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Predicting Patient Response to SCS

Aaron Calodney MD
Director Clinical Research
Precision Spine Care
Tyler, Texas



Conflicts of Interest

- Research support:
- Medtronic, Boston Scientific, Saluda, Nevro, Stryker, Spine BioPharma, Vivex, Regeltec

Predicting Outcomes with SCS for Chronic Pain

Recent literature...

ORIGINAL ARTICLE

Predictors of Pain Relief Following Spinal Cord Stimulation in Chronic Back and Failed Back Surgery Syndrome: Review and Meta-Regression

Rod S. Taylor, PhD*; Mehul J. Desai, MD[†]; Philippe J. Taylor, MSc[‡]

*Institute of Health Services Research, University of Exeter Medical School, Exeter, UK
†Department of Anesthesiology and Critical Care and of Neurosurgery, The University of Kansas Medical Center, Kansas City, Kansas, USA



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Predictors of spinal cord stimulation success

Priscilla De La Cruz, BS¹, Christopher Fama¹, Steven Roth, MS¹, Jessica Haller¹, Meghan Wilcock, PA¹, Steven Lange, BA¹, and Julie Pilitsis, MD, PhD^{1,2}

¹Department of Neurosurgery, Albany Medical Center, Albany NY

²Center for Neuroscience and Neuropharmacology, Albany Medical College, Albany NY

Abstract

Introduction—As many as 30% of SCS patients fail to obtain long term pain coverage, even with the strictest parameters of a successful trial, unremarkable psychological assessment, and ideal placement of the permanent device. Why these patients either never receive adequate benefit or lose benefit remains elusive.

Methods—We perform a retrospective review of our prospective database of SCS patients undergoing surgery for routine indications. Six month post-operative follow-up data was available for 57 patients. Two providers who routinely saw the patients were asked to independently grade the patient's outcome in a blinded fashion on a Global Outcome Ratings scale of 1 to 10, with 5 being 50% improvement at six months post-operation. A score of less than 5 was deemed a failure. The impact of Body Mass Index (BMI), random drug screen results, workers' compensation status, depression, and smoking were assessed.

Results—We report a phi correlation of 0.350 between smoking and failure ($p=0.017$). Smoking status is correlated with both lead migration revisions ($\phi=0.269$) ($p=0.044$) and with revision due to new pain symptoms ($\phi=0.241$) ($p=0.072$). Further, there is a trend of correlation ($\phi=0.289$) between drug use and patients ($n=3$) who underwent device removal ($p=0.045$). In this cohort, worker's compensation status, BMI, and depression did not impact outcome.

Conclusions—Tobacco use correlates with less success with SCS at 6-month follow-up. Whether that is because of issues with healing and our transmission of signals to the periphery warrants further exploration. This data provide further evidence that tobacco cessation is important to surgical results.

Keywords

spinal cord stimulation; tobacco; illegal drug use

Corresponding author: Julie G. Pilitsis MD, PhD, AMC Neurosurgery Group, 47 New Scotland Ave, MC 10, Physicians Pavilion, 1st Floor, Albany, NY 12208, Tel (518) 262–0739, Fax (518) 262–1017, jpilitsis@yahoo.com.

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Authorship Statement: Dr. Julie Pilitsis, Priscilla De La Cruz, Steven Roth, Steven Lange, Jessica Haller, Chris Fama, and Meghan Wilcock designed and conducted the study including patient recruitment, data collection, and data analysis. Priscilla De La Cruz, Chris Fama, and Dr. Julie Pilitsis prepared the manuscript draft. All authors approved the final manuscript.

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RESEARCH ARTICLE

Variables associated with nonresponders to high-frequency (10 kHz) spinal cord stimulation

Vinicius Tieppo Francio MD, MS^{1,2} | John Alm DO¹ | Logan Leavitt DO¹ | Daniel Mok DO¹ | B. Victor Yoon MD¹ | Niaman Nazir MD, MPH³ | Christopher Lam MD² | Usman Latif MD² | Timothy Sowder MD² | Edward Braun MD² | Andrew Sack MD² | Talal Khan MD² | Dawood Sayed MD²

¹Department of Physical Medicine and Rehabilitation, The University of Kansas Medical Center, Kansas City, Kansas, USA

²Department of Anesthesiology and Pain Medicine, The University of Kansas Medical Center, Kansas City, Kansas, USA

³Department of Population Health, The University of Kansas Medical Center, Kansas City, Kansas, USA

Abstract

Introduction: The use of spinal cord stimulation (SCS) therapy to treat chronic pain continues to rise. Optimal patient selection remains one of the most important factors for SCS success. However, despite increased utilization and the existence of general indications, predicting which patients will benefit from neuromodulation remains one of the main challenges for this therapy. Therefore, this study aims to identify the variables that may correlate with nonresponders to high-frequency (10kHz) SCS to distinguish the subset of patients less likely to benefit from this intervention.

Materials and Methods: This was a retrospective single-center observational study of patients who underwent 10kHz SCS implant. Patients were divided into nonresponders and responders groups. Demographic data and clinical outcomes were collected at baseline and statistical analysis was performed for all continuous and categorical variables between the two groups to calculate statistically significant differences.

Results: The study population comprised of 237 patients, of which 67.51% were responders and 32.49% were nonresponders. There was a statistically significant difference of high levels of kinesiophobia, high self-perceived disability, greater pain intensity, and clinically relevant pain catastrophizing at baseline in the nonresponders compared to the responders. A few variables deemed potentially relevant, such as age, gender, history of spinal surgery, diabetes, alcohol use, tobacco use, psychiatric illness, and opioid utilization at baseline were not statistically significant.

Conclusion: Our study is the first in the neuromodulation literature to raise awareness to the association of high levels of kinesiophobia preoperatively in nonresponders to 10kHz SCS therapy. We also found statistically significant differences with greater pain intensity, higher self-managed disability, and

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Factors Predicting Clinically Relevant Pain Relief After Spinal Cord Stimulation for Patients With Chronic Low Back and/or Leg Pain: A Systematic Review With Meta-Analysis and Meta-Regression

Ferdinand Bastiaens, MSc^{1,2,3} | Ilse H. van de Wijgert, MSc^{1,2}; Ewald M. Bronkhorst, PhD⁴; Bert-Kristian W. P. van Rosendaal, MD¹; Esther P. Z. van Heteren, MD¹; Christopher Gilligan, MD⁵; Peter Staats, MD⁶; Jessica T. Wegener, MD⁷; Miranda L. van Hooff, PhD^{2,7}; Kris C. P. Vissers, MD, PhD^{1,2}

ABSTRACT

Rationale: To optimize results with spinal cord stimulation (SCS) for chronic low back pain (CLBP) and/or leg pain, including persistent spinal pain syndrome (PSPS), careful patient selection based on proved predictive factors is essential. Unfortunately, the necessary selection process required to optimize outcomes of SCS remains challenging.

Objectives: This review aimed to evaluate predictive factors of clinically relevant pain relief after SCS for patients with CLBP and/or radicular leg pain, including PSPS.

Materials and Methods: In August 2013, PubMed, Cinahl, Cochrane, and EMBASE were searched to identify studies published between January 2010 and August 2013. Studies reporting the percentage of patients with a 50% pain relief after SCS in patients with CLBP and/or leg pain, including PSPS at 12 or 24 months, were included. Meta-analysis was conducted to pool results for back, leg, and general pain relief. Predictive factors for pain relief after 12 months were examined using univariable and multivariable meta-regression.

Results: A total of 27 studies (2220 patients) were included for further analysis. The mean percentages of patients with substantial pain relief were 68% for leg pain, 63% for back pain, and 73% for general pain at 12 months follow-up, and 63% for leg pain, 59% for back pain, and 71% for general pain at 24 months follow-up assessment. The implantation method and baseline Oswestry Disability Index made the multivariable meta-regression model for 250% back pain relief. Sex and pain duration made the final model for 250% leg pain relief. Variable stimulation and implantation method made the final model for general pain relief.

Conclusions: This review supports SCS as an effective pain-relieving treatment for CLBP and/or leg pain, and models were developed to predict substantial back and leg pain relief. To provide high-grade evidence for predictive factors, SCS studies of high quality are needed in which standardized factors predictive of SCS success, based on in-patient improvements, are monitored and reported.

Address correspondence to Ferdinand Bastiaens, MSc, Department of Anesthesiology, Pain, and Palliative Medicine, Radboud University Medical Center, Geert Groenouplein Zuid 10, 6525 GA Nijmegen, The Netherlands. Email: ferdinand.bastiaens@isg.umcn.nl

¹ Department of Anesthesiology, Pain, and Palliative Medicine, Radboud University Medical Center, Nijmegen, The Netherlands

² Department of Research, Sint Maartenskliniek, Nijmegen, The Netherlands

³ Department of Anesthesiology and Pain Medicine, Sint Maartenskliniek, Nijmegen, The Netherlands

⁴ Department of Health Evidence, Radboud University Medical Center, Nijmegen, The Netherlands

⁵ Division of Pain Medicine, Department of Anesthesiology, Perioperative and Pain Medicine, Brigham and Women's Hospital/Harvard Medical School, Boston, MA, USA

⁶ National Spine and Pain, ElectriCure, Inc, Jacksonville, FL, USA, and

⁷ Department of Orthopedics, Radboud University Medical Center, Nijmegen, The Netherlands

ARTICLE	MAIN CONCLUSIONS
Sharan AD, et al.. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. Pain Med. 2018 Apr 1;19(4):699-707.	Higher opioid use increased risk of explant
Poulsen DM, et al. Comparison of Spinal Cord Stimulation Outcomes Between Preoperative Opioid Users and Nonusers: A Cohort Study of 467 Patients. Neuromodulation. 2022 Jul;25(5):700-709.	Opioid use not correlated with pain outcomes
Poulsen DM, et al. Pain Catastrophizing Does Not Predict Spinal Cord Stimulation Outcomes: A Cohort Study of 259 Patients With Long-Term Follow-Up. Neuromodulation. 2021 Jan;24(1):76-85.	Pain Catastrophizing not associated with pain outcome
Goudman L, Van Buyten J-P, De Smedt A, Smet I, Devos M, Jerjir A, Moens M. Predicting the Response of High Frequency Spinal Cord Stimulation in Patients with Failed Back Surgery Syndrome: A Retrospective Study with Machine Learning Techniques. Journal of Clinical Medicine. 2020; 9(12):4131.	Some prediction value with pain relief in trial, location of pain, and previous surgeries, only 58% accuracy for >50% pain relief
Kayode A. Williams, et al, A Multi-Center Analysis Evaluating Factors Associated with Spinal Cord Stimulation Outcome in Chronic Pain Patients, Pain Medicine, Volume 12, Issue 8, August 2011, Pages 1142–1153,	Negative correlation with <50% PR in trial, and substance abuse, positive with allodynia and hyperalgesia
De La Cruz P, Fama C, Roth S, Haller J, Wilock M, Lange S, Pilitsis J. Predictors of Spinal Cord Stimulation Success. Neuromodulation. 2015 Oct;18(7):599-602; discussion 602. doi: 10.1111/ner.12325. Epub 2015 Jun 28. PMID: 26119040; PMCID: PMC4615463.	Smoking associated with worse outcomes
Taylor RS, Desai MJ, Rigoard P, Taylor RJ. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. Pain Pract. 2014;14(6):489–505	No predictive factors
Bastiaens, F., et al. (2024). "Factors Predicting Clinically Relevant Pain Relief After Spinal Cord Stimulation for Patients With Chronic Low Back and/or Leg Pain: A Systematic Review With Meta-Analysis and Meta-Regression." Neuromodulation 27(1): 70-82.	Baseline ODI correlated with back pain outcome, and sex and pain duration were predictive of leg pain responders
Tieppo Francio V, et al. Variables associated with nonresponders to high-frequency (10 kHz) spinal cord stimulation. Pain Pract. 2024 Apr;24(4):584-599.	Non-responders had higher levels of kinesiophobia, high self-perceived disability, greater pain intensity, and clinically relevant pain catastrophizing at baseline compared to the responders

Strong negative correlation with <50% PR in trial, and substance abuse, positive with allodynia and hyperalgesia

Kayode A. Williams, et al, A Multi-Center Analysis Evaluating Factors Associated with Spinal Cord Stimulation Outcome in Chronic Pain Patients, Pain Medicine, Volume 12, Issue 8, August 2011, Pages 1142–1153,

Clinical Trial > Pain Med. 2011 Aug;12(8):1142-53. doi: 10.1111/j.1526-4637.2011.01184.x.

Epub 2011 Jul 12.

A multi-center analysis evaluating factors associated with spinal cord stimulation outcome in chronic pain patients

Kayode A Williams¹, Marlis Gonzalez-Fernandez, Sayeh Hamzehzadeh, Indy Wilkinson, Michael A Erdek, Anthony Plunkett, Scott Griffith, Matthew Crooks, Thomas Larkin, Steven P Cohen

Affiliations + expand

PMID: 21749636 DOI: 10.1111/j.1526-4637.2011.01184.x

Abstract

Background: In addition to its conventional use as a treatment for refractory neuropathic extremity pain, spinal cord stimulation (SCS) has recently emerged as a possible treatment for visceral and arthritic pain. But concurrent with the expansion of possible conditions amenable to SCS, other studies have questioned the long-term efficacy of SCS for traditional indications. These disparate findings argue strongly for the refinement of selection criteria. The purpose of this study is to identify correlates of outcome for SCS.

Methods: Data were retrospectively collected on 244 patients who underwent a SCS trial at two academic medical centers. Success was predefined as $\geq 50\%$ pain relief sustained for ≥ 6 months. Variables analyzed for their association with outcome included demographics, location of pain, diagnosis, presence of coexisting diseases, pain descriptors, opioid and adjuvant medication use, duration and pain relief during trial, and complications.

Results: The presence of allodynia and/or hyperalgesia correlated with both a positive SCS trial ($P = 0.01$) and long-term implantation outcome ($P = 0.05$). History of substance abuse was associated with a negative permanent SCS outcome ($P = 0.05$) but bore no relationship to trial results. The variable most strongly associated with an SCS outcome was experiencing <50% pain relief during the trial, which strongly presaged a negative result ($P < 0.001$).

Conclusions: Although weak associations with outcome were noted for several clinical variables, none

lez-Fernandez-M&cauthor_id=21749636 trial and permanent implantation results. The strongest predictor of a

Multivariable meta-regression analysis showed no predictive patient or technology factors

Taylor RS, Desai MJ, Rigoard P, Taylor RJ. Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis. *Pain Pract.* 2014;14(6):489–505

Predictors of pain relief following spinal cord stimulation in chronic back and leg pain and failed back surgery syndrome: a systematic review and meta-regression analysis

Rod S Taylor¹, Mehul J Desai, Philippe Rigoard, Rebecca J Taylor

Affiliations + expand

PMID: 23834386 PMID: [PMC4238825](#) DOI: [10.1111/papr.12095](#)

Abstract

We sought to assess the extent to which pain relief in chronic back and leg pain (CBLP) following spinal cord stimulation (SCS) is influenced by patient-related factors, including pain location, and technology factors. A number of electronic databases were searched with citation searching of included papers and recent systematic reviews. All study designs were included. The primary outcome was pain relief following SCS, we also sought pain score (pre- and post-SCS). Multiple predictive factors were examined: location of pain, history of back surgery, initial level of pain, litigation/worker's compensation, age, gender, duration of pain, duration of follow-up, publication year, continent of data collection, study design, quality score, method of SCS lead implant, and type of SCS lead. Between-study association in predictive factors and pain relief were assessed by meta-regression. Seventy-four studies (N = 3,025 patients with CBLP) met the inclusion criteria; 63 reported data to allow inclusion in a quantitative analysis. Evidence of substantial statistical heterogeneity ($P < 0.0001$) in level of pain relief following SCS was noted. The mean level of pain relief across studies was 58% (95% CI: 53% to 64%, random effects) at an average follow-up of 24 months. Multivariable meta-regression analysis showed no predictive patient or technology factors. SCS was effective in reducing pain irrespective of the location of CBLP. This review supports SCS as an effective pain relieving treatment for CBLP with predominant leg pain with or without a prior history of back surgery. Randomized controlled trials need to confirm the effectiveness and cost-effectiveness of SCS in the CBLP population with predominant low back pain.

Keywords: back pain; meta-regression analysis; outcomes; predictive factors; spinal cord stimulation; systematic review.

Lower baseline ODI correlated with back pain outcome, and sex and shorter pain duration were predictive of leg pain responders

Bastiaens, F., et al. (2024). "Factors Predicting Clinically Relevant Pain Relief After Spinal Cord Stimulation for Patients With Chronic Low Back and/or Leg Pain: A Systematic Review With Meta-Analysis and Meta-Regression." *Neuromodulation* 27(1): 70-82. Authors include two previous WIP Presidents, Peter Staats and Kris Vissers

Review > *Neuromodulation*. 2024 Jan;27(1):70-82. doi: 10.1016/j.neurom.2023.10.188.

Factors Predicting Clinically Relevant Pain Relief After Spinal Cord Stimulation for Patients With Chronic Low Back and/or Leg Pain: A Systematic Review With Meta-Analysis and Meta-Regression

Ferdinand Bastiaens¹, Ilse H van de Wijert², Ewald M Bronkhorst³, Bert-Kristian W P van Roosendaal⁴, Esther P Z van Heteren⁴, Christopher Gilligan⁵, Peter Staats⁶, Jessica T Wegener⁷, Miranda L van Hooff⁸, Kris C P Vissers⁹

Affiliations + expand

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Abstract

Rationale: To optimize results with spinal cord stimulation (SCS) for chronic low back pain (CLBP) and/or leg pain, including persistent spinal pain syndrome (PSPS), careful patient selection based on proved predictive factors is essential. Unfortunately, the necessary selection process required to optimize outcomes of SCS remains challenging.

Objective: This review aimed to evaluate predictive factors of clinically relevant pain relief after SCS for patients with CLBP and/or radicular leg pain, including PSPS.

Materials and methods: In August 2023, PubMed, Cinahl, Cochrane, and EMBASE were searched to identify studies published between January 2010 and August 2023. Studies reporting the percentage of patients with $\geq 50\%$ pain relief after SCS in patients with CLBP and leg pain, including PSPS at 12 or 24 months, were included. Meta-analysis was conducted to pool results for back, leg, and general pain relief. Predictive factors for pain relief after 12 months were examined using univariable and multivariable meta-regression.

Results: A total of 27 studies (2220 patients) were included for further analysis. The mean percentages of patients with substantial pain relief were 68% for leg pain, 63% for back pain, and 73% for general pain at 12 months follow-up, and 63% for leg pain, 59% for back pain, and 71% for general pain at 24

Systematic review of 40 studies to identify patient-level predictors of outcome

- **no strong evidence of association between studied patient-level factors and treatment outcomes**

- Pain characteristics
- Demographics
- Clinical and functional measures
- Psychosocial factors
- Other health-related predictors

Systematic Review to Identify Patient-Level Predictors of Treatment Response to Spinal Cord Stimulation for Neuropathic Pain for Studies Published From 2012 to 2024

Anu Kansal ¹, Sue Copley ², Rui V Duarte ³, Fiona C Warren ⁴, Rod S Taylor ⁵, Sam Eldabe ²

Affiliations + expand

PMID: 40448993 DOI: [10.1016/j.neurom.2025.04.004](https://doi.org/10.1016/j.neurom.2025.04.004)

Abstract Neuromodulation August 2025

Objective: Chronic neuropathic pain is challenging to manage, but one recommended treatment is spinal cord stimulation (SCS), which may provide pain relief and improvements in physical function and health-related quality of life. Almost half of the patients do not obtain long-term relief, and selection of appropriate patients can be problematic. The objective of this study was to undertake a systematic review of the contemporary evidence base for patient-level predictors for the outcomes from all types of SCS.

Some machine learning models identified predictive value of pain relief in trial, location of pain, and previous surgeries,

58% accuracy for >50% pain relief

71% accuracy for >30% pain relief

Goudman L, Van Buyten J-P, De Smedt A, Smet I, Devos M, Jerjir A, Moens M.
Predicting the Response of High Frequency Spinal Cord Stimulation in Patients with Failed Back Surgery Syndrome: A Retrospective Study with Machine Learning Techniques.
Journal of Clinical Medicine. 2020; 9(12):4131.

Predicting the Response of High Frequency Spinal Cord Stimulation in Patients with Failed Back Surgery Syndrome: A Retrospective Study with Machine Learning Techniques

Lisa Goudman ^{1 2 3 4}, Jean-Pierre Van Buyten ⁵, Ann De Smedt ^{2 3 6}, Iris Smet ⁵, Marieke Devos ⁵, Ali Jerjir ⁵, Maarten Moens ^{1 2 3 7}

Affiliations + expand

PMID: 33371497 PMCID: [PMC7767526](#) DOI: [10.3390/jcm9124131](#)

Abstract

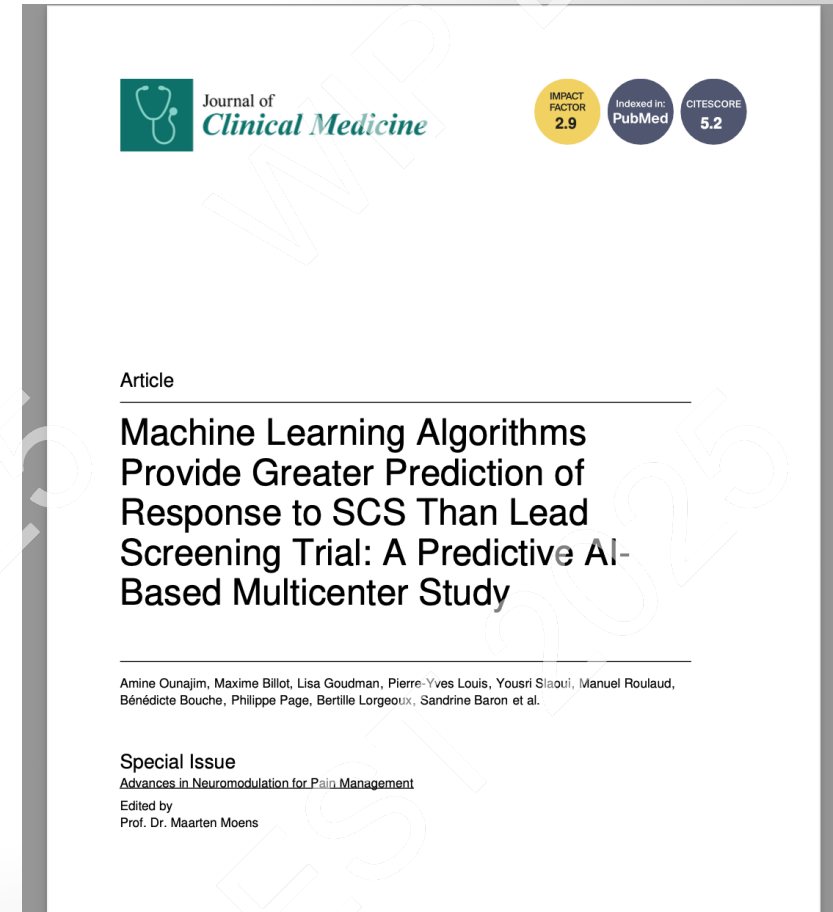
Despite the proven clinical value of spinal cord stimulation (SCS) for patients with failed back surgery syndrome (FBSS), factors related to a successful SCS outcome are not yet clearly understood. This study aimed to predict responders for high frequency SCS at 10 kHz (HF-10). Data before implantation and the last available data was extracted for 119 FBSS patients treated with HF-10 SCS. Correlations, logistic regression, linear discriminant analysis, classification and regression trees, random forest, bagging, and boosting were applied. Based on feature selection, trial pain relief, predominant pain location, and the number of previous surgeries were relevant factors for predicting pain relief. To predict responders with 50% pain relief, 58.33% accuracy was obtained with boosting, random forest and bagging. For predicting responders with 30% pain relief, 70.83% accuracy was obtained using logistic regression, linear discriminant analysis, boosting, and classification trees. For predicting pain medication decrease, accuracies above 80% were obtained using logistic regression and linear discriminant analysis. Several machine learning techniques were able to predict responders to HF-10 SCS with an acceptable accuracy. However, none of the techniques revealed a high accuracy. The inconsistent results regarding predictive factors in literature, combined with acceptable accuracy of the currently obtained models, might suggest that routinely collected baseline parameters from clinical practice are not sufficient to consistently predict the SCS response with a high accuracy in the long-term.

Keywords: 10 kHz spinal cord stimulation; machine learning; pain; prediction; responders.

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Almost all proposed machine learning models showed better predictive power than lead trial outcomes.

- Ounajim et al, 2021



Machine learning combined with intraop EEG data predicts SCS response with 88% accuracy

- A decision tree model with 12 spatio-spectral features predicted responders with 88% accuracy. (50% pain reduction at 3 months)

scientific reports

Nature March 2025

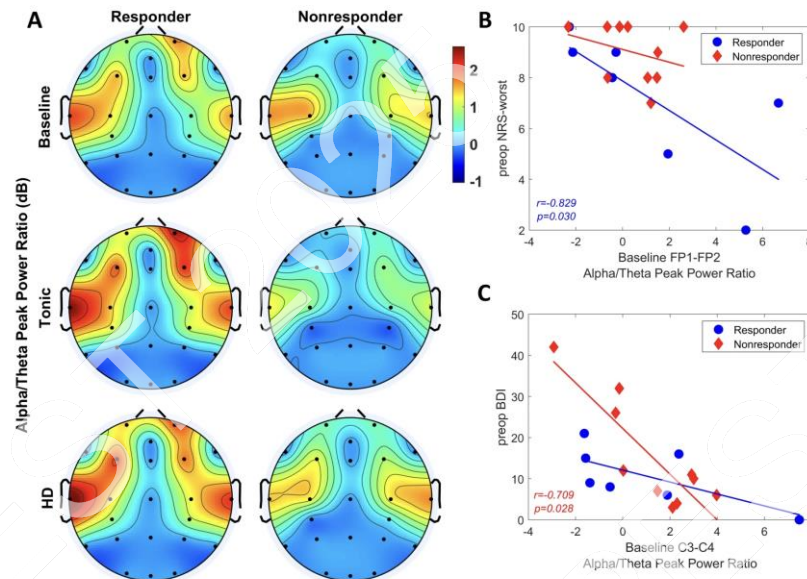


OPEN Machine learning predicts spinal cord stimulation surgery outcomes and reveals novel neural markers for chronic pain

Jay Gopal¹, Jonathan Bao², Tessa Harland³, Julie G. Pilitsis⁴, Steven Panicioli⁵, Rachael Grey⁵, Michael Briotte⁵, Kevin McCarthy⁵ & Ilknur Telkes^{4,6,7}✉

Spinal cord stimulation (SCS) is a well-accepted therapy for refractory chronic pain. However, predicting responders remain a challenge due to a lack of objective pain biomarkers. The present study applies machine learning to predict which patients will respond to SCS based on intraoperative electroencephalogram (EEG) data and recognized outcome measures. The study included 20 chronic pain patients who were undergoing SCS surgery. During intraoperative monitoring, EEG signals were recorded under SCS OFF (baseline) and ON conditions, including tonic and high density (HD) stimulation. Once spectral EEG features were extracted during offline analysis, principal component analysis (PCA) and a recursive feature elimination approach were used for feature selection. A subset of EEG features, clinical characteristics of the patients and preoperative patient reported outcome measures (PROMs) were used to build a predictive model. Responders and nonresponders were grouped based on 50% reduction in 3-month postoperative Numeric Rating Scale (NRS) scores. The two groups had no statistically significant differences with respect to demographics (including age, diagnosis, and pain location) or PROMs, except for the postoperative NRS (worst pain: $p = 0.028$; average pain: $p < 0.001$) and Oswestry Disability Index scores (ODI, $p = 0.030$). Alpha-theta peak power

From: Machine learning predicts spinal cord stimulation surgery outcomes and reveals novel neural markers for chronic pain



Comparison of alpha-theta peak power ratio between responders and nonresponders. (A) Topographical maps of alpha-theta peak power ratio in responders and nonresponders during stimulation OFF (top-row), tonic (middle-row) and HD (bottom-row). Color bar indicating alpha-theta peak power ratio in decibel (dB) scale. (B) Correlation analysis between alpha-theta peak power ratio in FP1-FP2 during baseline and preoperative Numeric Rating Scale (NRS) worst pain scores. Blue circle: Responders. Red diamond: Nonresponders. (C) Correlation analysis between alpha-theta peak power ratio in C3-C4 during baseline and preoperative Beck Depression Inventory (BDI) scores.

Summary

- Some factors showed up in multiple studies as being predictive of positive outcomes:
 - More disability at baseline (ODI) was predictor of worse outcome in two studies
 - Positive temporary trial results, the better pain relief in trial the higher chance of success with permanent implant
 - Pain quality associated with neuropathic pain – higher PainDETECT and higher allodynia and hyperalgesia associated with better outcomes
 - Pain catastrophizing was associated with being a non-responder in one of two studies
 - Machine learning algorithms improve predictive power
 - Intraop EEG characteristics greatly improved predictive power

Predictors of outcome with SCS – Nonsurgical back pain

Novel analysis of predictors in non-surgical
back pain patients only

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Retrospective Analysis

Demographics and PainDETECT as Predictors of 24-Month Outcomes for 10 kHz SCS in Nonsurgical Refractory Back Pain

Leonardo Kapural, MD, PhD¹, Chengyuan Wu, MD², Aaron Calodney, MD³, Julie Pilitsis, MD, PhD⁴, Markus Bendel, MD⁵, Erika Petersen, MD⁶, Dawood Sayed, MD⁷, Colleen Kelly, PhD⁸, Rose Province-Azalde, MS⁹, and Naresh P. Patel, MD¹⁰

From: ¹Carolina's Pain Institute, Winston-Salem, NC; ²Thomas Jefferson University Hospitals, Philadelphia, PA; ³Texas Spine and Joint Hospital, Tyler, TX; ⁴Albany Medical Center, Albany, NY; ⁵Mayo Clinic, Rochester, MN; ⁶University of Arkansas for Medical Sciences, Little Rock, AR; ⁷University of Kansas Hospital, Kansas City, KS; ⁸Kelly Statistical Consulting, San Diego, CA; ⁹Neuro Corp., Redwood City, CA; ¹⁰Mayo Clinic, Phoenix, AZ

Address Correspondence: Leonardo Kapural, MD, PhD
Carolina's Pain Institute
145 Kimmel Park Dr
Winston-Salem, NC 27103
E-mail: lkapuralmd@gmail.com

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Conflict of interest: See pg. 17 for this information.

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Free full manuscript: www.painphysicianjournal.com

Background: Nonsurgical refractory back pain (NSRBP) is broadly defined as chronic refractory back pain in patients who have not had previous spine surgery and, because they are deemed inappropriate candidates for surgery, are reliant on conventional medical management (CMM), which often provides poor long-term outcomes. High-frequency spinal cord stimulation (10kHz SCS) has demonstrated high rates of pain relief and improvements in functioning in patients with NSRBP. However, despite the use of temporary trial stimulation to select patients who will respond to therapy, some patients fail to achieve long-term therapy response with permanent implants. Prediction analysis founded on patients' baseline characteristics may enrich the appropriate selection of patients for permanent implantation.

Objectives: To examine baseline patient characteristics to predict long-term pain and functional responses to treatment with 10 kHz SCS for NSRBP.

Study Design: A retrospective analysis of baseline patient characteristics as predictors of 24-month pain and functional outcomes from a previous multicenter randomized controlled trial of 10 kHz SCS in patients with NSRBP.

Patients: Patients diagnosed with chronic, neuropathic, axial, low back pain refractory to CMM who had had no previous spine surgery, were deemed unsuitable candidates for it according to a spine surgeon, were implanted with 10kHz SCS and continued with CMM for up to 24 months.

Methods: The baseline characteristics of and 24-month outcomes in the 125 implanted patients who participated in the NSRBP randomized controlled trial (RCT) were included in this analysis. The baseline characteristics included demographics, baseline pain on the visual analog scale (VAS), baseline function based on the Oswestry Disability Index (ODI), mental health according to the patient health questionnaire-9 (PHQ-9), neuropathic pain as measured by PainDETECT, and each patient's temporary trial response. Patient response at 24 months was defined as absolute change from the baseline on the VAS and ODI, and each patient was also classified as a pain responder (achieving at least a 50% decrease in VAS pain score from the baseline) and a function responder (at least a 10-point decrease in ODI or a 24-month score of no more than 20 points). Multivariate prediction models based on regression and classification and regression tree (CART) techniques were developed using the response variables discussed above as the dependent variables and the baseline characteristics as the independent variables.

Results: Different factors contributed to pain and functional outcomes. Patients presenting with neuropathic pain (PainDETECT ≥ 19) and female gender had higher odds of being pain responders to 10 kHz SCS therapy than did males and those without neuropathic pain. Both higher age and depression score (PHQ-9) independently reduced the odds that a patient would be an ODI responder. Years since diagnosis, the reason the patient was deemed unsuitable for spine surgery, and pain etiology were not predictive of pain or functional outcomes.

Limitations: A retrospective sub-analysis of a single pragmatic randomized controlled trial.

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How to optimize patient selection?

Study Objective: Can we use pre-implant patient characteristics to predict 24-month outcomes from this multicenter NSRBP RCT?

NSRBP Patient Treatment Flow

Patient presents with moderate to severe back pain w/wo leg pain

Clinical Exam to rule out exclusions

Infection
Fracture
Tumor
Spinal Instability

Confirm all conservative medical management has been tried

Consult with orthopedic or neuro-surgeon

Surgical candidate?

Yes

No

Spine Surgery

Evidence Based Screening Algorithm

Pain Etiology

Years Since Diagnosis

Age

BMI

Sex

PainDetect Score

Mental Health (PHQ-9)

Baseline ODI

Pain Relief During Trial

Baseline Pain

NSRBP Patients

Best SCS Candidates

Prediction Analysis Methods

- Can we predict pain relief and/or functional improvement?
 - **Pain Relief:** point change in VAS between baseline and 24 months
 - **Functional Improvement:** point change in ODI between baseline and 24 Month
- Multivariate regression used to determine baseline parameters that had significant association with outcomes – **related to magnitude of change**
- Multivariate logistic regression to **predict Responder = Yes or No**

Analysis was based on 24M outcomes for all 125
implanted patients
(original = 69 and crossover arm n = 56)
Last observation carried forward used for missing data.

Which baseline characteristics were related to outcomes?

First step: Univariate regression analysis – highlighted items indicated significant relationship

Baseline Characteristic	VAS Change P value	ODI Change P value
Sex (1: Female, 0: Male)	0.014*	0.24
Age	0.18	0.004*
Nonsurgical candidate (1: not acceptable surgical candidate due to pathology, 0: not surgical candidate due to comorbidities or refusing surgery)	0.57	0.99
Obesity (1: BMI ≥ 30 kg/m ² , 0: BMI < 30 kg/m ²)	0.52	0.77
PHQ-9	0.95	0.45
Years Since Diagnosis (1: ≥ 4 yrs, 0: 0-3 yrs)	0.39	0.28
Degenerative Disc Disease and/or Internal disc disruption/annular tear	0.41	0.56
Spondylosis and/or Lumbar facet-mediated pain (1:yes, 0:no)	0.44	0.38
Radiculopathy (1:yes, 0:no)	0.44	0.36
Mild/moderate spinal stenosis (1:yes, 0:no)	0.58	0.87
Spondylolisthesis (1:yes, 0:no)	0.79	0.90
Sacroiliac dysfunction (1:yes, 0:no)	0.45	0.98
Neuropathic Pain (1: PainDetect ≥ 19 , 0: PainDetect < 19)	0.048*	0.003*
Nociceptive Pain (1: PainDetect ≤ 12 , 0: PainDetect > 12)	0.15	0.17
Pain Detect Score	0.003*	0.003*
Baseline ODI Score	0.52	0.021*

- Positively associated with outcomes:
 - Female sex (Pain)
 - Neuropathic Pain (Pain and ODI)
 - Higher Baseline ODI (ODI)
 - Higher pain relief at trial (Pain)
- Negatively associated with outcomes:
 - Older Age (ODI)
 - Higher PHQ-9 Score (ODI)

Predicting outcomes with
Machine learning applied to a
large PSR dataset

Patient Population

Product Surveillance Registry

6,504

Patients ever
enrolled in the
registry

1,608

Patients active in
the registry

10

Countries
contributing to the
registry

57,891

Years of device
experience in the
registry

721 patients included
with back and/or leg
pain

Enrolled between
August 2012-October
2023



Methods

Three modeling frameworks were utilized:

1. penalized logistic regression

- a form of linear regression where a penalty is imposed on the size of the coefficients to avoid overfitting and manage multicollinearity

2. random forest

- a machine learning algorithm that combines the output of multiple decision trees (DT) to reach a single result and to find the best split to subset the data

3. XGBoost

- creates decision trees in a sequential manner, weights are assigned to all the independent variables, which are then fed into the decision tree to predict results

Results

- Overall, 64% of (463/721) patients were responders
- 50% of patients (363/721) had both back and leg pain and of those patients 74% (274/363) were responders

Table 1. Summary of Variables by Responder and Non-Responder

Variable	Overall, N = 721	Non-Responder, N = 258	Responder, N = 463	p-value ¹
Age, Mean (SD)	61 (13)	61 (14)	62 (13)	0.6
BMI, Mean (SD)	30.5 (6.1)	30.4 (6.1)	30.6 (6.1)	0.6
EQ-5D Index Baseline, Mean (SD)	0.46 (0.25)	0.46 (0.24)	0.46 (0.25)	>0.9
ODI Index Baseline, Mean (SD)	50 (14)	50 (14)	50 (15)	0.7
Pain Baseline Score, Mean (SD)	6.84 (2.08)	5.82 (2.15)	7.40 (1.80)	<0.001
Depression Status (Yes), n (%)	201 (28%)	69 (27%)	132 (29%)	0.7
Pain Location ² , n (%)				<0.001
Back	176 (24%)	70 (27%)	106 (23%)	
Combined	363 (50%)	96 (37%)	267 (58%)	
Leg	78 (11%)	17 (6.6%)	61 (13%)	
Reference	104 (14%)	75 (29%)	29 (6.3%)	
Pain Type, n (%)				0.2
Mixed	394 (55%)	153 (59%)	241 (52%)	
Neuropathic	314 (44%)	101 (39%)	213 (46%)	
Nociceptive	13 (1.8%)	4 (1.6%)	9 (1.9%)	
Gender, n (%)				0.4
Female	406 (56%)	139 (54%)	267 (58%)	
Male	315 (44%)	119 (46%)	196 (42%)	
Race, n (%)				0.8
Other	232 (32%)	85 (33%)	147 (32%)	
White	489 (68%)	173 (67%)	316 (68%)	
Pain Category, n (%)				0.7
Complex Regional Pain Syndrome	32 (4.4%)	12 (4.7%)	20 (4.3%)	
Failed Back Pain	423 (59%)	156 (60%)	267 (58%)	
Other	266 (37%)	90 (35%)	176 (38%)	
Trial Status ³ , n (%)				0.7
Post Trial	301 (42%)	105 (41%)	196 (42%)	
Pre Trial	420 (58%)	153 (59%)	267 (58%)	
Medication Status ⁴ (Yes), n (%)	641 (89%)	223 (86%)	418 (90%)	0.15

¹Welch Two Sample t-test and Pearson's Chi-squared test were applied to numerical and categorical variables respectively.

²Back has baseline back pain ≥ 5 , leg has baseline leg pain ≥ 5 , Combined has both back and leg pain ≥ 5 , and reference has neither back nor leg pain ≥ 5 .

³Trial Status refers to when the baseline pain score was collected relative to SCS trial.

⁴Medication Status indicates whether the patient is taking any pain prescription medications at baseline.

Responders had:

- a higher baseline pain score
- were more likely to have combined back and leg pain
- neuropathic pain
- Taking prescription pain medication at baseline

Results

Confusion Matrix

	Real Responder	Real Non-Responder
Predicted Responder	True Positives (TP)	False Positives (FP)
Predicted Non-Responder	False Negatives (FN)	True Negatives (TN)

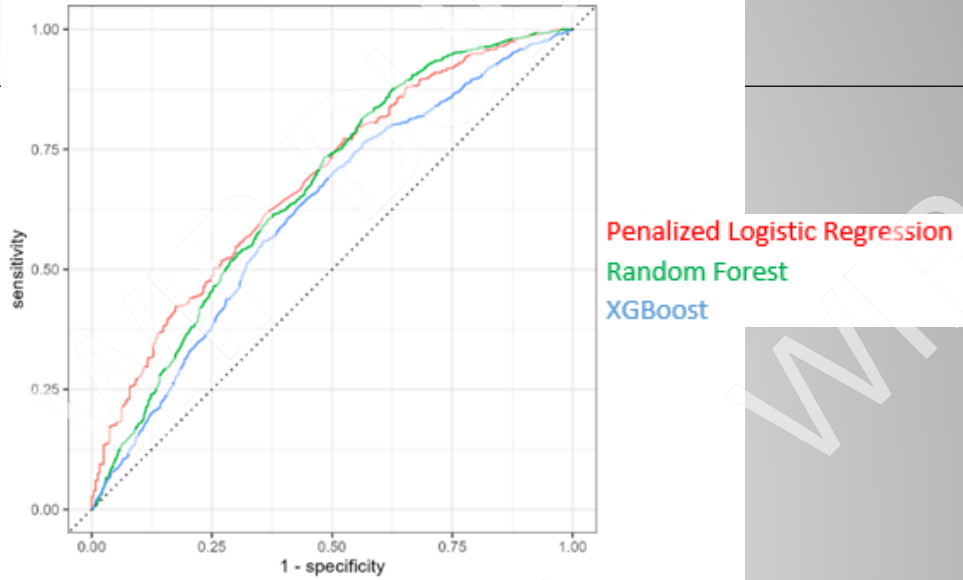
Performance Metrics Definition

Metric	Formula	Interpretation
Accuracy	$\frac{TP + TN}{TP + TN + FP + FN}$	The ratio between the number of correct predictions to the total number of predictions
Sensitivity	$\frac{TP}{TP + FN}$	Coverage of actual positive observations
Specificity	$\frac{TN}{TN + FP}$	Coverage of actual negative observations
Precision	$\frac{TP}{TP + FP}$	How accurate the positive predictions are
F1 score	$\frac{2TP}{2TP + FP + FN}$	The harmonic mean of precision and sensitivity, optimal value at 1 and worst value at 0

Performance Metrics Results

Metric	Elastic Net	Random Forest	XGBoost
Accuracy	0.680	0.691	0.685
Sensitivity	0.862	0.940	0.819
Specificity	0.354	0.246	0.446
Precision	0.704	0.690	0.725
F1 score	0.775	0.796	0.769

The ROC Curve



Main Take-Away

The Random Forest model has a relatively better performance in terms of sensitivity and F1 score.

Conclusions & Limitations in predicting SCS outcomes

- **Patient selection remains challenging-** there is conflicting evidence for most traditional predictive factors
- **Machine learning models consistently outperform traditional screening methods,** with EEG-based approaches showing particularly promising results
- **Multidisciplinary, integrated assessment approaches** are likely most effective for patient selection

Summary

- Accurate prediction of SCS outcomes is crucial
- ML can analyze large complex datasets and ID subtle patterns and interactions missed by traditional stats and clinical judgement
- ML and AI should be seen as tools to augment— and not replace— clinical judgement

Given the procedure's cost and risks, along with patient expectations for pain relief and functional improvement, our goal must be to ensure greater precision in selecting patients who will truly benefit long term.



Thank You

- Aaron Calodney MD
- Director Clinical Research
- Precision Spine Care
- Aaroncalodney@me.com



28th Annual Gabor Racz
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