mean	14,6	10,8	9,3	9,7	10,1	11,2
Delta		-26,5%	-36,7%	-33,6%	-31,3%	-23,8%



Mean	18,4	14,9	14,0	14,4	15,4	16,3
Delta		-19,1%	-23,8%	-21,5%	-16,5%	-11,4%

Medication count Responders

	Baseline	M01FU	M03FU	M06FU
Opioids n(%)	80(76,2%)	60(57,1%)	51(48,6%)	45(42,9%)
NSAIDs n(%)	40(38,1%)	29(27,6%)	21(20%)	17(16,2%)
Anticonvulsants n(%)	59(56,2%)	44(41,9%)	33(31,4%)	28(26,7%)

Number of patients using drug

Adverse Events & Complications for all 118 LBP patients enrolled

- Explantation of the system

  - 3 x due to infection of the leads (M01FU-M03FU)
  - 1 x due to infection of the leads (M03FU-M06FU)
  - 1 x due to skin irritation at IPG pocket site (M03FU – M06FU)
  - 2 x because of unpleasant stimulation (1 M01FU-M03FU, 1 M03FU-M06FU)
  - 3 x due to loss of efficacy

- AE ratio: 8,5%

In this section the question of whether the type of antibiotics administration („single shot" – SS or continuous" – CS) has an effect on the occurrence of infection is examined.

Breakdown based on number of patients: (p = 0,62)

	Antibiotic-Scheme			
Infection	SS		CS	
yes	2	6%	7	6%
no	29	94%	104	94%
	31	100%	111	100%

Conclusion

- ⇨ 118 Low Back Pain patients included
  - ⇨ considerably long follow-up time: 6 months

Results are promising, as

- ⇨ Mean pain reduction:
  - ⇨ - 45,3% (VAS 8,3 ⇨ 4,6) after 6 months
- ⇨ Quality of Life (Oswestry):
  - all: -11,4% 55,9 ⇨ 48,6 (6M)
- ⇨ Considerable reduction in medication: baseline - 6 months
  - ⇨ Opioid dosage:111 ⇨ 66 mg/day (- 41%)
  - ⇨ Opioid count: reduction 44%
  - ⇨ NSAIDs count: reduction 58%
  - ⇨ Anticonvulsants count: reduction 53%

CONCLUSION

PNFS can be considered as a promising effective therapy option for patients suffering from cLBP.

The technique of PNFS shows much less side effects than common medical therapy and in many cases even more effective.

In our presented data, PNFS seems to be a safe and reversible treatment option of cLBP with no loss of efficacy in the long run.

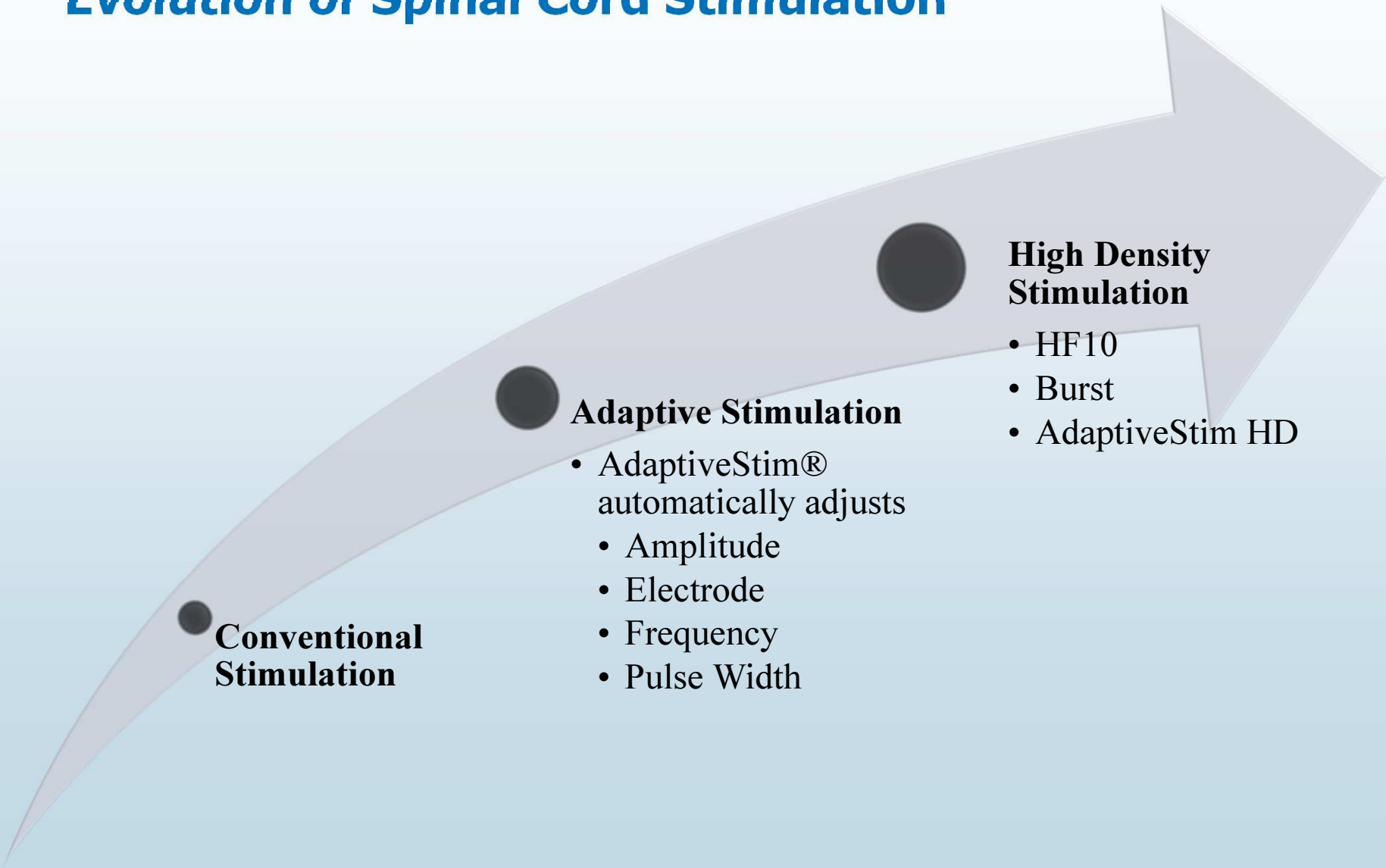
Kloimstein H., Likar R., Kern M. et al 2013. Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study. Neuromodulation 2013

Table 11. Selected and Chronologically Presented Peripheral Field Stimulation Guideline Statements.

Study	Society affiliation	Sponsorship/funding	Indications	Level of evidence	Recommendations	Recommendation strength
Cruccu et al. 2007 (13)	European Federation of Neurological Societies (EFNS)	Not reported	Chronic neuropathic pain		No conclusions	

Deer TR, Thomson S, Pope JE et al.International Neuromodulation Society Critical Assessment: Guideline Review of Implantable Neurostimulation Devices. Neuromodulation 2014; 17: 678–685

Evolution of Spinal Cord Stimulation



High-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back Pain Patients: Results of a Prospective Multicenter European Clinical Study

Jean-Pierre Van Buyten, MD1*, Adnan Al-Kaisy, MD1†, Iris Smet, MD*, Stefano Palmisani, MD†, Thomas Smith, MD†

Objective: The objective of this prospective, open-label, multicenter European clinical trial was to quantify the efficacy and safety

of a spinal cord stimulation (SCS) system that utilizes high-frequency (up to 10 kHz) waveforms, which do not produce paresthesia,

for the treatment of chronic, intractable pain of the back and/or limbs.

Material and Methods: Eighty-three patients, with significant back pain, were recruited for a trial of high-frequency stimulation

through two percutaneous eight-contact epidural leads. Patients' pain ratings, disability, sleep disturbances, and satisfaction, as

well as complication rates, were assessed for up to six months.

Results: After a trial period, 88% (72 out of 82) of patients reported a significant improvement in visual analog scale (VAS) scores

and underwent permanent implantation of the high-frequency SCS system. Mean back pain VAS of 8.4 was reduced to 2.7 at six

months ($p < 0.001$). Mean leg pain VAS of 5.4 was reduced to 1.4 at six months ($p < 0.001$). Seventy-four percent of patients had

greater than 50% back pain relief at six months. There were significant improvements in Oswestry disability score and sleep, and

reductions in pain medication use. Adverse events observed were those seen with conventional SCS therapy—lead migration,

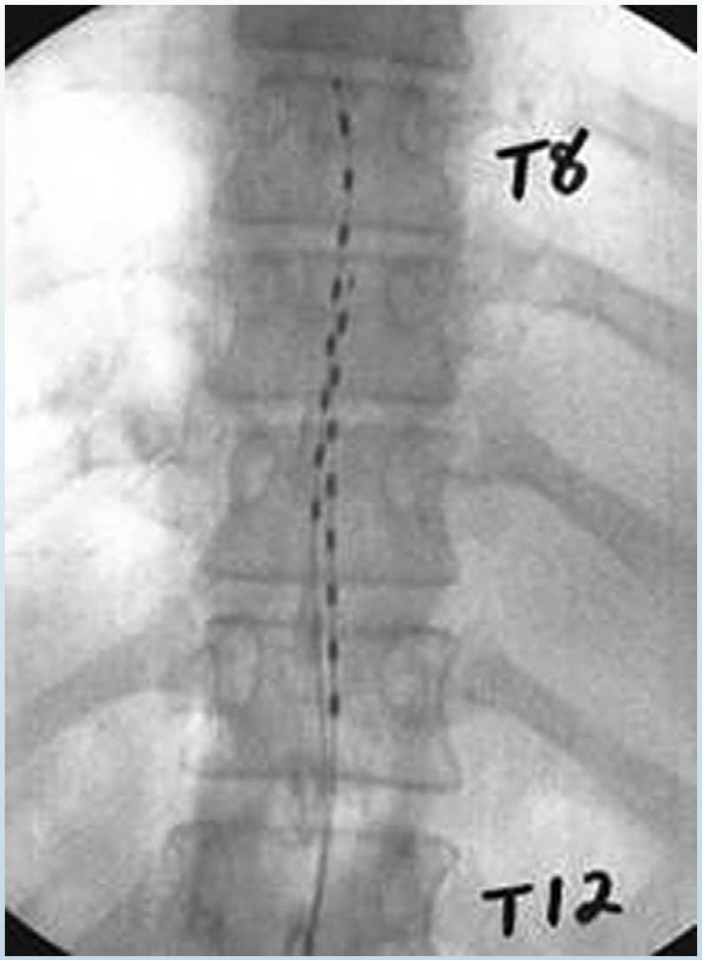
wound infection, and pain around implant site.

Conclusions: In a cohort of patients with difficult-to-treat chronic back pain, high-frequency SCS provided significant and

sustained low back pain and leg pain relief to more than 70% of treated subjects. Notably, this was achieved without paresthesia.

Patients also experienced significant improvement in disability and sleep. Overall, the results confirm a favorable safety and

efficacy profile of the high-frequency SCS system.

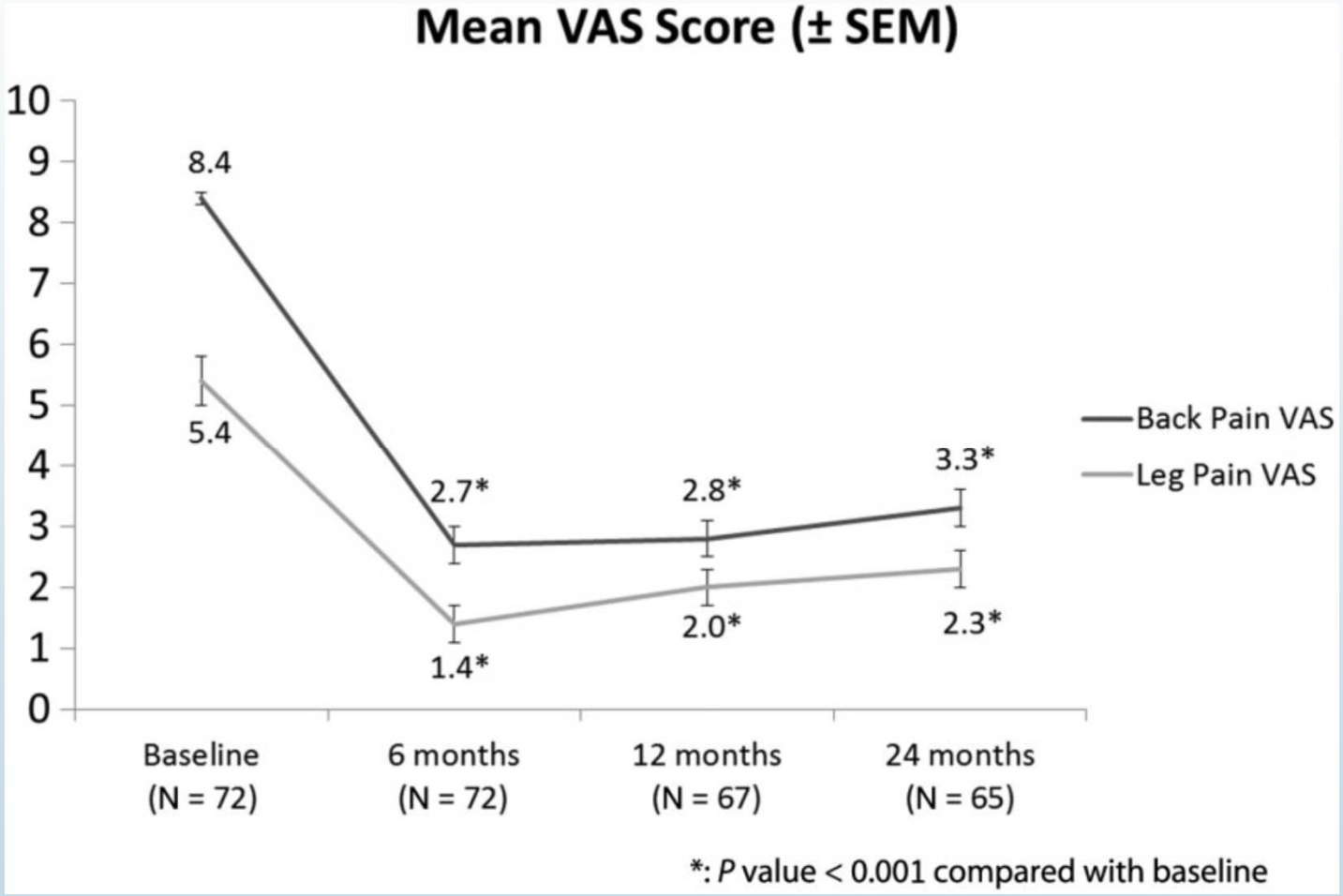

T8
T12

Results. After a trial period, 88% (72 of 82) of patients reported a significant improvement in pain scores and underwent the permanent implantation of the system. Ninety percent (65 of 72) of patients attended a 24-month follow-up visit. Mean back pain was reduced from 8.4 ± 0.1 at baseline to 3.3 ± 0.3 at 24 months ($P < 0.001$), and mean leg pain from 5.4 ± 0.4 to 2.3 ± 0.3 ($P < 0.001$). Concomitantly to the pain relief, there were significant decreases in opioid use, Oswestry Disability Index score, and sleep disturbances. Patients' satisfaction and recommendation ratings were high. Adverse Events were similar in type and frequency to those observed with traditional SCS systems.

Conclusions. In patients with chronic low back pain, HF10 SCS resulted in clinically significant and sustained back and leg pain relief, functional and sleep improvements, opioid use reduction, and high patient satisfaction. These results support the long-term safety and sustained efficacy of HF10 SCS.

Sustained Effectiveness of 10 kHz High-Frequency Spinal Cord Stimulation for Patients with Chronic, Low Back Pain: 24-Month Results of a Prospective Multicenter Study

Adnan Al-Kaisy, MD,*1 Jean-Pierre Van Buyten, MD,†1 Iris Smet, MD,† Stefano Palmisani, MD,* David Pang, MD,* and Thomas Smith, MD*


Mean VAS Score (± SEM)
10
9
8
7
6
5
4
3
2
1
0
8.4
5.4
2.7*
1.4*
2.8*
2.0*
3.3*
2.3*
Back Pain VAS
Leg Pain VAS
Baseline
(N = 72)
6 months
(N = 72)
12 months
(N = 67)
24 months
(N = 65)
*: P value < 0.001 compared with baseline

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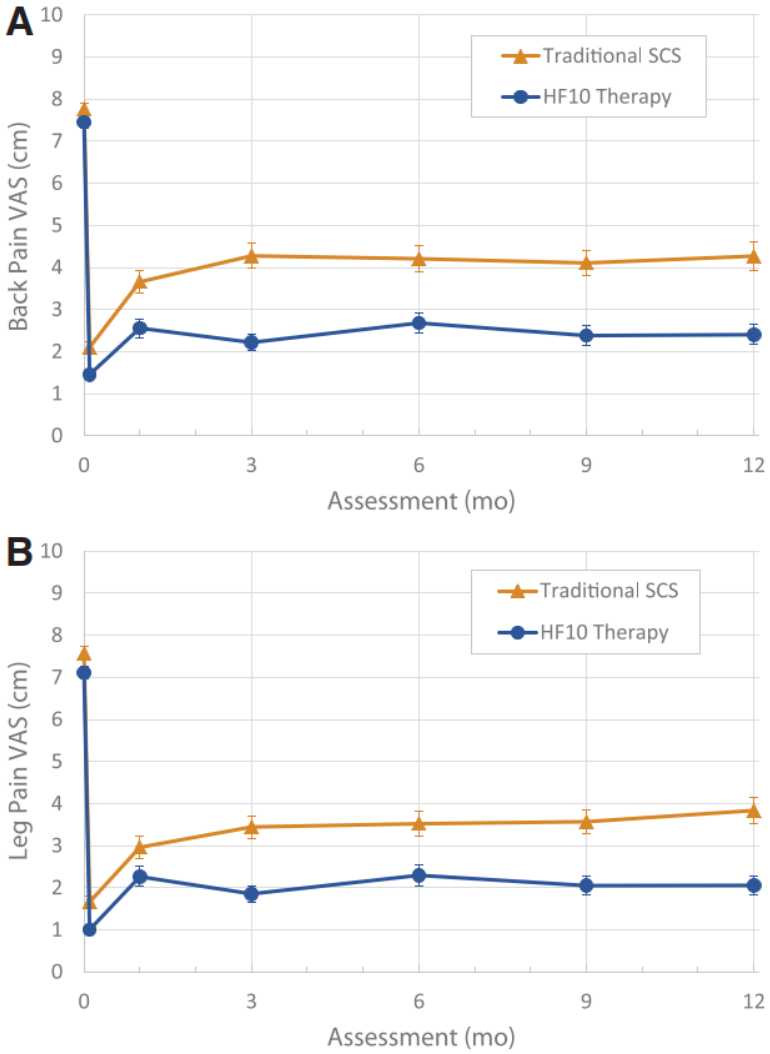
What We Already Know about This Topic

- Spinal cord stimulation (SCS) often relieves radicular pain but is relatively poorly effective for the treatment of back pain
- High-frequency SCS may improve the efficacy of SCS for the treatment of low back pain

What This Article Tells Us That Is New

- This randomized trial involving 198 participants demonstrated that high-frequency spinal cord stimulation (SCS) was superior to conventional SCS for the treatment of back pain and leg pain
- The effects of high-frequency stimulation relative to conventional stimulation persisted for 12 months

Kapural L, Cong Y, Doust MW et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg PainThe SENZA-RCT Randomized Controlled TrialAnesthesiology 2015; 123:851-60



Longitudinal back and leg pain visual analog scale (VAS) scores. Values at time 0 represent baselines scores, whereas values at time 0.1 represent results at the end of trial phase. (A) Back pain VAS, mean (SEM). (B) Leg pain VAS, mean (SEM). HF10 = 10-kHz high-frequency; SCS = spinal cord stimulation.

Kapural L, Cong Y, Doust MW et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg PainThe SENZA-RCT Randomized Controlled TrialAnesthesiology 2015; 123:851-60

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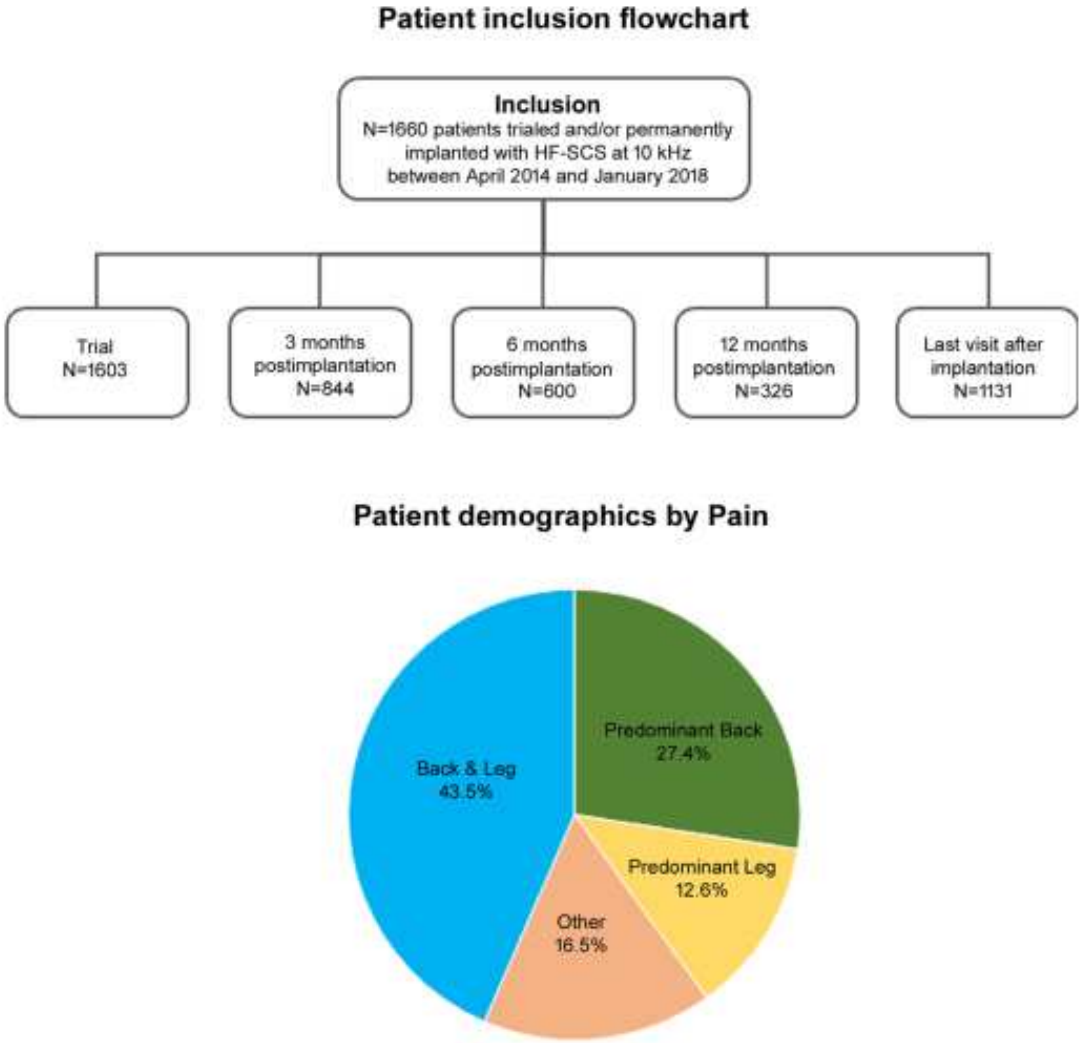

Figure 1. Flowchart detailing the number of patients included in the review and analyzed at each study time point for therapy response and pie chart showing patient demographics by pain type. Due to the collection of data in a real-world setting, only a fraction of patients had information at 3, 6, and 12 months, whereas majority had information at last visit assessment.

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

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Table 1. Patient characteristics at baseline. Data is presented as % (95% confidence lower limit-upper limit).

Characteristic	Europe (%)	USA (%)	All (%)
Pain distribution	*N* = 479	*N* = 1161	*N* = 1640
Back and leg	39.7% (36.9%–42.5%)	45.0% (40.5%–49.5%)	43.5% (41.1%–45.9%)
Predominant back	24.6% (22.1%–27.1%)	28.6% (24.6%–32.6%)	27.4% (25.2%–29.6%)
Predominant leg	14.8% (12.8%–16.8%)	11.7% (8.8%–14.6%)	12.6% (11.0%–14.2%)
Other	20.9% (18.6%–23.2%)	14.6% (11.4%–17.8%)	16.5% (14.7%–18.3%)
LF-SCS experience	*N* = 443	*N* = 1153	*N* = 1596
Prior experience	20.5% (16.7%–24.3%)	25.2% (22.7%–27.7%)	23.9% (21.8%–26.0%)
No prior experience	79.5% (75.7%–83.3%)	74.8% (72.3%–77.3%)	76.1% (74.0%–78.2%)
Pain intensity	*N* = 479	*N* = 1124	*N* = 1603
Median pain intensity score (VNRS)	9.0 (Q1–Q3, 8.0–9.5)	8.0 (Q1–Q3, 7.0–9.0)	8.0 (Q1–Q3, 7.0–9.0)

LF-SCS, Low-frequency spinal cord stimulation; VNRS, 11-point verbal numeric rating scale (0 = no pain to 10 = worst possible pain).

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

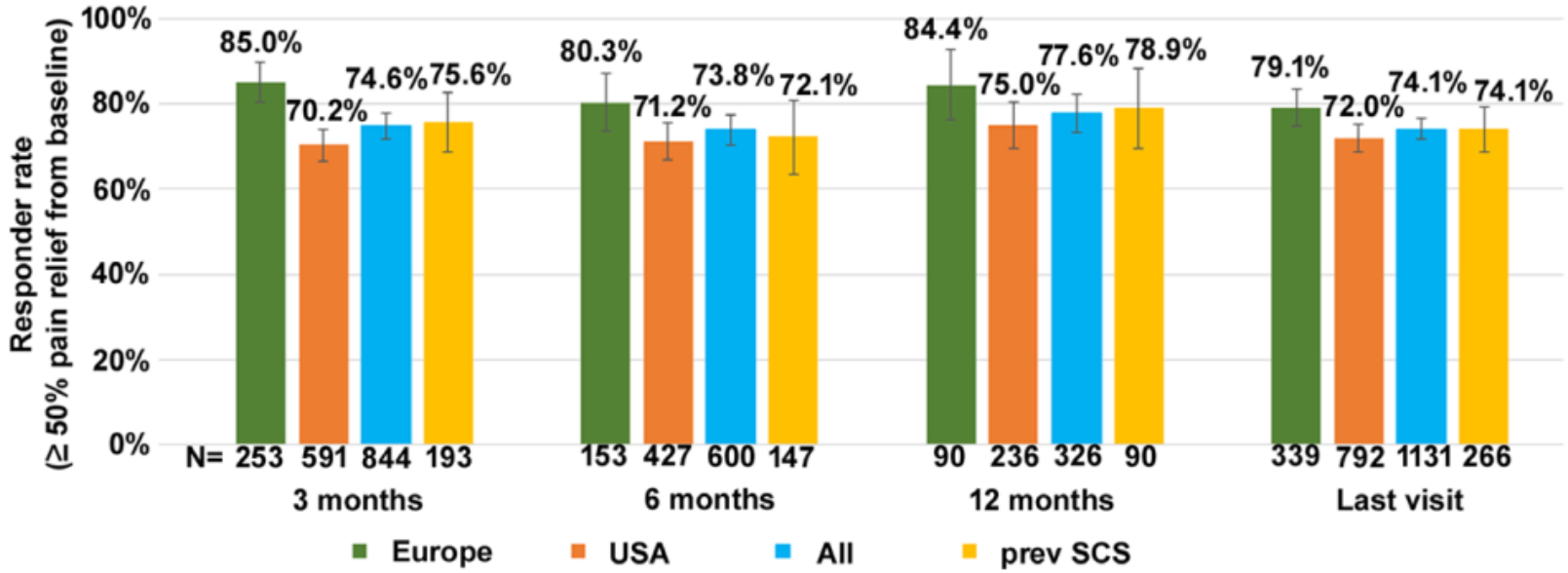

Figure 2. Responder rate (±95% confidence interval) at each study time point.

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

Table 2. Details of device explants in the population.

Reason for explant	*n* (%; 95% confidence range)
	N = 1290
Infection	22 (1.7%; 1.0%–2.4%)
Loss of efficacy	15 (1.2%; 0.6%–1.8%)
Other reasons	11 (0.8%; 0.3%–1.3%)
Total	48 (3.7%; 2.7%–4.7%)

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

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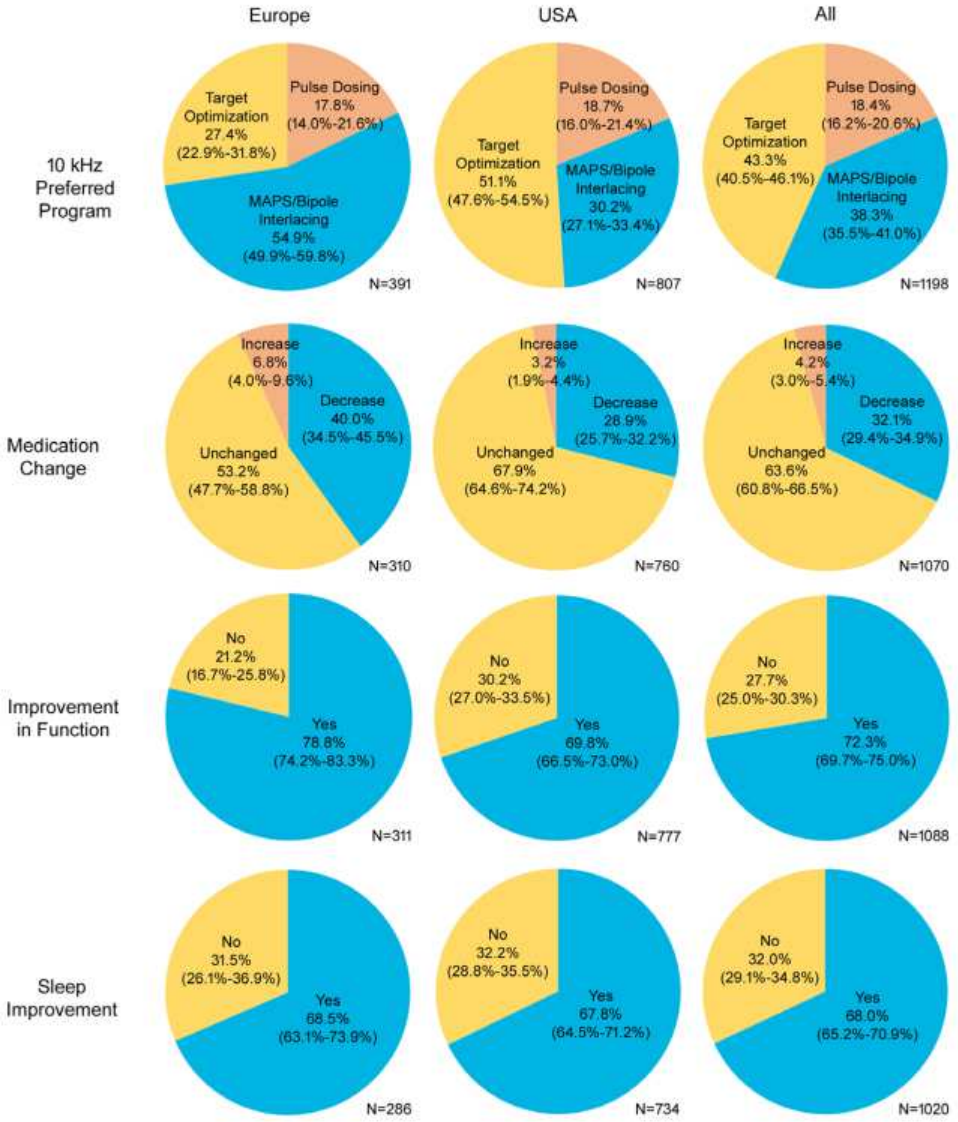

Figure 3. Evaluation of therapy optimization tools (10 kHz preferred program) and overall change in medication, function, and sleep, at the last visit. Therapy optimization tools: Multi-area pain sequencing (MAPS) combines different programs; bipole interlacing merges multiple bipole programs into one program; pulse dosing delivers stimulation in on-off cycles. Values given as % with 95% confidence interval.

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

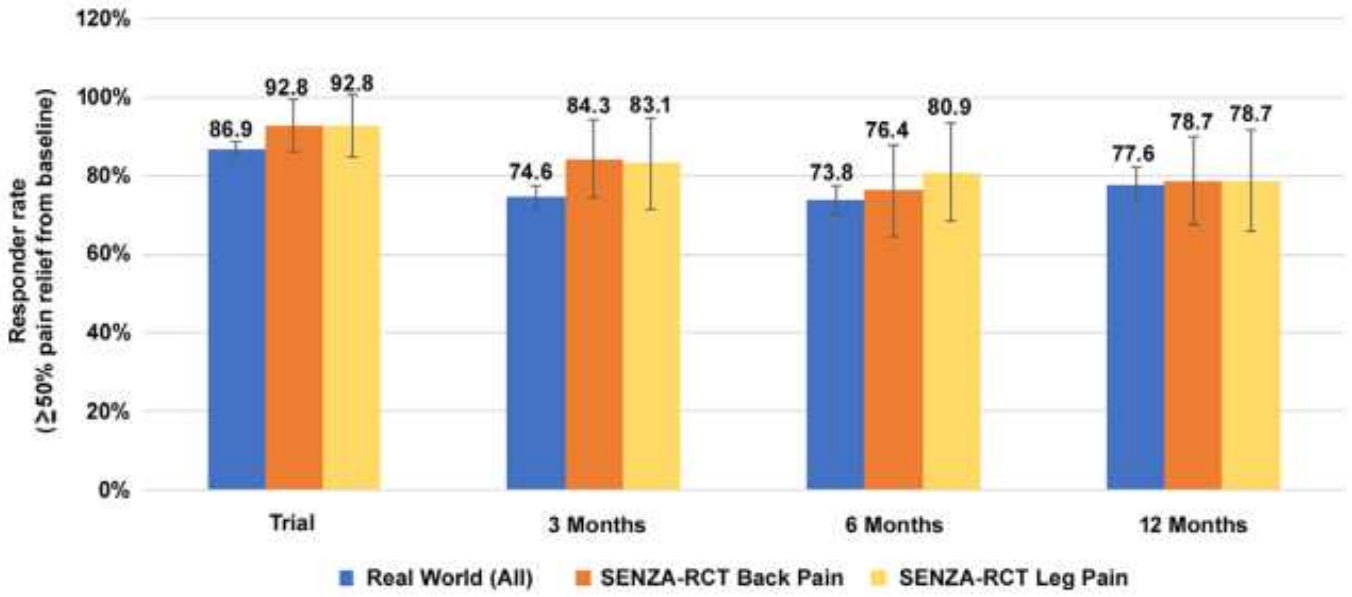

Figure 4. Comparison of responder rates (±95% confidence interval) between this real-world study and the SENZA-RCT.

Stauss T, Majoub FE, Sayed D et al.A multicenter real-world review of 10 kHz SCS outcomes for treatment of chronic trunk and/or limb pain. Annals of Clinical and Translational Neurology 2019; 6(3): 496–507

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Chronic pain is a common condition that affects the physical, emotional, and mental well-being of patients and can significantly diminish their quality of life.

Due to growing concerns about the substantial risks of long-term opioid use, both governmental agencies and professional societies have recommended prioritizing the use of nonpharmacologic treatments, when suitable, in order to reduce or eliminate the need for opioid use.

The use of 10 kHz spinal cord stimulation (10 kHz SCS) is one such nonpharmacologic alternative for the treatment of chronic, intractable pain of the trunk and limbs.

This review examines published clinical data regarding the efficacy of 10 kHz SCS for decreasing chronic pain in patients and its potential to reduce or eliminate opioid usage.

Multiple prospective and retrospective studies in patients with intractable pain demonstrated that 10 kHz SCS treatment provided ≥50% pain relief in >70% patients after at least 1 year of treatment. Pain relief with 10 kHz SCS therapy ranged from 54% to 87% in the studies.

More importantly, the mean daily dose of opioids required by patients in these studies was reduced after 10 kHz SCS treatment, and on average over 60% patients in studies either reduced or eliminated opioids at the last follow-up.

Al-Kaisy A, Buyten JPV, Amirdelfan K et al. Opioid-sparing effects of 10 kHz spinal cord stimulation:a review of clinical evidence. Ann. N.Y. Acad. Sci. xxxx (2019) 1–12

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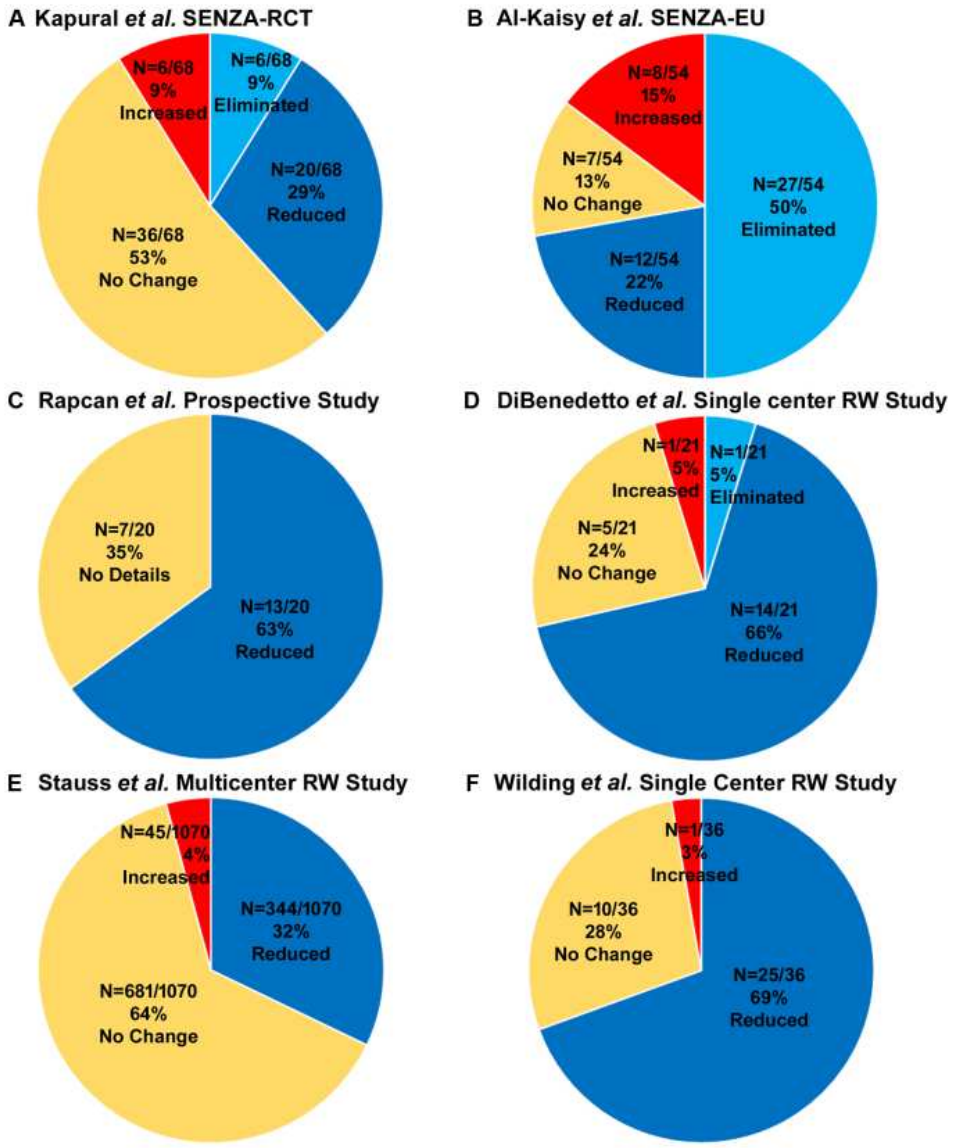

Figure 1. Studies reporting the opioid reduction in low back and leg pain patients. (A) SENZA-RCT study by Kapural *et al.* (B) SENZA-EU study by Al-Kaisy *et al.* (C) Prospective study by Rapcan *et al.* (D) Retrospective case–controlled study by DeBeneditto *et al.* (E) Retrospective real-world study by Stauss *et al.* (F) Retrospective real-world study by Wilding *et al.*

Al-Kaisy A, Buyten JPV, Amirdelfan K et al. Opioid-sparing effects of 10 kHz spinal cord stimulation:a review of clinical evidence. Ann. N.Y. Acad. Sci. xxxx (2019) 1–12

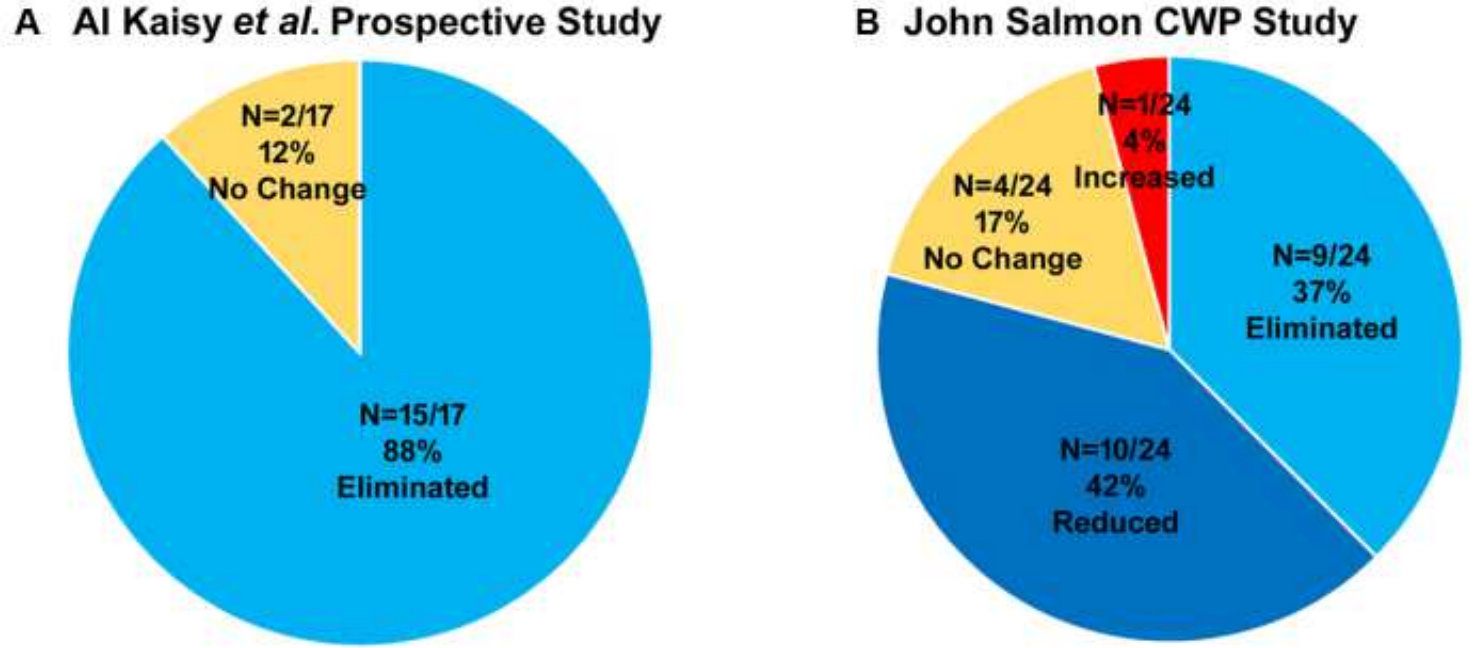

Figure 2. Studies reporting the opioid reduction in other neuropathic pain. (A) Prospective study in NSRBP subjects. (B) Retrospective study in chronic widespread pain patients.

Al-Kaisy A, Buyten JPV, Amirdelfan K et al. Opioid-sparing effects of 10 kHz spinal cord stimulation:a review of clinical evidence. Ann. N.Y. Acad. Sci. xxxx (2019) 1–12

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DOSING IN THE LITERATURE
CHARACTERIZING DOSE

Higher dose compared to conventional programs:

- Lower amplitude
- Higher duty cycle
- Higher charge per second

	Conventional	Burst	10 kHz
Amplitudes	3.6 mA	1.73 mA	1.6 mA
Charge per Pulse	1.25 µC	1.7 µC	0.05 µC
Duty Cycle Pulse width Frequency	**1.4%** 347 µs 39 Hz	20% 1000 µs 200 Hz	30% 30 µs 10 kHz
Charge Per Second (Stimulation dose)	**49 µC/sec**	**346 µC/sec**	**500 µC/sec**

Modified from Table 2: Miller JP, Eldabe S, Buchser E, et al. Parameters of Spinal Cord Stimulation and Their Role in Electrical Charge Delivery: A Review. *Neuromodulation*. 2016;19(4):373-384.
Deer T, Slavin KV, Amirdelfan K, et al., Success Using Neuromodulation With BURST (SUNBURST) Study: Results From a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform. Neuromodulation. 2017 Sep 29. doi: 10.1111/ner.12698. [Epub ahead of print]

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EVOLVE^{SM} WORKFLOW
WHAT IS IT?

Manage Patient Expectations

Manage Patient Expectations

Evolve^{SM} Workflow

Standardized guidance to simplify the trial and implant experience, and optimize patient options

1 **IF** lead placement spans the T9/T10 space after mapping,

THEN consider the Evolve^{SM} workflow deliberate dose strategy, using both HD and LD.

2 The suggested dose sequence begins with predefined HD settings.

HD → **LD**

3 **DILIGENT PATIENT FOLLOW-UP** TO ASSESS FOR OPTIMAL PROGRAMMING

Manage Patient Expectations

Manage Patient Expectations

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EVOLVE^{SM} WORKFLOW
WHY TARGET STIMULATION AT T9-T10

Barolat G, Massaro F, He J, Zeme S, Ketcik B. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. *J Neurosurg.* 1993;78(2):233-239.

- N=106, In our experience, the best location was at about T9-T10, with an electrode placed strictly at midline.

Sharan A, Camer… …le low back and leg pain. *Neuromodu…*

- N=26, low b…

North RB, Kidd DH… …mparing dual with single percutaneo…

- N=20, Axial…

Multiple studies provide evidence for targeted stimulation at or around T9-T10

North RB, Kidd DH, Olin J, Sieracki JN, Petrucci L. Spinal cord stimulation for axial low back pain: a prospective controlled trial comparing 16-contact insulated electrodes with 4-contact percutaneous electrodes. *Neuromodulation.* 2006;9(1):56-67

- N=16, Axial low back pain, Typical optimal electrode positions spanned T9/T10

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EVOLVE^{SM} WORKFLOW
WHY 1000 Hz & 90 µSEC

PREDEFINED HD PARAMETERS

WHY FOCUS ON 1000 HZ & 90µs?

- The Options Study suggests that patients respond to the HD setting of 1000 Hz, 90 µsec.
- Additionally, published literature shows improved NPRS pain scores utilizing 1000 Hz stimulation when compared to baseline.[2]

SCS TRIALING[1]

- 84% (37/44) reported ≥50% improvement in overall pain during the screening trial while programmed to HD.
- 70% of subjects had a successful trial when programmed to 1000 Hz and 90 µsec.

3 Month outcomes (N=32)[1]

- Overall pain change from: baseline -3.7 ($p<0.01$)
- Back pain change from baseline: -3.8 ($p<0.01$)
- Leg pain change from baseline: -4.1 ($p<0.01$)

1. Medtronic Options study, Final Clinical Report, version 1.0, clinicaltrials.gov – NCT02503787
2. North JM, et al. Clinical Outcomes of 1 kHz Subperception Spinal Cord Stimulation in Implanted Patients With Failed Paresthesia-Based Stimulation: Results of a Prospective Randomized Controlled Trial. Neuromodulation: Technology at the Neural Interface. 2016

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RETROSPECTIVE, MULTI-CENTER COHORT STUDY EVALUATING A NOVEL HIGH DOSE SCS WORKFLOW FOR POST-LAMINECTOMY BACK AND LEG PAIN

FULL ANALYSIS – PRESENTED AT AAPM APRIL, 2018

- 7 Centers across the US
- Inclusion Criteria:
  - FBSS, ICD 10
  - Back and Leg Pain
  - **Overall Baseline Pain ≥ 5**
  - **SCS screening trial beginning with HD (1000Hz, 90*μs*) at the T9-T10 interspace**
  - **Documented programming** (HD/LD/HD+LD) **during 1-3 month follow up period**
- Cohorts Evaluated:
  - **114 SCS Screening Trials**
  - **57 Patients had evaluations 1-3 months post operatively**
  - **39 Patients had an additional evaluation at 3+ months post operatively**

Verdolin M, Hatheway J, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Presented at the American Academy of Pain Medicine (AAPM) congress April 26-29, 2018; Vancouver Canada. Abstract LB004.

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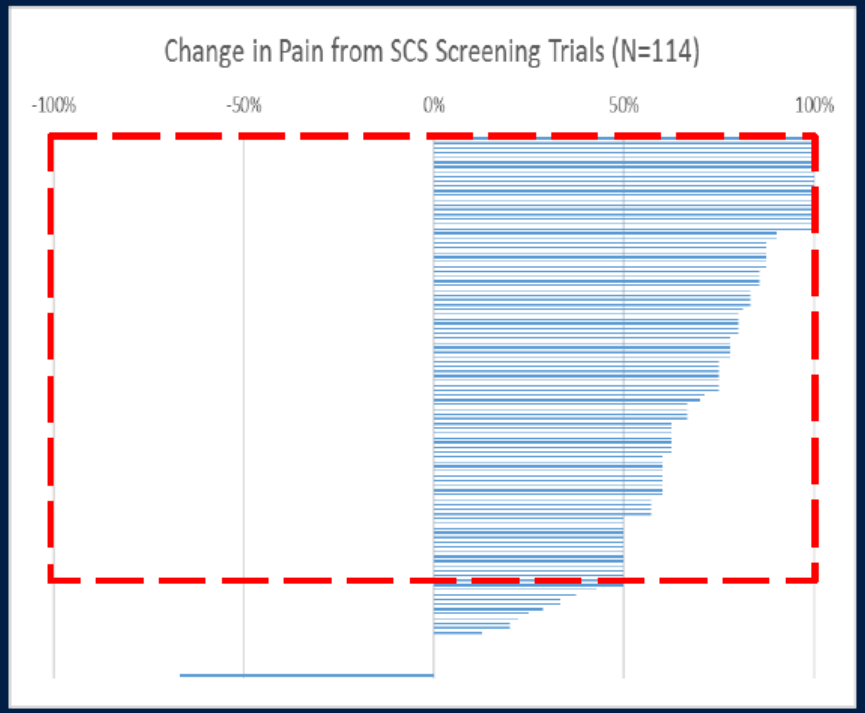
RETROSPECTIVE, MULTI-CENTER COHORT STUDY EVALUATING A NOVEL HIGH DOSE SCS WORKFLOW FOR POST-LAMINECTOMY BACK AND LEG PAIN

FULL ANALYSIS

SCS Screening Trial Outcomes (114)

Pre-Trial Pain	7.36
Post Trial Pain	2.62
Mean change in Pain	4.74
Number of Responders (50%)	95
Percentage of Responders (50%)	83.33%
% Improvement in Responder Group	75.16%



Verdolin M, Hatheway J, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Presented at the American Academy of Pain Medicine (AAPM) congress April 26-29, 2018; Vancouver Canada. Abstract LB004.

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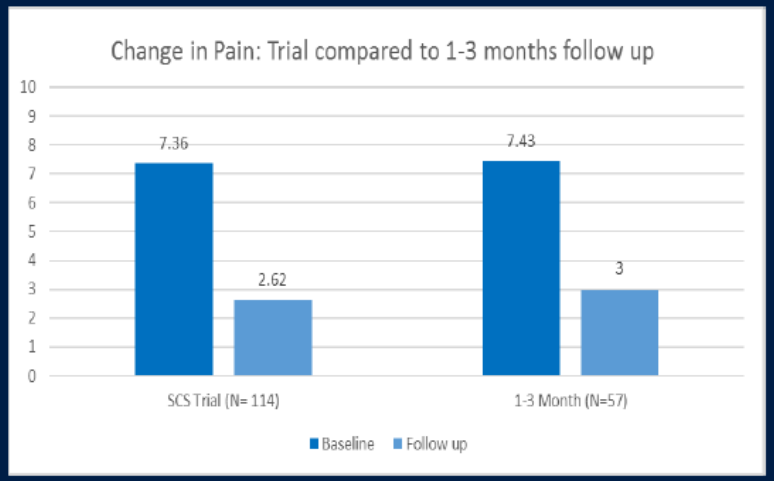
RETROSPECTIVE, MULTI-CENTER COHORT STUDY EVALUATING A NOVEL HIGH DOSE SCS WORKFLOW FOR POST-LAMINECTOMY BACK AND LEG PAIN

FULL ANALYSIS

1-3 Month Outcome Assessment

Visit Completed	57
Pre-Trial Pain	7.43
1-3 Month Pain Score	3
Mean change in Pain	4.43
Percentage change in Pain	59.72%
Percentage of Patients on HD	87.72%



Verdolin M, Hatheway J, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Presented at the American Academy of Pain Medicine (AAPM) congress April 26-29, 2018; Vancouver Canada. Abstract LB004.

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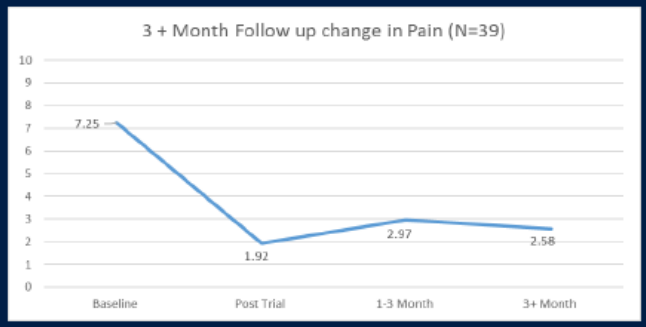
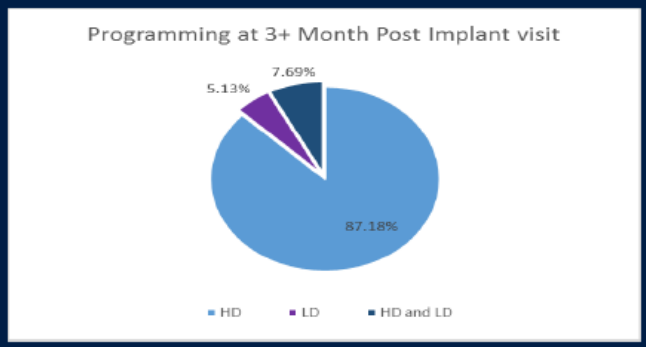
RETROSPECTIVE, MULTI-CENTER COHORT STUDY EVALUATING A NOVEL HIGH DOSE SCS WORKFLOW FOR POST-LAMINECTOMY BACK AND LEG PAIN

FULL ANALYSIS

3+ Month Outcome Assessment

Visit Completed (incl 1-3 month visit)	39
Pre-Trial Pain	7.25
Post-Trial	1.92
1-3 Month Pain Score	2.97
3+ Month Pain Score	2.58
Mean change in Pain	4.67
Percentage change in Pain	65.51%
Percentage of Patients on HD at 3 + Months	87.18%
Percentage of Patients on LD at 3 + Months	5.13%
Percentage using both HD and LD	7.69%





Verdolin M, Hatheway J, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Presented at the American Academy of Pain Medicine (AAPM) congress April 26-29, 2018; Vancouver Canada. Abstract LB004.

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KEY HIGHLIGHTS FROM VECTORS 6 MONTH RESULTS:

- Pain relief was statistically significant at 3-Months (primary outcome) and was sustained through 6-Month follow up.
- Responder rates (≥50% reduction in pain) at 6 months were; **67.7%** for Overall Pain, **59.4%** for Low-back pain and **74.0%** for Leg Pain
- Improvements in Quality of Life (EQ-5D) and reduced disability (ODI) remained significant and were sustained between 3-Months and 6-Months follow up.
- Therapy Satisfaction increased from 81% at 3 Months to **90%** at 6 Months.

Materials and methods (cont..)

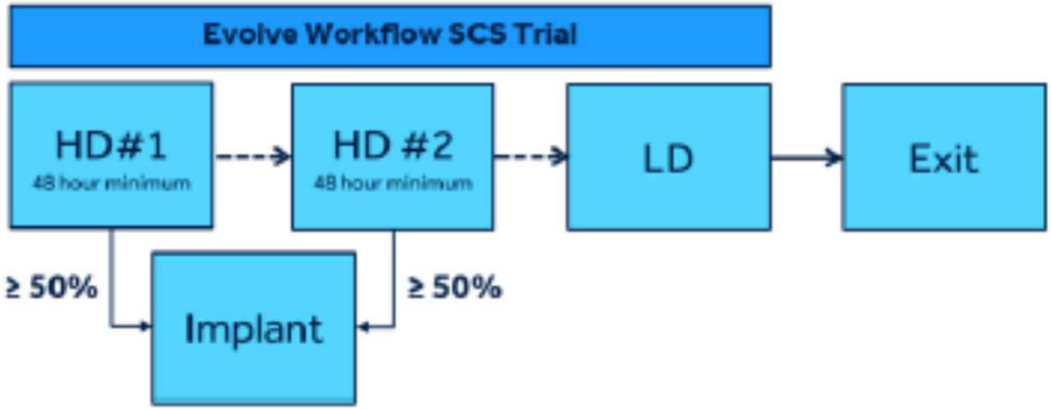

Figure 1: Programming workflow

M Fishman, MD1, D Provenzano, MD2, T Weaver et al.Vectors Study: Spinal cord stimulation (SCS) trialing duration and long-term pain relief following trial success

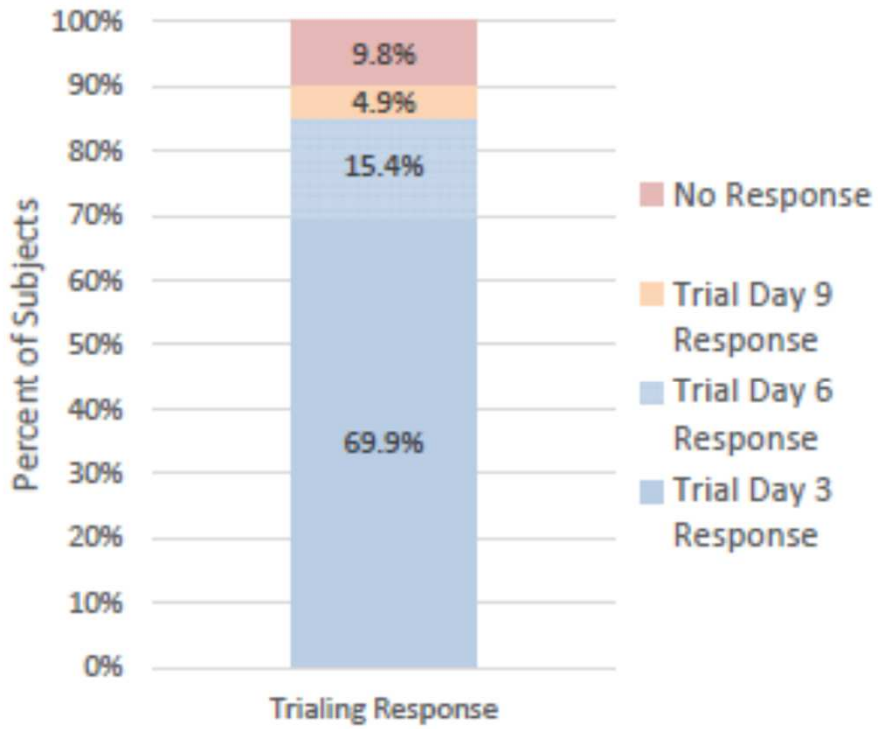

Figure 2: Trial outcome by Visit

M Fishman, MD1, D Provenzano, MD2, T Weaver et al.Vectors Study: Spinal cord stimulation (SCS) trialing duration and long-term pain relief following trial success

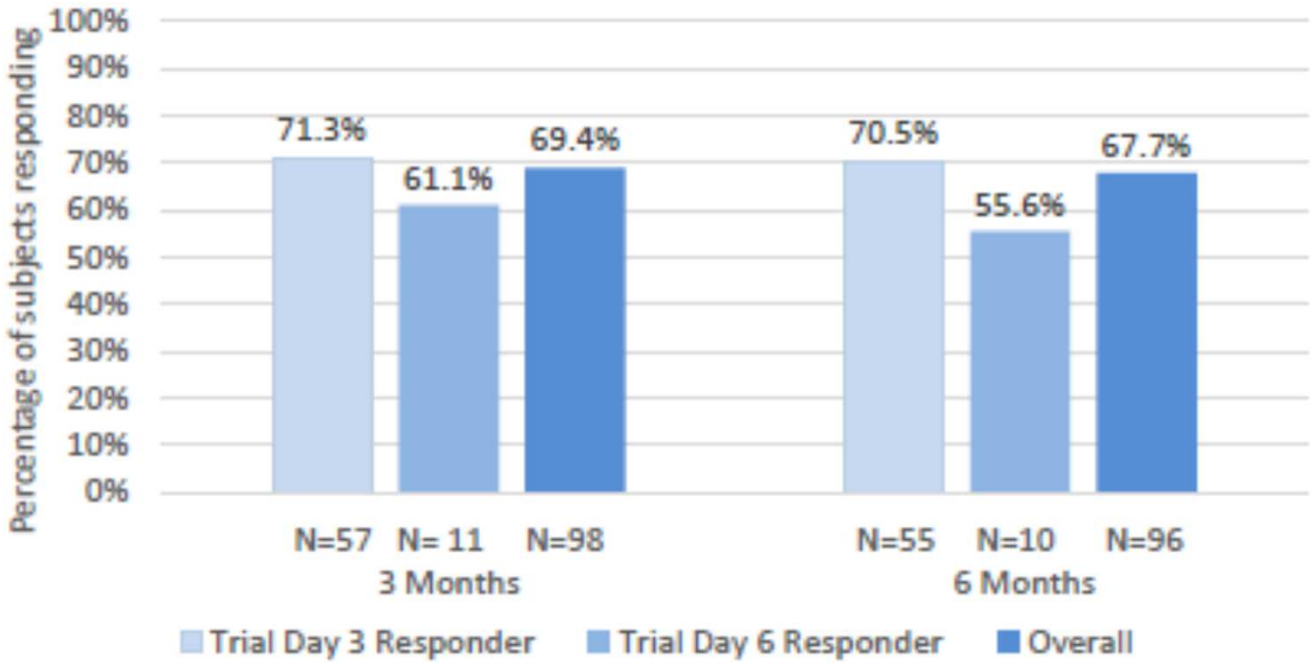

Figure 3: Overall responder rates by Trial-success duration at 3 and 6 months

M Fishman, MD1, D Provenzano, MD2, T Weaver et al.Vectors Study: Spinal cord stimulation (SCS) trialing duration and long-term pain relief following trial success

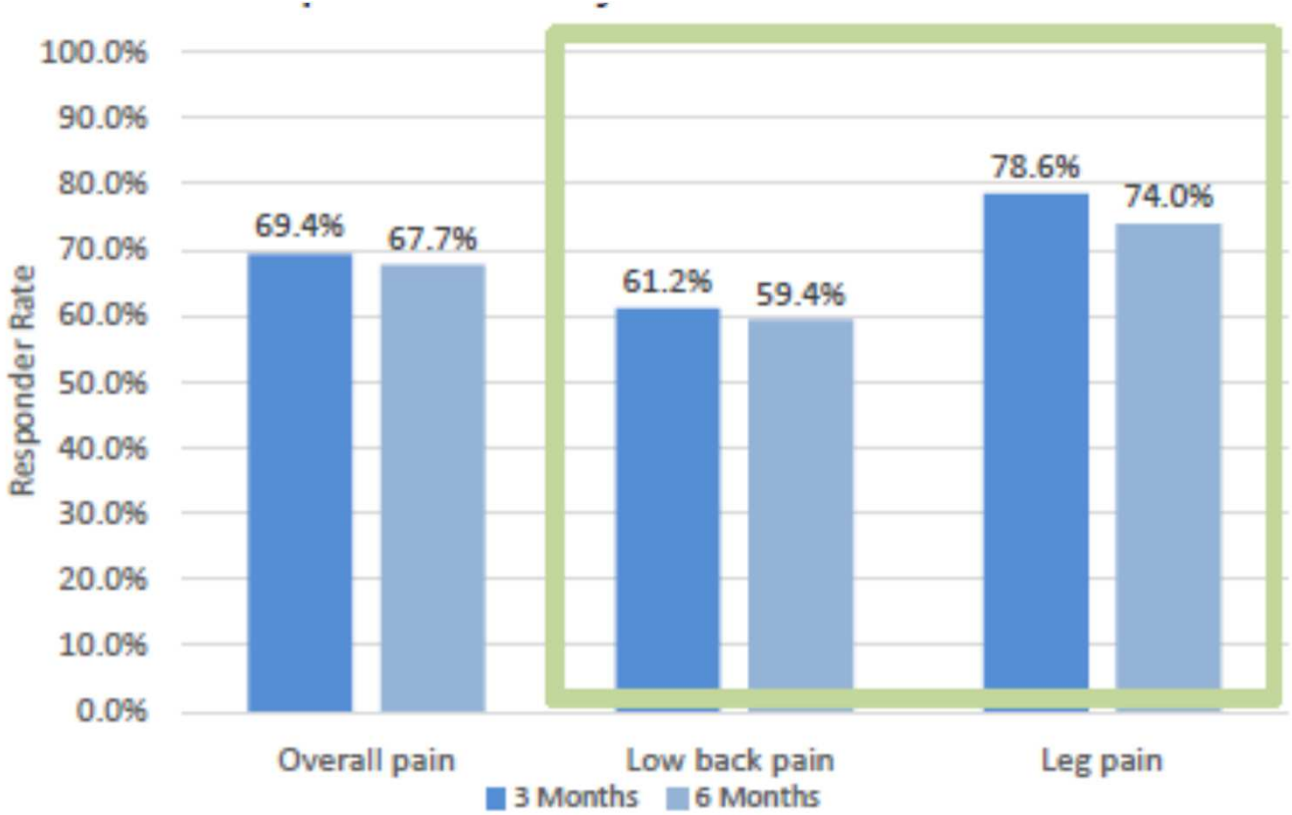

Figure 4: Overall, low-back and leg responder rates at 3 and 6 months

M Fishman, MD1, D Provenzano, MD2, T Weaver et al.Vectors Study: Spinal cord stimulation (SCS) trialing duration and long-term pain relief following trial success

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Conclusions

Results suggest that a positive trial within 3 days is indicative of longer-term pain relief. There is still a potential benefit for a group of patients to have a longer trial experience. Longer-term follow-up data will be useful to better understand the predictive role of trials and the sustained effectiveness of pain relief

- 71% of subjects with a positive trial at Day 3 were overall responders at 3 months
- 70% of subjects with a positive trial at Day 3 were overall responders at 6 months

References:

1.Barolat G, Massaro F, He J, ZemeS, KetcikB. Mapping of sensory responses to epidural stimulation of the intraspinal neural structures in man. J Neurosurg. 1993;78(2):233-239.

2.Barolat G, Oakley JC, Law JD, North RB, KetcikB, Sharan A. Epidural spinal cord stimulation with a multiple electrode paddle lead is effective in treating intractable low back pain. Neuromodulation. 2001;4(2):59-66.

3.North J, Hon K, Cho P, Clinical outcomes of 1 kHz subperceptionspinal cord stimulation in implanted patients with failed paresthesia-based stimulation: results of a prospective randomized controlled trial. 2016;19(7):731-737.

4.Benyamin R, HathewayJA, Galan V, et al. Evaluating high dose parameters with spinal cord stimulation in failed back surgery syndrome patients. Neuromodulation: Technology at the Neural Interface. 2018;21(3):e1-e149

5.Verdolin M, HathewayJ, Roy L. A Large Retrospective, Multi-Center Cohort Study Evaluating a Novel SCS Workflow for Failed Back Surgery Syndrome (FBSS) Back and Leg Pain: Final Analysis with 3+ Month Outcomes. Pain Medicine, Volume 19, Issue 5, 1 May 2018, Pages 1104–1106. Abstract LB004 & Poster from AAPM, April 2018.

Schmerztherapie
Möglichkeiten einer symptomatischen Therapie

- Physikalische Therapie
- Medikamentöse Schmerztherapie
- Physiotherapeutische-Maßnahmen
- Psychologische Therapie
- Neurochirurgische/invasive Verfahren
- TENS Akupunktur

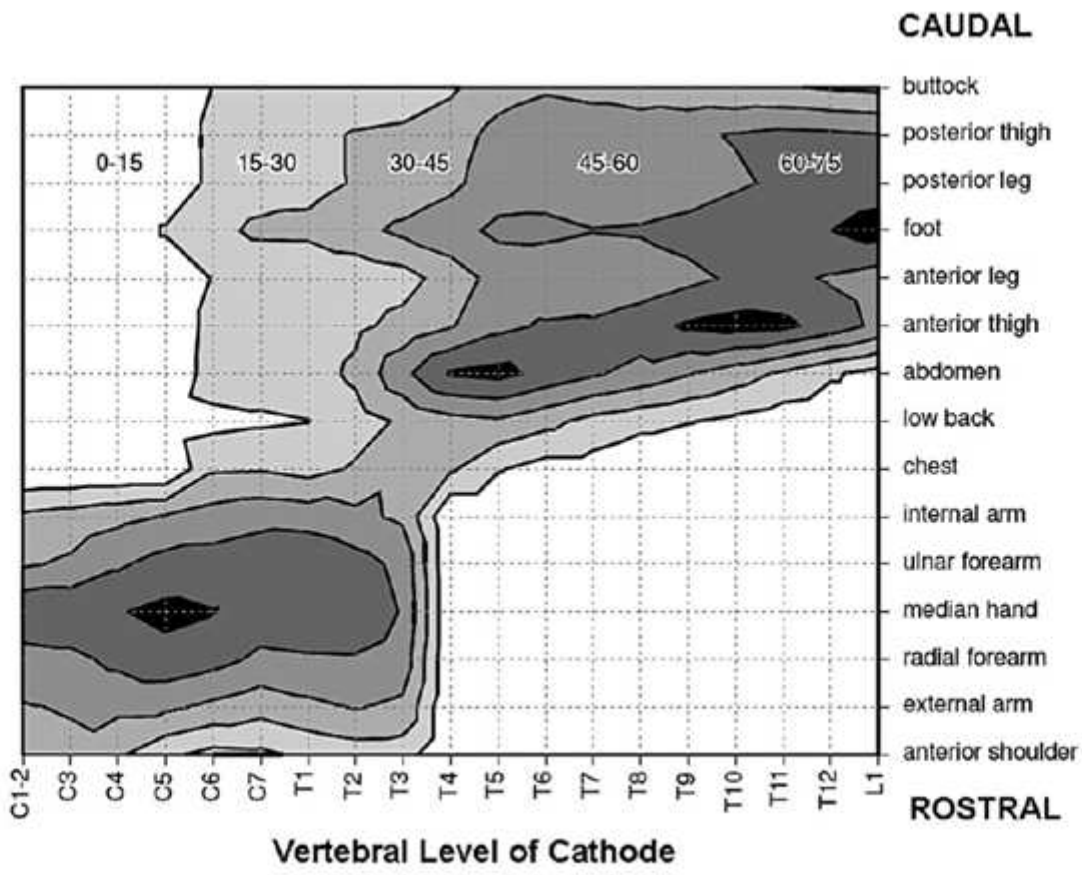
Danke für Ihre Aufmerksamkeit

Table 1. Clinical Correlates of Electrical Stimulation of Intraspinal Structures.

Anatomical structure(s)	Clinical correlates	Location in relation to the cathode
Dorsal root/dorsal root entry zone/dorsal horn	Paresthesia	Ipsilateral and at the same spine segment
Dorsal columns	Paresthesia	Ipsilateral and caudal
Ventral (anterior) roots/ventral motor neurons	Motor contractions	Ipsilateral and at the same spine segment
Corticospinal tract	Motor contractions	Ipsilateral and caudal
Spinothalamic tract*	Sensation of warmth	Contralateral and caudal
Autonomic fibers (inhibition of sympathetic fibers)	Sensation of warmth and vasodilation	Ipsilateral and caudal

*Cannot be obtained with dorsal epidural stimulation; has only been observed during the stimulation phase of percutaneous cordotomies.

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21



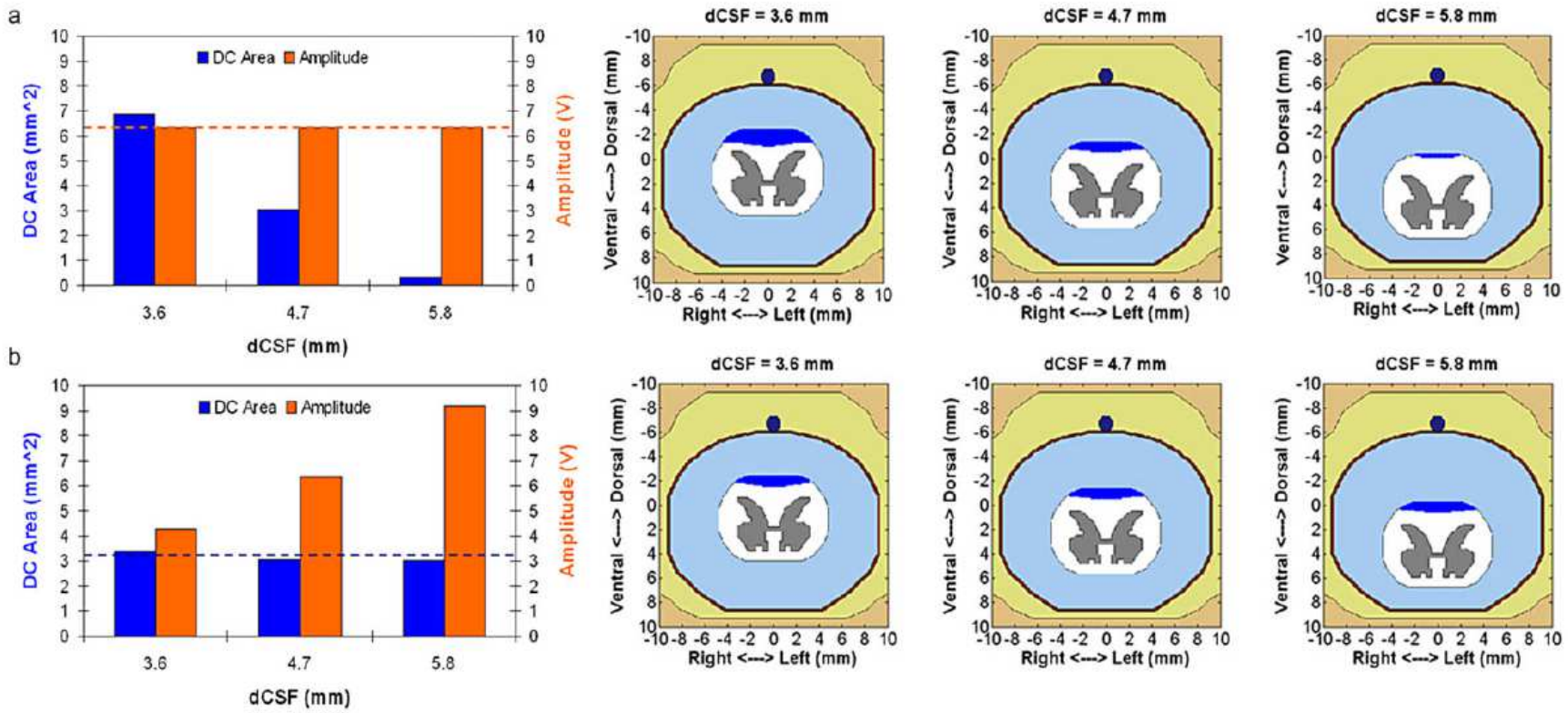
Probability of generating paresthesia in a particular body area as a function of vertebral level of the stimulating cathode. Figure modified from Holsheimer J, Barolat G. Neuromodulation. 1998;1 (3):129–136 (28).

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21

Table 2. Electrical Conductivity of Tissues Used in a Spinal Cord Stimulation Computer Model.

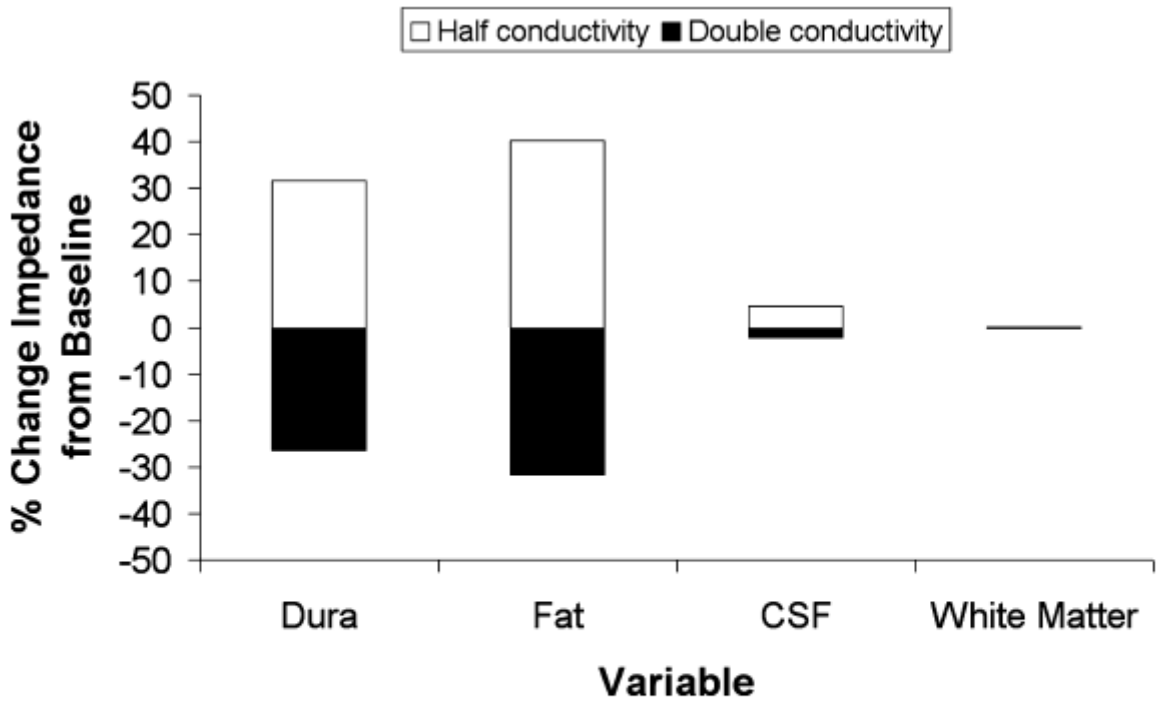
Structure	Conductivity (S/m)
Vertebral bone	0.02
Epidural fat	0.04
Dura mater	0.03
Cerebrospinal fluid (CSF)	1.7
White matter	0.6 longitudinal 0.083 transverse
Gray matter	0.23

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21



Neural activation patterns generated by varying dCSF (3.6, 4.7, and 5.8 mm) with a guarded cathode configuration and an amplitude at 60% of the usage range using (a) constant amplitude stimulation and (b) varying amplitude stimulation. The figures to the left of the neural activation patterns quantify the dorsal column recruitment area (DC area in mm^2) and stimulus amplitude as a function of dCSF.

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21



Doubling or halving the electrical conductivity of the tissues near the electrodes (fat, dura) in the spinal cord stimulation model results in larger changes in impedance compared with varying the electrical conductivity of tissues far away from the electrode (CSF or white matter).

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21

CONCLUSION

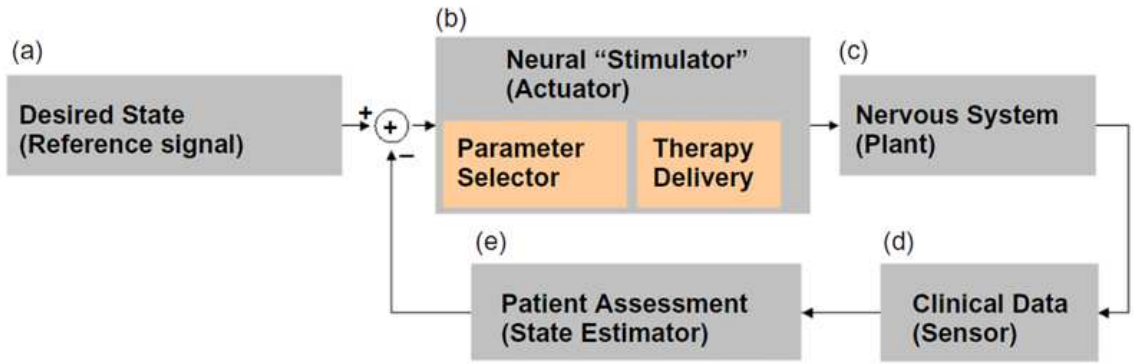
We have reviewed the basic principles of extracellular stimulation and their importance in understanding of the effects during SCS.

The electric field is influenced by the electrical properties of the tissue, the electrode placement and polarity, and the stimulation parameters.

The spatial extent of activation and the types of activated neural elements can be controlled by careful selection of stimulation parameters.

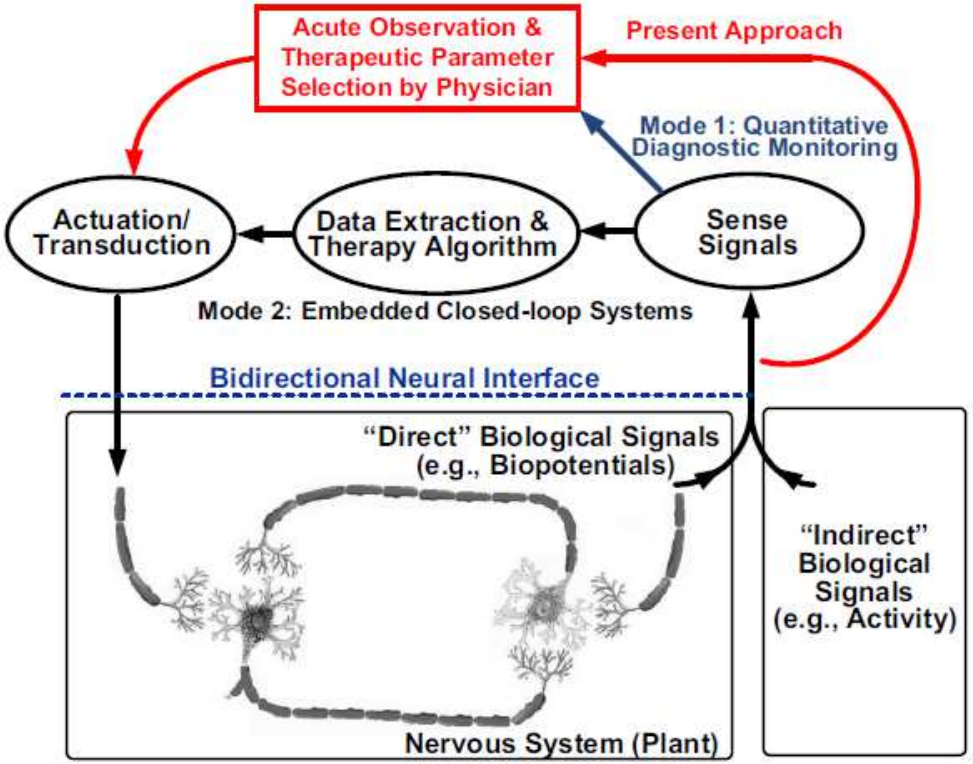
Better understanding of the interaction between the electric fields and the targeted neural elements may guide the selection of stimulation parameters and may lead to advances in engineering solutions for SCS.

Molnar G, Barolat G. Principles of Cord Activation During Spinal Cord Stimulation. Neuromodulation 2014; 17: 12–21



A dynamic control framework for analyzing neuromodulation systems. (a) Desired neurological state is the input reference signal; (b) the neural stimulator is the actuator; (c) the nervous system is the plant; (d) transducers and observations to collect clinical data are the sensors; and (e) patient assessment is the state estimator. In current clinical practice, the difference between a physician's observed estimate of the patient state and the desired clinical state drives parameter changes in the device, with adjustments often limited to sparsely sampled measurements. Figure reprinted with permission from Medtronic. © Medtronic, 2014

Denison T, Litt B. Advancing Neuromodulation Through Control Systems: A General Framework and Case Study in Posture-Responsive Stimulation. Neuromodulation 2014; 17: 48–57



Modeling clinical flow of a patient from a feedback perspective. The pathways can include clinician and/or patient feedback-based symptoms and observations, or be automated with embedded sensors and algorithms. In practice, most neuromodulation devices today are closed loop, but the clinician and patient form the feedback mechanism. Technology can improve these systems through two modes: (1) improving existing feedback paths with enhanced sensing of biomarkers or (2) closing the loop completely within the device. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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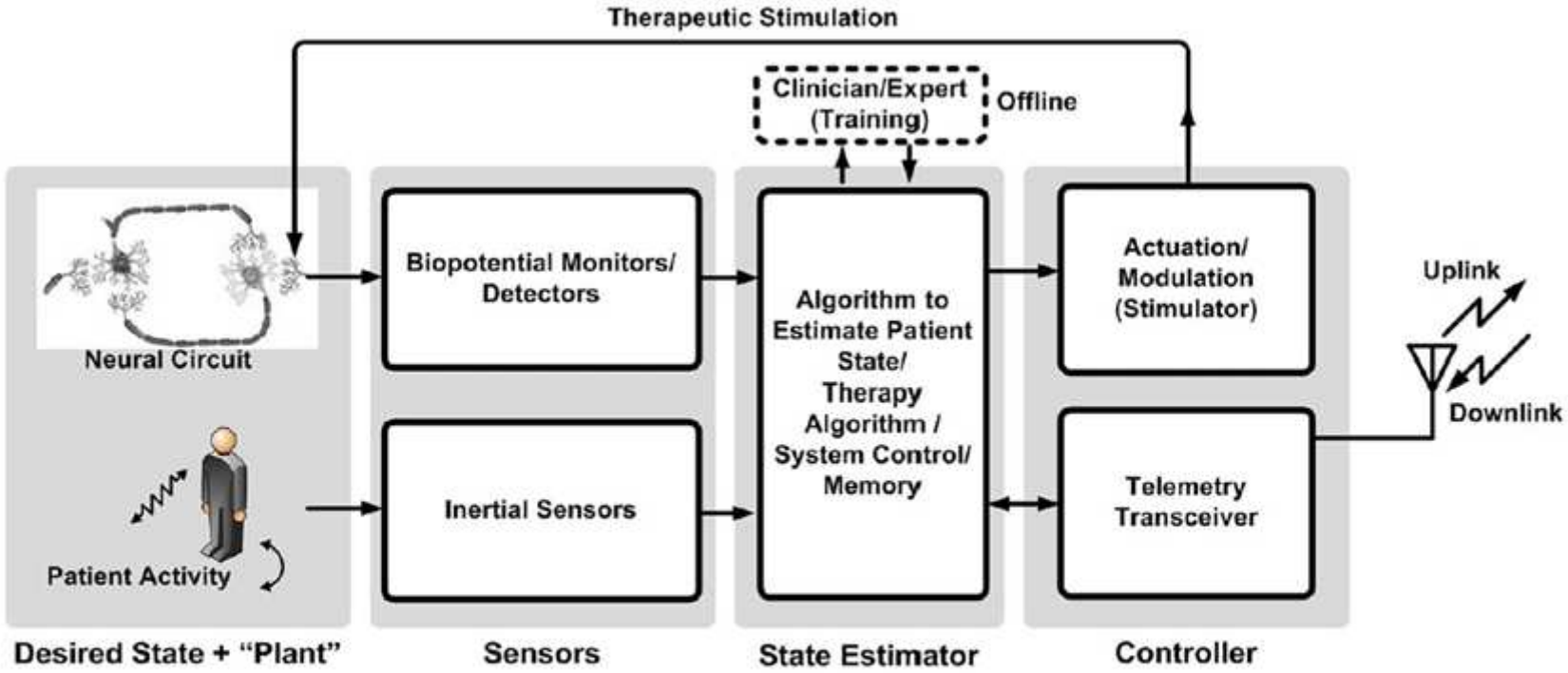
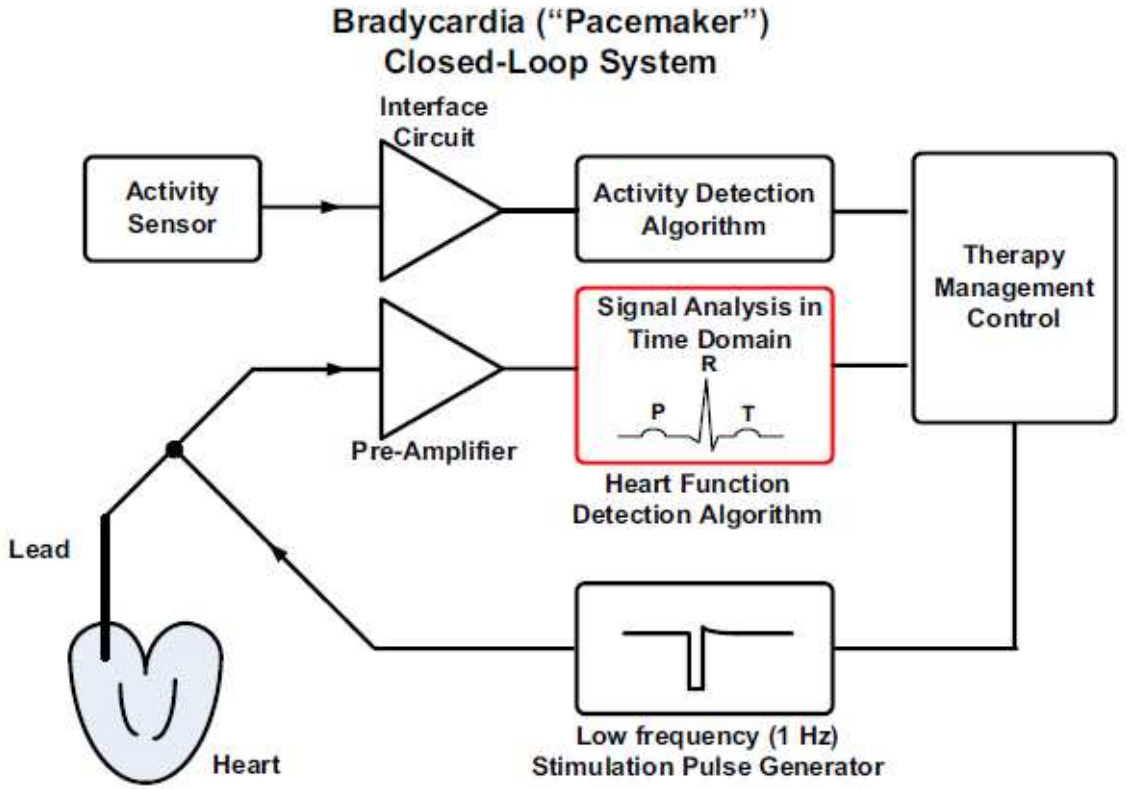


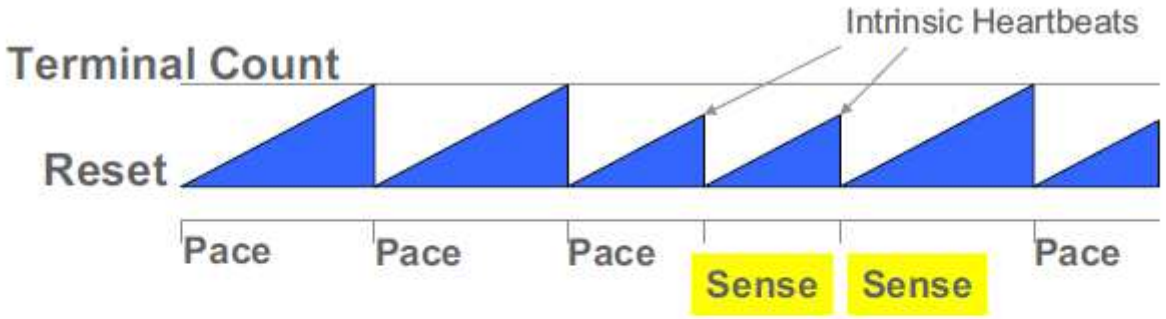
Mapping the abstracted feedback loops to a prototypical stimulator system. The key blocks in the diagram illustrate the technology required for the sensors, state estimator, and controller in a functional stimulator. Note that this is not an exhaustive list of components; for example, other sensors might include biochemical assays, impedance, and so on. Figure reprinted with permission from Medtronic. © Medtronic, 2014

Denison T, Litt B. Advancing Neuromodulation Through Control Systems: A General Framework and Case Study in Posture-Responsive Stimulation. Neuromodulation 2014; 17: 48–57



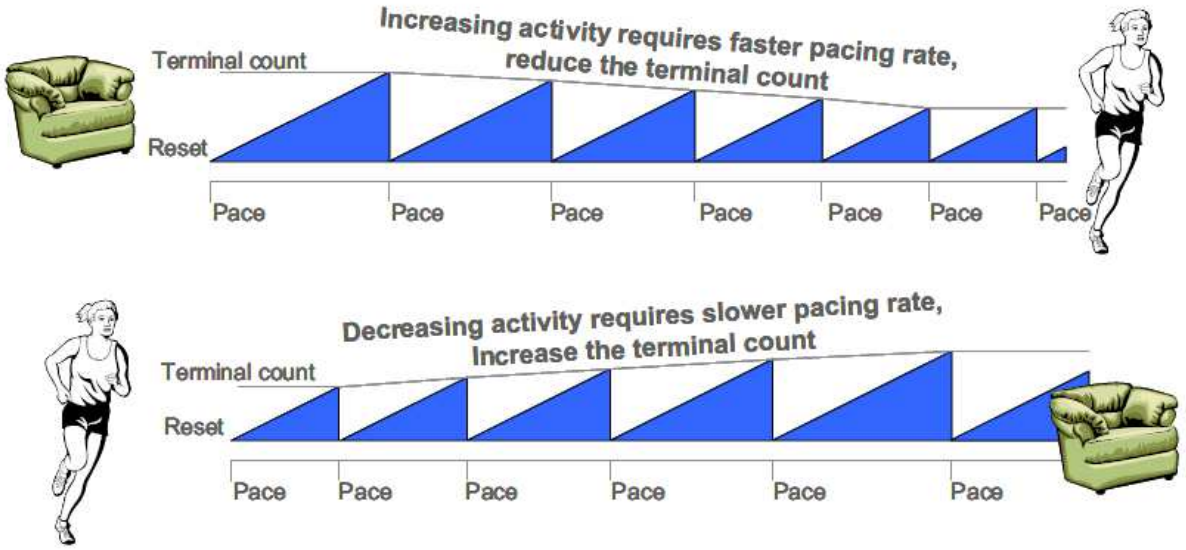
Model for bradycardia pacemaker closed-loop system. Note that there is a direct pathway of sensing physiology through an amplifier and an indirect pathway through an accelerometer. Other sensor inputs such as impedance, pressure, and chemical assays might show promise in the future. Figure reprinted with permission from Medtronic. © Medtronic, 2014

Denison T, Litt B. Advancing Neuromodulation Through Control Systems: A General Framework and Case Study in Posture-Responsive Stimulation. Neuromodulation 2014; 17: 48–57



Inhibitory responsive pacing. A counter increases until hitting a terminal count which, once hit, triggers a heart pace and resets the counter. The terminal count setting determines the minimum pacing rate. Any detected intrinsic heartbeat, measured as an electrocardiogram with a biopotential amplifier attached to the pacing lead, resets the counter without a pacing event. This allows the heart to regulate itself whenever possible and extends battery life. Figure reprinted with permission from Medtronic. © Medtronic, 2014

Denison T, Litt B. Advancing Neuromodulation Through Control Systems: A General Framework and Case Study in Posture-Responsive Stimulation. Neuromodulation 2014; 17: 48–57



Rate-responsive pacing. The terminal count setting still determines the minimum pacing rate, but is set dynamically by monitoring the activity of the patient. The dynamic variation is set by extending the terminal count in proportion to the activity rate (higher activity lowers the terminal variable, leading to a faster required rate). Dynamic thresholds allow for the pacing system to provide more variable hemodynamic settings, which are appropriate to the immediate needs of the patient. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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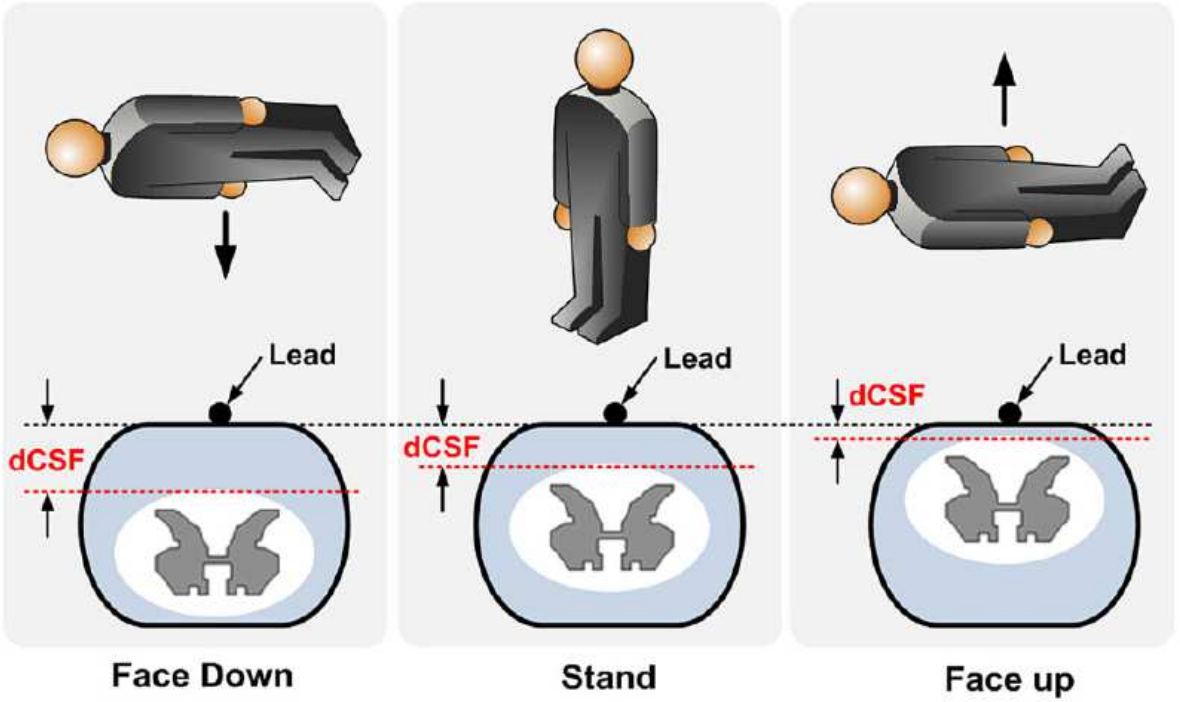

Abstracted model for variations in electrode-to-spinal cord distances within the cerebrospinal fluid due to posture. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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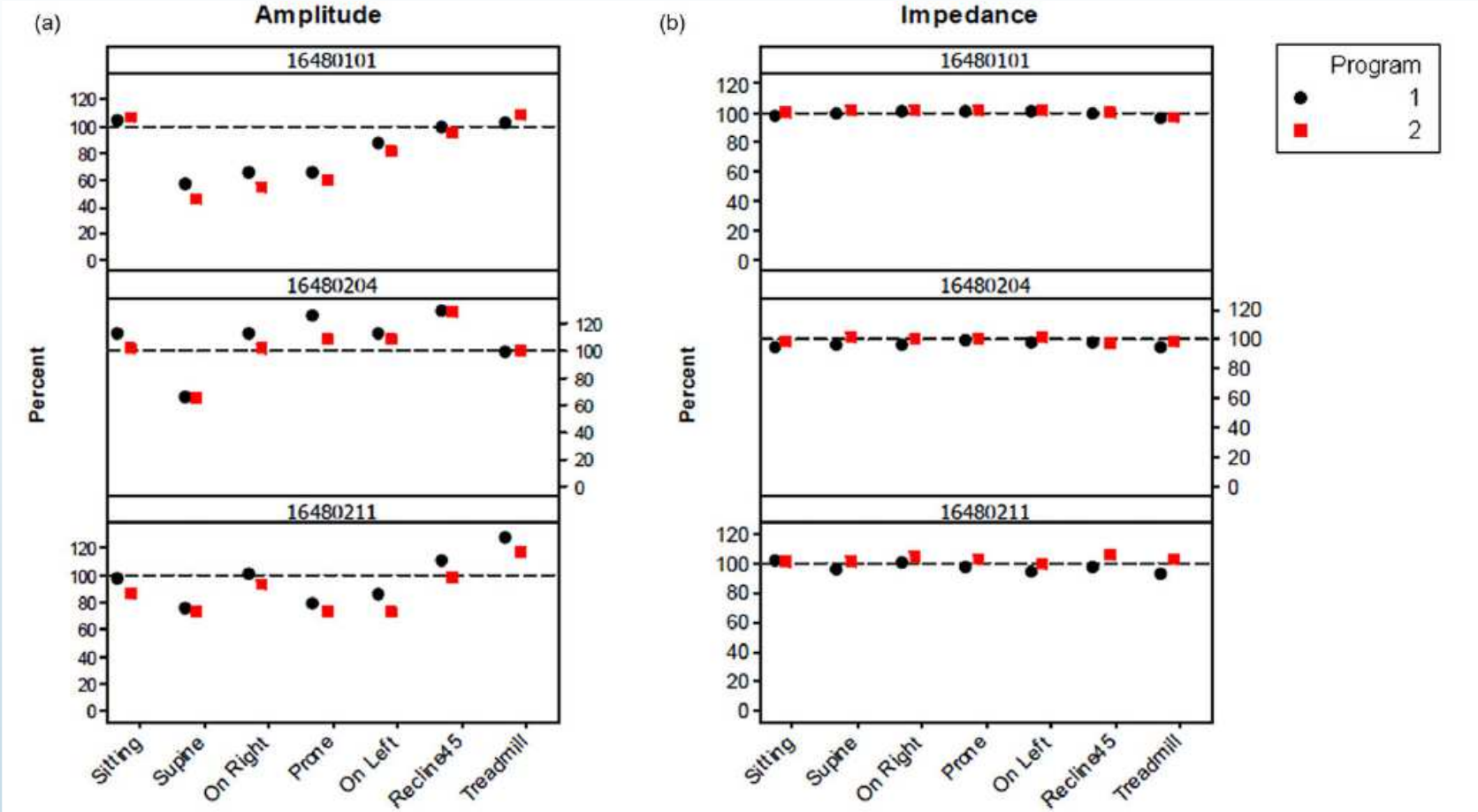

Figure 8. Percent change of patient-preferred stimulation amplitudes (a) and corresponding impedances (b) relative to standing with various postures, including sitting, supine, on right side, prone, on left side, reclining at a 45° angle, and walking on a treadmill. Three different patients are shown. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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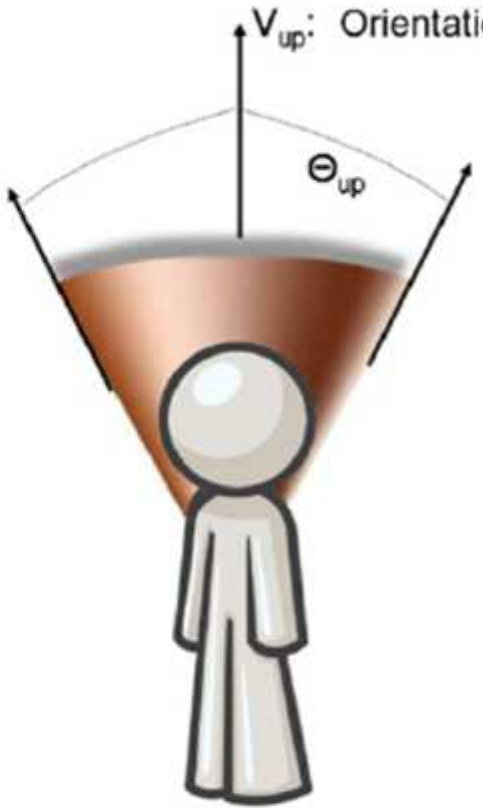

Determination of the upright cone for classification. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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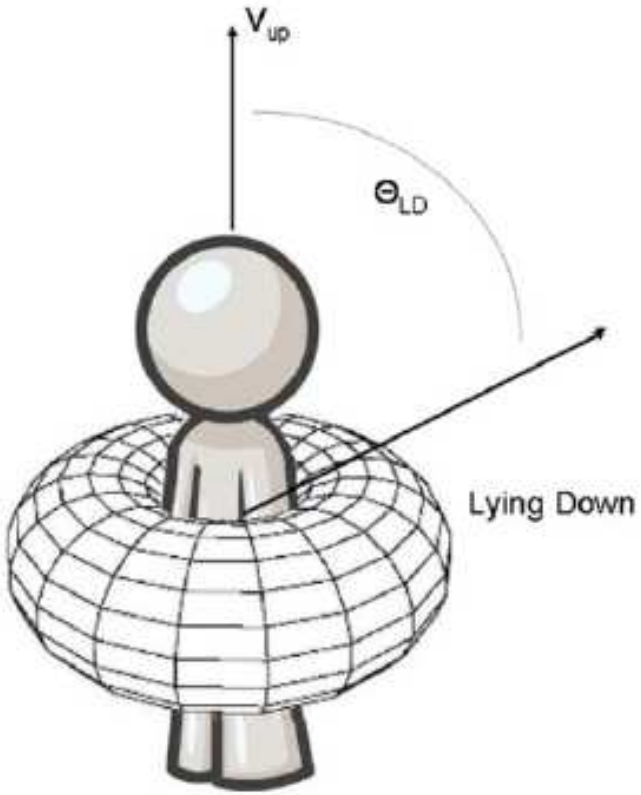

Determination of the lying cone for classification. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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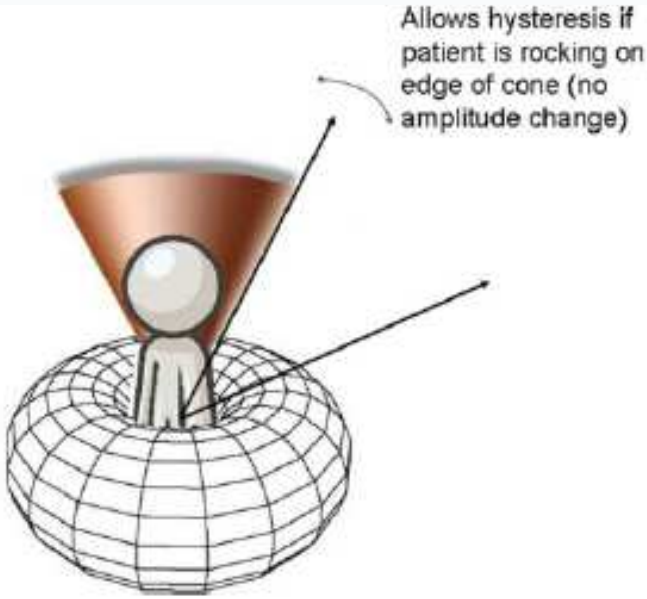

Adding hysteresis for transitions; the concern is that if the patient's posture puts them close to a transition vector, residual noise in the sensor might lead to rapid "chatter" in the actuator settings which might cause discomfort. To prevent this state, hysteresis can be added so that once a transition has been noted in the algorithm, the actuator will not go back to the prior state until a greater rotation occurs. If the hysteresis is designed to be greater than the noise, minimal chatter results. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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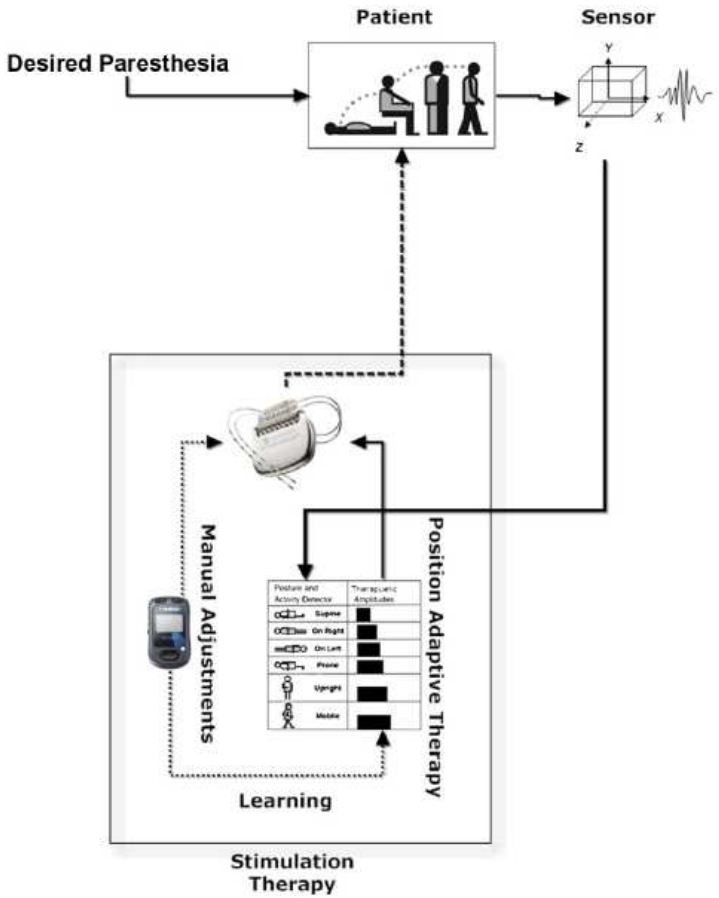

A posture-responsive SCS control loop: from the top left, a clinician interactively works with the patient to set desired parameter settings for different posture states. This mapping is then stored within the implantable device. Once the control loop is engaged, the position and activity sensor detects the patient's state and continuously updates the appropriate stimulation parameters based on the mapping. If the optimal settings vary over time, the patient's programmer allows for manual adjustments to compensate, and these settings are passed to the embedded mapping table as the new optimal settings. The patient programmer allows for the system to continue "learning" chronically. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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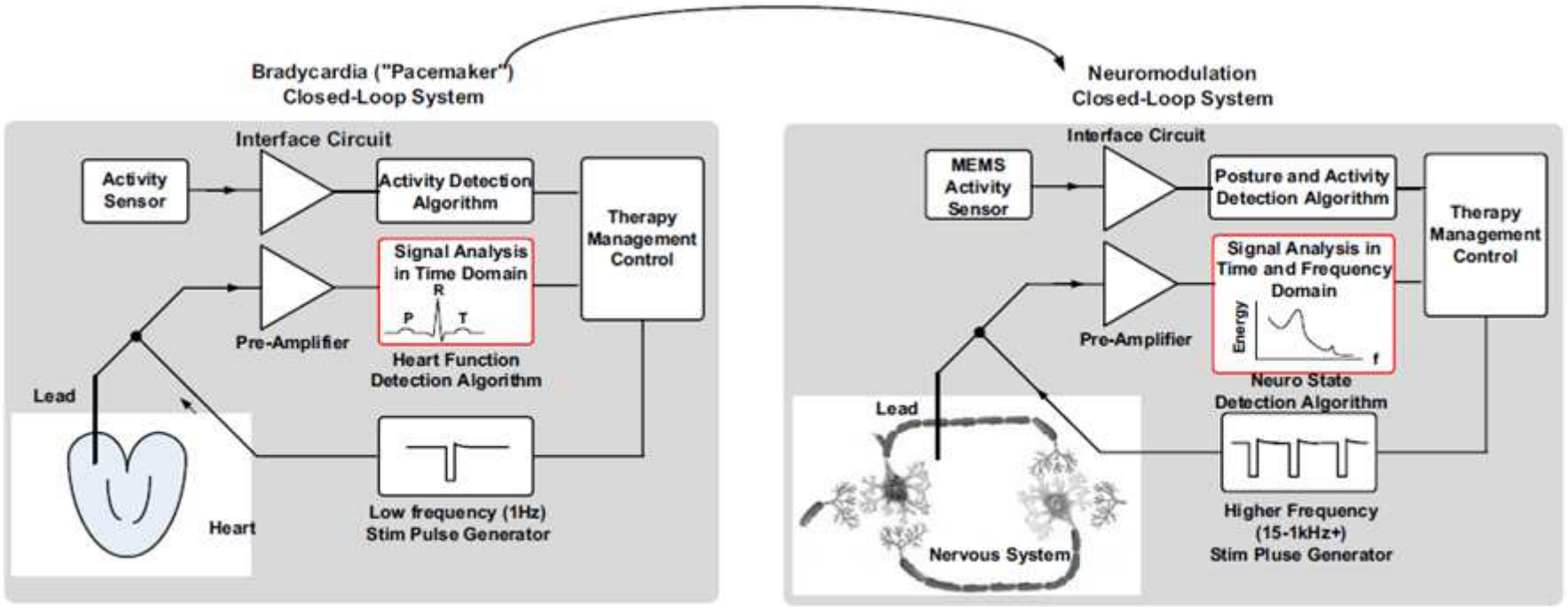

Mapping pacemaker architectures to neuromodulation systems. Designers must be mindful of the similarities and differences between the cardiac and nervous system to avoid oversimplifying the mapping of existing architectures to future therapies. Note that this representation shows just a handful of the potential sensors and algorithms that might be used in the future. Figure reprinted with permission from Medtronic. © Medtronic, 2014

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The Neurostimulation AppropriatenessConsensus Committee (NACC):Recommendations for Surgical Techniquefor Spinal Cord Stimulation

Univ. Prof. Dr. Rudolf Likar, MSc

Vorstand der Abteilung für Anästhesiologie, allgemeine Intensivmedizin, Notfallmedizin, interdisziplinäre Schmerztherapie und Palliativmedizin
Klinikum Klagenfurt am Wörthersee
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Lehrstuhl für Palliativmedizin SFU
SFU Fakultät für Medizin

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Preoperative Checklist

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Procedure checklist

Preoperative medical issues

- __Check for evidence of active or potential dermal, dental, urologic, or other infections and treat as necessary.
- __Order urinalysis before procedure. Coordinate with clinical signs and symptoms.
- __Address previous history of infection and make a plan for prophylaxis adjustment.
- __Review MRI of the spine in the past 12 mo depending on diagnosis and planned placement of stimulator tip.
- __Discontinue anticoagulation with approval of treating physician for a length of time before procedure that is appropriate for the specific anticoagulant and surgical bleeding risk. The appropriate timing for discontinuation should be based on the medication half-life and whether the patient is taking the medication for primary or secondary prevention. Consider ASRA guidelines for medication management.[4]
  - Off nonsteroidal anti-inflammatory drugs for one week if desired
  - Off acetylsalicylic acid for seven d
  - Off warfarin or fondaparinux for five d, clopidogrel for seven to ten d, and ticlopidine for 10 to 14 d
- __If patient was on warfarin, order prothrombin time testing on or before the morning of the procedure.
- __Review psychological evaluation and address any recommendations.
- __Examine the potential sites of implantation and battery pocket for infection or inflammatory process.
- __If there are any potential technical or patient-specific concerns, communicate with the treating physician and/or the anesthesiologist before implant.
- __Educate the patient/caregiver(s).
- __Obtain insurance coverage and document medical necessity.

Surgical considerations

- __Assess health status the day of surgery.
- __Have patient empty bladder preoperatively.
- __Consider COVID-19 testing based on local health care policy recommendations.
- __Obtain baseline pain score and review overall goals of the implant.
- __Review postoperative instruction sheet with patient/caregiver preoperatively.
- __Check that adult driver has been arranged to take patient home.
- __Order preoperative antibiotics and administer 30 to 60 min before incision or within two hours for vancomycin. Antibiotic doses should be based on the patient's weight.
- __Arrange for family to observe programming and learn about recharging.
- __Confirm follow-up appointment before discharge.
- __Answer any questions from the patient or caregivers regarding postoperative wound management.

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Preoperative planning. Patient morphology can influence the choice of IPG implantation site and should be considered before the implantation procedure. Photo courtesy of Philippe Rigoard and used with permission.

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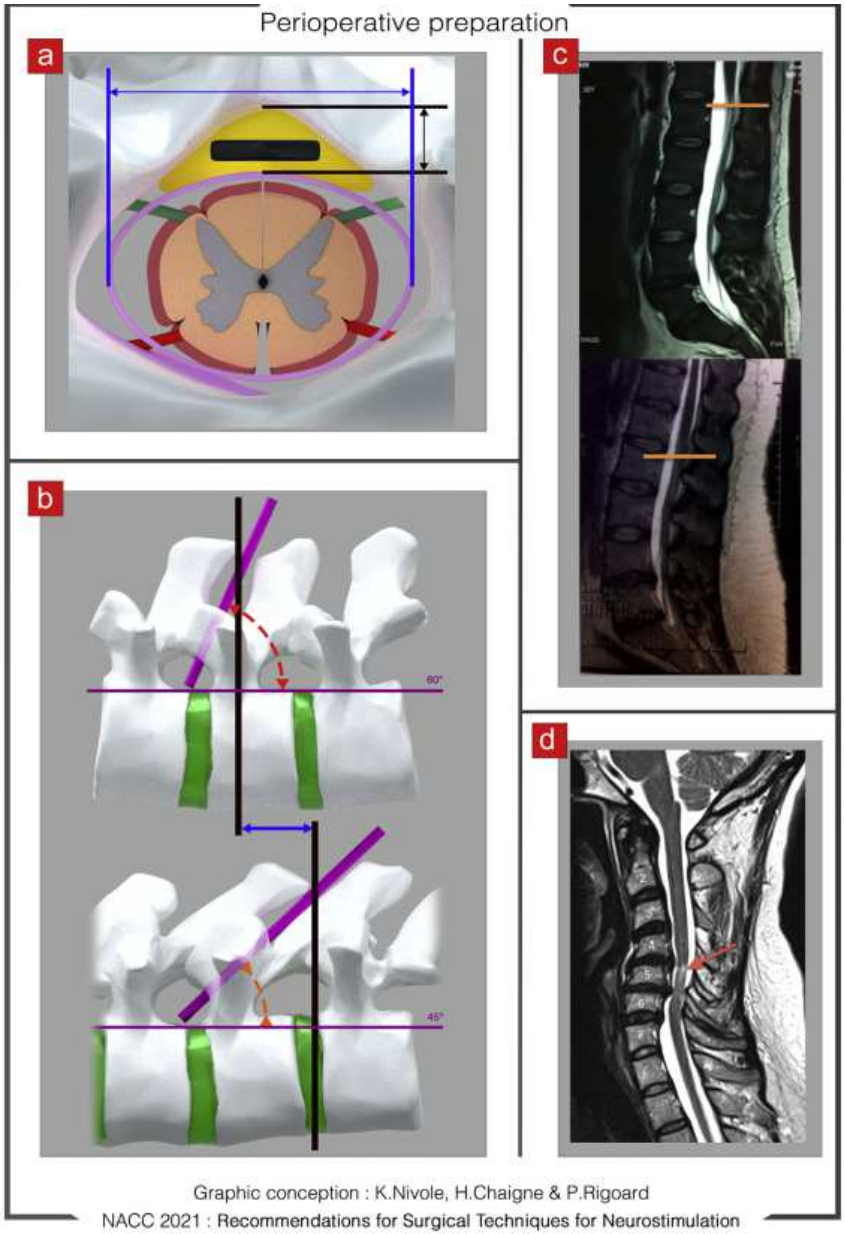

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Perioperative preparation. a. Preoperative posterior epidural space morphometric assessment. b. Individual differences in spinal anatomy (here, the obliquity of spinous processes) can affect the lead implantation entry level. Fuchsia lines indicate angle of entry. c. Individual differences in spinal cord anatomy, here showing the conus medullaris at the L1 vertebral level (upper image) and at L2 (lower image), should be considered to optimize lead positioning. d. In this case of cervical stenosis with myelopathy, an implant should not be done without previous surgical decompression of the stenosis. Photos courtesy of Philippe Rigoard and used with permission.

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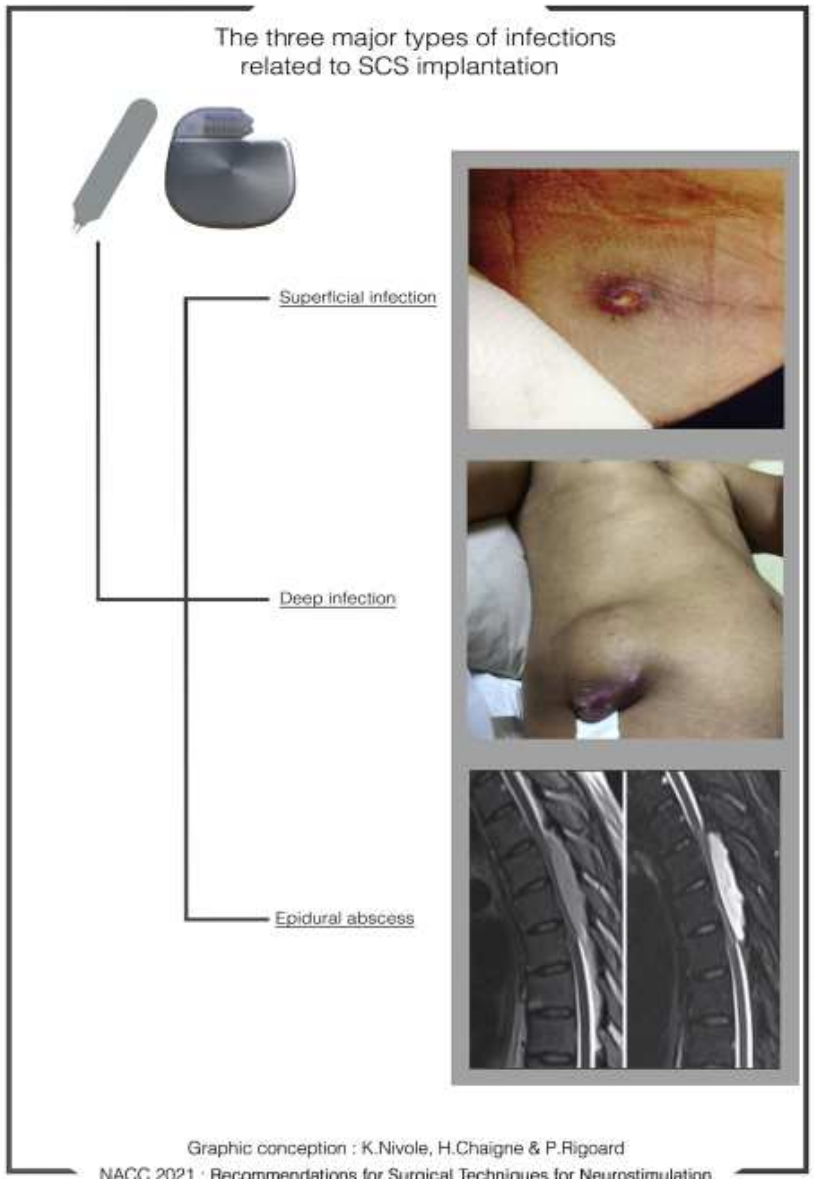

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The three major types of infections related to SCS implantation. Photos courtesy of Philippe Rigoard and used with permission.

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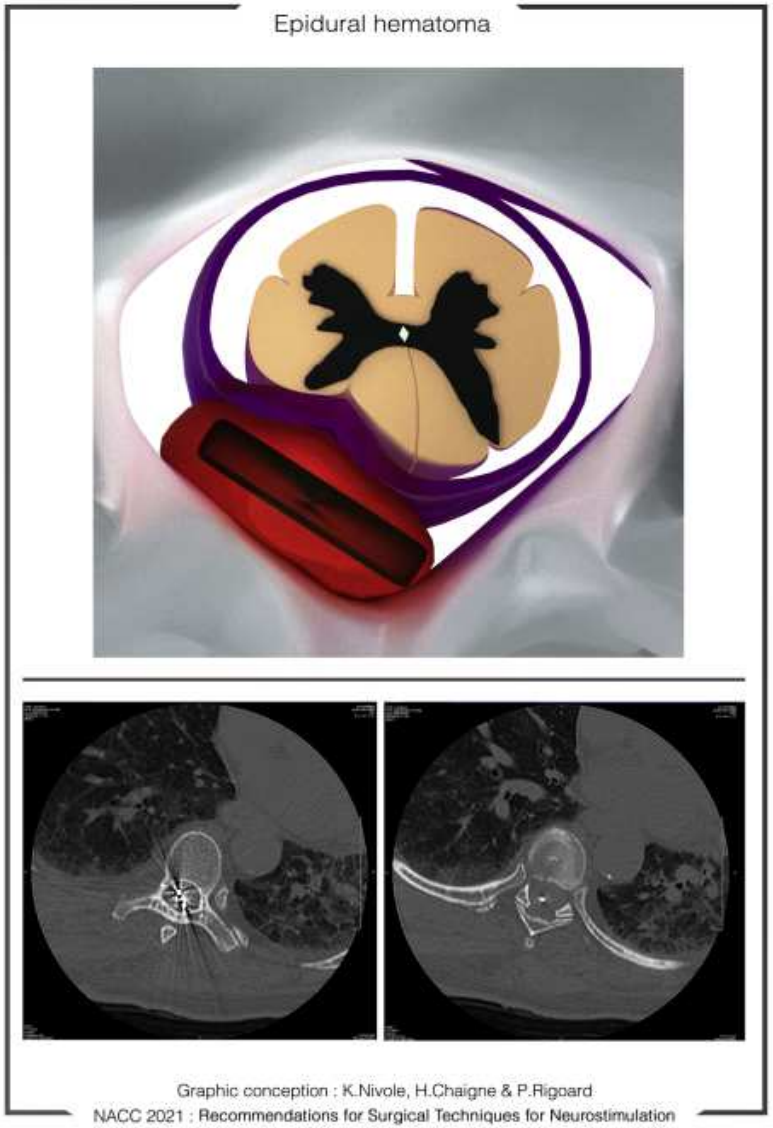

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Epidural hematoma. Immediate imaging and decompression are essential. Diagrammatic view (top). Indirect CT-radiological signs of spinal cord
compression visible despite lead artifacts (bottom). The multicolumn lead and adjacent wires appear asymmetric because of lead lateralization. External materials are projected in the middle of the spinal canal. Photos courtesy of Philippe Rigoard and used with permission.

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Recommended Infection-Management Practices with Defined Origin of Practice.

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Statements	Origin of recommended practice*	Evidence levels†	Recommendation strength	Consensus strength
Preoperative practices				
Identify and treat all remote infections for neuromodulation trials and implants	CDC IA	II-2	B	Strong
Optimize glucose control for neuromodulation implants	CDC IA	II-2	B	Strong
Discontinue tobacco use for neuromodulation implants	CDC IB	II-2	B	Strong
Decolonize MSSA and MRSA carriers through the application of mupirocin nasal ointment and chlorhexidine baths	NICE	I	A	Strong
Use preoperative antibiotics for neuromodulation trials and implants	CDC IB and NICE	I	A	Strong
Use preoperative weight-based antibiotic dosing for neuromodulation trials and implants	CDC IB and NICE	I	A	Strong
Use appropriate preoperative timing (within 1 h before surgical incision excluding vancomycin) of prophylactic antimicrobial administration for neuromodulation trials and implants	CDC IB, NICE, and SCIP	I	A	Strong
All patients should bathe or shower and use regular or antimicrobial soap the day before or day of surgery	CDC IB, NICE, and WHO	I	B	Strong
Remove hair (when required) with electric clippers immediately before the surgical procedure	CDC IA and NICE	I	A	Strong
Perform preoperative surgical scrub for a minimum of 2 to 5 min with an appropriate antiseptic before neuromodulation trials and implants	CDC IB and NICE	II-2	B	Strong
Keep nails short and do not wear artificial nails for neuromodulation trials and implants	CDC IB and NICE	II-3	B	Strong
Do not wear hand or arm jewelry for neuromodulation trials or implants	CDC IB and NICE	III	B	Strong
Intraoperative practices				
Wear a surgical mask for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Wear a cap or hood to fully cover hair for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Use sterile gown and gloves for neuromodulation trials and implants	CDC IB	II-3	B	Strong
Double glove	CDC II and NICE	II-1	B	Strong
Use alcohol-based CHG for preoperative skin antiseptic agent. If chlorhexidine is contraindicated, use alcohol-based solution of povidone-iodine	CDC IA and NICE	I	A	Strong
If an incise drape is used, then an iodophor-impregnated drape for neuromodulation implants is recommended	NICE	I	A	Strong
Use laminar flow and HEPA filters in OR for neuromodulation implants	CDC IB	I	A	Strong
Limit procedure room traffic for neuromodulation trials and implants	CDC II and NICE	I	A	Strong
Keep procedure room doors closed during neuromodulation trials and implants	CDC IB	II-3	B	Strong
Limit tissue trauma, maintain hemostasis, eradicate dead space, and avoid electrocautery at tissue surface	CDC IB and NICE	III	B	Strong
Irrigate with saline through a bulb syringe before closure of surgical wound	NICE	I	B	Moderate
Use implant strategies to limit operative time		II-2	B	Strong
Postoperative practices				
Apply an occlusive dressing following neuromodulation trials and implants for 24 to 48 h	CDC IB and NICE	II-2	B	Strong
Do not routinely use topical antimicrobial agents for surgical wounds that are healing by primary intention	NICE	I	B	Strong
Understand maximum time criterion for defining a deep SSI of an implantable device (1 y post implant)	CDC	III	B	Strong

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Recommended Infection-Management Practices with Defined Origin of Practice.

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Statements	Origin of recommended practice*	Evidence levels†	Recommendation strength	Consensus strength
Do not continue antibiotics into the postoperative period for neuromodulation trials and implants beyond 24 h	SCIP	I	A	Strong
Educate patient and family on proper incision care, symptoms of SSI, and importance of reporting symptoms	CDC II and NICE	III	B	Strong
Wash hands before and after dressing changes	CDC IB	III	B	Strong
Use sterile technique for dressing changes	CDC II and NICE	III	B	Moderate
When SSI is suspected, prescribe an antibiotic that covers the likely causative organisms. Consider local resistance patterns and culture results in choosing an antibiotic	NICE	III	B	Strong

HEPA, high efficiency particulate air; MSSA, methicillin-sensitive *S aureus*; NICE, National Institute for Health and Care Excellence; OR, operating room; SCIP, Surgical Care Improvement Project.
*The origin of recommended practice defines the supporting surgical guideline.
†I: at least one controlled and randomized clinical trial; II-1: well-designed, controlled, nonrandomized clinical trials; II-2: cohort or case studies and well-designed controls, preferably multicenter; II-3: multiple series compared over time, with or without interventions, and surprising results in noncontrolled experiences; III: clinical experience-based opinions, descriptive studies, clinical observations, or reports of expert committees.
Adapted from Deer et al.[43]

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Prophylactic Antibiotic Recommendations.

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Antibiotic	Standard intravenous dosing	Timing before incision	Redosing interval	Indications
Cefazolin*	1 g ≤ 60 kg 2 g > 60 kg 3 g > 120 kg	Within 30–60 min	3–4 h (CrCl > 50 mL/min) 8 h (CrCl 20–50 mL/min) 16 h (CrCl < 20 mL/min)	First-line
Clindamycin	600 mg ≤ 80 kg 900 mg > 80 kg 1200 mg > 120 kg	Within 30–60 min	6 h (CrCl > 50 mL/min) 6 h (CrCl 20–50 mL/min) 6 h (CrCl < 20 mL/min)	β-Lactam allergy
Vancomycin	15 mg/kg	Within 60–120 min	8 h (CrCl > 50 mL/min) 16 h (CrCl 20–50 mL/min) None (CrCl < 20 mL/min)	β-Lactam allergy Known MRSA colonization

CrCl, creatinine clearance.
*To simplify cefazolin weight-based dosing, the American Society of Health-System Pharmacists recommends 2 g for individuals weighing <120 kg and 3 g for individuals weighing ≥120 kg.
Adapted from Deer et al.[61]

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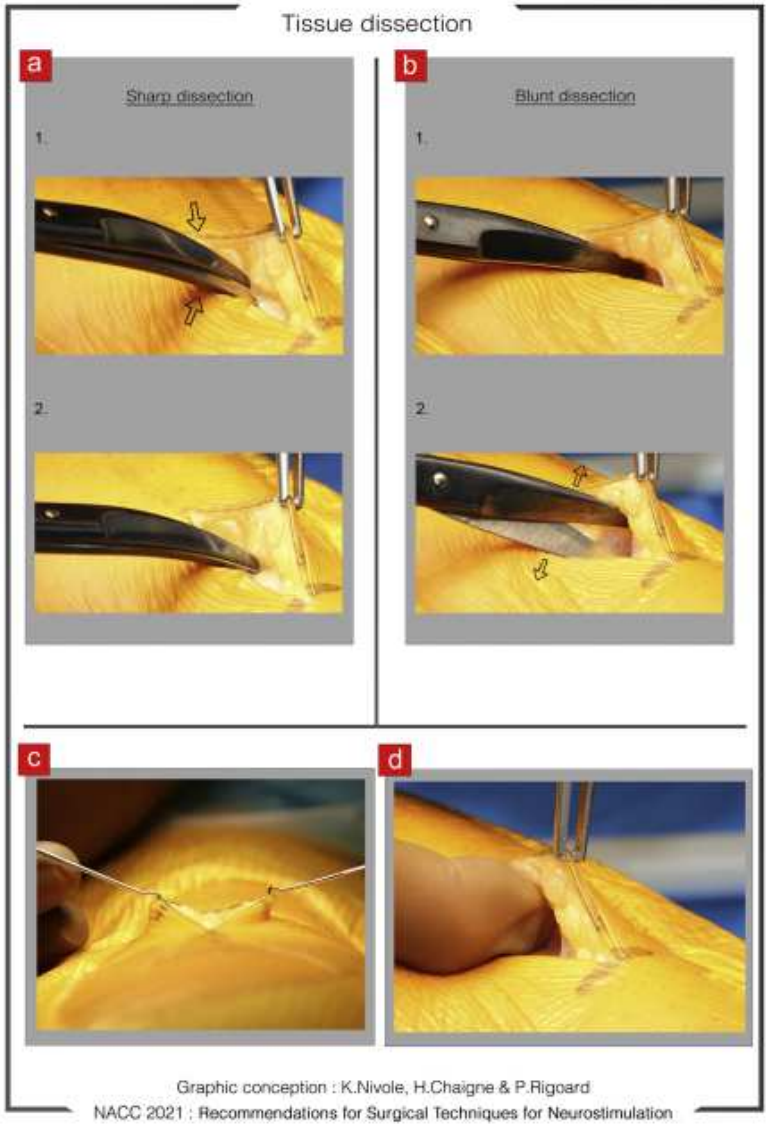

Tissue dissection. a. Sharp dissection technique: 1) use of scissors to separate the tissue by cutting the anatomical structures, 2) definition of tissue planes relies on the implanter's perception. b. Blunt dissection technique: 1) careful separation of tissues along the tissue planes by inserting a closed scissors, 2) opening of
the scissors to bluntly separate the tissue. c. Use of skin hooks to minimize the potential tissue damage. d. Use of toothed forceps to avoid handling the skin repetitively. Once forceps are placed, preferably a finger was used to separate the tissue planes. Photos courtesy of Philippe Rigoard and used with permission.

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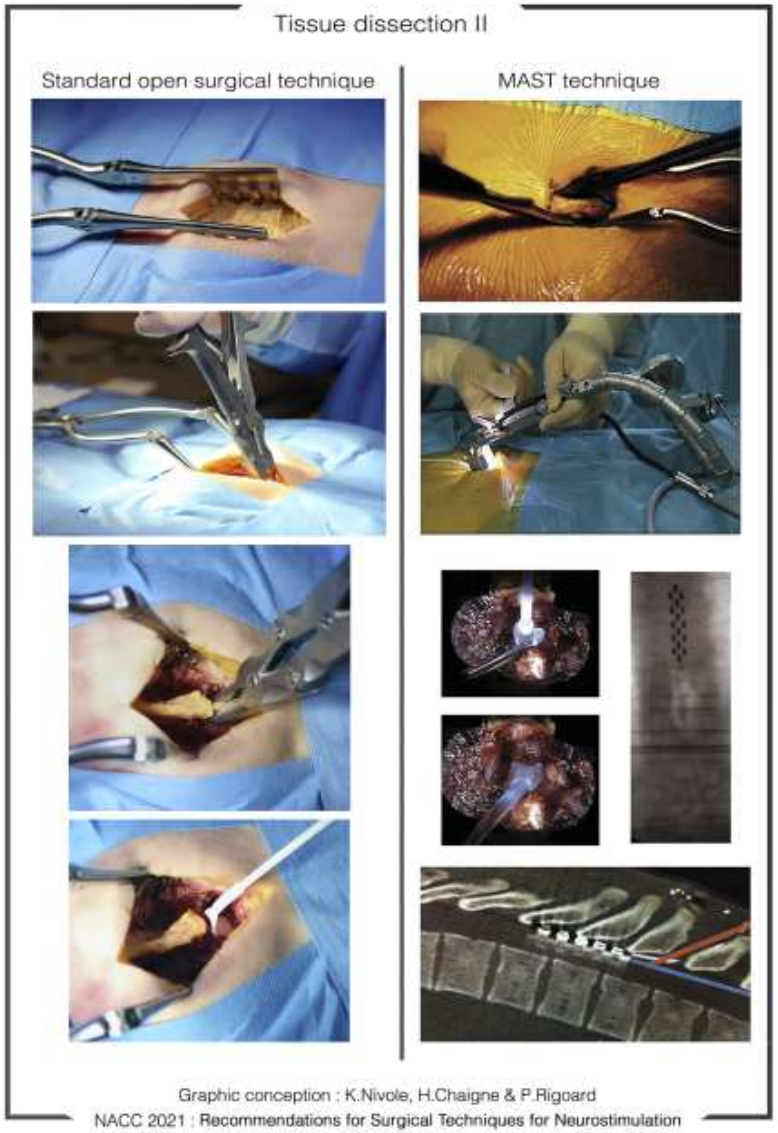

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Tissue dissection II. Conventional surgical approach (at the left). Surgical approach consists in separating paraspinal fascia and muscles from the spinous process and ligaments. Once the spinous process and laminae have been exposed, removal of the supraspinous, the interspinous ligament, and the ligamentum flavum is possible thanks to a small gouge or an arthrectomy pinch. Kerrison rongeurs can be used to remove a small portion of the inferior lamina of the upper vertebra to place the lead phantom and then the paddle lead in the epidural space. Aspects of the minimally invasive (MAST) procedure (at the right). Surgical approach on one or both sides of the supraspinous process, with careful dissection of the paravertebral musculature. Full system set. Insertion of the phantom lead and implantation of the lead in the median position, verified by intraoperative x-ray. The aspects of lead implantation angle: a high approach at the thoracic spine level is possible by using the minimally invasive technique. The bony removal can be minimized, and a shallow, safe angle of insertion achieved with a good retractor system and illumination. Photos courtesy of Philippe Rigoard and used with permission.

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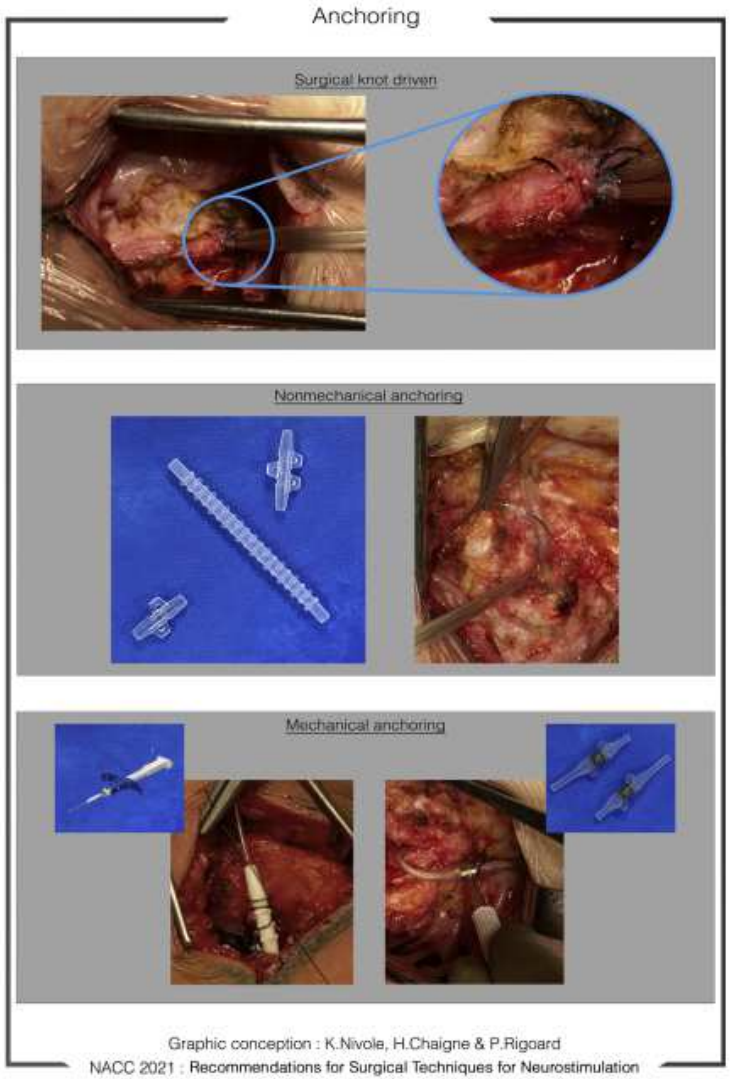

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Anchoring. Many anchoring strategies have been developed over the years, from surgical knot driven (top), nonmechanical anchors (middle), to mechanical anchors with a “locking” strategy (examples presented [bottom], courtesy of manufacturers). Photos courtesy of Philippe Rigoard and used with permission.

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Anchor Type and Reported Rates of Lead Migration and Fracture in Randomized Studies of SCS.

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Study	No. of patients implanted	Follow-up	Lead type, paddle vs percutaneous	Anchor type	Migration rate, % (*N*)	Fracture rate, % (*N*)
North et al[80]	30	Mean follow-up 2.9 y	Unknown	Unknown		
Kumar et al[81]	52	24 mo	Unknown	Unknown	17.13 (9)	
Kemler et al[82]	54	60 mo	Unknown			
Kapural et al[83]	171	12 mo	Perc all patients	Mechanical	4 (7)	None
Deer et al[84]	100	12 mo	Perc all patients	Mechanical		None
Deer et al[85]	DRG control arm 76	12 mo	Perc all patients	Nonmechanical	10.5 (8)	NR
De Andres et al[86]	55	12 mo	Perc all patients		12.7 (7)	None

NR, not reported; Perc, percutaneous.

North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery. 2005;56:98–106 [discussion: 106–107].
Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain.2007;132:179–188.
Kemler MA, de Vet HC, Barendse GA, van den Wildenberg FA, van Kleef M. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. J Neurosurg. 2008;108:292–298.
Kapural L, Yu C, Doust MW, et al. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial. Anesthesiology. 2015;123:851–860.
Deer T, Slavin KV, Amirdelfan K, et al. Success using neuromodulation with BURST (SUNBURST) study: results from a prospective, randomized controlled trial using a novel burst waveform. Neuromodulation. 2018;21:56–66.
Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017;158:669–681.
De Andres J, Monsalve-Dolz V, Fabregat-Cid G, et al. Prospective, randomized blind effect-on-outcome study of conventional vs high-frequency spinal cord stimulation in patients with pain and disability due to failed back surgery syndrome. Pain Med. 2017;18:2401–2421.

Anchor Type and Reported Rates of Lead Migration and Fracture in Randomized or Prospective Studies of PNS.

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Study	No. of patients implanted	Follow-up	Anchor type	Migration rate, % (*N*)	Fracture rate, % (*N*)
Deer et al[91]	94	12 mo	Silicone anchor with tines	NR	NR
Gilmore et al[92]	28	12 mo	Coiled lead with tine	NR	NR
Serra et al[93]	31	12 mo	NR, SCS lead	9.6 (3)	None
Deckers et al[94]	53	12 mo	Lead with opposing lead tines	1.8 (1)	24 (13)

Before the introduction of leads designed specifically for PNS, SCS leads were used. There have been no prospective, randomized comparative studies of one type of lead or anchoring strategy to another in PNS applications. Randomized or prospective studies of PNS are described here.
NR, not reported.

Deer T, Pope J, Benyamin R, et al. Prospective, multicenter, randomized, double blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. Neuromodulation. 2016;19:91–100.
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Deckers K, De Smedt K, Mitchell B, et al. New therapy for refractory chronic mechanical low back pain-restorative neurostimulation to activate the lumbar multifidus: one year results of a prospective multicenter clinical trial. Neuromodulation. 2018;21:48–55.

Anchor Type in DRG Studies.

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Study	No. of patients implanted	Follow-up	Anchor type	Migration rate	Fracture rate
Deer et al[85]	DRG 76	12 mo	Provided plastic anchor	NR	NR
Chapman et al[95]	756 leads from 249 patients; 565 anchored, 191 unanchored		Suture or silastic anchor	Unanchored: 16 leads (8.4%) from 13 patients (21%) Anchored: 8 leads (1.4%) from 5 patients (2.7%)	Unanchored: 6 leads (3.1%) from 6 patients (9.7%) Anchored: 11 leads (1.9%) from 9 patients (4.8%)

NR, not reported.

Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017;158:669–681.
Chapman KB, Mogilner AY, Yang AH, et al. Lead migration and fracture rate in dorsal root ganglion stimulation using anchoring and non-anchoring techniques: a multicenter pooled data analysis. Pain Pract. 2021;21:859-870. https://doi.org/10.1111/papr.13052.

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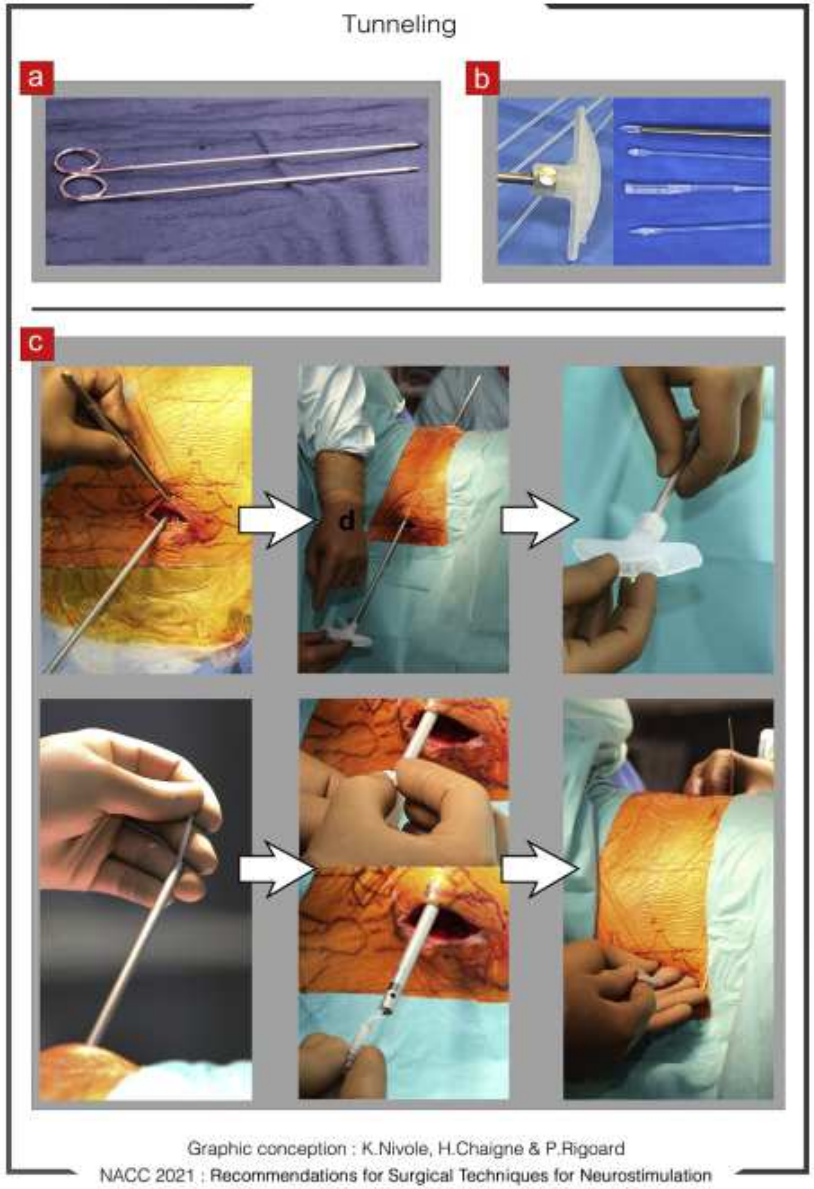
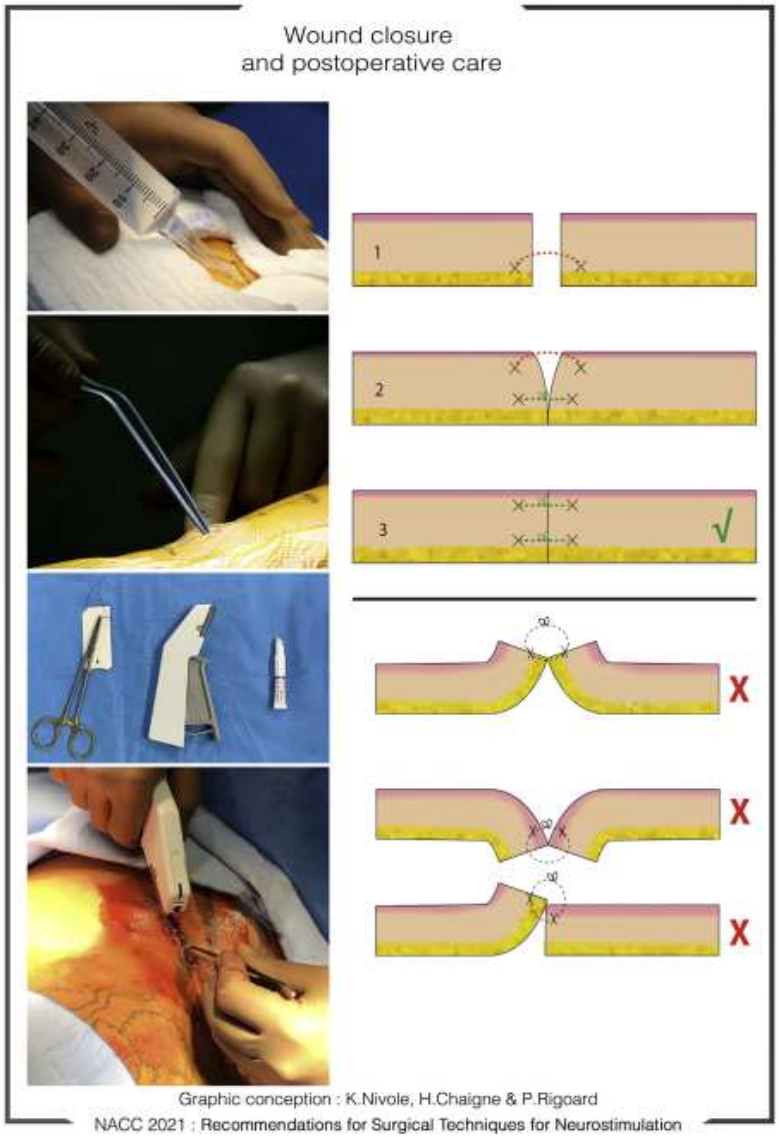


Tunneling. a. The tool is usually composed of a solid metal trocar with a plastic straw on the outer shaft of the trocar. Depending on SCS manufacturer, the sharp tip may need to be screwed onto the end of the trocar to keep the straw in place while passing the tunneling device (b) and also facilitate passage through the
subcutaneous tissues (c). With the courtesy of manufacturers. Photoscourtesy of Philippe Rigoard and used with permission.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:1-34.



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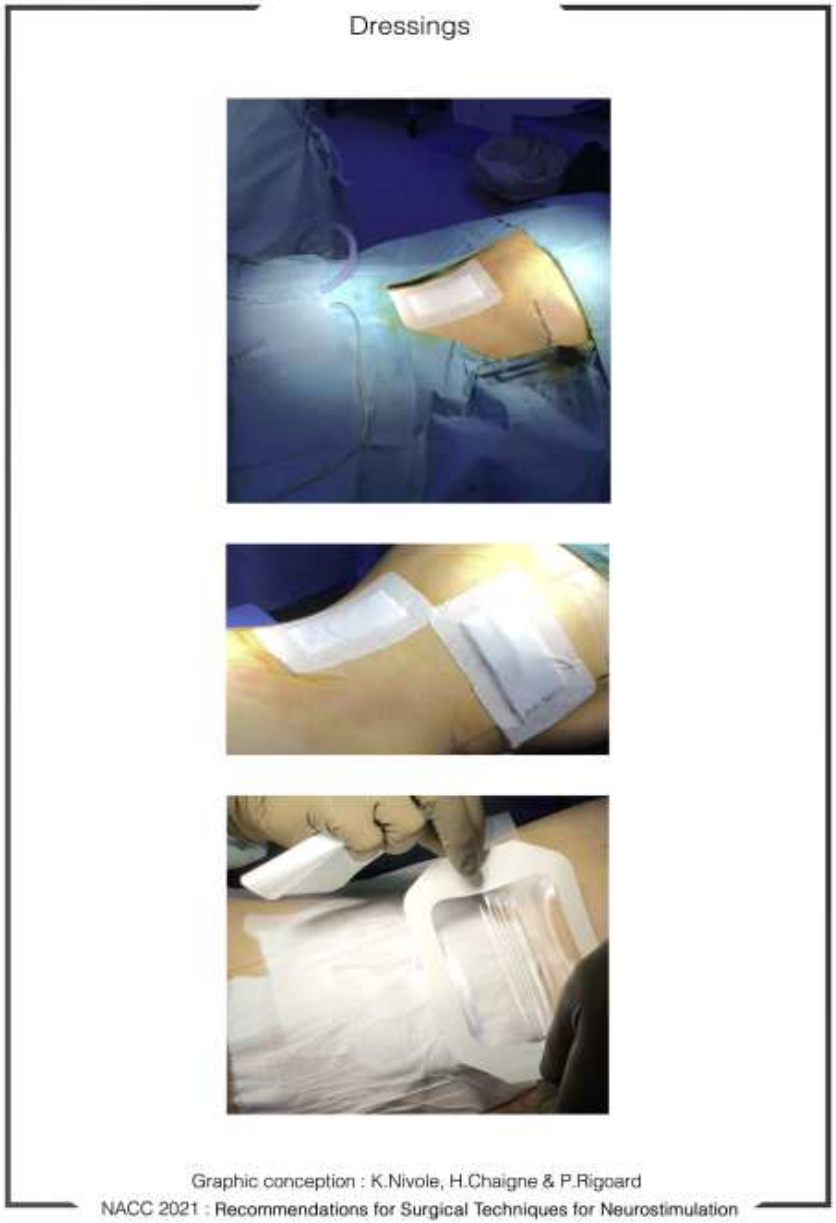
Suture Classification.

Absorbable	Nonabsorbable
Monofilament • Surgical gut (plain, chromic) • PDS II (polydioxanone) • Monocryl (poliglecaprone 25)	Monofilament • Ethilon (nylon) • Mersilene (ethylene terephthalate) • Prolene (polypropylene)
Braided • Vicryl (polyglactin 910) • Triclosan-coated Vicryl	Braided • Silk • Ethibond (coated ethylene terephthalate)

Considerations of Staple Skin Closure.

Positive	Negative
Increased speed of closure decreases operative times	Possible increased risk of SSI has been suggested in the orthopedic surgery literature
No long-term difference in cosmetic outcome compared with suture closure	Increased expense compared with suture closure
	Staples will need to be removed in clinic upon wound healing

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:1-34.



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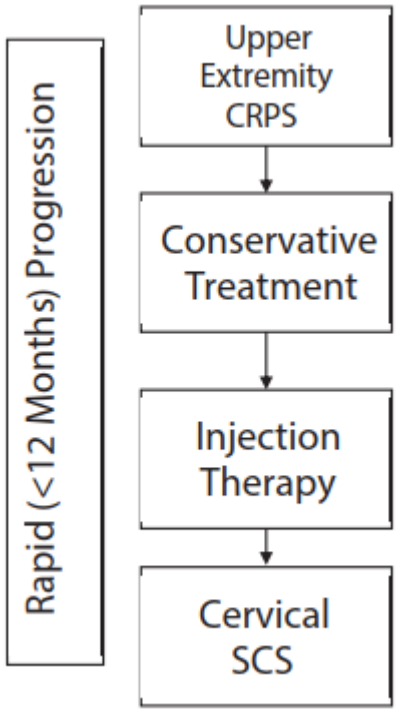
Dressings. The dressings should cover the entire wound to offer full protection. Significant reduction in postoperative infection has been observed in some studies when sterile occlusive dressing is applied in the operating room. Photos courtesy of Philippe Rigoard and used with permission.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Surgical Technique for Spinal Cord Stimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:1-34.



The suggested role of cSCS in the treatment algorithm for CRPS. An individualized treatment plan for patients with CRPS includes multiple treat-
ment options from the pain management toolbox.49,50 For example, conser-
vative care may include nonopioid analgesics and/or other medications, physical therapy, or behavioral health measures.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Cervical Neurostimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:35-52.

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Average Anatomical Dimensions (mm).

Spinal level	Thickness of dorsal CSF layer	Thickness of ventral CSF layer	Spinal cord anterior-posterior diameter	Spinal canal diameter
C4	2.6	3.4	7.3	13.6
C5	2.6	3.8	6.9	13.4
C6	2.2	4.6	6.7	13.0

Holsheimer J, den Boer JA, Struijk JJ, Rozeboom AR. MR assessment of the normal position of the spinal cord in the spinal canal. AJNR Am J Neuroradiol. 1994;15:951–959.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Cervical Neurostimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:35-52.

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Feasibility of Inserting Epidural Leads in the Presence of Previous Spine Surgery.

Surgical procedure previously performed	Cylindrical leads	Paddle leads
Anterior approach	Yes	Yes
Laminectomy	No	Yes
Laminoplasty	Yes	Yes
Hemi-laminotomy	Yes, on the contralateral side (rarely used method)	Yes
Foraminotomy	Yes, on the contralateral side Possibly on the ipsilateral side, depending on the extent of bone removal and consequent epidural scarring* (rarely used method)	Yes

*MRI is recommended prior to consideration for lead placement with careful consideration of potential anatomical barriers.

Deer T. R., Russo M. A., Grider J. S. et al. The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations for Cervical Neurostimulation. Neuromodulation: Technology at the Neural Interface. 2022. 25:35-52.

Absolute criteria for the consideration of SCS, selected by the expert panel

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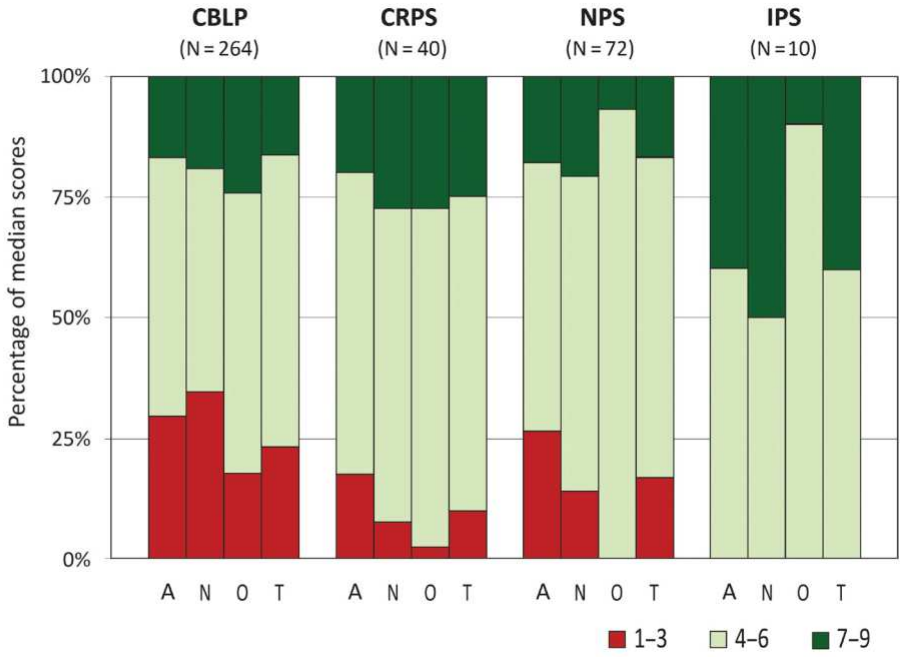
Inclusion criteria	Exclusion criteria

• Age ≥ 18 years
• Chronic pain with a duration of least 6 months
• One of the following primary indications:
  • Chronic low back/leg pain
  • Complex regional pain syndrome
  • Neuropathic pain syndrome
  • Ischaemic pain syndrome
• Pain severity at least moderate (VAS ≥ 5) having a substantial impact on daily functioning and quality of life
• Insufficiently responding to appropriate trials of medication and/or minimally invasive treatments (such as local anaesthetic nerve blocks) and/or experiencing intolerable side effects of these treatments
• No clear benefits of surgery expected
	• Unwilling to have an implant
	• Unable to manage the device
	• Absolute contra-indications for active treatment (e.g. unfit for undergoing SCS, pregnancy, spine infection, coagulation disorder)
	• Uncontrolled disruptive psychological or psychiatric disorder
	• Ongoing alcohol and drug misuse
	• Widespread pain

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.



Appropriateness results by indication area and specialty of the panel members. Percentages of median scores in each of the sections 1–3 (inappropriate), 4–6 (equivocal) and 7–9 (appropriate). CBLP, chronic low back/leg pain; CRPS, complex regional pain syndrome; IPS, ischaemic pain syndrome; NPS, neuropathic pain syndrome. A, anaesthesiologists; N, neurosurgeons; O, other specialists (psychologist, physiotherapist, nurse specialist); T, total

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

Variables/categories	Previous surgery (%)			No previous surgery (%)		
	I	E	A	I	E	A
Dominant location of pain						
Leg	0	61	39	3	75	22
Mixed	23	48	29	25	60	15
Back	38	62	0	40	60	0
Dominant type of pain						
Neuropathic	8	53	39	8	67	25
Neuropathic-like	3	64	33	11	72	17
Mixed	11	83	6	12	88	0
Nociceptive	88	12	0	88	12	0
Response to root block, TENS, RF and/or neuropathic pain medication						
No	27	59	14	32	65	3
At least partial or temporary	17	54	29	17	63	20
Anatomic abnormality						
Recurrent disc	14	63	23	14	72	14
Scar tissue	14	45	41	14	63	23
Iatrogenic nerve lesion	14	45	41	14	63	23
Spinal/foraminal stenosis	18	64	18	18	77	5
Spinal instability	50	50	0	59	41	0
None/not concordant with symptoms	23	72	5	27	68	5

Abbreviations: A, appropriate; E, equivocal; I, inappropriate.

Appropriateness of (referral for) SCS by clinical
variables for patients with chronic low back and/or leg pain.
Appropriate indications; percentage of clinical scenarios by subgroup. Row totals per variable are 100%

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

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Variables/categories	Inappropriate (%)	Equivocal (%)	Appropriate (%)
Dominant symptom			
Neuropathic	0	50	50
Neuropathic-like	0	75	25
Ischaemic/vasomotor	0	62	38
Mixed	12	75	13
Nociceptive	38	62	0
Response to nerve block and/or neuropathic pain medication			
No	15	80	5
At least partial or temporary	5	50	45
Spread of pain			
One limb	0	50	50
Two upper or two lower limbs	10	70	20
One upper and one lower limb	0	70	30
Three or more limbs	30	70	0

Appropriateness by clinical variables for patients with complex regional pain syndrome. Percentage of clinical scenarios by variable. Row totals are 100%

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

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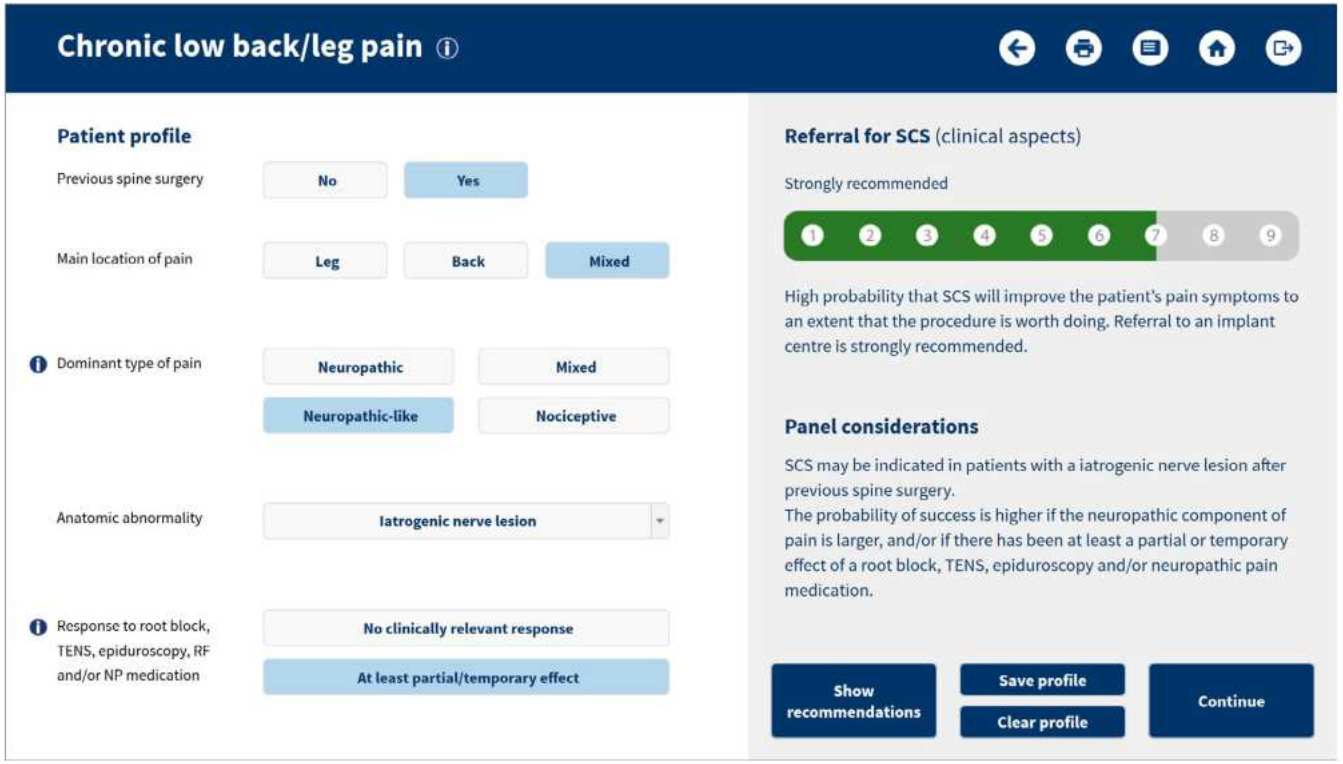
Variables/categories and related definitions
Lack of engagement (no; partly; total)
Failing to attend appointments (offered by the neuromodulation or other services)
Failing to follow up on agreed recommendations, e.g. self-referral to psychological therapy service
Non-compliance with treatment
Attending treatment (e.g. a pain management programme) but with a clear lack of engagement with the programme (e.g. frequently attending late, non-participation in group tasks, not completing homework tasks/exercise programme)
Dysfunctional coping (no or mild; moderate; severe)
Avoidance of movement/activity
Avoidance, misuse of medication/illegal drugs
Unrealistic expectations (no or mild; moderate; severe)
Total pain relief
Inability to articulate post-implant goals
Inadequate daily activity level (no or mild; moderate; severe)
Inconsistency between what patient reports they can do and what they have shown they can do, e.g. patient reporting they cannot get out of bed for short period but attends all appointments
Low self-efficacy
Lack of, or very restricted, participation in activities of daily living
Problematic social support (no or mild; moderate; severe)
No social/family support
Poor quality support, e.g. patient reports they have friends/family but are unreliable, patient has not sought their support
Secondary gain (no; probably; yes or very likely)
Litigation
Presence of factors that mean that the patient might (unconsciously) have an incentive for remaining "ill"
Psychological distress/mental health problems (no or mild; moderate; severe)
For example: low mood, anxiety, panic disorder, post-traumatic stress disorder
Unwilling to reduce high-dose opioids (no, or not applicable; probably; very likely)
Use of high-dose opioids, and unwilling to reduce these to an acceptable level according to the opinion of the treating physician

Psychosocial factors judged relevant for the consideration of SCS in patients with chronic pain

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.



User interface of the e-health tool (clinical aspects)

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

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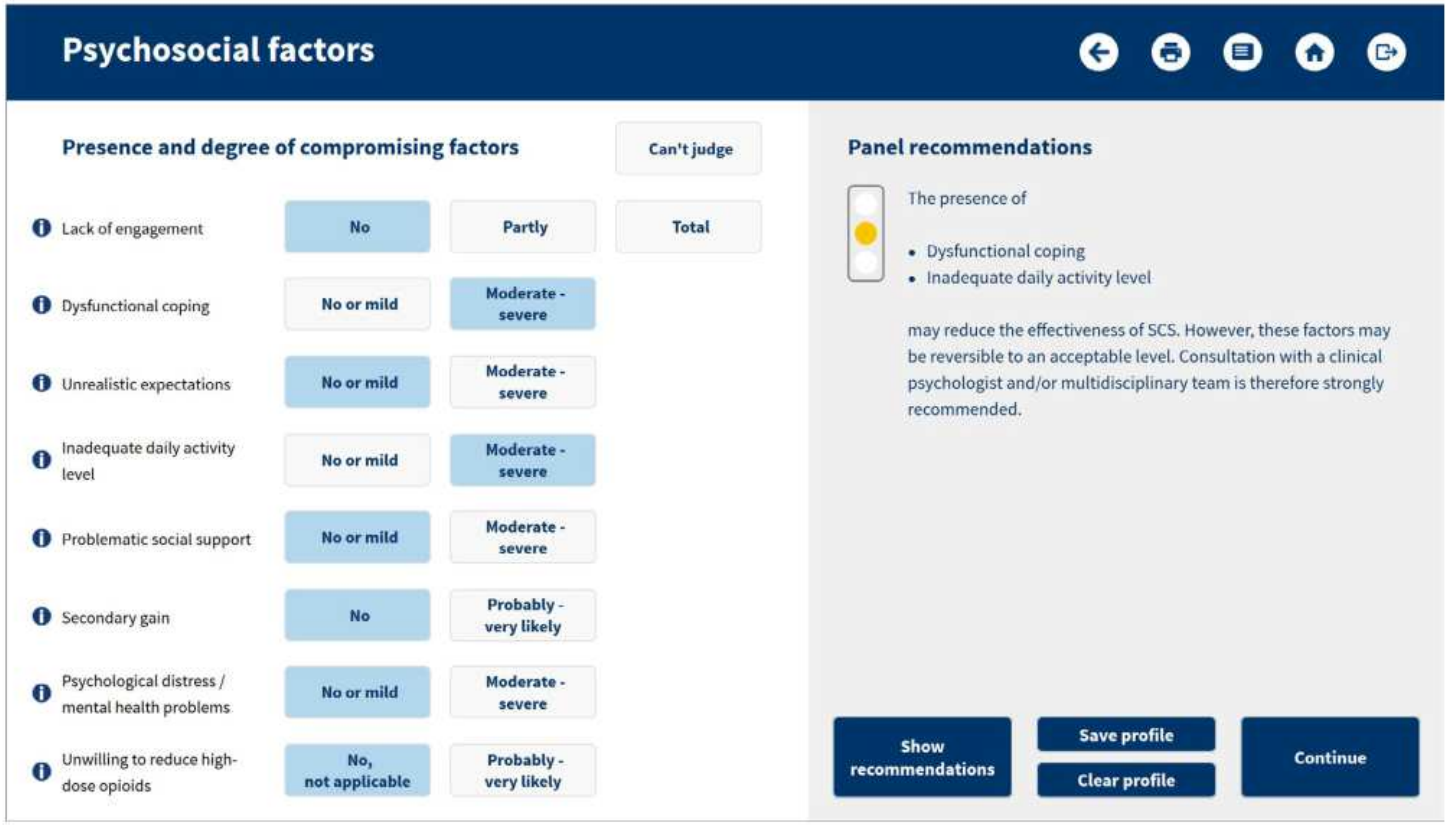

User interface of the e-health tool (psychosocial factors)

Thomson S., Huygen F., Prangnell S. et al.; Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: European consensus recommendations and e-health tool. Eur J Pain. 2020;24:1169-1181.

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Abstract: Given the differing mechanisms thought to underlie therapeutic sub- and supra-perception based neurostimulative modalities, Spinal Cord Stimulation (SCS) systems designed for combined delivery of these approaches may help improve analgesic outcomes and quality of life, and reduce treatment failures. This multicenter, observational case-series evaluated 188 patients with chronic back and/or leg pain implanted with an SCS device capable of sequential or simultaneous delivery of sub-perception and supra-perception stimulation programming (i.e., combination therapy) at 16 in Europe. Following implantation, patients were provided with an array of advanced supra-perception programs (e.g., paresthesia-based SCS using multiple independent current sources), and a custom set of sub-perception programs optimized with specific waveforms and/or field shapes. A mean overall pain score of 7.9 ± 1.7 (Standard Deviation (SD)) was reported pre-trial (Baseline). Overall pain was reduced by 4.4 ± 2.8 points (NRS) at 3-months (n = 117) and at 12 months post-implant (n = 90), respectively ($p < 0.0001$). Substantial quality-of-life (EQ-5D-5L) improvement as assessed at last follow-up was also observed (n = 60). These results suggest that an implanted SCS device capable of combination therapy, while also enabled with patient-specific waveform optimization and stimulation field targeting capabilities, can enable highly effective pain relief and improve quality of life in patients suffering with chronic pain.

Kallewaard J. W., Paz-Solis J. F., De Negri P. et al.; Real-World Outcomes Using a Spinal Cord Stimulation Device Capable of Combination Therapy for Chronic Pain: A European, Multicenter Experience. Journal of Clinical Medicine. 2021, 10, 4085.

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Baseline and demographic characteristics in analyzed patients (n = 188).

Gender—Females (%)	53.1% (101/188)
Age (Mean (SD))	60.0 (12.3) years $n = 180$
Key Diagnosis (patients may have multiple diagnoses)	Lumbosacral Radiculopathy 21%
	Failed Back Surgery Syndrome 64%
Pain Location (%)	Low Back and Legs (85.6%)
Baseline NRS (Mean (SD))	7.9 (1.7) $n = 188$
Follow-up duration (Mean (SD))	296 (207) days $n = 187$

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Patient Disposition.

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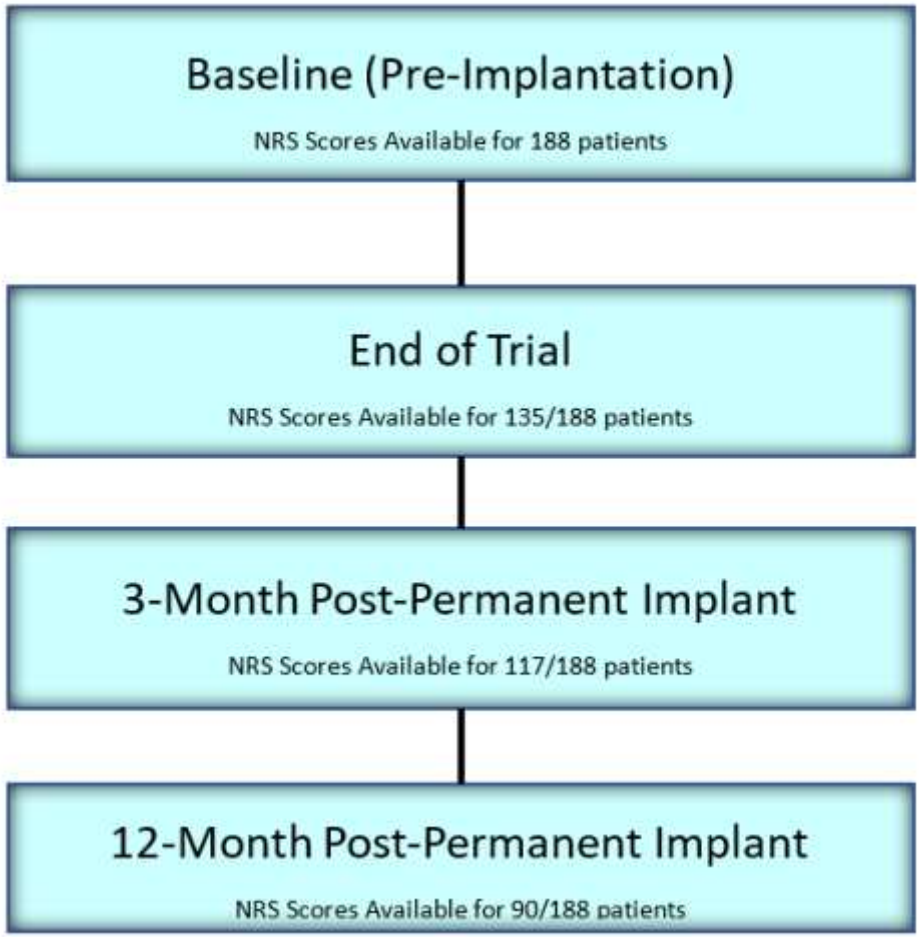

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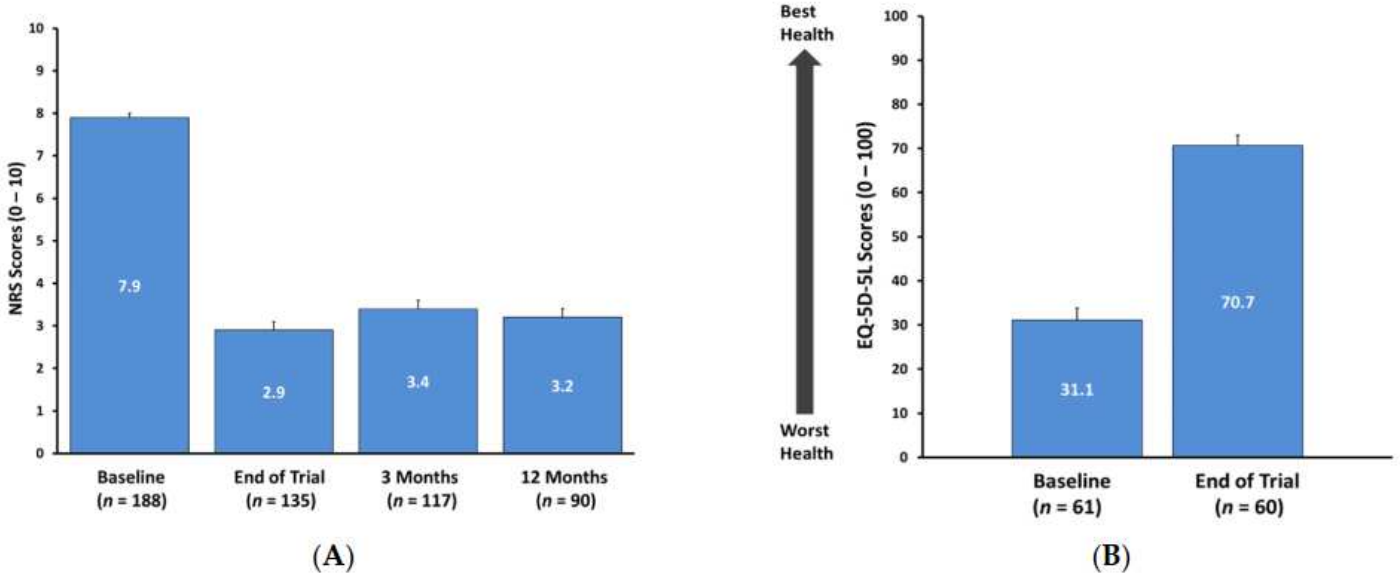
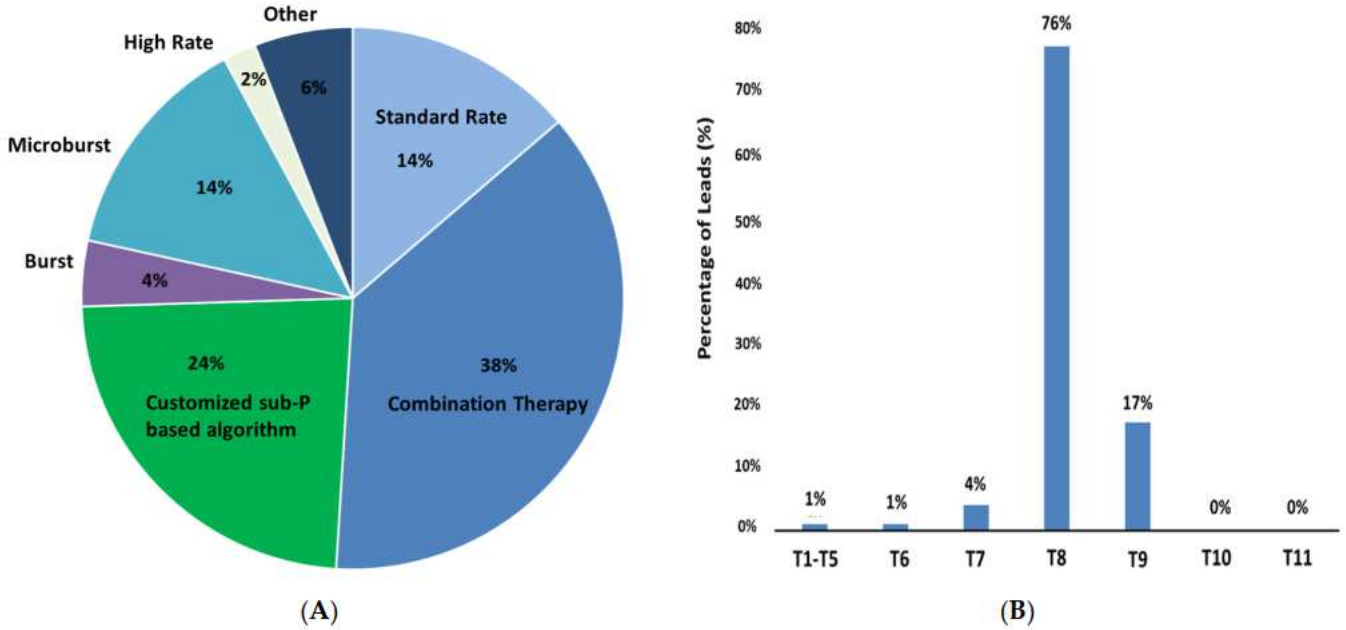


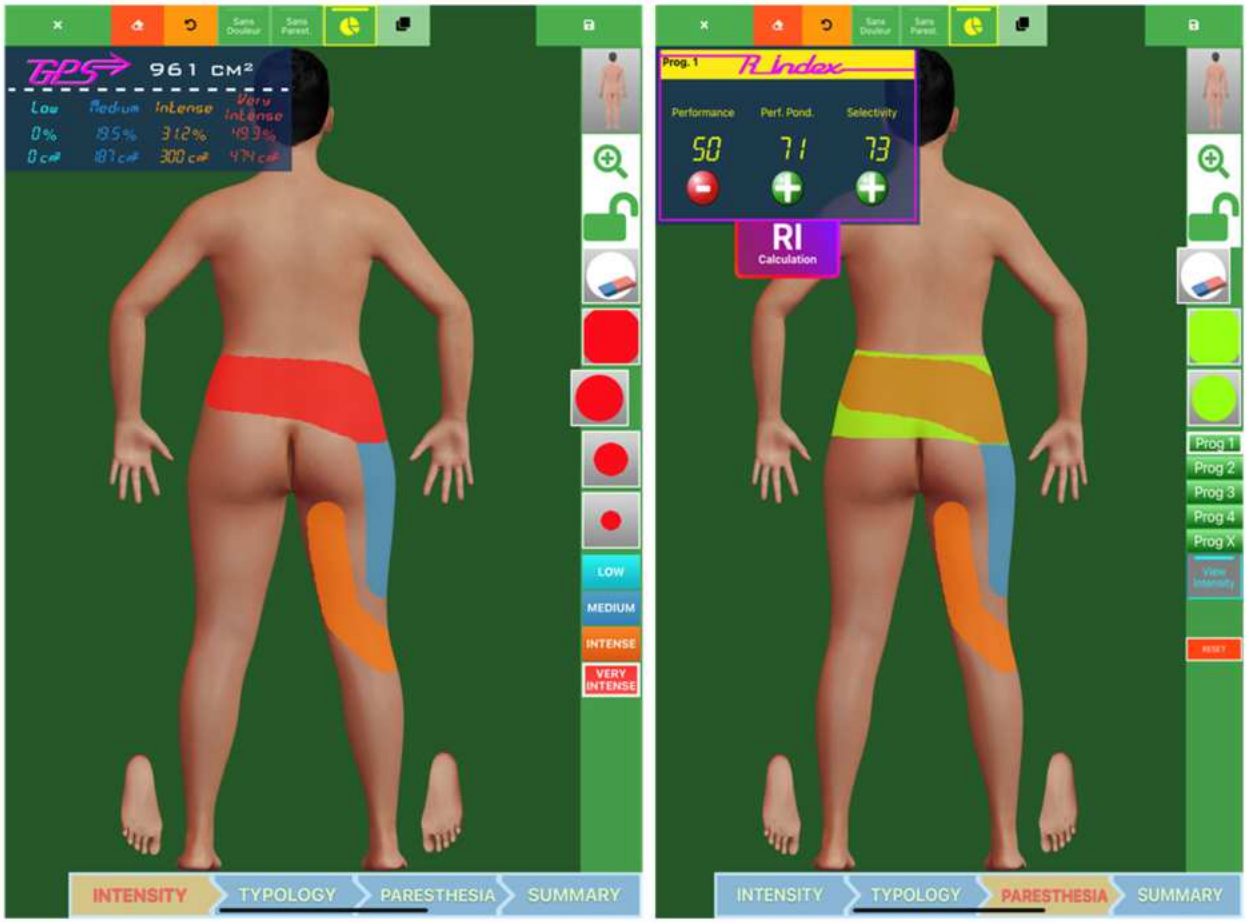
(A) Baseline, end of trial, and 3 and 12 months post-implant mean overall NRS pain scores. Error bars signify standard error (SE). $p < 0.0001$. (B) Overall quality of life, as assessed by EQ-5D-5L at Baseline and Last follow up. Error bars represent standard error (SE).

Kallewaard J. W., Paz-Solis J. F., De Negri P. et al.; Real-World Outcomes Using a Spinal Cord Stimulation Device Capable of Combination Therapy for Chronic Pain: A European, Multicenter Experience. Journal of Clinical Medicine. 2021, 10, 4085.



(A) Patient preferred programs at last follow-up. Combination Therapy is the ability to allow for simultaneous delivery of sub- and supra-perception stimulation modalities. Customized sub-perception-based algorithm designed to engage anti-nociceptive terminals over a broader area producing a stronger dorsal horn effect. (B) Vertebral location of top of implanted dual 16-contact leads (n = 69).

Kallewaard J. W., Paz-Solis J. F., De Negri P. et al.; Real-World Outcomes Using a Spinal Cord Stimulation Device Capable of Combination Therapy for Chronic Pain: A European, Multicenter Experience. Journal of Clinical Medicine. 2021, 10, 4085.



Pain mapping software used to assess pain surface and pain coverage where the patient could draw different painful zones. The pixels in the patient drawing are then converted into cm2, using several anatomical landmarks, patient morphology and morphometry. Four colors are available for patients to represent the different pain intensities. Pain coverage can then be obtained by drawing paresthesia (in green), which is converted to a percentage of pain coverage (performance).

Rigoard P., Ounajim A., Goudman L., et al. The Challenge of Converting „Failed Spinal Cord Stimulation Syndrome“ Back to Clinical Success, Using SCS Reprogramming as Salvage Therapy, through Neurostimulation Adapters Combined with 3D-Computerized Pain Mapping Assessment: A Real Life Retrospective Study. J Clin. Med. 2022, 11, 272.

Patients baseline sociodemographic and clinical characteristics.

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Variable	(n = 27)
Age mean ± SD	53.2 ± 11.6
Sex: Female/Male (n, percentage)	12 (44.4%)/15 (55.6%)
Lead type	
Octade	45 (18.5%)
Quad	4 (14.8%)
Octrode	1 (3.7%)
Penta	3 (11.1%)
Octade + quad	1 (3.7%)
5-6-5	3 (11.1%)
Octade + linear 3-6	2 (7.4%)
Vectris	2 (7.4%)
5-6-5 + linear 3-6	12 (37.84%)
5-6-5 + octade	1 (3.7%)
5-6-5 + quad	1 (3.7%)
vectris + octade	1 (3.7%)
Infinion + octade	1 (3.7%)
Octade	45 (18.5%)
Quad	4 (14.8%)
Implantation	
Percutaneous	7 (26.9%)
Subcutaneous	2 (7.4%)
Surgical	9 (33.3%)
Percutaneous + subcutaneous	5 (18.5%)
Surgical + subcutaneous	4 (14.8%)
Pain localization	
Leg pain	2 (7.4%)
Upper limbs pain	3 (11.1%)
Cluster headache	1 (3.7%)
Back and leg pain	19 (70.4%)

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Variable	(*n* = 27)
Groin pain	2 (7.4%)
Lead placement	
Thoracic	13 (48.1%)
Cervical	2 (7.4%)
Occipital	1 (3.7%)
Thoracic + subcutaneous	9 (33.3%)
Conus terminalis	2 (7.4%)
Duration between previous SCS and adapter implantation (years)	5.9 (5.2)
Follow-up duration	
Baseline	27
1 month	19/27 (70.4%)
3 months	16/27 (59.3%)
6 months	18/27 (66.7%)
12 months	16/27 (59.3%)
Baseline VAS (mean ± SD)	75.1 (14.9)
Baseline ODI (mean ± SD)	48.5 (15.9)
Baseline EQ5D (mean ± SD)	0.25 (0.2)

SCS: Spinal Cord Stimulation; VAS: Visual Analogic Scale; ODI: Oswestry Disability Index; EQ-5D-5L: EuroQol-5 Dimensions 5 Levels.

Rigoard P., Ounajim A., Goudman L., et al. The Challenge of Converting „Failed Spinal Cord Stimulation Syndrome“ Back to Clinical Success, Using SCS Reprogramming as Salvage Therapy, through Neurostimulation Adapters Combined with 3D-Computerized Pain Mapping Assessment: A Real Life Retrospective Study. J Clin. Med. 2022, 11, 272.

Outcomes comparisons between baseline and 1-month, 3-month, 6-month and 12-month follow-ups (n = 19).

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Outcomes	Before Mean ± SD	After Mean ± SD	CI95% of the Difference	*p*-Value
		1-month follow-up (n = 19)		
Global VAS	75.26 ± 16.45	45.56 ± 24.31	[16.04; 43.96]	0.001
ODI score	48.81 ± 12.55	31.69 ± 12.78	[6.61; 23.21]	0.001
EQ-5D index	0.25 ± 0.17	0.53 ± 0.23	[−0.38; −0.13]	0.004
HADS depression	5.82 ± 3.52	3.6 ± 2.56	[0; 4]	0.044
HADS anxiety	8.88 ± 4.55	6.53 ± 3.78	[0; 4]	0.049
Pain surface (cm^2)	938.26 ± 840.56	441.82 ± 597.72	[182.96; 903.51]	0.001
Very intense pain surface (cm^2)	638.33 ± 862.57	28.24 ± 82.65	[192; 1103.3]	0.002
Perceived pain relief		68.3/100 ± 21.6		
PGIC		6.1 ± 1.0		
		3-month follow-up (n = 16)		
Global VAS	71.88 ± 16.82	46.25 ± 19.96	[13.17; 38.08]	0.005
ODI score	45.4 ± 16.97	28.12 ± 12.36	[5.22; 36.23]	0.020
EQ-5D index	0.29 ± 0.21	0.53 ± 0.19	[−0.45; −0.07]	0.021
HADS depression	6.08 ± 3.87	3.5 ± 3.03	[0.26; 6.41]	0.042
HADS anxiety	8.0 ± 4.84	6.7 ± 3.8	[0.08; 3.25]	0.056
Pain surface (cm^2)	919.75 ± 926.34	569.79 ± 878.56	[68.09; 403.77]	0.014
Very intense pain surface (cm^2)	493.12 ± 920.89	288.5 ± 913.49	[−57.82; 507.82]	0.021
Perceived relief		72.2 ± 14.8		
PGIC		6.0 ± 0.7		

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Outcomes	Before Mean ± SD	After Mean ± SD	CI95% of the Difference	*p*-Value
		6-month follow-up (n = 18)		
Global VAS	78.33 ± 12	36.67 ± 23.26	[28.76; 54.57]	<0.001
ODI score	43.11 ± 15.77	31.9 ± 13.85	[−0.12; 25.52]	0.042
EQ-5D index	0.32 ± 0.22	0.53 ± 0.26	[−0.43; −0.08]	0.022
HADS depression	5.07 ± 3.34	4.3 ± 3.89	[0.61; 2.51]	0.019
HADS anxiety	7.93 ± 4.62	6.6 ± 6.15	[−0.1; 2.54]	0.055
Pain surface (cm^2)	848.22 ± 778.08	711.89 ± 969.23	[−106.8; 379.47]	0.088
Outcomes	**Before Mean ± SD**	**After Mean ± SD**	**CI95% of the Difference**	***p*-Value**
Very intense pain surface (cm^2)	562.53 ± 903.3	223.61 ± 809.48	[45.48; 606.05]	0.021
Perceived relief		72.8 ± 21.9		
PGIC		5.8 ± 0.8		
		12-month follow-up (n = 16)		
Global VAS	78.12 ± 11.09	33.75 ± 21.87	[33.03; 55.72]	<0.001
ODI score	47.71 ± 14.62	34 ± 22.84	[−6.66; 73.86]	0.098
EQ-5D index	0.27 ± 0.19	0.48 ± 0.36	[−0.88; 0.1]	0.181
HADS depression	6.33 ± 3.85	5 ± 5.55	[−2.13; 13.13]	0.125
HADS anxiety	8.75 ± 5.19	8 ± 5.8	[−1.5; 8]	0.181
Pain surface (cm^2)	887 ± 804.4	545.12 ± 859.58	[60.19; 623.56]	0.012
Very intense pain surface (cm^2)	573.4 ± 950.46	240.12 ± 858.75	[16.84; 617.7]	0.019
Perceived relief		67.5 ± 28.9		
PGIC		6.4 ± 0.5		

VAS: Visual Analogic Scale; ODI: Oswestry Disability Index; EQ-5D: EuroQoL 5-Dimensions; HADS: Hospital Anxiety and Depression Scale; PGIC: Patient Global Impression of Change.

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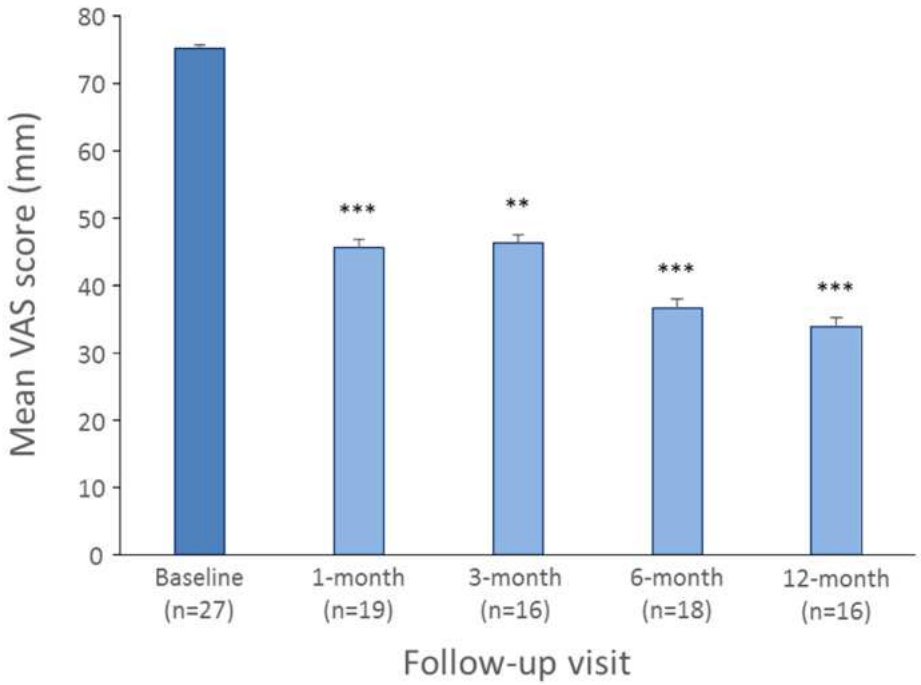

Mean VAS scores (and its standard error) obtained at baseline and at each follow-up visit.
*** $p < 0.001$, ** $p < 0.01$ significant difference between baseline and follow-up visits.

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Outcome comparisons between baseline and last follow-up visit (n = 27).

Outcomes	Before Mean ± SD	After Mean ± SD	CI95% of the Difference	*p*-Value
Global VAS	75.06 ± 14.91	39.13 ± 27.90	[23.7; 48.16]	<0.001
ODI score	48.48 ± 15.93	38.89 ± 20.45	[2.05; 28.15]	0.021
EQ5D	0.25 ± 0.20	0.39 ± 0.30	[−0.34; −0.05]	0.023
HADS depression	6.19 ± 3.71	5.08 ± 4.55	[−0.45; 5.25]	0.067
HADS anxiety	8.52 ± 4.32	7.50 ± 4.15	[0.35; 3.65]	0.036
Pain surface	1085.19 ± 1360.69	718.85 ± 1430.0	[117.26; 509.82]	0.001

VAS: Visual Analogic Scale; ODI: Oswestry Disability Index; EQ-5D: EuroQoL 5-Dimensions; HADS: Hospital Anxiety and Depression Scale.

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Comparisons of percentage of pain intensity decrease, percentage of pain surface decrease and paresthesia coverage between the "loss of coverage" group (n = 11) and the "SCS tolerance" group (n = 16).

Variable	LoC Group (n = 11)	SCStol Group (n = 16)	p-Value
Age	54.6 ± 11.6	52.2 ± 11.8	0.68
Sex			0.76
Male	7 (63.6%)	8 (50.0%)	
Female	4 (36.4%)	8 (50.0%)	
Duration between SCS implantation and adapter rescue therapy (years)	6.4 ± 5.1	5.6 ± 5.4	0.73
1-month follow-up	n = 10	n = 9	
Percentage of VAS decrease	32.56 ± 41.81	26.13 ± 33.33	0.60
Percentage of pain surface decrease	64.3 ± 33.86	11.77 ± 65.81	0.034
Paresthesia coverage	73.88 ± 35.77	27.6 ± 32.99	0.048
3-month follow-up	n = 8	n = 8	
Percentage of VAS decrease	36.89 ± 29.98	31.75 ± 39.61	0.75
Percentage of pain surface decrease	47.01 ± 38.69	20.13 ± 69.85	0.047
Paresthesia coverage	55.57 ± 46.23	30.5 ± 47.49	0.35
6-month follow-up	n = 8	n = 10	
Percentage of VAS decrease	50.56 ± 31.83	36.36 ± 43.69	0.59
Percentage of pain surface decrease	34.47 ± 44.77	18.13 ± 64.32	0.60
Paresthesia coverage	51.25 ± 48.66	38.56 ± 52.7	0.92
12-month follow-up	n = 8	n = 8	
Percentage of VAS decrease	58.68 ± 32.79	35.77 ± 44.09	0.19
Percentage of pain surface decrease	51.32 ± 42.31	26.61 ± 54.39	0.21
Paresthesia coverage	63.62 ± 46.26	21.5 ± 47.25	0.14

SCS: Spinal Cord Stimulation; VAS: Visual Analogic Scale.

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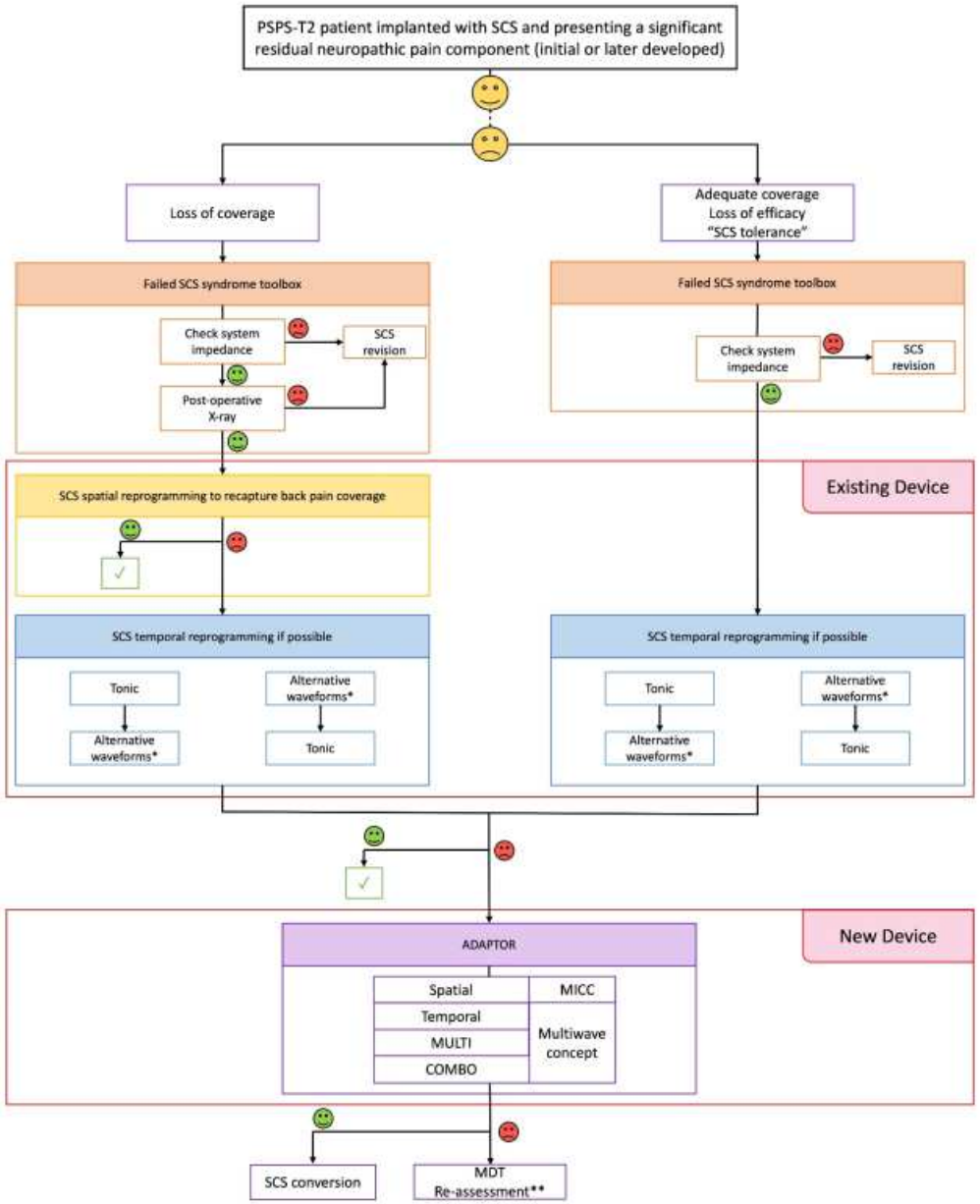

A theoretical proposal of SCS rescue algorithm in case of failed SCS syndrome.

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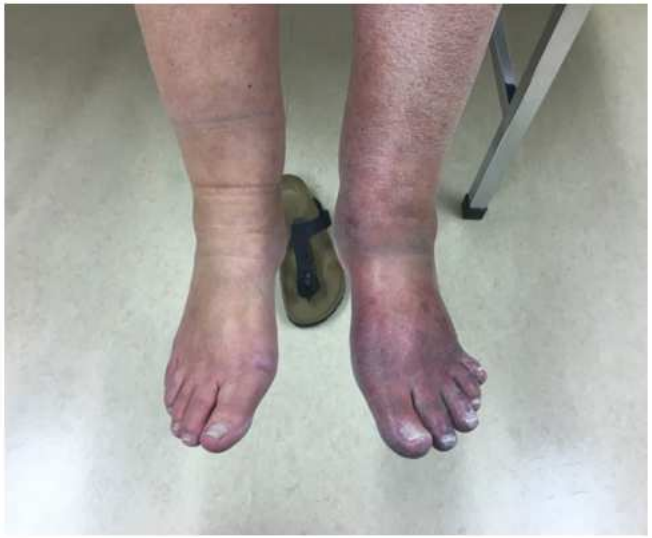
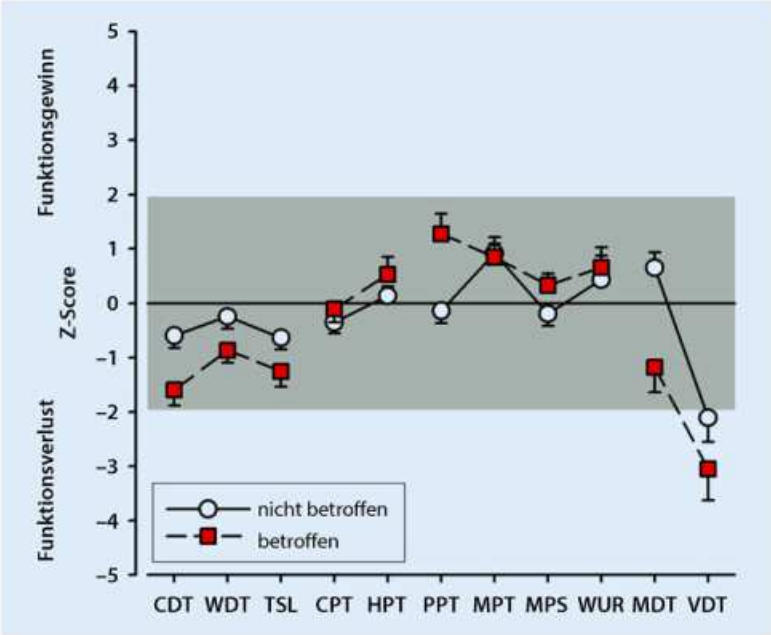


Bild eines chronischen komplexen regionalen Schmerzsyndroms
(CRPS) des linken Fußes mit ausgeprägten trophischen Störungen mit Ver-
änderung des Hautkolorits und Ödem

Rebhorn C., Dimova V., Birklein F., Komplexes regionales Schmerzsyndrom – ein Update. Schmerz 2022. 36:141-149.



Ein typisches QST(quantitativ sensorische Testung)-Profil (n = 50) von akuten CRPS(komplexes regionales Schmerzsyndrom)-Patienten: Auf der Y-Achse sind Z-Werte, d. h. Standardabweichungen von Gesunden, abgetragen; der Mittelwert ist normiert auf 0. Die roten Symbole stellen die betroffene Seite dar, die offenen Kreise die gesunde Seite. Auf der kranken Seite haben Patienten mit CRPStypischerweise eine thermische Hypästhesie (Kaltschwelle [„cold detection threshold“, CDT], Warmschwelle [„warm detection threshold“, WDT], Kombination [„thermal sensory limen“, TSL]), der Z-Wert ist niedriger als auf der gesunden Seite. Daneben findet sich eine mechanische Hyperalgesie (Druckschmerzschwelle [„pain pressure threshold“, PPT]), der Z-Wert ist größer. Nicht schmerzhafte mechanische Reize mit Von-Frey-Haaren („mechanical detection treshold“, MDT) werden weniger wahrgenommen. Die Vibration („vibration detection treshold“, VDT) wird beidseits weniger gespürt, was sich aber bei vielen chronischen Schmerzerkrankungen findet und aufmerksamkeitskorreliert sein dürfte. CPT „current perception threshold“, HPT „heat pain threshold“, MPT „mechanical pain threshold“, MPS „mechanical pain sensitivity“, WUR „wind-up ratio“

Rebhorn C., Dimova V., Birklein F., Komplexes regionales Schmerzsyndrom – ein Update. Schmerz 2022. 36:141-149.