



29th Annual Gabor Racz
Advanced Interventional
Pain Conference and Workshop
Budapest, Hungary August 24-26, 2026

Expanding Indications for Early and Late Stage Chronic Pain

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29th Annual Gabor Racz Advanced Interventional Pain Conference and Workshop Budapest, Hungary August 24-26, 2026

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.



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SCS Indications

Expanding indications

What does 'indications' mean, and who decides?

- Regulatory indication (the "label")
- Evidence/guideline indication
- Reimbursement/coverage indication





Indications for Spinal Cord Stimulation

US FDA

On label use

- Failed Back surgery syndrome/Post-Surgical Pain Syndrome (PSPS II)
- CRPS I and II
- Intractable Low Back Pain and Leg Pain
- Ischemic Limb Pain
- Diabetic Peripheral Neuropathy (DPN)

Off label uses

- 'Virgin back'/NSLBP/PSPS I
- GI disorders/abdominal pain
- Pelvic pain/GU disorders
- Occipital nerve stimulation/migraines/headache
- Locomotion in Parkinson's disease
- Peripheral neuropathies/plexopathies
- Multiple Sclerosis
- Postherpetic neuralgia
- Post-thoracotomy pain/intercostal neuralgias
- Phantom limb pain
- Spinal cord injuries



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Field is under attack

Negative articles

[Home](#) | [JAMA](#) | [Vol. 328, No. 15](#)

Original Investigation

FREE

Effect of Spinal Cord Burst Stimulation vs Placebo Stimulation on Disability in Patients With Chronic Radicular Pain After Lumbar Spine Surgery A Randomized Clinical Trial

Sozaburo Hara, MD^{1,2}; Hege Andresen, RN, MSc^{1,2,3}; Ole Solheim, MD, PhD^{1,2}; Sven M. Carlsen, MD, PhD^{4,5}; Terje Sundstrøm, MD, PhD^{6,7}; Greger Lønne, MD, PhD^{3,8}; Vette V. Lønne, MD^{1,2}; Kristin Taraldsen, PT, PhD⁹; Erling A. Tronvik, MD, PhD^{2,10}; Lise R. Øie, MD, PhD^{2,10}; Agnete M. Gulati, MD, PhD^{11,12}; Lisa M. Sagberg, RN, PhD^{1,13}; Asgeir S. Jakola, MD, PhD¹⁴; Tore K. Solberg, MD, PhD^{15,16}; Øystein P. Nygaard, MD, PhD^{1,2,3}; Øyvind O. Salvesen, MSc, PhD¹³; Sasha Gulati, MD, PhD^{1,2,3}

JAMA

QUESTION Among patients with chronic radicular pain after lumbar spine surgery, does spinal cord burst stimulation affect back pain-related disability?

CONCLUSION Among patients with chronic radicular pain after lumbar spine surgery, spinal cord burst stimulation, compared with placebo stimulation, resulted in no significant difference in back pain-related disability.

POPULATION

27 Women
23 Men

Adults with chronic radiculopathy after surgery for degenerative lumbar spine disorders

Mean age: 52 years

LOCATIONS

1
University
hospital in Norway



INTERVENTION



Burst stimulation allocations

Closely spaced, high-frequency stimuli delivered to the spinal cord lasting for 3 months

Placebo stimulation allocations

Placebo stimulation lasting for 3 months

PRIMARY OUTCOMES

Change from baseline in self-reported Oswestry Disability Index

FINDINGS

Change in Oswestry Disability Index score (range, 0 [no disability] to 100 [maximum disability])

Mean baseline score: 44.7 points

Burst stimulation

Change: **-10.6 points**

Placebo stimulation

Change: **-9.3 points**

The difference was not significant:

Mean between-group difference, **-1.3 points**
(95% CI, -3.9 to 1.3 points); $P = .32$

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Hara S, Andresen H, Solheim O, et al. Effect of spinal cord burst stimulation vs placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery: a randomized clinical trial. JAMA. Published October 18, 2022. doi:10.1001/jama.2022.18231

Hara S, Andresen H, Solheim O, Carlsen SM, Sundstrøm T, Lønne G, Lønne VV, Taraldsen K, Tronvik EA, Øie LR, Gulati AM, Sagberg LM, Jakola AS, Solberg TK, Nygaard ØP, Salvesen ØO, Gulati S. Effect of Spinal Cord Burst Stimulation vs Placebo Stimulation on Disability in Patients With Chronic Radicular Pain After Lumbar Spine Surgery: A Randomized Clinical Trial. JAMA. 2022 Oct 18;328(15):1506-1514. doi: 10.1001/jama.2022.18231. PMID: 36255427; PMCID: 36255427



Diabetic Peripheral Neuropathy (DPN)

Expanding Indication #1

- Up to ~25% of people with diabetes develop PDN; pharmacotherapy has limited efficacy
- SENZA-PDN RCT (n=216): at 6 months, 79% responders with 10-kHz SCS + CMM vs 5% CMM alone; VAS fell from 7.6 to 1.7 cm; 62% showed neurologic exam improvement; ~2% infection requiring explant
- Level I evidence supporting addition of 10-kHz SCS to CMM in refractory PDN

Research

JAMA Neurology | **Original Investigation**

Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy A Randomized Clinical Trial

Erika A. Petersen, MD; Thomas G. Stauss, MD; James A. Scowcroft, MD; Elizabeth S. Brooks, PhD; Judith L. White, MD; Shawn M. Sills, MD; Kasra Amirdelfan, MD; Maged N. Guirguis, MD; Jijun Xu, MD, PhD; Cong Yu, MD; Ali Nairizi, MD; Denis G. Patterson, DO; Kostandinos C. Tsoulfas, MD; Michael J. Creamer, DO; Vincent Galan, MD; Richard H. Bundschu, MD; Christopher A. Paul, MD; Neel D. Mehta, MD; Heejung Choi, MD; Dawood Sayed, MD; Shivanand P. Lad, MD, PhD; David J. DiBenedetto, MD; Khalid A. Sethi, MD; Johnathan H. Goree, MD; Matthew T. Bennett, MD; Nathan J. Harrison, MD; Atef F. Israel, MD; Paul Chang, MD; Paul W. Wu, MD; Gennady Gekht, MD; Charles E. Argoff, MD; Christian E. Nasr, MD; Rod S. Taylor, PhD; Jeyakumar Subbaroyan, PhD; Bradford E. Gliner, MS; David L. Caraway, MD, PhD; Nagy A. Mekhail, MD, PhD

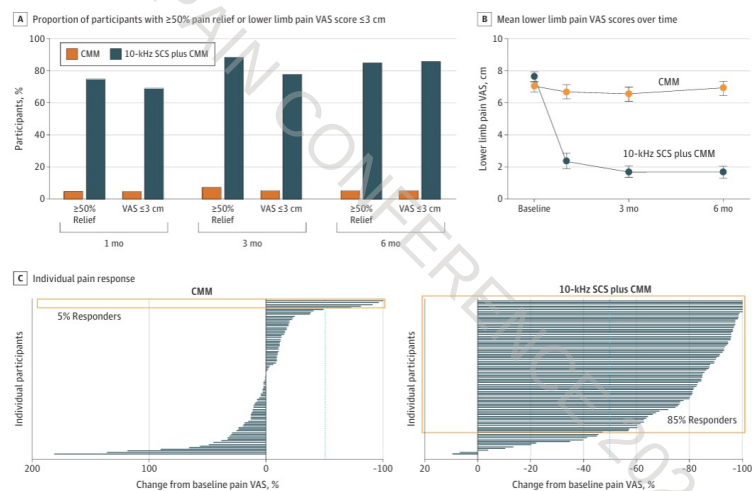


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Diabetic Peripheral Neuropathy (DPN)

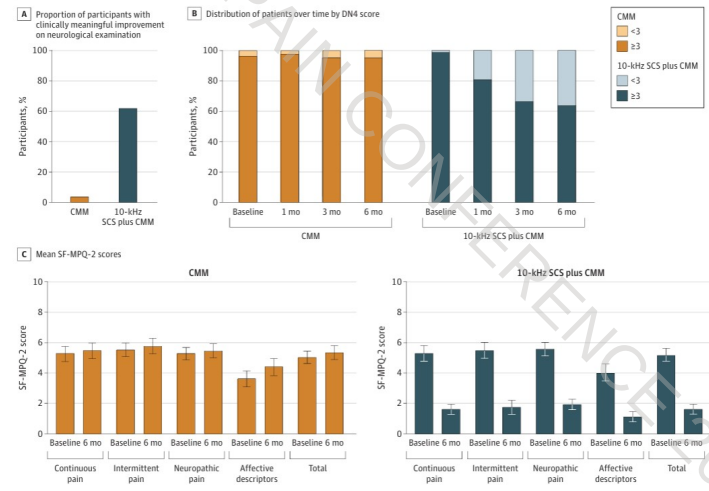
Petersen et al.

Figure 2. Pain Relief Over Time Measured by a 10-cm Visual Analogue Scale (VAS)



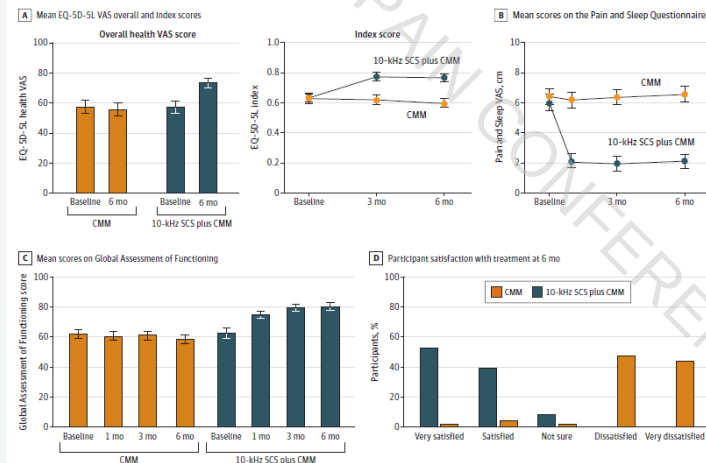
A, Proportion of patients with at least 50% pain relief on a VAS from baseline or lower limb pain of 3 cm or less using the VAS at 1, 3, and 6 months for conventional medical management (CMM) and 10-kHz spinal cord stimulation (SCS) plus CMM. The dotted blue line represents the threshold for treatment responders of at least 50% pain relief. In the CMM group, 5% of patients were responders compared with 85% of patients in the 10-kHz SCS plus CMM group. Error bars indicate 95% CIs. C, Individual pain response. Each line represents the change in a single patient's lower limb pain VAS score at 6 months relative to baseline for 93 patients in the CMM group and 87 in the 10-kHz SCS plus CMM group. The dotted blue line represents the threshold for treatment responders of at least 50% pain relief. In the CMM group, 5% of patients were responders compared with 85% of patients in the 10-kHz SCS plus CMM group (orange boxes).

Figure 3. Changes in Neurological Assessment and Quality of Pain



A, Proportion of patients with clinically meaningful improvement in motor, sensory, or reflex neurological examination scores and without a clinically meaningful deficit in any category as determined by the investigator at 6 months compared with baseline for 93 patients in the conventional medical management (CMM) group and 84 in the 10-kHz spinal cord stimulation (SCS) plus CMM group. B, Distribution of patients over time with Douleur Neuropathique (DN4) score of less than 3 and 3 or more for 91 patients in the CMM group and 84 in the 10-kHz SCS plus CMM group. DN4 score measures the severity of neuropathic pain. C, Mean Short-Form McGill Pain Questionnaire (SF-MPQ-2) scores for each subscale at baseline and 6 months for 93 patients in the CMM group and 87 in the 10-kHz SCS plus CMM group. SF-MPQ-2 is a patient-reported measure of the intensity of pain descriptors. Error bars indicate 95% CIs.

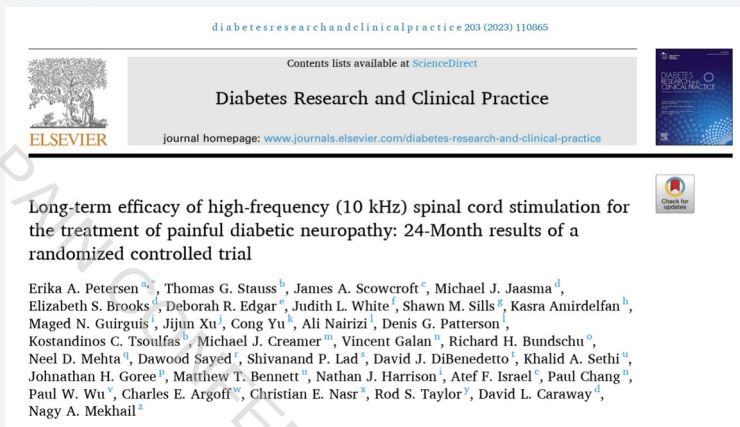
Figure 4. Health-Related Quality of Life Outcomes and Patient Satisfaction



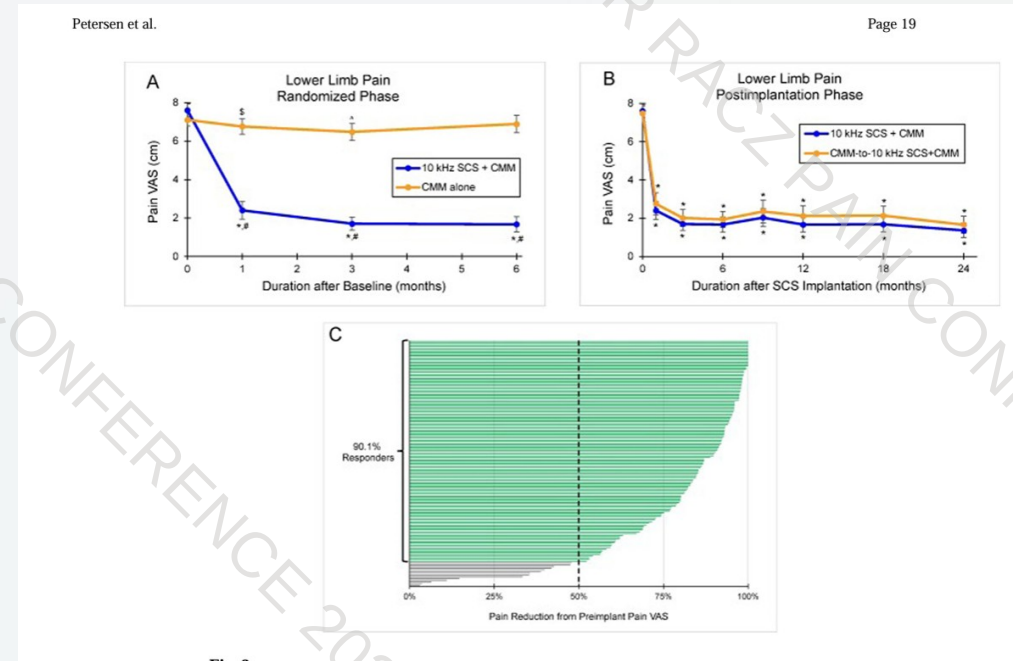
A, Mean EuroQol 5-Dimension Questionnaire (EQ-5D-SL) overall health visual analogue scale (VAS) score (left) and index score (right) for 92 patients in the conventional medical management (CMM) group and 87 in the 10-kHz spinal cord stimulation (SCS) plus CMM group from baseline to 6 months. The minimally important difference in index scores is estimated between 0.03 to 0.05. B, Mean scores for the Pain and Sleep Questionnaire assessing how often pain disturbs sleep. A score of 0 indicates never and a score of 10 indicates always. Scores are shown for 93 patients in the CMM group and 87 in the 10-kHz SCS plus CMM group. Error bars indicate 95% CIs. C, Mean scores on Global Assessment of Functioning at baseline and at 1, 3, and 6 months for 91 patients in the CMM group and 86 in the 10-kHz SCS plus CMM group. The Global Assessment of Functioning represents the physician's evaluation of how much a patient's symptoms affect psychological, social, and occupational functioning. D, Patient satisfaction with treatment at 6 months. Scores are shown for 93 patients in the CMM group and 87 in the 10-kHz SCS plus CMM group. Error bars indicate 95% CIs.

DPN 24 month follow up

Expanding indications #1



- At 24 months, 10 kHz SCS reduced pain by a mean of 79.9% compared to baseline, with 90.1% of participants experiencing $\geq 50\%$ pain relief. Participants had significantly improved HRQoL and sleep, and 65.7% demonstrated clinically meaningful neurological improvement.





Terminology

Review Nomenclature

Persistent Spinal Pain Syndrome (PSPS)

- **PSPS type 1 (PSPS-T1):**

- the clinical picture of signs and symptoms of failed back surgery syndrome (persistent/recurrent back and/or leg pain) but **without any prior spinal surgery** — i.e., non-surgical persistent spinal pain.

- **PSPS type 2 (PSPS-T2):**

- the same clinical syndrome occurring **after spinal surgery** — this term formally replaced "failed back surgery syndrome" (FBSS).



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Non-Surgical Refractory LBP (PSPS -Type 1)

Expanding Indication #2

- Historically SCS required prior surgery; data now validating tx patients who are NOT surgical candidates
- 10-kHz NSRBP RCT: 80.9% responders at 3 months vs 1.3% CMM; sustained to 12 months.
- SOLIS RCT: 89.5% responders with SCS+CMM vs 8.1% CMM; ODI improved -27.5 vs -7.2; benefits sustained to 12 months.
- Meta-analysis: consistent improvement in pain, function, and HRQoL for PSPS-T1.



Kapural L et al. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. J Neurosurg Spine. 2022 Feb 11;37(2):188-199. doi: 10.3171/2021.12.SPINE211301. PMID: 35148512.

North J et al. Spinal cord stimulation plus conventional medical management versus conventional medical management alone for severe, non-surgical, refractory back pain: a randomized clinical trial followed by crossover. Reg Anesth Pain Med. 2025 Oct 5;rapm-2024-106335. doi: 10.1136/rapm-2024-106335. Epub ahead of print. PMID: 41047246.

Kallewaard JW, Et al. Systematic Review and Meta-Analysis of Spinal Cord Stimulation for Chronic Nonsurgical Refractory Back Pain With or Without Leg Pain (Persistent Spinal Pain Syndrome Type 1). Neuromodulation. 2026 Aug;29(6):853-867. doi: 10.1016/j.neurom.2025.10.001. Epub 2025 Nov 29. PMID: 41313285.



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Non-Surgical Refractory LBP (PSPS 1)

Expanding Indication #2

ORIGINAL ARTICLE

High-Frequency Spinal Cord Stim 10 kHz for the Treatment of No Refractory Back Pain: Design of a Multicenter, Randomized Contro

Naresh Patel, MD*; Aaron Calodney, MD[†]; Leonardo Kapural , MD, PhD^{‡,§};
Rose Province-Azalde, MS[¶]; Shivanand P. Lad, MD, PhD^{**}; Julie Dillenschneider, MD,
PhD^{††}; Chengyuan Wu, MD^{‡‡}; Taissa Cherry, MD^{§§}; Jeyakumar

Treatment of Refractory Low Back Pain Using Passive Recharge Burst in Patients Without Options for Corrective Surgery: Findings and Results From the DISTINCT Study, a Prospective Randomized Multicenter Controlled Trial

Timothy Deer, MD¹, Christopher Gilligan, MD², Steven Falowski, MD³, Mehul Desai, MD⁴,
Julie Pilitsis, MD, PhD⁵, Jessica Jameson, MD⁶, Susan Moeschler, MD⁷, Robert Heros,
MD⁸, Edward Tavel, MD⁹, Anne Christopher, MD¹⁰, Denis Patterson, MD¹¹, Sayed Wahezi,
MD¹², Jacqueline Weisbein, MD¹³, Ajay Antony, MD¹⁴, Robert Funk, MD¹⁵, Mohab Ibrahim,
MD¹⁶, Chi Lim, MD¹⁷, Derron Wilson, MD¹⁸, Michael Fishell, MD¹⁹, Keith Scarfo, MD²⁰,
David Dickerson, MD²¹, Edward Braun, MD²², Patrick Buchanan, MD²³, Robert M. Levy, MD,
PhD²⁴, Nathan Miller, MD²⁵, Jonathan Duncan, MD²⁶, Jijun Xu, MD²⁷, Kenneth Candido,
MD²⁸, Scott Kreiner, MD²⁹, Marie E. Fahey, PhD³⁰, James Yue, MD³¹

ORIGINAL ARTICLE

OPEN

Network Meta-analysis and Economic Evaluation of Neurostimulation Interventions for Chronic Nonsurgical Refractory Back Pain

Sam Eldabe, MD,* Sarah Nevitt, PhD,[†] Anthony Bentley, MSc,[‡]
Nagy A. Mekhail, MD, PhD,[§] Christopher Gilligan, MD,^{||} Bart Billet, MD,[¶]
Peter S. Staats, MD,[#] Michelle Maden, PhD,^{**} Nicole Soliday, MPH,^{††}
Angela Leitner, MS,^{‡‡} and Rui V. Duarte, PhD^{***††}



Spinal cord stimulation plus conventional medical management versus conventional medical management alone for severe, non-surgical, refractory back pain: a randomized clinical trial followed by crossover

James North,¹ Aaron Calodney,² Drew Trainor,³ Zachary L. McCormick,⁴ Julio Paez,⁵
Eric Loudermilk,⁶ Anne Christopher,⁷ John Noles,⁸ Gregory Phillips,⁹ Suneil Jolly,¹⁰
Michael I. Yang,¹¹ Maged Guirgis,^{12,13} Daniel Kloster,¹³ Daniel J. Pak,¹⁴
Jeffery Peacock,¹⁵ Mitchell Engle,¹⁶ Binit Shah,¹⁷ Derron Wilson,¹⁸
Magdalena Anitescu,¹⁹ Joseph Atallah,²⁰ John Chatas,²¹ Tim Leier,²² Steven Rosen,²³
Edward Goldberg²⁴

JNS SPINE

CLINICAL ARTICLE

J Neurosurg Spine 37:188–199, 2022

Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial

Leonardo Kapural, MD, PhD,¹ Jessica Jameson, MD,² Curtis Johnson, MD,³ Daniel Kloster, MD,⁴
Aaron Calodney, MD,⁵ Peter Kosek, MD,⁶ Julie Pilitsis, MD, PhD,⁷ Markus Bendel, MD,⁸
Erika Petersen, MD,⁹ Chengyuan Wu, MD, MSBME,¹⁰ Taissa Cherry, MD,¹¹
Shivanand P. Lad, MD, PhD,¹² Cong Yu, MD,¹³ Dawood Sayed, MD,¹⁴ Johnathan Goree, MD,⁹
Mark K. Lyons, MD,¹⁶ Andrew Sack, MD,¹⁴ Diana Bruce, DMS, PA-C,¹¹ Frances Rubenstein, PhD,¹⁵
Rose Province-Azalde, MSBME,¹⁵ David Caraway, MD, PhD,¹⁵ and Naresh P. Patel, MD¹⁶

Received: 22 January 2024 | Revised: 10 June 2024 | Accepted: 13 June 2024
DOI: 10.1002/eqp.2306

ORIGINAL ARTICLE



European randomized controlled trial evaluating differential target multiplexed spinal cord stimulation and conventional medical management in subjects with persistent back pain ineligible for spine surgery: 24-month results

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Agustin Mendiola⁶ | Isaac Peña⁷ | Pablo López⁸ | Javier Carceller⁸ |
Carlos Tornos⁹ | Xander Zuidema^{10,11} | Jan Vesper¹² | Jens Lehmborg¹³ |
Wim Laloo¹⁴ | David L. Cedeño¹⁴ | Ricardo Vallejo¹⁴



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PSPS –Type 1 Multiple Studies in Literature

Study Name	Authors / Year	Waveform / System	Stimulation Mechanism Details	Perception Type	Patient Population / Indication	N Randomized (Total)	N Treatment Arm	N Control Arm	N Permitted by Implant Used	Trial-to-Implant Conversion Rate	Primary Outcome Measure	Primary Outcome Timepoint	Primary Outcome - Treatment Result	Primary Outcome - Control Result	Primary Outcome p-value	ODI Change - Treatment	ODI Change - Control	QoL Change (EQ-5D-5L or PROMIS)	Opioid (MME) Reduction	PGIC (Much/Very Much Improved)	Patient Satisfaction	Crossover Rate (Control to Treatment)	12-Month Outcome	24-Month Outcome / Durability	Notes / Additional Secondary Outcomes
DISTINCT RCT	Deer et al. 2023; Yue BurstDR (Passive Recharge Burst SCS)		5-pulse train at 40 Hz, internal frequency 500 Hz; 1-ms pulse width followed by passive energy discharge; intermittent dosing (30s ON / 90-360s OFF)	Sub-perception (60% of sensory threshold)	Non-surgical Refractory Chronic Low Back Pain (NS-CLBP)	269	162	107	115/142 (81%)	81%	Back Pain Responder Rate (NRS $\geq 50\%$ relief)	5 Months	73.1% (ITT); 85.3% (As-Treated)	5.2%	<0.0001	-29.4 points	-0.7 points	PROMIS Physical Function +27.8% vs +1.4%; PROMIS Pain Interference -17.9% vs -0.9%	65.3% vs 11.1% (CMM)	75.5% vs 2.5%	80% at 24 months	86.2% (CMM to SCS)	NRS responder: 78.0% (SCS); 71.4% (Crossover) at 24M; ODI reduction 27.8 pts (SCS)/28.2 pts (Crossover)	NRS responder 77% (SCS)/79% (Crossover) at 24M; ODI reduction 27.8 pts (SCS)/28.2 pts (Crossover)	Composite Responder (NRS $\geq 50\%$ or ODI ≥ 13): 91.2% vs 16.0%; PCS Responders: 88.2% vs 23.5% Additional citations captured in the Kallewaard et al. 2025/2026 systematic review; Yue et al. 2024 (surgical/implant findings) and Deer et al. 2024 (12-month CMM-crossover comparison), both reporting on the same DISTINCT cohort.
European DTM SCS RCT	Kallewaard et al. 2024	DTM (Differential Target Multiplexed) SCS	50 Hz base program (200 μ s PWM) multiplexed with three 300 Hz programs (170 μ s PWM); targets neurons and glial cells	Sub-perception	Persistent Spinal Pain Syndrome Type 1 (PSPS-T1), ineligible for surgery	112	55	57	47	n/a (47 permanent implants of 55 randomized to DTM)	Back Pain Responder Rate (VAS $\geq 50\%$ relief)	5 Months	85.1%	3.6%	Statistically superior at all timepoints (value not specified)	24.3 (6M); -22.7 (12M); -25.7 points (24M)	n/a (CMM crossed over)	EQ-5D-5L Index: mean improvement >0.3 points (baseline 0.39)	38%-58% MME reduction over 24 months	n/a (not specified)	>84% satisfied through 24M	91% (50/55 CMM to DTM at 6 months)	CLBP responder rate sustained $\geq 80\%$; mean VAS reduction +5.5 cm (>70%)	CLBP responder rate $\geq 80\%$ sustained through 24 months; Leg Pain Responder Rate 93.1% at 24 months	Composite Responder Index (CRI): $\geq 87\%$ responded in ≥ 2 clinical measures
Fishman DTM SCS RCT	Fishman et al. 2021	DTM SCS vs Traditional (Tonic) SCS	DTM: 50 Hz base + three 300 Hz programs; Traditional: Tonic 50-60 Hz (paresthesia-based)	DTM: Sub-perception; Traditional: Paresthesia-based	Chronic intractable back and leg pain (mostly PPS-12)	128	67	61	94	94/128 permanently implanted (73%)	Back Pain Responder Rate (VAS $\geq 50\%$ relief)	3 Months	80.1% (DTM)	51.2% (Traditional)	n/a (ODI reported as % minimal/moderate at 12M)	n/a	PROMIS Excellent/Very Good/Good/Pain: 88% (DTM) vs 76% (Traditional); baseline -39%	n/a (not reported)	n/a (not reported)	n/a (not reported)	n/a (both arms active treatment, no CMM crossover)	Back Pain Responder: 83.7% (DTM) vs 51.1% (Traditional); Profound Responder ($\geq 80\%$ relief): 69% vs 35%; Mean LBP reduction 5.48 cm vs 3.62 cm; Leg Pain Responder 80.0% vs 75.0%	n/a (12-month data reported as long term; no 24M data in source)	Disability (ODI Minimal/Moderate): 76% (DTM) vs 62% (Traditional), from baseline -27%	
SOLIS RCT	North et al. 2025	WaveWriter System (Paresthesia, Sub-perception, or Combination/Blend)	FAST: sub-perception (low frequency) 90 Hz, high-active recharges; Contour: sub-perception (field-shaping at 200 Hz); Combination (supra-perception standard rate + sub-perception Contour)	Mixed: Paresthesia, Sub-perception, and Pain (NSRP) Combination	Non-surgical Refractory Back Pain (NSRPB)	147	79	68	63	63/79 permanently implanted (~80%)	Responder Rate ($\geq 50\%$ relief and no daily MME increase)	3 Months	89.5% (mITT completer); 65% (ITT)	8.1% (mITT completer); 7% (ITT)	<0.0001	-27.5 points (from severe/crippled)	-7.2 points	EQ-5D-5L Index Change: +0.247 vs +0.031	n/a (not reported as MME reduction; responder definition included no MME increase)	86.0% vs 3.2%	86.5% satisfied (TSQ 9m) vs 32.3% CMM	51/64 CMM patients crossed over (~59%)	Back Pain Responder: 88% ($\geq 50\%$ relief), 56% ($\geq 80\%$ relief); Mean ODI reduction 27.7 points; EQ-5D-5L index improvement +0.225 (Completer analysis, N=105)	n/a (not reported beyond 12 months in source)	Percent Pain Relief (PPR): mean 78.3% vs 12.5%; Waveform settings at 3M endpoint: 60% sub-perception alone, 35% combination, 5% paresthesia alone
SENZA-NSRPB RCT	Patel et al. 2021; Kapural et al. 2022	10 kHz High-Frequency SCS	Constant 10,000 Hz frequency, 30 μ s pulse width	Sub-perception	Non-surgical Refractory Back Pain (NSRPB)	211	n/a (not split out in source)	n/a (not split out in source)	n/a (not specified)	n/a (not specified)	Back Pain Responder Rate (VAS $\geq 50\%$ relief)	3 Months	80.9%	1.3%	n/a (not specified; study stopped early for efficacy)	n/a (not reported in source)	n/a (not reported in source)	n/a (not reported in source)	n/a (not reported in source)	n/a (not reported in source)	n/a (not reported in source)	84% (CMM to SCS at 6 months)	Responder Rate: 78.2% (SCS)	Durability highly maintained; no explants reported due to loss of efficacy	Trial stopped early due to strong efficacy signal (power reached ahead of schedule); Additional citation captured in the Kallewaard et al. 2025/2026 systematic review; Patel et al. 2024 (2024 durability results, J Neurosurg Spine, reporting on the same SENZA-NSRPB cohort, with 24-month follow-up including CMM-crossover data to 18 months)
L2 DRG Pilot Study	Kallewaard et al.	Dorsal Root Ganglion (DRG) Stimulation at L2	Tonic, constant current DRG stimulation targeting L2 sensory afferents innervating low lumbar discs	Tonic (paresthesia-based)	Homogeneous discogenic chronic low back pain sub-population	16	n/a (single-arm pilot, no control arm)	n/a (single-arm pilot, no control arm)	12	85.7% (12/14 trialed successfully)	Back Pain Relief (NPRS)	End of Trial	NPRS reduced from 7.19 to 2.29 (68.2% reduction)	n/a (single-arm, no control)	n/a (single-arm, no control)	60.0% (average disability decrease)	EQ-5D: average QoL increased by 54.6%	n/a (not reported as opioid data)	73% (8/11) at 3 months; 100% (8/8) at 6 months	n/a (not reported)	n/a (single-arm pilot; no crossover design)	n/a (6-month data reported below in place of 12-month)	6-Month: NPRS 1.67 (76.8% reduction); 50.0% (3/6) reported score of zero	2-Week follow-up: 91.7% reported $\geq 50\%$ pain relief; Mood Disturbance (POMS) decreased by 110.5% at 6 months	N=11 available at 6-month follow-up (of 13 implanted)
BurstDR Discogenic Pilot	Kallewaard et al.	BurstDR SCS (Burst)	Passive recharge burst stimulation	Sub-perception	Chronic discogenic low back pain, surgical non-candidates	15	n/a (single-arm pilot, no control arm)	n/a (single-arm pilot, no control arm)	13	87% (13/15 trialed successfully and implanted)	Back Pain Relief (VAS)	3 and 6 Months	VAS reduced from 74 mm to 34.5 mm (3M) and 41.2 mm (6M)	n/a (single-arm, no control)	n/a (single-arm, no control)	ODI decreased from severe (42.4%) to moderate (24.0%) impairment	n/a (not reported; data)	n/a (not reported as opioid data)	73% at 3 months; 100% at 6 months	n/a (not reported)	n/a (single-arm pilot; no crossover design)	6-Month: 100% (11/11) achieved MCD (at 13-point ODI reduction) for functional improvement	Same cohort extended to 12-month	Possible overlap: see newly added row "More et al. (2023) BurstDR SCS Discogenic Pain Study" below — same senior author (Kallewaard M) and population; may be the peer-reviewed publication of this same pilot cohort. Recommend verifying before treating as fully separate studies.	
White et al. (2024) DTM SCS vs C-SCS RCT	White, Justiz, Almonte et al. 2024	DTM SCS vs Conventional (Tonic) SCS	DTM: 50 Hz base program multiplexed with three 300 Hz programs; C-SCS: traditional low frequency tonic paresthesia-based stimulation	DTM: Sub-perception; C-SCS: Paresthesia-based	Persistent Spinal Pain Syndrome Type 1 (PSPS-T1); chronic refractory axial low back pain not eligible for spine surgery	105	51	54	n/a (not specified in source)	n/a (not specified in source)	Back pain reduction (VAS/NRS) and $\geq 50\%$ responder rate, DTM vs Conventional SCS	3 and 6 Months	Pain reduction MD +3.51 (RCT phase); 12 Months: DTM: Responder OR 27.20 (3mo) / 19.50 (6mo) favoring DTM	Reference arm = Conventional SCS (comparator; not an independent result)	Not given numerically n +14.80 (3mo) / +14.80 (6mo) favoring DTM vs C-SCS exclude the null value	EQ-5D reduction MD +10.70 (3mo) / +14.80 (6mo) favoring DTM vs C-SCS	Conventional SCS (comparator; not an independent result)	EQ-5D-5L Index MD +0.12 (3mo) / +0.14 (6mo) favoring DTM vs C-SCS	n/a (not reported as MME data in source)	PGIC OR 3.64 (3mo, CI crosses 1) / 3.68 (6mo, CI crosses 1) favoring DTM — not statistically significant at 3mo	Satisfaction OR 2.10 (3mo, CI crosses 1) / 3.43 (6mo, CI crosses 1) favoring DTM — not statistically significant	n/a (both arms active SCS; no CMM crossover design)	12-month single-arm/crossover data reported in systematic review Table 2; values not broken out numerically in source text	n/a (12 months is longest follow-up reported for this RCT)	Added from Kallewaard et al. 2025/2026 systematic review (Neuromodulation 2025;29:853-867), Table 1 and Figure 2: Point estimates (MD/OR) are individual-study values extracted from the review's forest plots, not the original White et al. primary publication. Full citation: White T, Justiz R, Almonte W, et al. N Am Spine Soc. J. 2024;19:100528.
Al-Kaisy et al. (2017) HF-SCS Pilot	Al-Kaisy et al. 2017	10 kHz High-Frequency SCS (HF-SCS)	Preliminary, prospective, open-label, proof-of-concept study; 10 kHz HF-SCS	Sub-perception (10 kHz)	Chronic axial low back pain, no history of spinal surgery; lateral recess stenosis, facet joint arthropathy/hypertrophy, foraminal stenosis, nerve impingement; mean pain duration 7.0 $\pm$ 5.8 years	16	21	n/a (single-arm, no control)	n/a (not specified; data separately from N error)	n/a	Pain reduction (VAS/NRS)	12 Months	Improved from baseline; contributes to pooled meta-analysis estimate (individual value not isolable from source text)	n/a (single-arm)	n/a	Improvement in ODI reported (value not isolable from source text)	n/a	HRQoL (EQ-5D utility) improvement reported	Opioid reduction or cessation (no patients reported)	PGIC (no patients reported)	Very satisfied/satisfied (no patients reported)	n/a (single-arm pilot)	Included in meta-analysis pooled 12-month single-arm estimates MD -4.73 pain reduction; 74% responder rate, pooled across 9-12 studies)	Same cohort extended to 2018 months in Al-Kaisy et al. 2018	Part of pooled single-arm meta-analysis (Table 2; Fig 3). Baseline report of the cohort followed long-term in Al-Kaisy et al. 2018 (36-month extension, below).
Al-Kaisy et al. (2018) HF-SCS 36-Month Extension	Al-Kaisy et al. 2018	10 kHz High-Frequency SCS (HF-SCS)	Same cohort as Al-Kaisy et al. 2017, followed to 36 months	Sub-perception (10 kHz)	Chronic axial low back pain, no history of spinal surgery (same cohort as 2017 pilot)	16	21	n/a (single-arm, no control)	n/a	n/a	Pain reduction (VAS/NRS)	36 Months	Statistically significant reduction from baseline; only study in review reporting a 36-month timepoint	n/a (single-arm)	n/a	Improvement in ODI reported	n/a	HRQoL (EQ-5D utility) improvement reported	Opioid cessation (no patients reported)	n/a (not listed as an outcome at this timepoint)	Very satisfied/satisfied (no patients reported)	n/a (superseded by 36-month data below)	Longest follow-up in the entire review (36 months); statistically significant improvements sustained in pain, ODI, and satisfaction	Single-study result at 36 months (no pooling possible — only study with this follow-up duration)	
Al-Kaisy et al. (2020) HF-SCS Pooled Subanalysis	Al-Kaisy et al. 2020	10 kHz High-Frequency SCS (HF-SCS)	Subanalysis of pooled data from two prospective studies (cohorts SENZA-RCT and SENZA-EU)	Sub-perception (10 kHz)	Combined population: degenerative disk disease, radiculopathy, spondylosis, sacroiliac dysfunction	27	27	n/a (single-arm, no control)	n/a	n/a	Proportion of patients with $\geq 50\%$ pain reduction	12 Months	SENZA-RCT cohort (N=12, mean pain duration 6.8 $\pm$ 3.3y) and SENZA-EU cohort (N=15, mean pain duration 5.1 $\pm$ 3.3y); responder proportions reported but not isolable from source text	n/a (single-arm)	n/a	Improvement in ODI (n) reported	n/a	n/a (not listed as an outcome for this study)	Opioid reduction or cessation (no patients) and change in opioid dose (MME) both reported	n/a	n/a	n/a (12 months is longest follow-up for this subanalysis)	Included in meta-analysis pooled 12-month single-arm estimates	Known as the "MAIDEN BACK" study; notably short baseline pain duration (7.2 months) vs years-long duration in most other cohorts	
Baranidharan et al. (2021) MAIDEN BACK Study	Baranidharan et al. 2021	10 kHz High-Frequency SCS (HF-SCS)	Prospective research study; 10 kHz HF-SCS	Sub-perception (10 kHz)	Persistent nonoperated low back pain of neurogenic origin, confirmed via 5-LANSS, PainDETECT, or clinical exam; mean pain duration 7.2 $\pm$ 5.5 months	16	21	n/a (single-arm, no control)	n/a	n/a	Pain reduction (VAS/NRS)	12 Months	Improved from baseline (value not isolable from source text)	n/a (single-arm)	n/a	Improvement in ODI reported	n/a	HRQoL (EQ-5D utility) improvement reported	Opioid reduction or cessation (no patients) and change in opioid dose (MME) reported	n/a (not listed for this study)	n/a (not listed for this study)	n/a (not listed for this study)	Included in meta-analysis pooled 12-month single-arm estimates	n/a (12 months is longest follow-up reported)	Known as the "MAIDEN BACK" study; notably short baseline pain duration (7.2 months) vs years-long duration in most other cohorts
Campwala et al. (2021) Mixed-Modality SCS Study	Campwala et al. 2021	Conventional SCS, Subparesthesia SCS (10 kHz, 1 kHz, or Burst), or Combination	Real-world cohort using conventional tonic SCS, a subparesthesia modality, or a combination of both — no single fixed waveform	Mixed: Paresthesia-based and Sub-perception	Neuropathic back pain not amenable to surgery; spondylosis, sacroiliac dysfunction, spinal cord pathology; mean pain duration ~6.8 years (81.7 $\pm$ 11.1 months)	52	52	n/a (single-arm, no control)	n/a	n/a	Pain reduction; Improvement in ODI	12 Months	Improved from baseline (value not isolable from source text)	n/a (single-arm)	n/a	Improvement in ODI reported	n/a	n/a (not listed as an outcome for this study)	n/a (not listed as an outcome for this study)	n/a	n/a	n/a	Included in meta-analysis pooled 12-month single-arm estimates	n/a	One of only two studies in the review not funded/sponsored by industry (along with Vallejo et al. 2012); mixed real-world modality cohort rather than a single fixed waveform
Hunter et al. (2025) Closed-Loop SCS Subgroup Analysis	Hunter et al. 2025	Closed-Loop SCS (ECAP-controlled)	Evoked compound action potential sub-perception, iEAP-controlled closed-loop SCS; closed-loop titrated automatically adjusts stimulation to maintain a target ECAP amplitude	Sub-perception	Chronic non-surgical refractory back pain; radiculopathy, degenerative disk disease, spondylosis, spinal stenosis; mean pain duration 15.4 $\pm$ 7.8 years	68	68	n/a (single-arm, no control)	n/a (subgroup analysis)	n/a	Pain reduction; Proportion with $\geq 50\%$ pain reduction	12 Months	Improved from baseline (value not isolable from source text)	n/a (single-arm)	n/a	Improvement in ODI reported	n/a	HRQoL (EQ-5D utility) improvement reported	Opioid reduction or cessation (no patients) and % change in opioid dose (MME) reported	PGIC (no patients reported)	Very satisfied/satisfied (no patients reported)	n/a (single-arm subgroup analysis, not a crossover design)	Included in meta-analysis pooled 12-month single-arm estimates	n/a (12 months is longest follow-up reported)	Longest average baseline pain duration (15.9 years) of all included studies; subgroup analysis drawn from two prospective multicenter clinical trials



PSPS –Type 1

Expanding Indication #2

- 19 studies , 1319 patients

SCS vs. CMM at 6 months (2 RCTs, 283 participants):

- Pain: average reduction of **5.67 points on the 0–10 scale** (95% CI: 4.60–6.74)
- ODI: average reduction of **27.97 points on the 0–100 scale** (95% CI: 24.24–31.69)
- Responder rate: roughly **60% of SCS patients vs. ~4% of CMM patients** achieved $\geq 50\%$ pain relief — this is the basis for the review's number-needed-to-treat of 2

Single-arm SCS follow-up (no CMM comparator, tracking the same patients over time):

- Pain reduction: **4.73 points at 12 months** (706 participants) rising to **6.01 points at 24 months** (184 participants)



Terminology

Lets get the names right

- **CRPS Type I (formerly reflex sympathetic dystrophy):**
 - develops after an injury — fracture, sprain, surgery, or immobilization — **without a confirmed nerve injury.**
- **CRPS Type II (formerly causalgia):**
 - the same clinical syndrome occurring after a **documented peripheral nerve injury** with a focal neurological deficit.
 - *Both share the same clinical picture — pain, sensory, vasomotor, sudomotor, and motor/trophic changes — per the Budapest criteria the distinction rests solely on the presence of a documented nerve injury.*

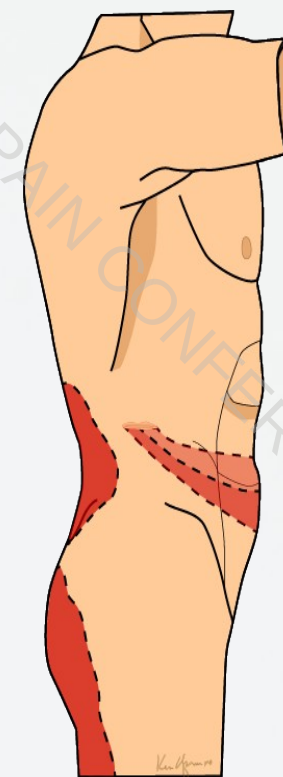
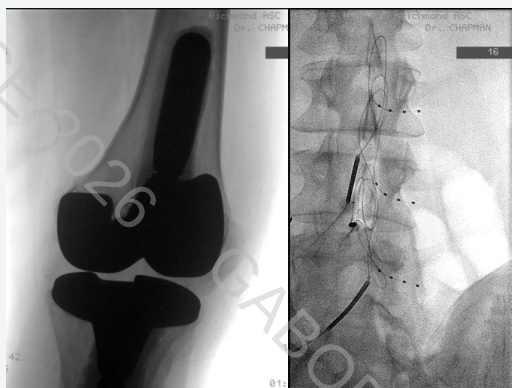


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DRGS for Post Surgical Pain Syndromes (CRPS II)

Expanding Indication #3

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





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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



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SCS for post TKR Pain

Limited in Literature

Study	Number of participants	Follow up	Outcome Measures	Results: Efficacy	Results: Complications
Lowry & Simopoulos (2010) CR	1 post-TKA patient	1 year	OKS, pain, function	OKS 39→26 at 1 year	None reported
Gillis et al. (2022) CS	3 post-TKA patients	Case-based follow up	Pain relief, function, sleep, meds	3/3 improved; 60% relief, >50% relief, or pain 6-7/10→1-2/10	None reported after implantation; 1 prior explant for loss of efficacy/paresthesia intolerance
Urits et al. (2019) CR	1 post-TKA CRPS knee patient	6 months	VAS, symptom resolution, opioid use	Complete symptom resolution through 6 months; opioid discontinued	None reported

Lowry AM, Simopoulos TT. Spinal cord stimulation for the treatment of chronic knee pain following total knee replacement. Pain Physician. 2010;13(3):251-6.

Granville M, Berti A, Jacobson RE. Use of Spinal Cord Stimulation in Elderly Patients with Multi-Factorial Chronic Lumbar and Non-Radicular Lower Extremity Pain. Cureus. 2017;9(11).

Urits I, et al. Use of spinal cord stimulation for the treatment of post total knee arthroplasty pain. Best Pract Res Clin Anaesthesiol . 2020;34(3):633-42. doi.org/10.1016/j.bpa.2020.07.006

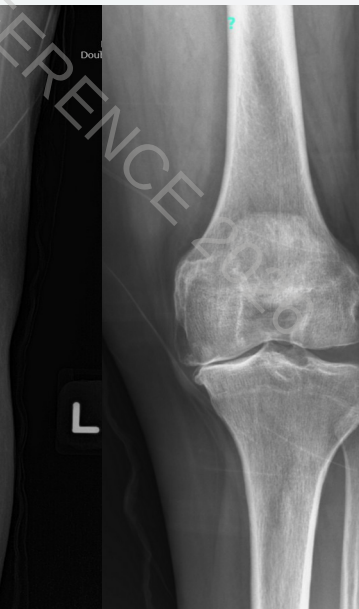


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DRGS for Nociceptive Pain

Expanding Indication #3b

DRGS Outcomes for the Treatment of
Mechanical Knee Pain Among Patients
With Osteoarthritis of the Surgical and
Non-Surgical Knee





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Investigator Device Exemption (IDE)

Category B Study

- Investigator Initiated Study:
 - Investigator Initiates, designs, and executes the study
 - Holds regulatory responsibility.
 - Maintains data
 - Limited Role by Industry
- IDE Study:
 - Evaluates the safety and effectiveness of a new or modified medical device that has not yet received FDA approval/clearance
 - FDA grants an IDE to exempt the device from certain marketing requirements so the study can proceed

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Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

Approved IDE Studies

Approved IDE Studies

The following IDE studies have met CMS' standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.

Show entries: 5 per page Filter On NCT05103527 Apply

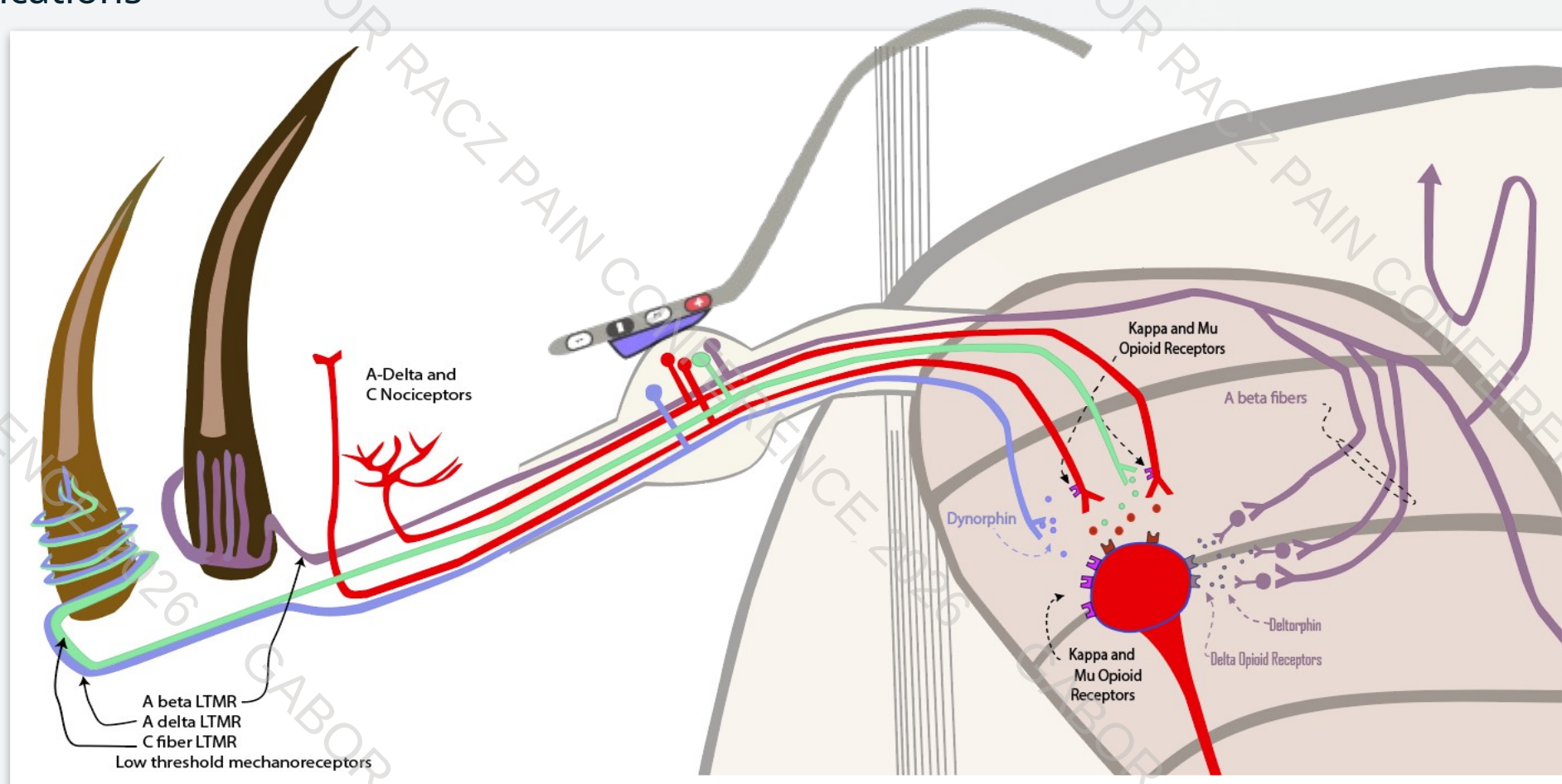
Showing 1-1 of 1 entries

Study Title	Sponsor Name	NCT Number	IDE Number	CMS Approval Date	Category
Dorsal Root Ganglion Stimulation Outcomes for the Treatment of Mechanical Knee Pain Among Patients With Osteoarthritis of the Surgical and Non-surgical Knee	Kenneth B Chapman	NCT05103527	G210274	2021-11-18	B

Low Threshold Mechanoreceptors (LTMRs)

Touch and Pain Modifications

- LTMR- Hair Follicles
 - C-fiber LTMR: Endorphins
- K, δ , μ opioid receptors are pivotal in this process
 - Inhibit pre-synaptically and post-synaptically



1. Arcourt et al. Touch Receptor-Derived Sensory Information Alleviates Acute Pain Signaling and Fine-Tunes Nociceptive Reflex Coordination. *Neuron* Jan 4;93(1):179-93.
2. Snyder et al. Kappa Opioid Receptor Distribution and Function in Primary Afferents. *Neuron* [Internet]. 2018 Sep 19 [cited 2019 Jun 24];99(6):1274-1288.e6.



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Demographics

DRGS for OA study

	N	%
Total Permanent Implants	20	
Gender		
Male	7	35
Female	13	65
Race		
White	13	65
Black	4	15
Hispanic/Latino	1	10
Asian	2	10
Index Knee		
Right	9 *	45
Left	11 *	55

	Mean	Range
Other Patient Characteristics		
Age at Implant, years	66	(45–83)
BMI	34.4 ± 7.4	(22.6–51.6)
Opioid use, MME (mg/day)		
All patients, N=20	9.7	(0.0–60.0)
Patients using opioids, N=4	41.3	(15–60)
Patients using opioids for knee		
	Baseline	
Visual Analog Scale (VAS)	86.5 ± 6.3	
Western Ontario McMaster University Osteoarthritis Index (WOMAC)	60.4 ± 18.3	
EuroQol-5D (EQ-5D)	0.472 ± 0.147	
Timed Up-and-Go (TUG)	18.5 ± 6.0 s	
Pain Disability Index (PDI)	33.7 ± 14.9	



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DRGS for Nociceptive Pain

Results of the DRGS OA Study

20 Pts reached primary outcome

Multi-dimensional improvements

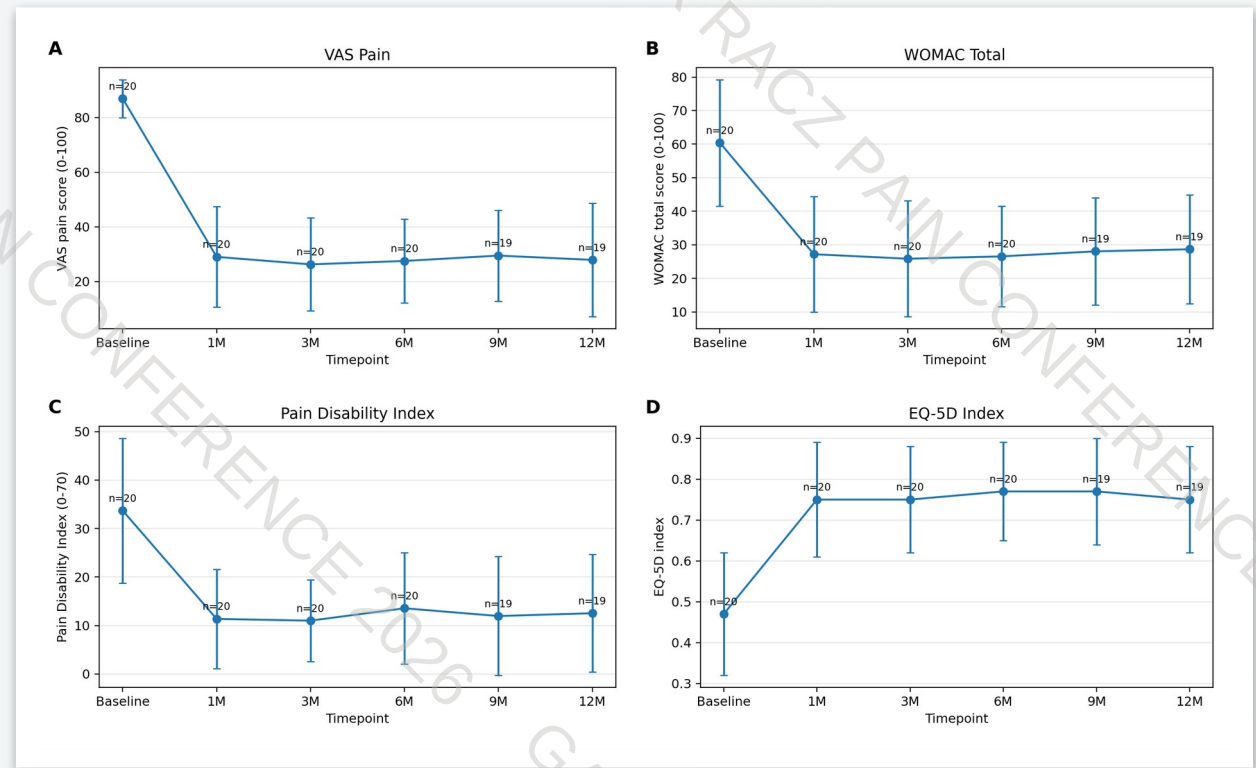
Programming:

All patients started at 4 Hz 1 min on 1 min off.

20/20 at 1 year have 3.0V or <3.0V on IPG

Adverse Events:

1 infection (Explant), 1 neuralgia post
implant (revision), 1 lead fracture



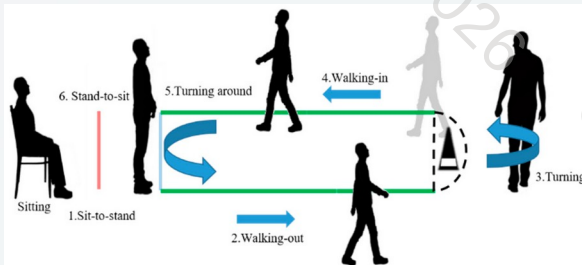
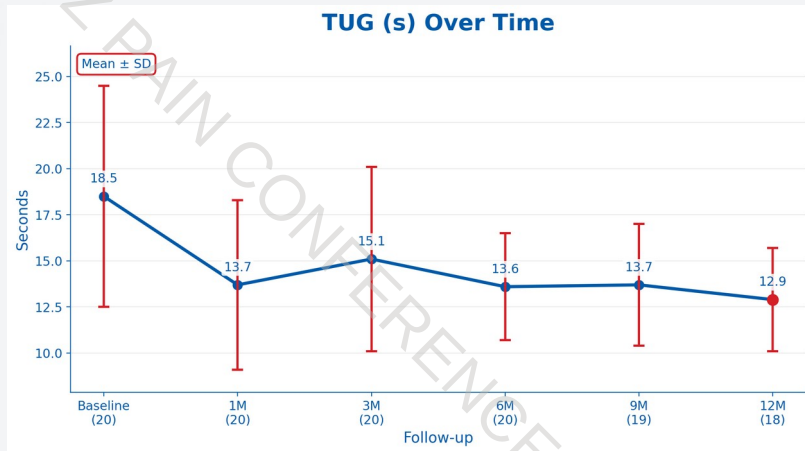


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Functional Improvements

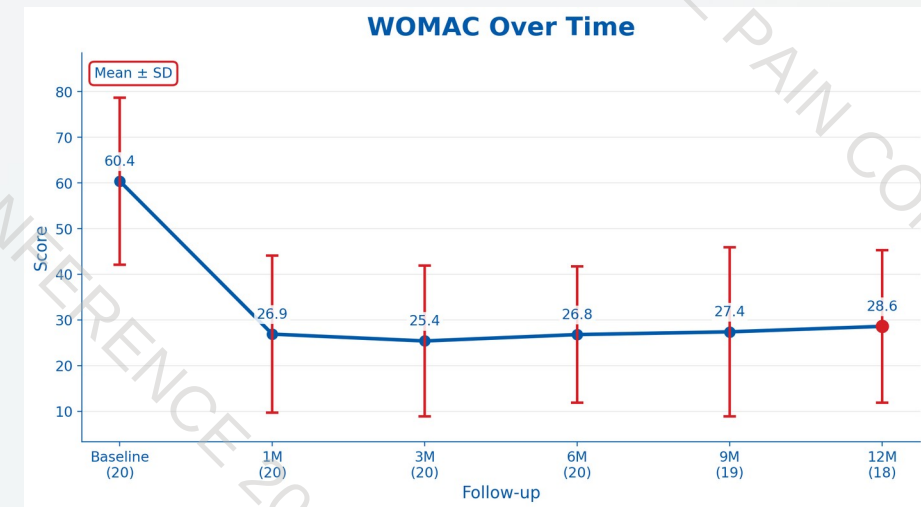
Results of the DRGS OA Study

Timed Up and Go



Western Ontario and McMaster Osteoarthritis Index (WOMAC)

Standard Questionnaire TKA



Tool used for people with hip or knee OA to **measure physical function, pain, and stiffness**.

24 items measuring 3 subscales: physical function (17 items), pain (5 items), and stiffness (2 items)



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Gait Improvement with DRGS

Baseline, 3, and 6 months





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Conclusion

Expanding Indications

- We need to expand neuromodulation to new diagnoses
 - Diabetic Peripheral Neuropathy (PDN) new indication showing promising results
 - Plethora of SCS for PSPS –Type I demonstrating efficacy
 - Consider neurostimulation for CRPS I and CRPS II
 - Consider DRGS for when nociceptive component of pain present