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The Art and Evidence of Choosing Between SCS and DRG

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Conflicts of Interest

- Scientific Advisory Board: n/a
- Scientific Research: Research funded by Abbott. I personally do not receive any funds. NCT Clinical trial registry number: 05103527. Category B IDE Study Number: G210274
- Speaker's Bureau: n/a
- Stockholder: n/a
- Stock Options: n/a
- Product Royalties: n/a
- Employed by: self

Any off-label uses of devices or products will be disclosed and discussed in a balanced manner.

No commercial company or product names or logos will be used in this presentation.

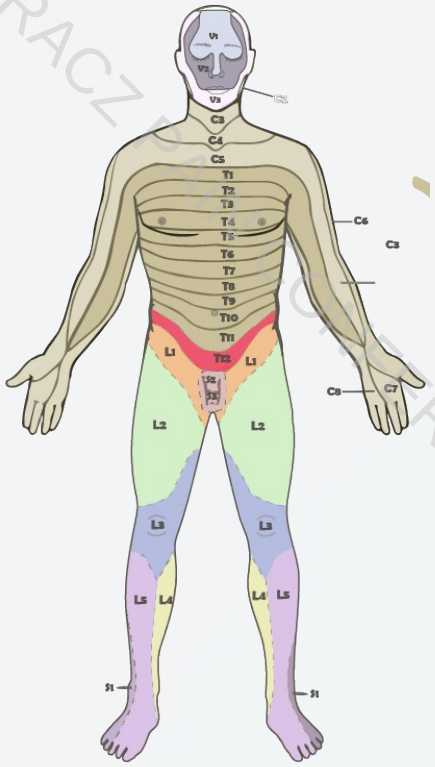
When should DRGS be a First Line Therapy?

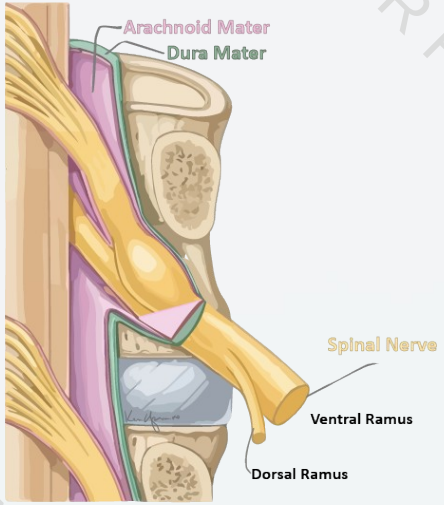
SCS gold standard in most cases

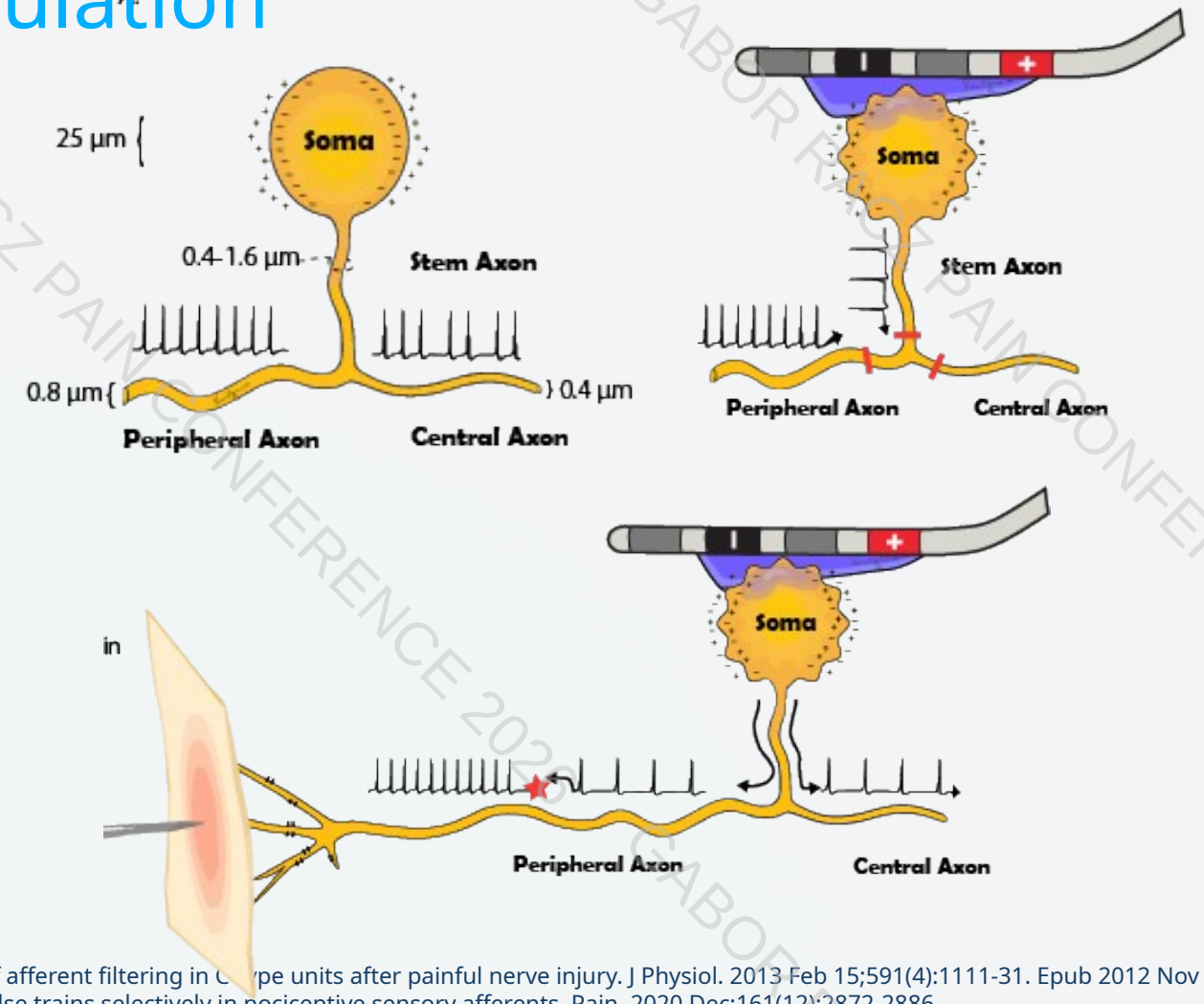
- Patient Specific
  - Underlying diagnosis
  - Patient limiting factors: anatomy, desire for invasiveness
  - Where they are on treatment algorithm
- Provider
  - Training/experience
- Regional limitations
  - Availability/Coverage

Dorsal Root Ganglion Stimulation

What is DRGS?







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Koopmeiners AS, Mueller S, Kramer J, Hogan QH. Effect of Electrical Field Stimulation on Dorsal Root Ganglion Neuronal Function. Neuromodulation. 2013 Jul;16(4):304–11.

Designed to meet the shortcomings of SCS

Better Distal Dermatomal Coverage

Check for updates

Neuromodulation: Technology at the Neural Interface

Received: September 17, 2018 Revised: November 14, 2018 Accepted: November 30, 2018

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12920

Comparison of Paresthesia Coverage of Patient's Pain: Dorsal Root Ganglion vs. Spinal Cord Stimulation. An ACCURATE Study Sub-Analysis

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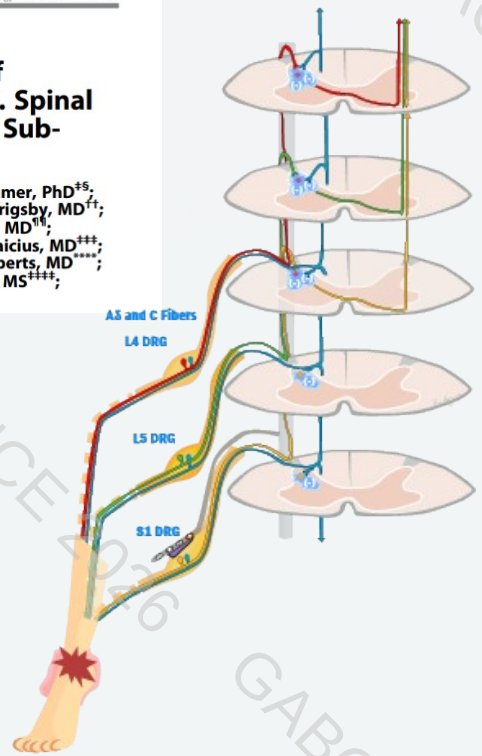
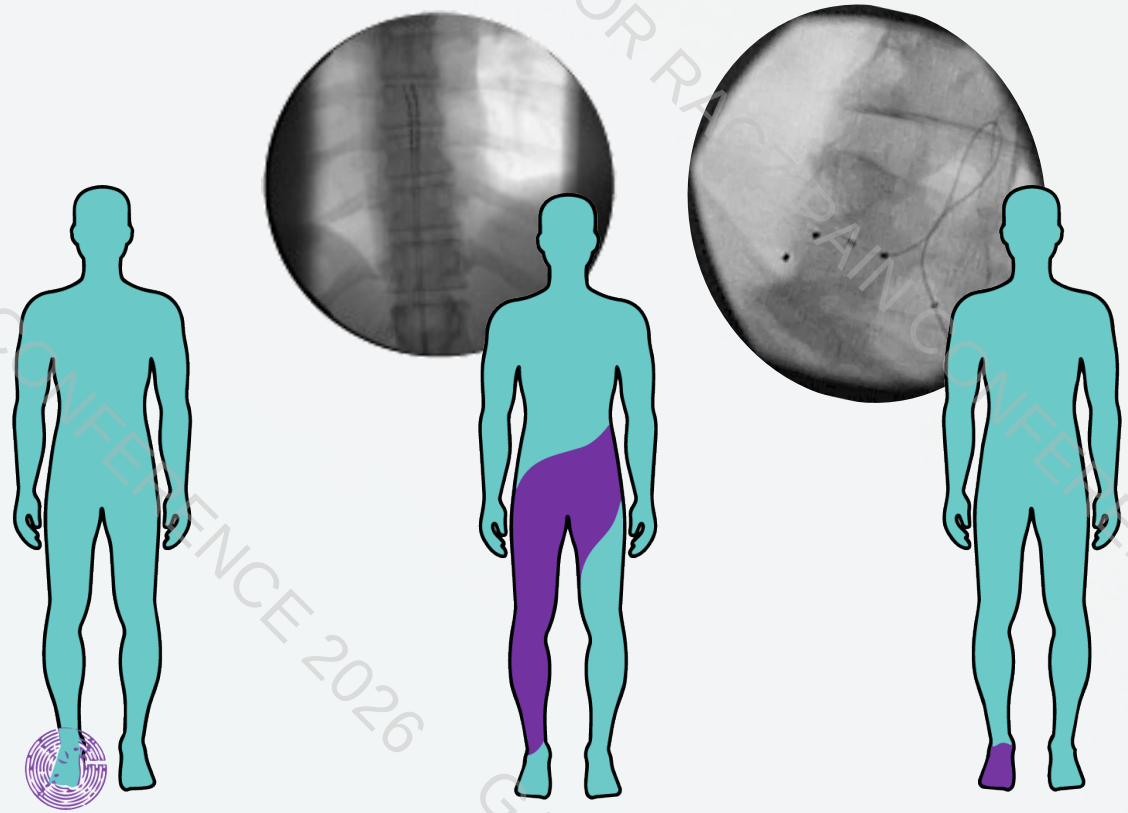


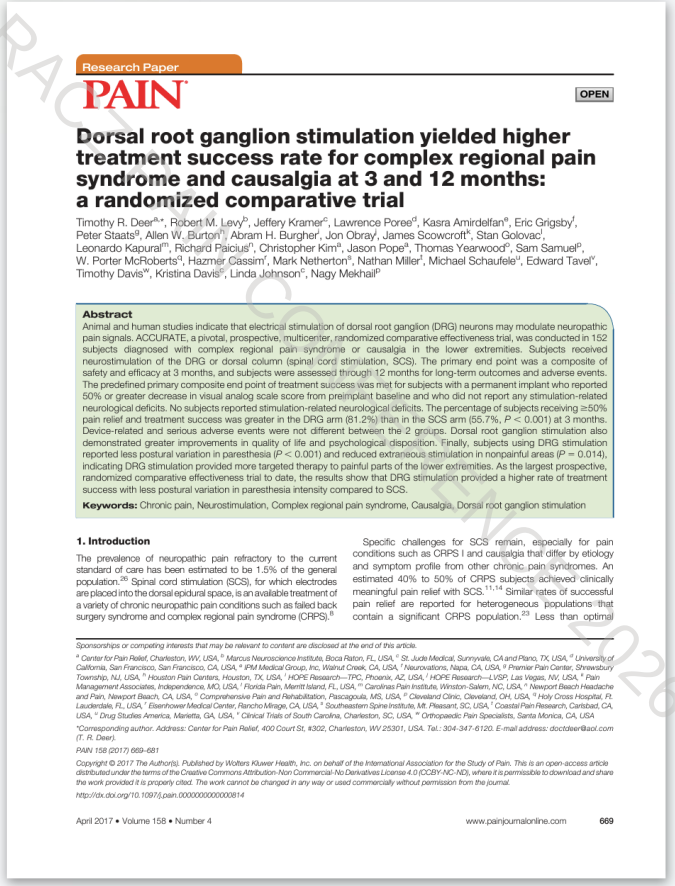


Deer TR et al. DRG Stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017 Apr;158(4):669-681. doi: 10.1097/j.pain.0000000000000814. PMID: 28030470; PMCID: PMC5359787.

Deer TR.et al. Comparison of Paresthesia Coverage of Patient's Pain: DRG vs. SCS. An ACCURATE Study Sub-Analysis. Neuromodulation. 2019 Dec;22(8):930-936. doi: 10.1111/ner.12920. Epub 2019 Jan 9. PMID: 30624003.

The ACCURATE Study

DRGS' Pivotal Study



Research Paper

PAIN

OPEN

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

Timothy R. Deer[a,*], Robert M. Levy[b], Jeffery Kramer[c], Lawrence Poree[d], Kasra Amirdelfan[e], Eric Grigsby[f], Peter Staats[g], Allen W. Burton[h], Abram H. Burgher[i], Jon Obray[j], James Scowcroft[k], Stan Golovac[l], Leonardo Kapural[m], Richard Paicius[n], Christopher Kim[a], Jason Pope[a], Thomas Yearwood[o], Sam Samuel[p], W. Porter McRoberts[q], Hazmer Cassim[r], Mark Netherton[s], Nathan Miller[t], Michael Schaufele[u], Edward Tavel[v], Timothy Davis[w], Kristina Davis[x], Linda Johnson[c], Nagy Mekhail[b]

Abstract

Animal and human studies indicate that electrical stimulation of dorsal root ganglion (DRG) neurons may modulate neuropathic pain signals. ACCURATE, a pivotal, prospective, multicenter, randomized comparative effectiveness trial, was conducted in 152 subjects diagnosed with complex regional pain syndrome or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column (spinal cord stimulation, SCS). The primary end point was a composite of safety and efficacy at 3 months, and subjects were assessed through 12 months for long-term outcomes and adverse events. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in visual analog scale score from preimplant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%, $P < 0.001$) at 3 months. Device-related and serious adverse events were not different between the 2 groups. Dorsal root ganglion stimulation also demonstrated greater improvements in quality of life and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia ($P < 0.001$) and reduced extraneous stimulation in nonpainful areas ($P = 0.014$), indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. As the largest prospective, randomized comparative effectiveness trial to date, the results show that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS.

Keywords: Chronic pain, Neurostimulation, Complex regional pain syndrome, Causalgia, Dorsal root ganglion stimulation

1. Introduction

The prevalence of neuropathic pain refractory to the current standard of care has been estimated to be 1.5% of the general population.[26] Spinal cord stimulation (SCS), for which electrodes are placed into the dorsal epidural space, is an available treatment of a variety of chronic neuropathic pain conditions such as failed back surgery syndrome and complex regional pain syndrome (CRPS).[8]

Specific challenges for SCS remain, especially for pain conditions such as CRPS I and causalgia that differ by etiology and symptom profile from other chronic pain syndromes. An estimated 40% to 50% of CRPS subjects achieved clinically meaningful pain relief with SCS.[11,14] Similar rates of successful pain relief are reported for heterogeneous populations that contain a significant CRPS population.[23] Less than optimal

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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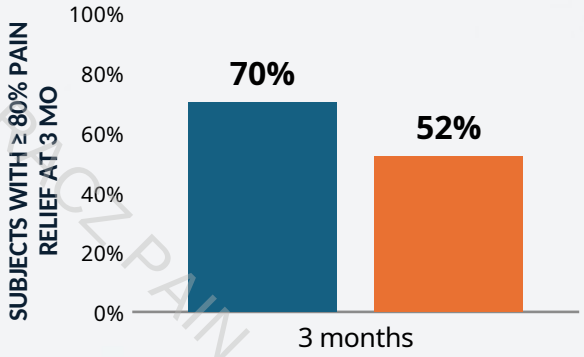
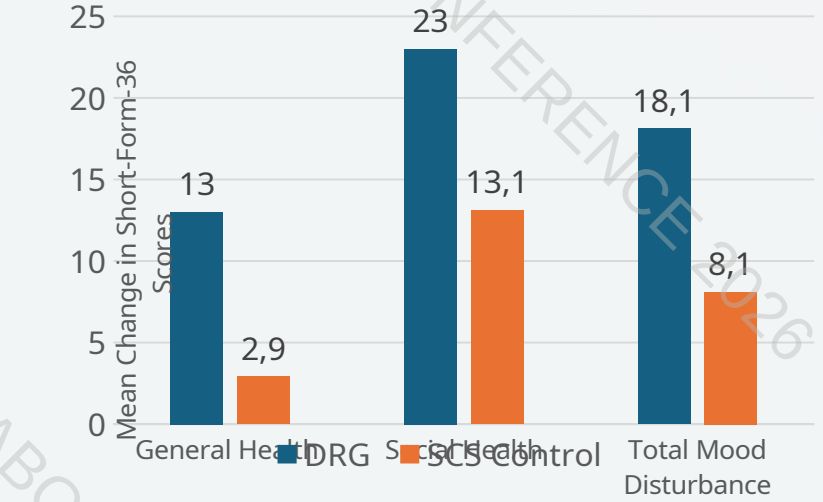
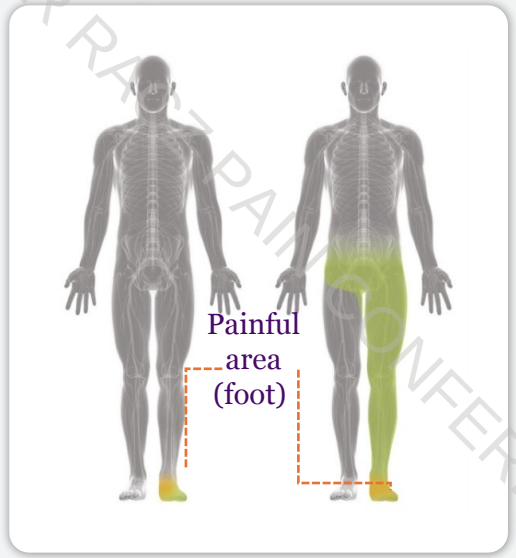




Greater Improvement in General Health, Social Health and Mood Disturbance



DRG	SCS CONTROL
95%	61%

Subjects receiving targeted stimulation in the area of pain without extraneous paresthesia

Deer T. et al. DRGS yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. Pain. 2017;158(4):669-681.

Less Loss of Efficacy

Clinical impact

- **Levy et al. ACCURATE Subgroup Analysis**

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US ASSOCIATION FOR THE STUDY OF PAIN
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Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II

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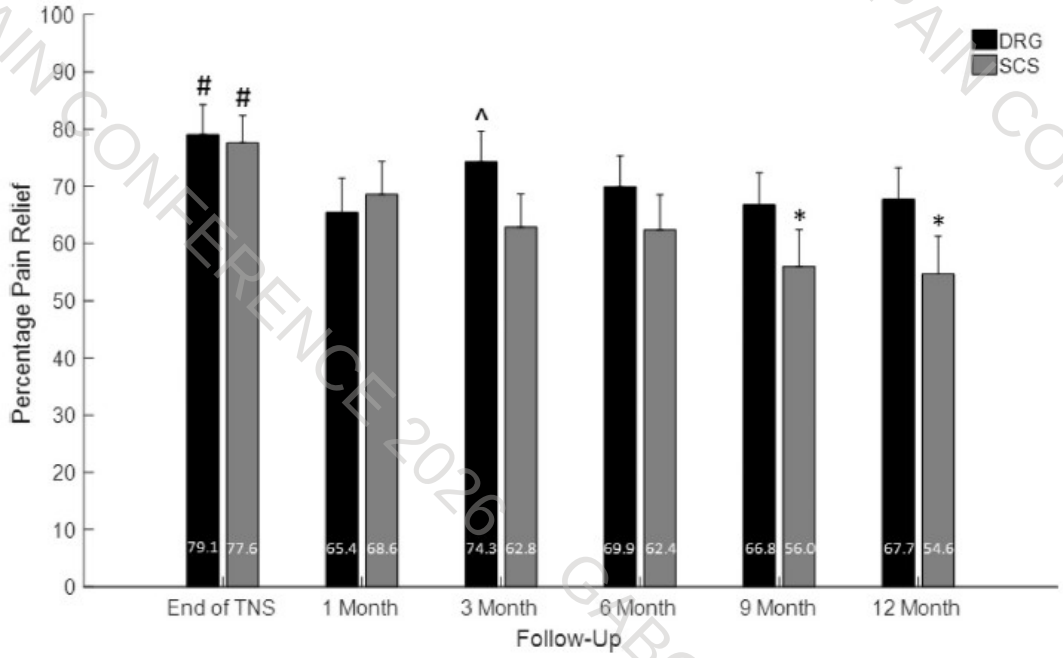
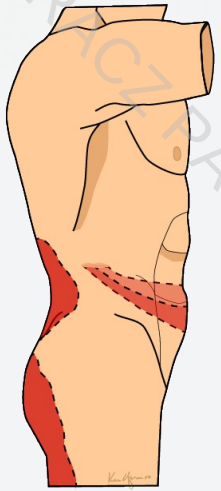
Abstract: The ACCURATE randomized, controlled trial compared outcomes of dorsal root ganglion (DRG) stimulation versus tonic spinal cord stimulation (SCS) in 152 subjects with chronic lower extremity pain due to complex regional pain syndrome (CRPS) type I or II. This ACCURATE substudy was designed to evaluate whether therapy habituation occurs with DRG stimulation as compared to SCS through 12-months. A modified intention-to-treat analysis was performed to assess percentage pain relief (PPR) and responder rates at follow-up visits (end-of-trial, 1, 3, 6, 9, 12-months postpermanent implant) for all subjects that completed trial stimulation (DRG:N = 73, SCS:N = 72). For both groups, mean PPR was significantly greater at end-of-trial (DRG = 82.2%, SCS =0 77.0%) than all other follow-ups. Following permanent DRG system implantation, none of the time points were significantly different from one another in PPR (range = 69.3–73.9%). For the SCS group, PPR at 9-months (58.3%) and 12-months (57.9%) was significantly less than at 1-month (66.9%). The responder rate also decreased for the SCS group from 1-month (68.1%) to 12-months (61.1%). After stratifying by diagnosis, it was found that only the CRPS-I population had diminishing pain relief with SCS. DRG stimulation resulted in more stable pain relief through 12-months, while tonic SCS demonstrated therapy habituation at 9- and 12-months.
Trial Registration: The ACCURATE study was registered at ClinicalTrials.gov with Identifier NCT01923285.

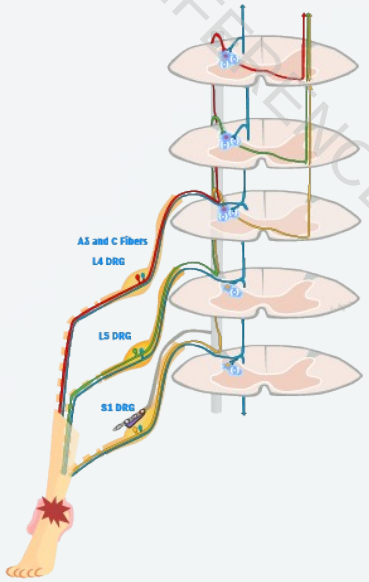


Levy et al. Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus DRGS for Complex Regional Pain Syndrome Type I and II. J Pain. 2020 Mar-Apr;21(3-4):399-408
Chapman KB et al. Dorsal root ganglion stimulation device explantation: A multicenter pooled data analysis. *Pain Pract*. 2022;22(5):522-531. doi:10.1111/papr.13113

Further Advantages with DRGS

Unforeseen benefits





Coverage

Dermatomal, Visceral/Sympathetic, Diffuse pain

Pain Syndromes

Neuropathic, Mixed, Nociceptive, etc.

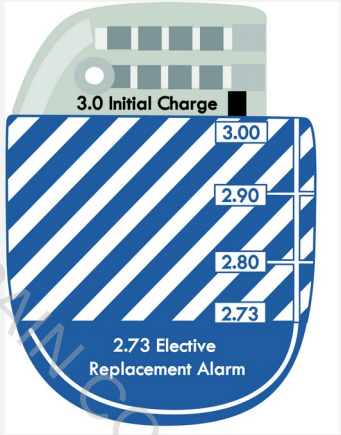
Lowest Energy Consumption

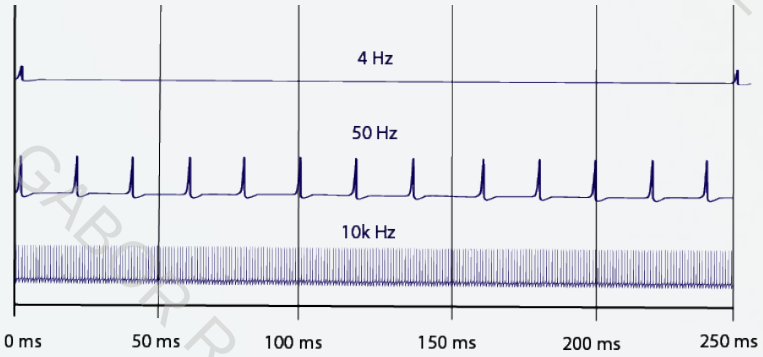
Meet Patient Satisfaction Measures

Paresthesia Free/no recharge/IPG longevity

Sympathetic Modulation

Habituation?

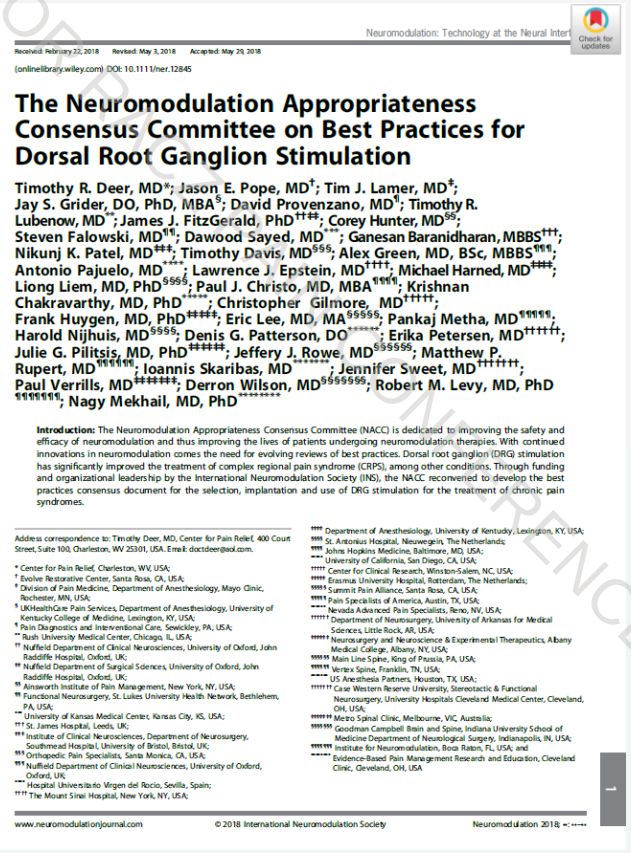




DRGS Consensus Statements

DRGS for CRPS I and CRPS II

- 2018: International Neuromodulation Society (INS) evaluated level of peer reviewed evidence
- 2023: The American Society of Pain and Neuroscience (ASPN) Best Practice Guideline
- Conclusion: DRGS recommended for patients with CRPS type I and type II:
  - DRGS is considered primarily for patients with focal neuropathic pain syndromes; **Level I, Grade A, Consensus Strong**
  - DRGS is an effective therapy for the treatment of CRPS type I or type II of the lower extremity; **Level I, Grade A, Consensus Strong**



Neuromodulation: Technology at the Neural Interface

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The Neuromodulation Appropriateness Consensus Committee on Best Practices for Dorsal Root Ganglion Stimulation

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Introduction: The Neuromodulation Appropriateness Consensus Committee (NACC) is dedicated to improving the safety and efficacy of neuromodulation and thus improving the lives of patients undergoing neuromodulation therapies. With continued innovations in neuromodulation comes the need for evolving reviews of best practices. Dorsal root ganglion (DRG) stimulation has significantly improved the treatment of complex regional pain syndrome (CRPS), among other conditions. Through funding and organizational leadership by the International Neuromodulation Society (INS), the NACC reconvened to develop the best practices consensus document for the selection, implantation and use of DRG stimulation for the treatment of chronic pain syndromes.

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Deer, et al. 2018. The Neuromodulation Appropriateness Consensus Committee on Best Practices for Dorsal Root Ganglion Stimulation. Neuromodulation 2018; E-pub ahead of print. DOI:10.1111/ner.12845

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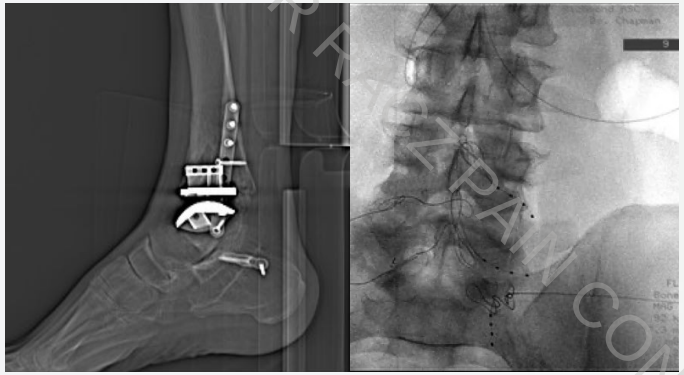
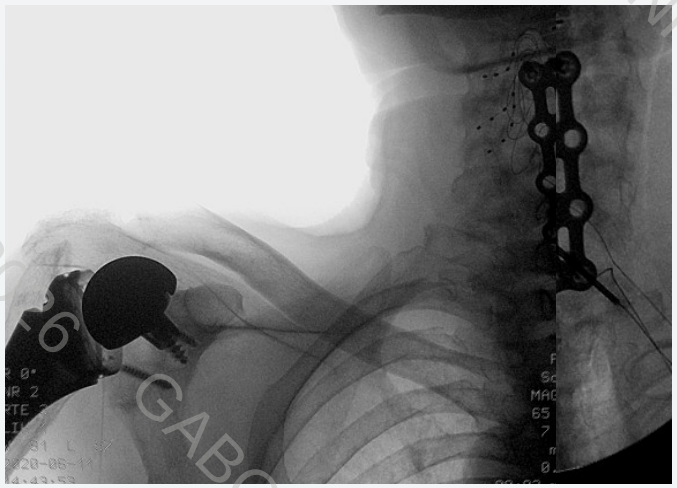
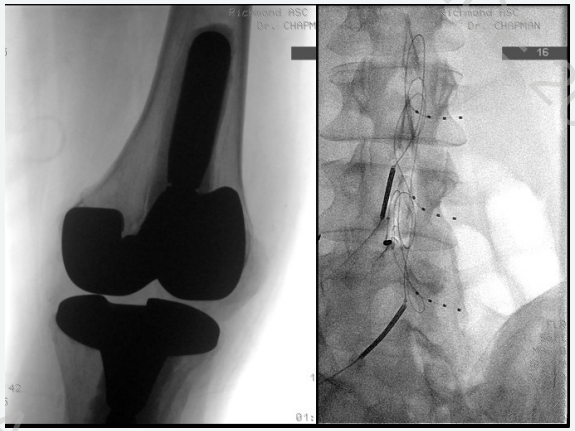
Post Surgical Pain Syndromes and Distal Pain

CRPS-Type 2

- Abdominal wall post surgical pain
- Visceral post surgical pain
- Pelvic pain post surgical
- Post-thoracotomy pain
- Post-joint replacement pain syndromes

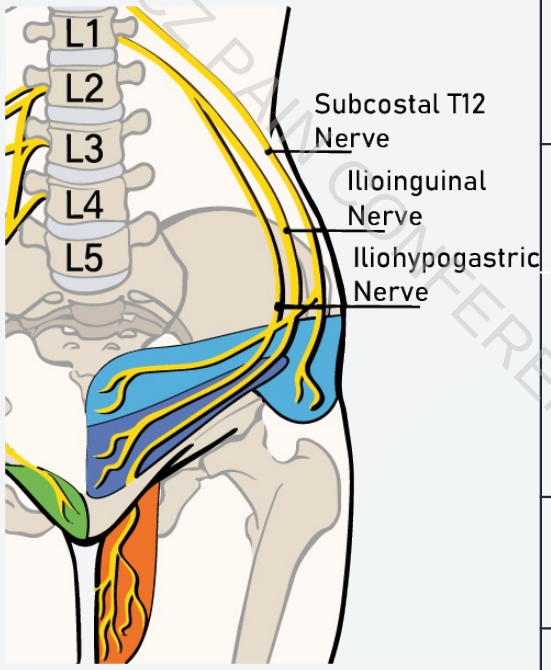






Ilioinguinal Neuralgia

DRGS Post Herniorrhaphy Repair



Study	Trialed/ Implanted	Follow up	Outcome Measures	Results: Efficacy	Results: Complications
Morgalla et al. (2018) Pros.	34/34	3 months, 1, 2, and 3 years (11 at 3 years)	VAS (median), PDI, PCS, BPI, BDI	Overall VAS 8 to 4.5. VAS at 3 months:3, 1 year: 3.5 VAS at 2 yrs: 4, VAS at 3 yrs: 4.5. PDI decreased 48 to 23. PCS 31 to 16. BPI 76 to 30. BDI 17 to 7.	5 complications: (16.7%) 2 lead fx, 1 infection during trial, 1 IPG relocation, 1 additional lead
Schu et al. (2015) Pros.	25/29	Mean 27.8 (±4.3) wks Median 26(0-68) wks	VAS	Baseline VAS: 74.5 (±1.8) to 20.7 (±3.9) Mean Reduction 71.4% (±5.6%). >80% reduction 47.8% (12/23), > 50% reduction (82.6%) (19/23)	Not reported. 1 explanted reason (not given)
	Post hernia 10/12 (83.3%)	Mean 17.4 (±5.7)wks		Mean VAS reduction was 76.8 (± 8.2%) >50% Reduction 80% >80% Reduction 50%	
	Post hernia >6 mo follow up	>6 mo 30.6(±7.6) wks		Baseline VAS: 67.6 (±2.3) to 17.4 (±7.0) Mean reduction 74.3% (± 11%). >50% Reduction 80% (4/5) >80% Reduction 40% 2/5)	
Zuidema et al. (2014) CR	3/3	1 week, 1,3,6, and 12 months	VAS, QOL	Patient 1: baseline VAS: 90 VAS at 2 weeks and 3 months: 0 Patient 2: baseline VAS: 90 VAS at 1 week and 2 months: 10 Patient 3: baseline VAS: 95 VAS at 1 week and 2 months: 10	No SAEs occurred
Hunter et al. (2019) Pros.	8 post hernia repair	Trial success	VAS	Mean Relief:67.5%, NRS Reduction: 5.75. NRS Reduction 69.4%, Trial/ Implant 75%	N/A

Zuidema X, Breel J, Wille F. Paresthesia mapping: a practical workup for successful implantation of the dorsal root ganglion stimulator in refractory groin pain. Neuromodulation. 2014;17(7):665–669. Discussion 9.
Schu S, Gulve A, Eldabe S, et al. Spinal cord stimulation of the dor-sal root ganglion for groin pain-a retrospective review. Pain Pract. 2015;15(4):293–299.
Morgalla M et al. Dorsal root ganglion stimulation (DRGs) for the treatment of chronic neuropathic pain: a single-center study with long-term prospective results in 62 cases. Pain Physician. 2018;21(4):E377–E87.
Hunter et al. DRG FOCUS: A Multicenter Study Evaluating Dorsal Root Ganglion Stimulation and Predictors for Trial Success. Neuromodulation. 2019 Jan;22(1):61-79. doi: 10.1111/ner.12796. PMID: 30085382.

Post Surgical Joint Pain

DRGS for post TKR and THR pain

Study	Number of participants	Follow up	Outcome Measures	Results: Efficacy
Morgala et al (2018) PR	51 implanted (27 knee pain)	1yr: 40, 2 years: 3 years: 25	VAS, PDI, PCS BPI, BDI	3 years VAS 8→4. PDI 45→ 23. PCS 34→21. BPI 73→30. BDI 36 →21
Hunter et al (2019) Pros.	Accurate subgroup 14 pt (12 knee, 2 hip)	Trial	VAS	Knee: NRS decreased 71.7% Hip NRS decreased 68.6%
Martin et al (2020) Pros.	14 consecutive knee (7 post op, 7 trauma)	mean of 34 months (15-78 mo) L3 only : 8 L4 only:8 L3+L4 : 3	VAS	VAS Median 8.5 > 2.0 Median % imp. 80% Responder rate 100% Mean ME 45-20
Kretzschmar et al. (2020) CS	23 patients (10 knee, 2 hip)	36 months	VAS, MCS, PCS, QLIP	Improvement Vas 73% MCS 25% PCS 18% QLIP 102%
van Bussel et al. (2018) Pros. Crossover	12 knee CRPS pts	16-day trial	Preference, VAS/NRS, GPE	10/12 (83.3%) preferred DRGS over SCS; all leads at L3/L4
Gravius/Kinfe et al. (2019) mechanistic knee study	12 postsurgical neuropathic knee pts	3 mo	NRS + biomarkers	~61.3% pain reduction with associated biologic signal changes
Schultheis et al. (2024) RS	11 chronic postsurgical knee pain pts	Mean 18.4 mo	NRS, WOMAC, TUG, ROM	NRS 8.6 -> 3.0; WOMAC 45.7 -> 20.4; TUG 28.0s -> 17.7s; flexion 80.7° -> 85.2°; extension deficit 11.9° -> 6.0°
Chapman et al. (2023) CS	5 joint-pain pts (hip/knee/ankle)	Mean 28 mo	NRS, ODI, EQ-5D	Mean NRS 9.2->2.4 (-74%); ODI 66->23; EQ-5D 0.371->0.797
Lopez et al. (2022) CR	1 pt bilateral post-patellectomy knee pain	7-day trial; 7 and 9 mo post-implant	NRS, ODI, PROMIS Pain Intensity, Physical, Depression	Trial: 90% relief; 9-mo NRS 9->0 Lt 9->2 Rt; ODI 46->28; PROMIS Phys 30.7->40.4; Pain 6->1; Depression 55.7->41
Victor et al. (2018) CR	1 hip AVN pt	6-day trial; 3 mo	NRS, function, ambulation	Pain 9/10 -> ~95% relief; improved walking/function
van Bussel et al. (2015) CR	1 knee CRPS-I pt after arthroscopy	3 mo	NRS, pain area, knee movement	NRS 9 -> 1-2; ~90% painful-area coverage; improved knee movement

Choose DRGS

CRPS I and CRPS II

- Abdominal wall post surgical pain
- Visceral post surgical pain
- Pelvic pain post surgical
- Post-thoracotomy pain
- Post-joint replacement pain syndromes

Chapman KB, Sayed D, Lamer T, Hunter C, Weisbein J, Patel KV, Dickerson D, Hagedorn JM, Lee DW, Amirdelfan K, Deer T, Chakravarthy K. Best Practices for Dorsal Root Ganglion Stimulation for Chronic Pain: Guidelines from the American Society of Pain and Neuroscience. J Pain Res. 2023 Mar 14;16:839-879. doi: 10.2147/JPR.S364370. PMID: 36942306; PMCID: PMC10024474.

DRGS as a Salvage Therapy

High Success if Previously Benefit from SCS

Neuromodulation: Technology at the Neural Interface

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Dorsal Root Ganglion Stimulation as a Salvage Therapy Following Failed Spinal Cord Stimulation

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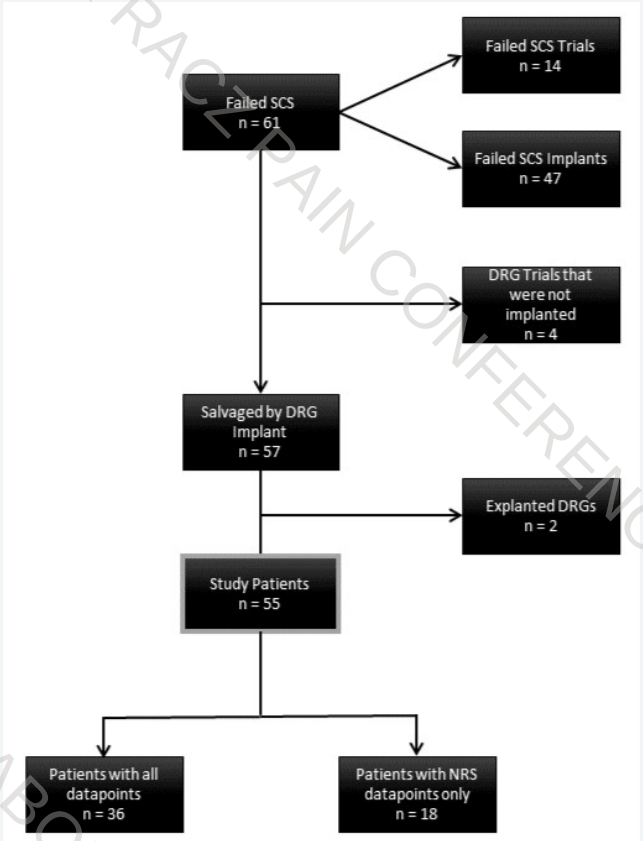
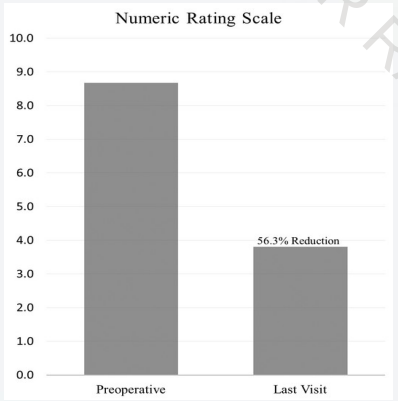
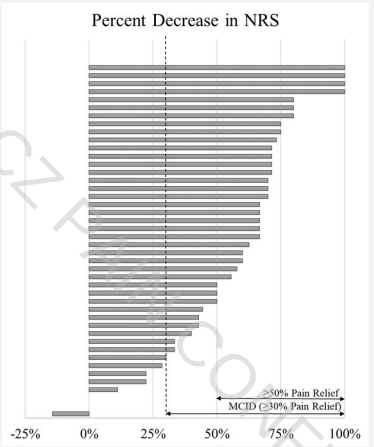
Baseline Patient Characteristics	*n = 61*
Sex, n (%)	
Female	*35 (57)*
Male	*26 (43)*
Age (at DRG-S Implant)	
Median (Range)	*57 (15-78)*
Diagnosis, n (%)	
CRPS	*28 (46)*
FBSS	*25 (41)*
Non-Surgical low back pain	*3 (5)*
Pelvic Pain	*3 (5)*
Radicular pain	*3 (5)*
Peripheral neuropathy	*1 (1.6)*
Nociceptive knee pain	*1 (1.6)*
Median Implant Time	*836 days*
Median Follow-up Time	*347 days*
Baseline HRQOL Scores, mean	
NRS (SD)	*9 (1)*

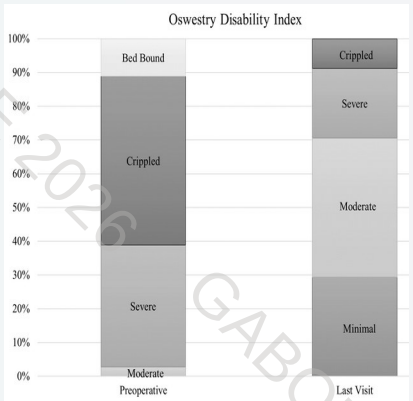
	Failed Trials n=12	*Failed Implants n=43*
Tonic SCS	5	22
Hf-SCS	4	5
Burst	3	15
Both Tonic and Hf-SCS	0	1

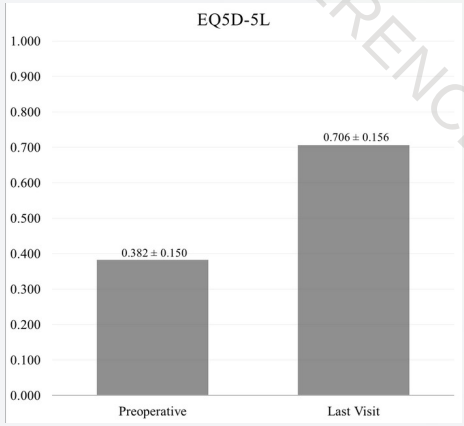
Table 2: Listing of failed SCS trials and devices due to loss of efficacy.











Chapman KB et al. DRGS as a Salvage Therapy Following Failed Spinal Cord Stimulation. Neuromodulation. 2022 Oct;25(7):1024-1032. doi: 10.1016/j.neurom.2022.04.050. Epub 2022 Jun 25. PMID: 35760751.

T12 DRGS for Low Back Pain

T12 lead placement and LBP coverage

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T12 Dorsal Root Ganglion Stimulation to Treat Chronic Low Back Pain: A Case Series

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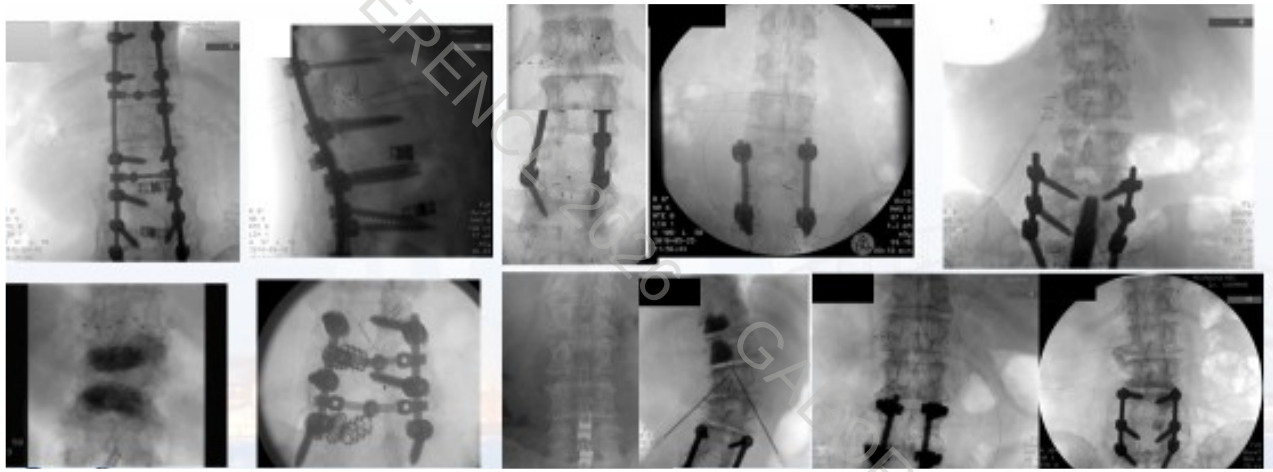
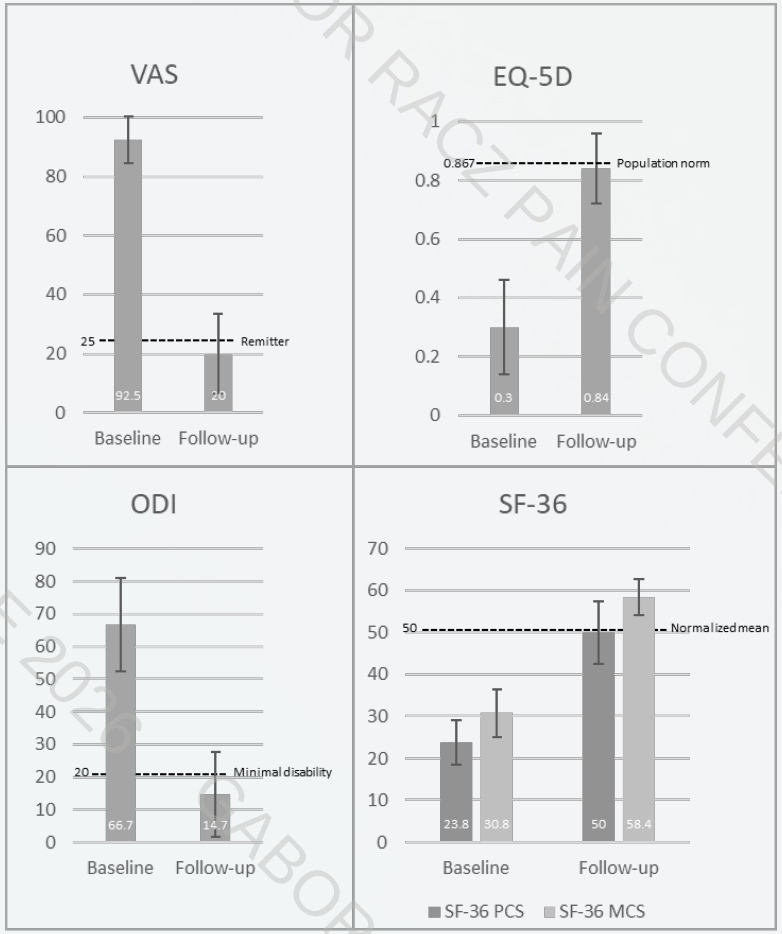


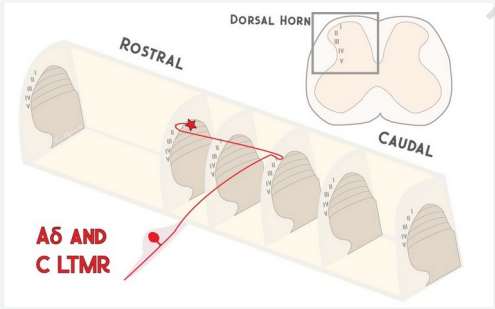


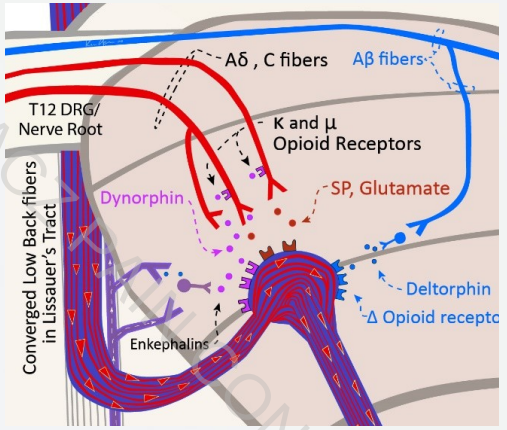
Chapman KB et al. T12 Dorsal Root Ganglion Stimulation to Treat Chronic Low Back Pain: A Case Series. Neuromodulation. 2020 Feb;23(2):203-212. doi: 10.1111/ner.13047. Epub 2019 Oct 6. PMID: 31588662.

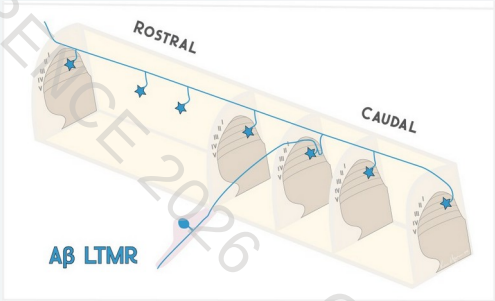
T12 and S1 DRGS for Low Back Pain

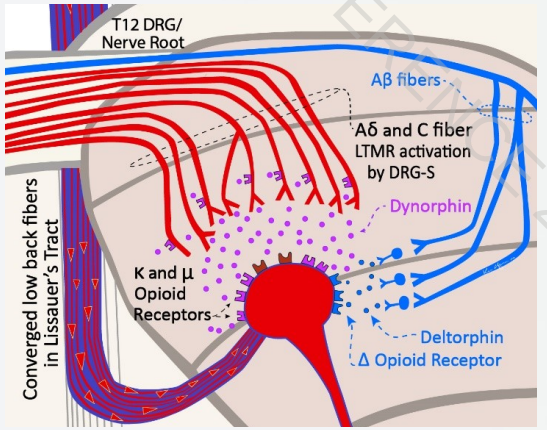
T12 and S1 provide diffuse, multi-dermatomal coverage

Patient Demographics	(n)	%	Diagnosis, n (%)	(n)	%
Pts. Implanted w/ T12/S1 DRGS	90		Post surgical LBP w/ radic.	54	(60)
Gender, N (%)			NSLBP with radiculopathy	32	(36)
Male	42	47%	NSLBP with other*	4	(4)
Female	48	53%	Time implanted (mean)	25.2mo.	
Age in years, mean (range)	63	(34-86)	Therapy exit	7	









Prospective database DRGS patients

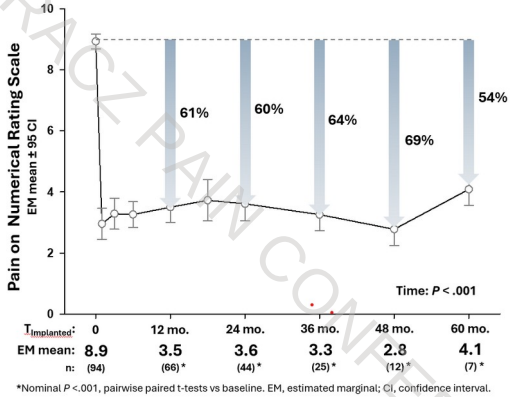
Longest 5 years

Data thus far reflects prior back pain work with DRG (NRS, ODI, EQ5)

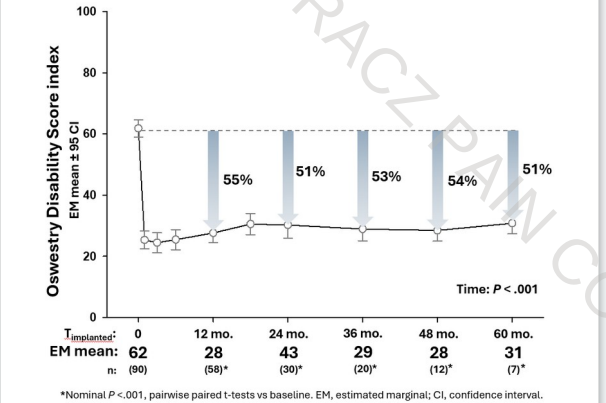
S1 lead had multi-dermatomal coverage

T12 and S1 DRGS for Back and Leg Pain

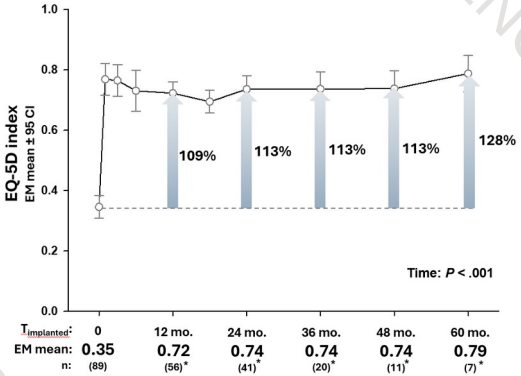
T12/S1 provides diffuse unilateral coverage



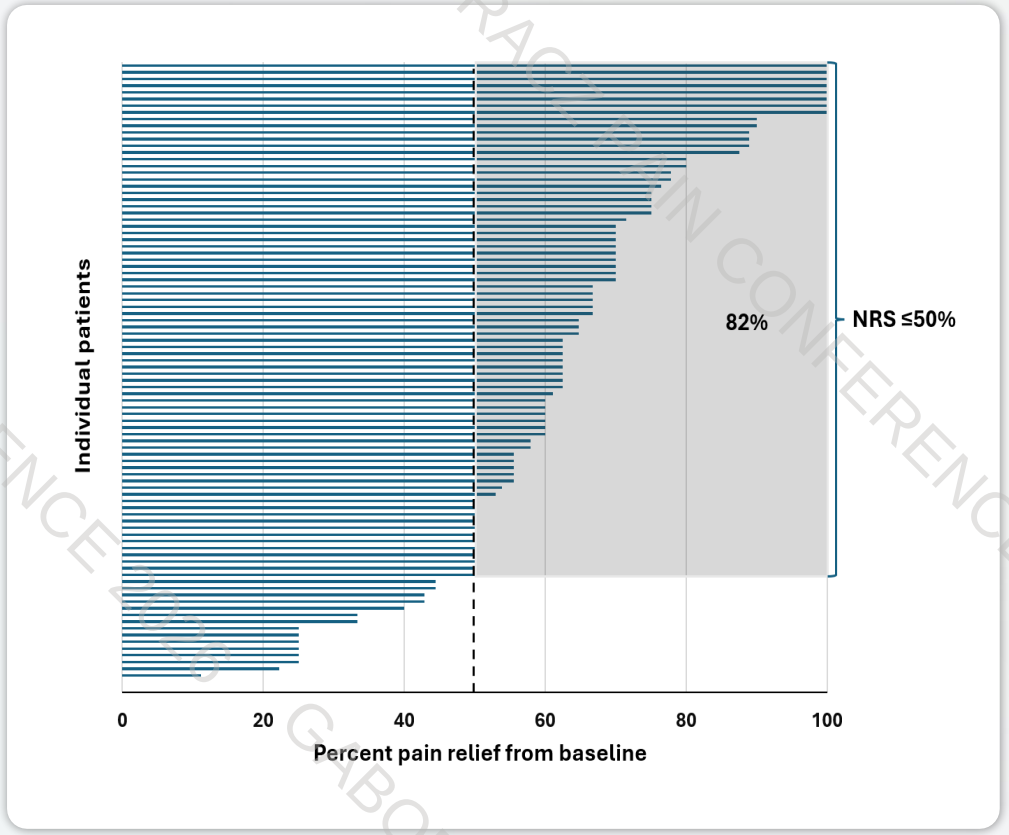
*Nominal P <.001, pairwise paired t-tests vs baseline. EM, estimated marginal; CI, confidence interval.



*Nominal P <.001, pairwise paired t-tests vs baseline. EM, estimated marginal; CI, confidence interval.



*Nominal P <.001, pairwise paired t-tests vs baseline. EM, estimated marginal; EQ-5D, EuroQoL 5 Dimensions; CI, confidence interval.



Less Loss of Efficacy

Clinical impact

- **Levy et al. ACCURATE Subgroup Analysis**

US ASP
US ASSOCIATION FOR THE STUDY OF PAIN
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Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus Dorsal Root Ganglion Stimulation for Complex Regional Pain Syndrome Type I and II

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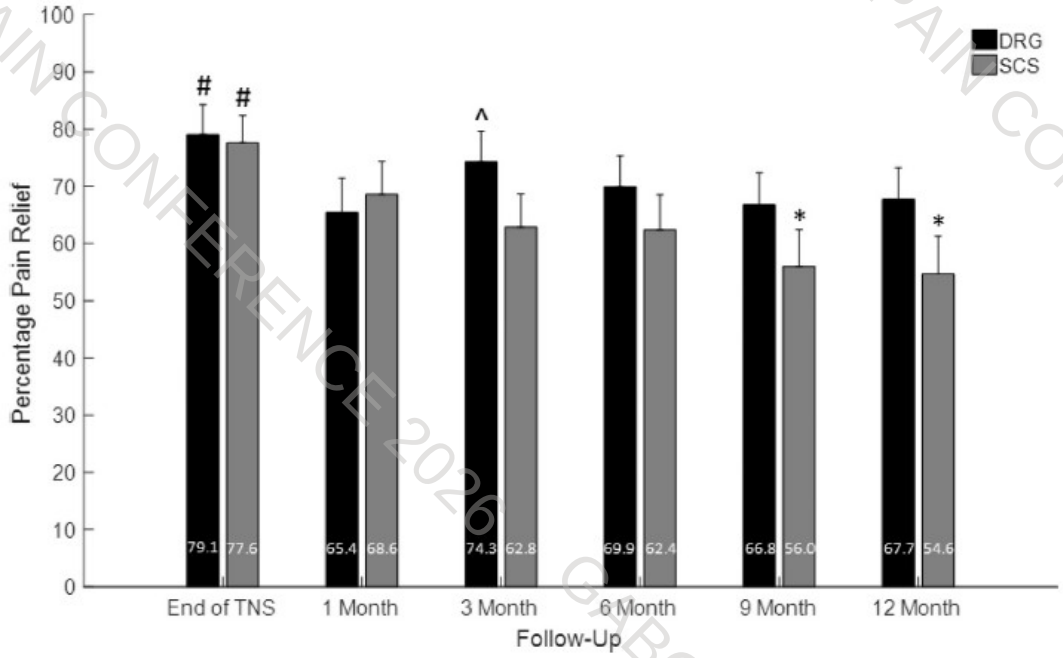
Abstract: The ACCURATE randomized, controlled trial compared outcomes of dorsal root ganglion (DRG) stimulation versus tonic spinal cord stimulation (SCS) in 152 subjects with chronic lower extremity pain due to complex regional pain syndrome (CRPS) type I or II. This ACCURATE substudy was designed to evaluate whether therapy habituation occurs with DRG stimulation as compared to SCS through 12-months. A modified intention-to-treat analysis was performed to assess percentage pain relief (PPR) and responder rates at follow-up visits (end-of-trial, 1, 3, 6, 9, 12-months postpermanent implant) for all subjects that completed trial stimulation (DRG:N = 73, SCS:N = 72). For both groups, mean PPR was significantly greater at end-of-trial (DRG = 82.2%, SCS =0 77.0%) than all other follow-ups. Following permanent DRG system implantation, none of the time points were significantly different from one another in PPR (range = 69.3–73.9%). For the SCS group, PPR at 9-months (58.3%) and 12-months (57.9%) was significantly less than at 1-month (66.9%). The responder rate also decreased for the SCS group from 1-month (68.1%) to 12-months (61.1%). After stratifying by diagnosis, it was found that only the CRPS-I population had diminishing pain relief with SCS. DRG stimulation resulted in more stable pain relief through 12-months, while tonic SCS demonstrated therapy habituation at 9- and 12-months.
Trial Registration: The ACCURATE study was registered at ClinicalTrials.gov with Identifier NCT01923285.



Levy et al. Therapy Habituation at 12 Months: Spinal Cord Stimulation Versus DRGS for Complex Regional Pain Syndrome Type I and II. J Pain. 2020 Mar-Apr;21(3-4):399-408
Chapman KB et al. Dorsal root ganglion stimulation device explantation: A multicenter pooled data analysis. *Pain Pract*. 2022;22(5):522-531. doi:10.1111/papr.13113

Loss of Efficacy with SCS

Habituation accepted with SCS

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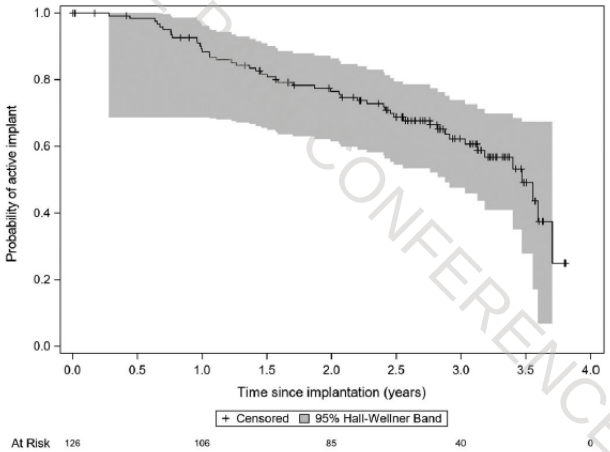
Therapy-Related Explants After Spinal Cord Stimulation: Results of an International Retrospective Chart Review Study

Jean-Pierre Van Buyten, MD, PhD*; Frank Wille, MD†‡; Iris Smet, MD*; Carin Wensing, MSc†‡; Jennifer Breel, MPA†‡; Edward Karst, MS§; Marieke Devos, MSc*; Katja Pöggel-Krämer, RN¶; Jan Vesper, MD, PhD¶



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(onlinelibrary.wiley.com) DOI: 10.1111/ner.13280

Explantation Rates of High Frequency Spinal Cord Stimulation in Two Outpatient Clinics

Victor C. Wang, MD, PhD; Vickie Bounkousohn, BA; Kara Fields, MS; Clifford Bernstein, MD; Richard M. Paicius, MD; Christopher Gilligan, MD

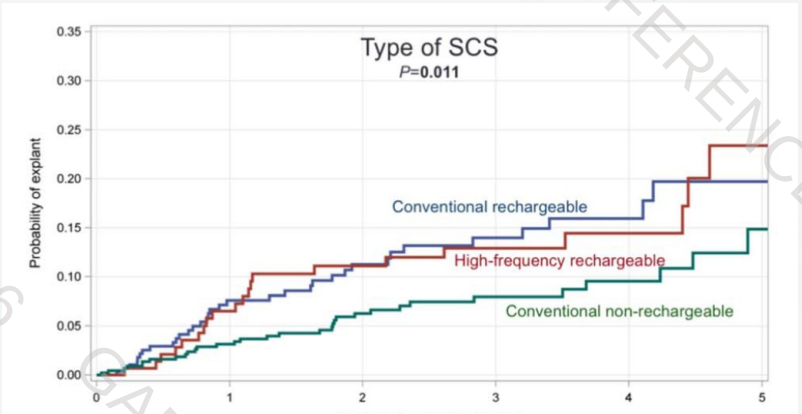


Table 2. Kaplan-Meier Implant Survival Probabilities Beyond 1, 2, and 3 Years Post Implantation.

Time since implant (years)	Cumulative risk of explantation (95% CI)	Number of patients at risk	Number of patients explanted	Number of patients censored	Cumulative number of patients explanted	Cumulative number of patients censored
0–0.99	88.4% (81.3–93.0%)	126	14 (11.1%)	6	14	6
1.00–1.99	76.5% (67.8–83.2%)	106	14 (22.2%)	7	28	13
2.00–3.03	60.7% (50.2–69.6%)	85	13 (32.5%)	32	41	45

Note: Censored observations are those obtained from patients who were lost to follow-up and/or did not have enough time elapsed since implantation by study end to allow for complete follow-up. Patients at risk were those who had not yet been explanted or censored by the start of the corresponding time interval.

Van Buyten JP et al. Therapy-Related Explants After SCS: Results of an International Retrospective Chart Review Study. Neuromodulation. 2017 Oct;20(7):642-649. doi: 10.1111/ner.12642. Epub 2017 Aug 18. PMID: 28834092; PMCID: PMC5656934.

Wang VC et al.. Explantation Rates of High Frequency Spinal Cord Stimulation in Two Outpatient Clinics. Neuromodulation. 2021 Apr;24(3):507-511. doi: 10.1111/ner.13280. Epub 2020 Oct 5. Erratum in: Neuromodulation. 2021 Dec;24(8):1503. doi: 10.1111/ner.13544. PMID: 33016570.

DRGS Loss of Efficacy

Pooled Data Analysis

DOI: 10.1111/papr.13113

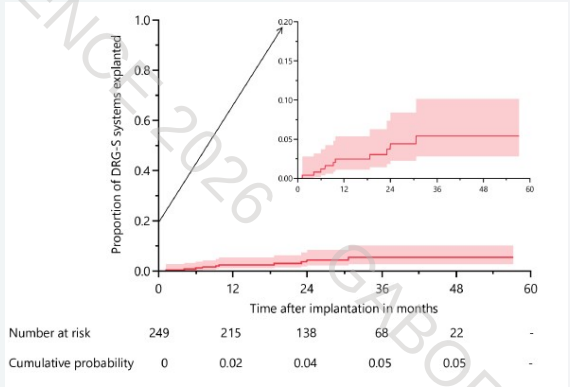
RESEARCH ARTICLE

Dorsal root ganglion stimulation device explantation: A multicenter pooled data analysis

Kenneth B. Chapman MD[1,2,3] | Ajax Yang MD[1,3] | Alon Y. Mogilner MD, PhD[4] | Nataniel Mandelberg MD, PhD[4] | Kiran V. Patel MD[1,3] | Timothy Lubenow MD[5] | Timothy Deer MD[6] | Jan Willem Kallewaard MD, PhD[7] | Noud van Helmond MD, PhD[1,8]

Explants 10/249 over 27 months:				
	Diagnosis	**Reason**	**Prior Complication?**	**T to Explant Months**
1	CRPS 2	generator site pain	Transient neuritis post op	3
2	FBSS	inadequate pain relief after migration	S1 migration	4
3	CRPS 2	inadequate pain relief	No	9
4	CRPS	inadequate pain relief	No	18
5	CRPS	Inadequate pain relief	L5 fracture	30
6	CRPS	worsening pain	S1 migration	23
7	CRPS	Inadequate pain relief	1 migration C8, then 1 fracture C8	23
8	neuropathy	lack of efficacy	No	5
9	FBSS	lack of efficacy	No	12
10	FBSS	Infection	No	2

- **T in Months to exit therapy: 13 m (± 10m)**
- **6/249 patients were explanted for inadequate pain relief.**
- **% Exit Therapy per year rate: 2%**
- **% that had complication: 60% (6/10)**



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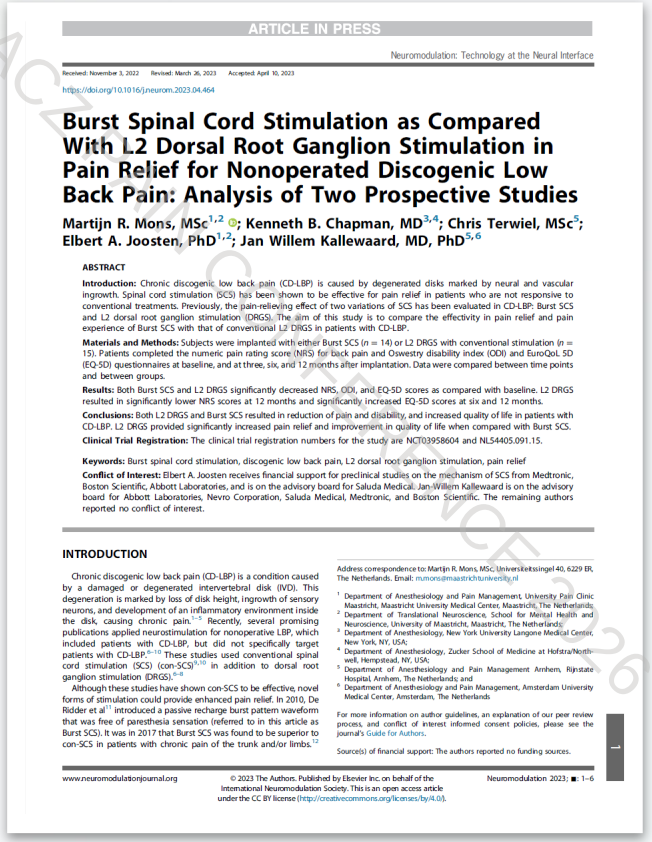
Chapman KB, Yang A, Mogilner AY, et al. Dorsal root ganglion stimulation device explantation: A multicenter pooled data analysis. *Pain Pract*. 2022;22(5):522-531. doi:10.1111/papr.13113

SCS vs DRGS Followed over 1 year

SCS vs DRGS Discogenic Pain



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Burst Spinal Cord Stimulation as Compared With L2 Dorsal Root Ganglion Stimulation in Pain Relief for Nonoperated Discogenic Low Back Pain: Analysis of Two Prospective Studies

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ABSTRACT

Introduction: Chronic discogenic low back pain (CD-LBP) is caused by degenerated disks marked by neural and vascular ingrowth. Spinal cord stimulation (SCS) has been shown to be effective for pain relief in patients who are not responsive to conventional treatments. Previously, the pain-relieving effect of two variations of SCS has been evaluated in CD-LBP: Burst SCS and L2 dorsal root ganglion stimulation (DRGS). The aim of this study is to compare the effectivity in pain relief and pain experience of Burst SCS with that of conventional L2 DRGS in patients with CD-LBP.

Materials and Methods: Subjects were implanted with either Burst SCS ($n = 14$) or L2 DRGS with conventional stimulation ($n = 15$). Patients completed the numeric pain rating score (NRS) for back pain and Oswestry disability index (ODI) and EuroQoL 5D (EQ-5D) questionnaires at baseline, and at three, six, and 12 months after implantation. Data were compared between time points and between groups.

Results: Both Burst SCS and L2 DRGS significantly decreased NRS, ODI, and EQ-5D scores as compared with baseline. L2 DRGS resulted in significantly lower NRS scores at 12 months and significantly increased EQ-5D scores at six and 12 months.

Conclusions: Both L2 DRGS and Burst SCS resulted in reduction of pain and disability, and increased quality of life in patients with CD-LBP. L2 DRGS provided significantly increased pain relief and improvement in quality of life when compared with Burst SCS.

Clinical Trial Registration: The clinical trial registration numbers for the study are NCT03958604 and NL54405.091.15.

Keywords: Burst spinal cord stimulation, discogenic low back pain, L2 dorsal root ganglion stimulation, pain relief

Conflict of Interest: Elbert A. Joosten receives financial support for preclinical studies on the mechanism of SCS from Medtronic, Boston Scientific, Abbott Laboratories, and is on the advisory board for Saluda Medical. Jan-Willem Kallewaard is on the advisory board for Abbott Laboratories, Nevro Corporation, Saluda Medical, Medtronic, and Boston Scientific. The remaining authors reported no conflict of interest.

INTRODUCTION

Chronic discogenic low back pain (CD-LBP) is a condition caused by a damaged or degenerated intervertebral disk (IVD). This degeneration is marked by loss of disk height, ingrowth of sensory neurons, and development of an inflammatory environment inside the disk, causing chronic pain.[1–5] Recently, several promising publications applied neurostimulation for nonoperative LBP, which included patients with CD-LBP, but did not specifically target patients with CD-LBP.[6–10] These studies used conventional spinal cord stimulation (SCS) (con-SCS)[9,10] in addition to dorsal root ganglion stimulation (DRGS).[6–8]

Although these studies have shown con-SCS to be effective, novel forms of stimulation could provide enhanced pain relief. In 2010, De Ridder et al[11] introduced a passive recharge burst pattern waveform that was free of paresthesia sensation (referred to in this article as Burst SCS). It was in 2017 that Burst SCS was found to be superior to con-SCS in patients with chronic pain of the trunk and/or limbs.[12]

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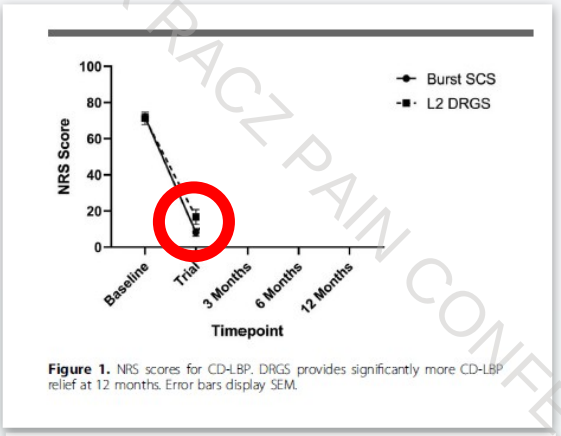

Figure 1. NRS scores for CD-LBP. DRGS provides significantly more CD-LBP relief at 12 months. Error bars display SEM.

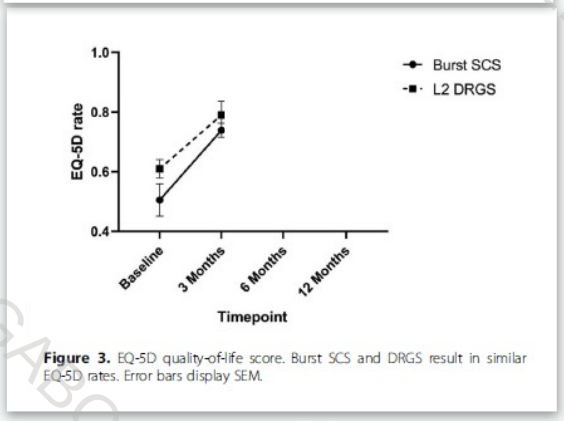

Figure 3. EQ-5D quality-of-life score. Burst SCS and DRGS result in similar EQ-5D rates. Error bars display SEM.

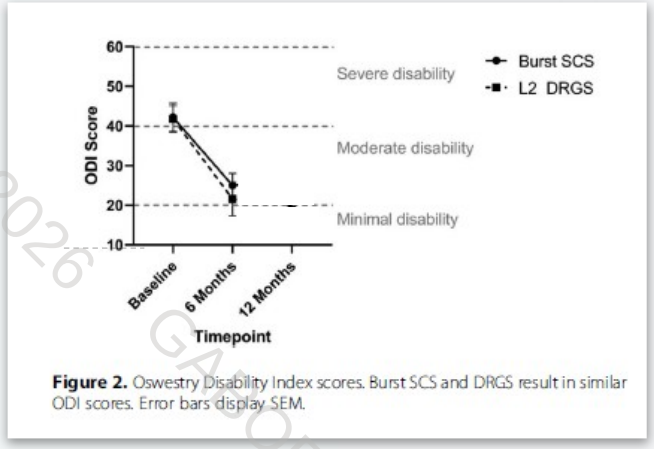

Figure 2. Oswestry Disability Index scores. Burst SCS and DRGS result in similar ODI scores. Error bars display SEM.

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Conclusions

Consider DRGS

- SCS remains the gold standard for most chronic neuropathic pain syndromes
- DRGS is a unique form of neuromodulation as compared to SCS and can be considered in certain cases.
- Appears to be less loss of efficacy as compared to other forms of Neurostimulation.
- Working for nociceptive pain conditions
- Consider DRGS for gold standard for treatments of CRPS

Thank you!

Questions?

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