Washington State Health Care Authority

November 17, 2023 Meeting Materials
Health Technology Clinical Committee

Spinal Cord Stimulation

Contents

- ☐ HTCC clinical expert information
- ☐ Agency Medical Director presentation
- ☐ Scheduled public comments presenters and presentations
- ☐ SCS evidence presentation
- ☐ HTCC decision aid
- ☐ SCS final key questions

Joseph D. Strunk, MD

[redacted]

EDUCATION

Years	Degree	Institution (Area of Study)
2006 - 2010	BS	Northwest Nazarene University (Physics) Nampa, ID
2010 - 2014	MD	University of Utah (Medicine) Salt Lake City, UT

GRADUATE MEDICAL EDUCATION

Years	Degree	Institution (Area of Study)
2014 - 2015	Intern	Providence Sacred Heart Medical Center (Transitional Medicine) Spokane, WA
2015 - 2018	Resident	Virginia Mason Medical Center (Anesthesiology) Seattle, WA
2018 - 2019	Fellow	Virginia Mason Medical Center (Pain Management) Seattle, WA

LICENSURE AND CERTIFICATION

MEDICAL LICENSURE

2018 - present	State of Washington Medical License
2015 - 2018	State of Washington Medical License (Training)

BOARD CERTIFICATION

06/2019-12/2029	American Board of Anesthesiology
09/2019-12/2029	American Board of Anesthesiology Pain Medicine

OTHER CERTIFICATIONS

2012 - present	Advanced Cardiovascular Life Support (ACLS) Certification
2012 - present	Basic Life Support (BLS) Certification
2020 – present	Neonatal Resuscitation Program Certification

PROFESSIONAL EMPLOYMENT

08/2018 – 12/2020	Clinical Anesthesiologist Virginia Mason Medical Center, Seattle, WA
01/2021 – present	Academic Anesthesiologist Virginia Mason Medical Center, Seattle, WA

PROFESSIONAL ORGANIZATIONS

American Society of Regional Anesthesia and Pain Medicine

American Society of Anesthesiologists

Washington State Society of Anesthesiologists

PROFESSIONAL ACTIVITIES

2016 – 2018	Virginia Mason Perioperative Services Steering Committee, Member
05/2017	Washington State Delegation to ASA Legislative Conference, Member
2018 – 2021	Comparison of TAP vs IV Lidocaine After Kidney Transplant Surgery Principle Investigator
2019 – present	The Effect of an Opioid Free Anesthetic on Post-Operative Opioid Consumption after Laparoscopic Bariatric Surgery Sub-Investigator
2020 – present	Virginia Mason Department of Anesthesiology, Complex Spine Team, Member
2021 – present	Virginia Mason Department of Anesthesiology, Scheduling Consultant
2021 – present	ASA Summaries of Emerging Evidence, Question Writer
2021 – present	Virginia Mason Pain Medicine Fellowship Program, Associate Program Director

PUBLICATIONS AND PRESENTATIONS

Peer Reviewed Publications

Velagapudi M, Nair AA, Strodtbeck W, Flynn DN, Howell K, Liberman JS, **Strunk JD**, Horibe M, Harika R, Alamdari A, Hembrador S, Kantamneni S, Nair BG. Evaluation of machine learning models as decision aids for anesthesiologists. *J Clin Monit Comput.* 2022 Jun 9. doi: 10.1007/s10877-022-00872-8. Online ahead of print. PMID: 35680771

Hanson, N. A., **Strunk, J**., Saunders, G., Cowan, N. G., Brandenberger, J., Kuhr, C. S., Oryhan, C., Warren, D. T., Slee, A. E., & Strodtbeck, W. (2021). Comparison of continuous intravenous lidocaine versus transversus abdominis plane block for kidney transplant surgery: a randomized, non-inferiority trial. *Regional anesthesia and pain medicine*, rapm-2021-102973. Advance online publication. https://doi.org/10.1136/rapm-2021-102973. PMID: 34417343.

Davis, J. J., Bankhead, B. R., Eckman, E. J., Wallace, A., & **Strunk, J.** (2012). Three-times-daily subcutaneous unfractionated heparin and neuraxial anesthesia: a retrospective review of 928 cases. *Regional anesthesia and pain medicine*, *37*(6), 623–626. https://doi.org/10.1097/AAP.0b013e31826a8d10

Poster Presentations

Strunk, J., Hanson, N., Oryhan, C., Rouse, J., Strodtbeck, W. (2018) *Thoracic Epidural Catheter Removal in a Patient with Heparin Induced Thrombocytopenia on an Argatroban Infusion.* Submitted for presentation at: American Society of Regional Anesthesia, Pain Medicine Meeting; San Antonio, TX.

Strunk J., Porteous G. (2017) *Blood Product Utilization and Outcomes after Implementation of a Massive Transfusion Protocol in a non-trauma hospital.* Poster presented at: Anesthesiology; Boston, MA.

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Conflict of Interest Form

This form must be completed by individuals who are:

- Appointed to, or applying for, the Health Technology Clinical Committee; or
- Are providing certain consultant services.

Depending on the appointment or position, certain interests are permitted, but must be disclosed. In addition to providing disclosure on this form, applicants may be required to affirmatively recuse themselves from discussions or deliberations of a technology topic for which the applicant has an interest. The applicant may not participate in any agenda item for which a conflict of interest is identified and may not vote on any such matter. The applicant's terms of appointment or contract should be consulted for specific dates and limitations.

If a conflict of interest is so great as to make it difficult for an applicant to participate meaningfully in the work to which they have been appointed or contracted for, that member may be asked to resign.

Submission or re-submission of this form is required annually by July 1st. If, during the course of any year, a material change in any of the information occurs, this form should be updated prior to the next public meeting of the committee. It is advised applicants retain a copy of this form for their records.

Definitions

For purposes of this disclosure statement, the following definitions apply:

Business: Any corporation, partnership, proprietorship, firm, enterprise, franchise, association, organization, self-employed individual and any other legal entity operated for economic gain. This does not include income-producing not-for-profit corporations that are tax-exempt under section 501(c) of the Internal Revenue Code with which service is performed in a non-compensated capacity.

Committee: Means the Health Technology Clinical Committee (HTCC) or the consulting service that the person completing this form is applying for, contracting for, or serving on.

Honorarium: A payment or something of economic value given in exchange for services, upon which custom or propriety prevents the setting of a price. Services include, but are not limited to, speeches or other services connected with an event where an appearance is made in an official capacity.

Income: Gross, pre-tax income of any nature, derived from any source, including but not limited to, any salary, wage, advance payment, dividend, interest, rent, honoraria, return of capital, forgiveness of indebtedness, income from government sources (i.e. Social Security, public salary, etc.) retirement income, real estate transactions, inheritance income, or anything of economic value received as income.

Legislative or Administrative Interest: An economic interest, distinct from that of the general public, in one or more bills, resolutions, regulations, proposals or other matters.

Member of Household: Any relative who resides in the household of the person completing this form.

Person: A natural person or a corporation, partnership, joint venture, and any other similar organization or association.

Relative: The spouse of the person completing this form, and any children, siblings or parents whether by birth, adoption or marriage.

Applicant Name	Joseph D. Strunk
Address	[redacted]

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
None	None	None

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
None	None	None

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
American Society of Anesthesiologists: Summaries of Emerging Evidence	1061 American Lane, Schaumburg, IL 60173	Question Writer

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
Virginia Mason Franciscan Health 1100 9th Ave, Seattle WA, 98101	Joseph Strunk	Salary

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
None	None	None

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
None	None	None

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
None	None	None

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
None	None

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name Joseph D. Strunk

Check One: ☒ Committee Member ☐ Subgroup Member ☐ Contractor

[redacted] 09/03/23

Signature Date

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Agency medical director comments

Spinal Cord Stimulator: Re-review

Christopher Chen, MD, MBA
Medical Director, Medicaid
WA Health Care Authority

November 17, 2023

Spinal Cord Stimulator Background: Device

- First commercial implantable stimulator developed by Medtronic in 1968[1]
- **Electrodes connected to a generator** placed within the **epidural space**
- **Electrical impulses** are sent to the electrodes with remote control when patient feels pain
  - Traditional SCS systems are **low frequency**, 30Hz to 200 Hz
  - "**High-frequency**"/"paresthesia free" SCS systems with frequency greater than 200Hz, up to 10,000 Hz
  - Impulses may be transmitted as constant stimulation ("**Tonic Stimulation**") or in bursts ("**Burst Stimulation**")
- Exact **mechanism of action unknown**
- Spinal cord stimulators require two procedures to test and implant the device: **the trial and the implantation**
- **Common complications** include lead migration, lead fracture, implant-related pain, infection, hematomas, seromas, and cerebrospinal fluid leakage.

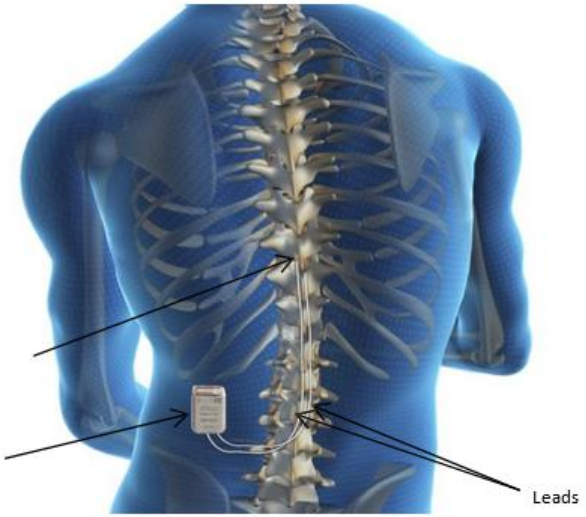

Photo credit: Nevro, FDA

1 History of Electrical Neuromodulation for Chronic Pain | Pain Medicine | Oxford Academic (oup.com)

Conditions treated with Spinal Cord Stimulators

- Estimates suggest that about 8% of US adults have **chronic severe back pain**[1]
  - **Failed Back Surgery Syndrome** (FBSS): lumbar spinal pain of unknown origin either persisting despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same topographical location[2]; affects 10-40% of patients following back surgery
- **Complex Regional Pain Syndrome** (CRPS): "an array of painful conditions that are characterized by a continuing (spontaneous and/or evoked) regional pain that is seemingly disproportionate in time or degree to the usual course of any known trauma or other lesion"[3]
- **Painful Diabetic Neuropathy** (PDN): long-term uncontrolled diabetes results in peripheral nerve damage; estimated 50% of diabetic patients will eventually develop diabetic neuropathy[4]

1 U.S. National Survey Identifies Associations Between Chronic Severe Back Pain and Disability | NCCIH (nih.gov)
2 Failed Back Surgery Syndrome - StatPearls - NCBI Bookshelf (nih.gov)
3 Proposed new diagnostic criteria for complex regional pain syndrome - PubMed (nih.gov)
4 Towards prevention of diabetic peripheral neuropathy: clinical presentation, pathogenesis, and new treatments - PubMed (nih.gov)

Spinal Cord Stimulator Background: FDA Approval

- Currently about **12 devices approved**[2] and about **30-50K implanted annually**
- Implanted spinal cord stimulators (Product code LGW) considered **Class III devices**; approvals generally granted on basis of **supplements to original Pre-Market Approval** (PMAs)
- Modified devices under this approval pathway **may deviate significantly from the original PMA**[2]

1 Establishment Registration & Device Listing (fda.gov)
2 Risk of Recall Associated With Modifications to High-risk Medical Devices Approved Through US Food and Drug Administration Supplements | Health Policy | JAMA Network Open | JAMA Network

Spinal Cord Stimulator Background: Post-market surveillance

- FDA issued a "Dear Health Care Providers" letter 2021; Re-review of **Medical Device Reports (MDRs)** between 2016 and 2020 (for events from 2005 to 2020) showed:
  - 107,728 MDRs for SCS related to pain
  - 77,937 patient injuries
  - 30,321 inadequate pain relief
  - 29,294 device malfunctions
  - 8,073 infections
  - 428 deaths
- **High number of events relative to the implantation rate** (only higher devices are hip prosthetics and insulin pumps)
- **42 recalls since 2008** identified in MAUDE Database[1]

1 MAUDE - Manufacturer and User Facility Device Experience (fda.gov)

Previous HTCC decisions

- Spinal cord stimulation (SCS) was first reviewed by the HTA program in 2010:

  "Spinal Cord Stimulation for chronic neuropathic pain is not a covered benefit."

- Searches of SCS medical literature were conducted in 2014, 2016, and 2018 to determine if newly available published evidence could change the original coverage determination. The technology was not selected for rereview.

- In 2022, the HCA director selected SCS for rereview based on published evidence that could change the original coverage determination.

Scope of discussion today

In scope	Out of scope/not reviewed
• Chronic Back Pain • Failed Back Surgery Syndrome • Complex Regional Pain Syndrome • Painful Diabetic Neuropathy	• Dorsal root ganglion stimulators • Devices not approved by the FDA • Patients < 18 years old • Patients with prior use of SCS • Pregnant individuals • All other pain conditions

Agency medical director concerns - overall

Efficacy = High

Safety = High

Cost = High

AMDG Evidence Considerations: Evidence Report

- Last review in 2010 with 3 RCTs, 1 cohort, 11 observational
- This rereview in 2023 with 13 RCTs; more studies, though **still lacking:**
  - **Higher quality studies**: Most studies industry funded with high risk of bias, including either significant industry involvement or other conflicts of interest
  - **Well-powered studies**: Relatively small study sizes
  - **Longer term outcomes**: Generally remain insufficiently studied beyond 6 months

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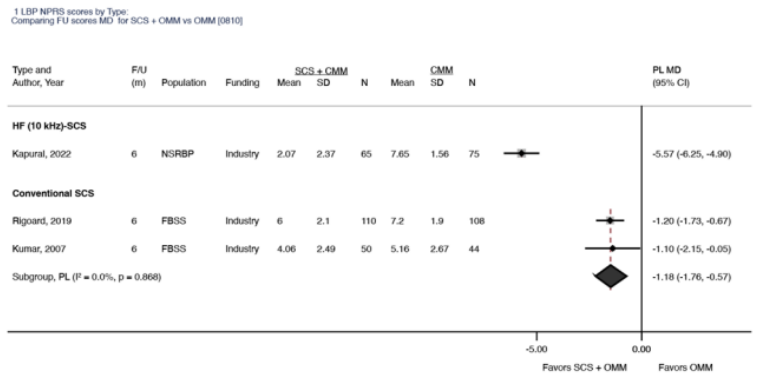
Evidence Report: Key Questions

- What is the evidence of **short and long-term effectiveness of SCS** compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?
- What is the evidence of the **safety of SCS** compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?
- What is the evidence that SCS has **differential efficacy or safety issues in sub-populations of interest**?
- What is the evidence of **cost-effectiveness of SCS** compared with other medical or surgical options that do not include neuromodulation?

Efficacy - Chronic Back Pain

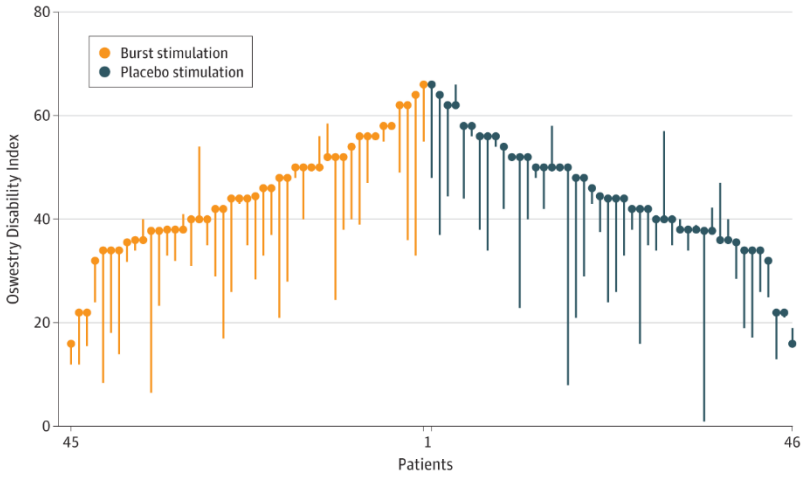
- 3 parallel RCTs: N=477
- Cochrane Review 2023 comments on **Kapural 2022**:
  - "Substantially **different loss to follow-up** in SCS vs CMM groups. Loss in 76 randomised to CMM group = 1 at 3 months and 6 months (1.3%); loss in 83 randomised to SCS = 15 at 3 months (18.1%) and 18 at 6 months (21.6%).
  - **Enrichment-type design**: sample selected based on going poorly with CMM. Control group then receives treatment they are going poorly with. Intervention arm is given SCS and followed up only if they respond. Those who are in the n = 65 are only those who responded. No such treatment given to control arm (i.e. delete those who do not respond to CMM, keep those who do)"

Figure 4. Back pain scores (VAS or NPRS, 0-10 scale): SCS versus CMM for chronic back pain



Efficacy – Chronic Back Pain/FBSS

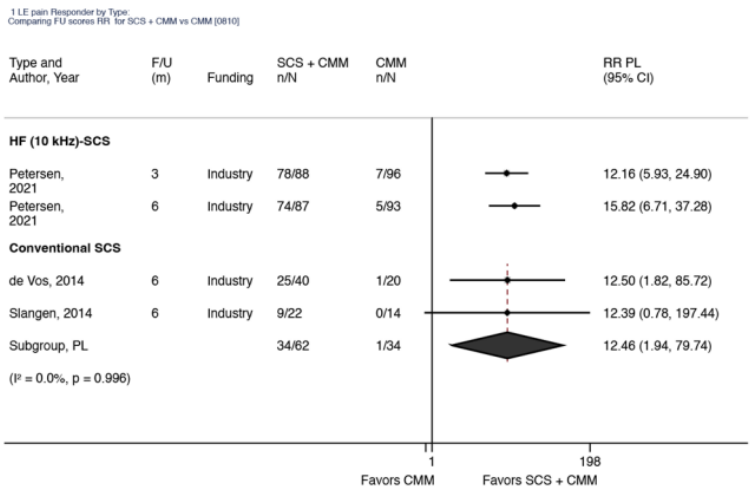
- 3 crossover RCTs: N=98
- **Hara 2022**:
  - **Only good quality study**
    - Government funded (Norway)
    - No COI disclosures
    - Independent/blinded outcome assessors
    - Providers and patients blinded
  - **No significant difference** in disability index, pain, quality of life, physical activity level



Efficacy - Painful diabetic neuropathy

- 3 RCTs, N=312
  - **No long-term outcomes**: only 3-6 months follow up
  - **No functional outcomes** reported
  - **No blinding** of providers and patients
- **Petersen 2021** with high risk of bias:
  - *"The **sponsor participated in the design of the study** in collaboration with an outside expert advisory committee as well as the conduct of the study by supporting patient optimization in collaboration with the investigators and monitoring data at the sites…The **sponsor participated in the analysis and interpretation of the data** along with the authors and an independent biostatistician. The **sponsor also participated in the preparation, review, and approval of the manuscript and decision to submit the manuscript for publication** in collaboration with the authors."*

Figure 9. Lower Extremity Pain Responders (≥50% reduction on VAS or NRS): SCS versus CMM for PDN

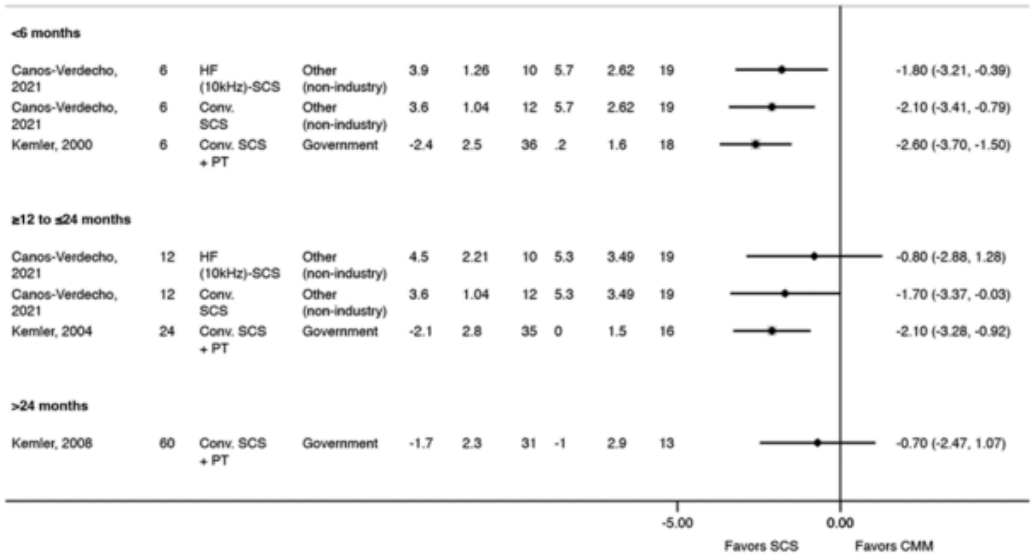


Efficacy – Complex Regional Pain Syndrome

- 1 crossover trial (N=33) and 2 parallel trials (N=104) **without long term outcomes**
- **Kemler 2000**:
  - **Small, unblinded** study
  - Only significant difference on visual analog pain scale; **no functional change, no change in quality of life**

Figure 14. Pain scores (VAS or NRS, 0-10 scale): SCS versus CMM for CRPS

FU and Author, Year	F/U (m)	Type	Funding	SCS + CMM Mean	SCS + CMM SD	SCS + CMM N	CMM Mean	CMM SD	CMM N	PL MD (95% CI)
<6 months										
Canos-Verdecho, 2021	6	HF (10kHz)-SCS	Other (non-industry)	3.9	1.26	10	5.7	2.62	19	-1.80 (-3.21, -0.39)
Canos-Verdecho, 2021	6	Conv. SCS	Other (non-industry)	3.6	1.04	12	5.7	2.62	19	-2.10 (-3.41, -0.79)
Kemler, 2000	6	Conv. SCS + PT	Government	-2.4	2.5	36	.2	1.6	18	-2.60 (-3.70, -1.50)
≥12 to ≤24 months										
Canos-Verdecho, 2021	12	HF (10kHz)-SCS	Other (non-industry)	4.5	2.21	10	5.3	3.49	19	-0.80 (-2.88, 1.28)
Canos-Verdecho, 2021	12	Conv. SCS	Other (non-industry)	3.6	1.04	12	5.3	3.49	19	-1.70 (-3.37, -0.03)
Kemler, 2004	24	Conv. SCS + PT	Government	-2.1	2.8	35	0	1.5	16	-2.10 (-3.28, -0.92)
>24 months										
Kemler, 2008	60	Conv. SCS + PT	Government	-1.7	2.3	31	-1	2.9	13	-0.70 (-2.47, 1.07)



Safety – Evidence Report

- **Strength of evidence across most outcomes was considered low** primarily due to the potential risk of bias across nonrandomized studies and lack of consistency across studies on reported frequency of events
- Concerns around SCS:
  - Implanted device with **risk of infection, morbidity, and death**
  - **High risk for further interventions** (revision, removal, reimplantation)
- **Kemler 2008**: Five-year final follow-up of patients in a RCT, N=56
  - Complication rate: 38%, at 2 years of follow-up
    - 9 of 24 patients with SCS implants underwent reoperation for 21 complications
  - Complication rate: 42%, during 5 years of treatment
    - 10 of 24 patients with SCS implants underwent reoperation as a result of 29 complications

Safety – AMDG concerns

- ASRA Pain Medicine states that **complications estimated to range from 30-40%**[1]
  - **Biologic complications**: infection, epidural hemorrhage, seroma, paralysis, CSF leakage, pain, allergic reaction, skin breakdown
  - **Device failures**: lead migration, lead breakage, over/under stimulation, intermittent stimulation, hardware malfunction, battery failure

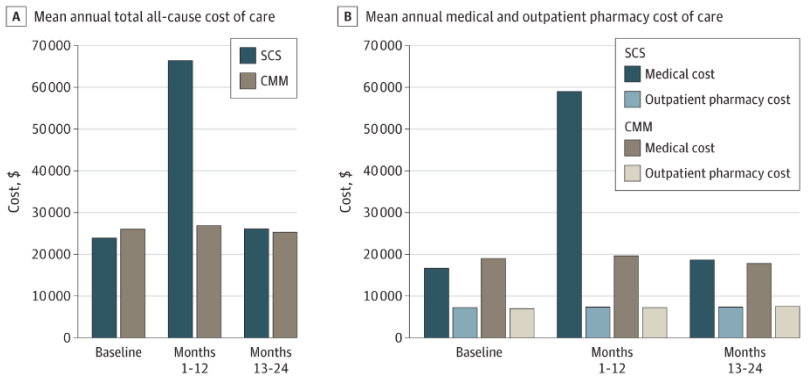
TABLE 1. Totals Per Year of Spinal Cord Stimulators Implanted and Removed and Number of TGA Reported Adverse Events[2]

Year	Units Implanted	Units Removed	Adverse events
2012/13	2307	897	120
2013/14	2918	1073	53
2014/15	3217	1251	29
2015/16	4280	1577	35
2016/17	4433	1788	40
2017/18	4837	1996	103
2018/19	4794	2120	140*
Total	**26786**	**10702**	**520**

1 Complications of Spinal Cord Stimulator Implantation (asra.com) accessed October 2023
2 Spinal Cord Stimulators: An Analysis of the Adverse Events: Journal of Patient Safety August 2022

Cost – Evidence report

- 8 studies reviewed in the report suggested that SCS may be cost-effective versus conventional medical management; however, only two studies based in the US, and five industry sponsored
- **Dhruva 2022**:
  - Propensity matched population 7560 patients using administrative claims data
  - **Total costs of care in the first year were $39000 higher with SCS** than CMM, and similar between SCS and CMM in the second year



Long-term Outcomes in Use of Opioids, Nonpharmacologic Pain Interventions, and Total Costs of Spinal Cord Stimulators Compared With Conventional Medical Therapy for Chronic Pain. JAMA Neurol. 2023;80(1):18-29. doi:10.1001/jamaneurol.2022.4166

Cost – Agency Experience & Medicare Reimbursement

- Agency Experience
  - No utilization for LNI or ERB
  - Inability to accurately estimate costs for Apple Health/Medicaid
- Medicare Reimbursement

CPT	Description	Total RVU	Average Payment-Physician	Average Payment – OP Hospital
63650	Percutaneous implantation of neurostimulator electrode array, epidural	69.08 12.27 (facility)	$2,342 $416 (facility)	$6,604
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural	25.32	$858	$21,515
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling	10.84	$367	$29,358

MS-DRG	Description	Base Payment – IP Hospital
029	Spinal Procedures with CC or Spinal Neurostimulator	$23,443
518	Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device/Neurostimulator	$25,570

Current Coverage: SCS

- **Medicare NCD** (1995):
  - "Late resort if not last resort", other treatment modalities tried, screening including psychosocial eval, successful trial[2]
- **Aetna**[1]:
  - Indications: Chronic back pain, CRPS, PDN
  - Trial: screening including psychosocial eval, no untreated SUD, other modalities tried and failed x 6 months, documented pathology/basis for pain, ODI > 21%
  - Implantation: 3-7 day trial successful with pain reduction > 50%
- **WA Medicaid, LNI, ERB**:
  - Consistent with current HTCC for non-coverage

1 Spinal Cord Stimulation - Medical Clinical Policy Bulletins | Aetna
2 NCD - Electrical Nerve Stimulators (160.7) (cms.gov)

Clinical practice guidelines

- **NICE** (2008)[1]: Spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who:
  - continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management, and
  - who have had a successful trial of stimulation as part of the assessment specified in recommendation 1.3.

- **American Society of Regional Anesthesia and Pain Medicine** (2023)[2]: In patients with chronic low back pain and/or leg pain, limb ischemia due to peripheral vascular disease, painful diabetic neuropathy, and/or CRPS type I or II a trial of SCS should be performed prior to a definitive SCS implant.

1 Guidance | Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin | Guidance | NICE
2 Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain | Regional Anesthesia & Pain Medicine (bmj.com)

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Agency Medical Director Group
Recommendation

- Spinal Cord Stimulation is not a covered benefit for:
  - Chronic back pain (including FBSS)
  - Painful Diabetic Neuropathy
  - Complex Regional Pain Syndrome

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Questions?

More Information:

shtap@hca.wa.gov

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Spinal cord stimulation

Order of scheduled presentations:

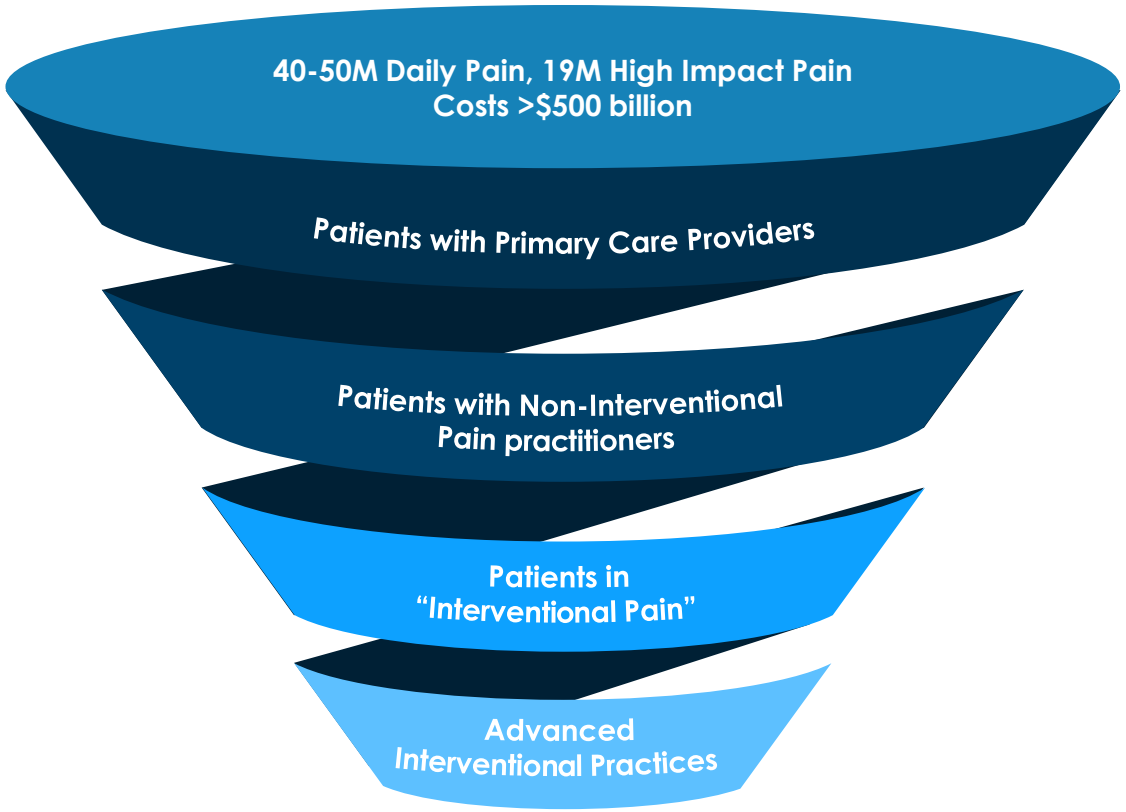
	Name
1	Julie Pilitsis, MD – President of North American Neuromodulation Society (NANS)
2	Christopher Gharibo, MD – WASIPP/ASIPP
3	Manufacturer's Group • Nilesh Patel, MD – Boston Scientific, Inc. • Charles Schneider, Vice President – Boston Scientific, Inc. • Karl Lindner – Boston Scientific, Inc. • Leslie Duffy – Boston Scientific, Inc. • David Watts – Boston Scientific, Inc. • Ash Sharan, MD – Medtronic • Christine Ricker – Medtronic • Wendy Chan – Medtronic • Todd Davis – Saluda Medical • David Caraway, MD, MPH – Nevro Corporation • Allen Burton, MD – Abbott
4	Washington State Physicians SCS Workgroup • Virtaj Singh, MD • Steven Stanos, DO • Paul Dreyfuss, MD • James Babington, MD • Michele Curatolo, MD • Fangfang Xing, MD • Brett Stacey, MD • Paul DeJulio, MD • Katherin Peperzak, MD • Sunay Patel, DO • Elisabeth Powelson • Jiang Wu, MD • Emilie Jones, DPT • Mastaneh Nikravesh, MD • Diane Lindsley, RN • Yian Chen, MD • Rebecca Siegel, MD • James Robinson • Bethany Pester, PhD • Jennifer Lee, MD • Peter Lee

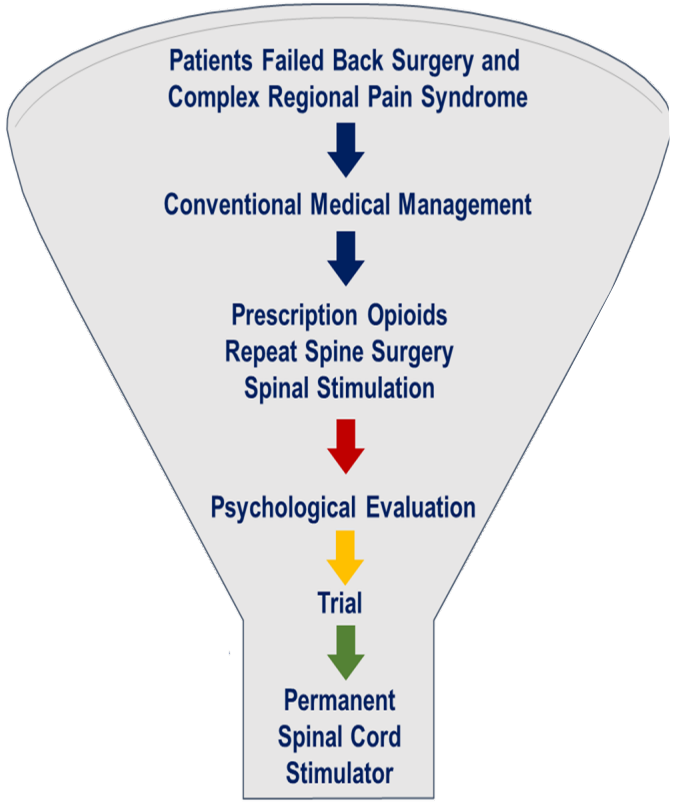
NANS
NORTH AMERICAN NEUROMODULATION SOCIETY

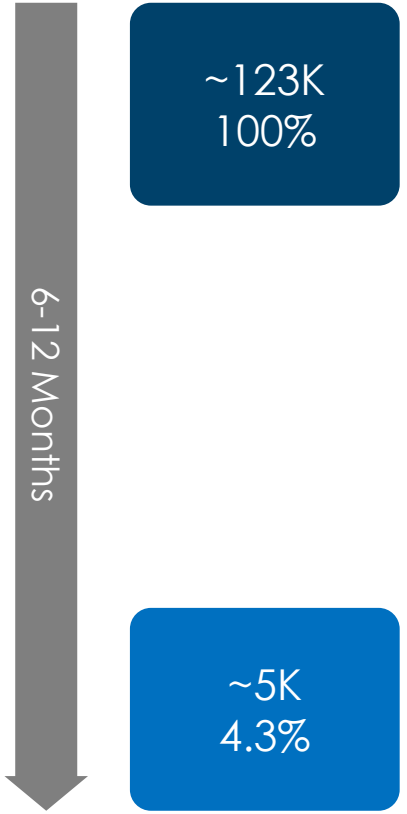
NATIONAL COMMUNITY STANDARDS OF CARE SPINAL CORD STIMULATION

Julie Pilitsis, MD, PhD, MBA
Professor of Neurosurgery, NIH-funded researcher on SCS
President of NANS (on behalf of NANS and Multispecialty Pain Workgroup)

Chronic Pain Management: National Burden of Illness & Impact







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NANS
NORTH AMERICAN NEUROMODULATION SOCIETY

National Professional Societies Recommend Spinal Cord Stimulation for High Impact Chronic Pain

- American Academy of Pain Medicine
- American Academy of Physical Medicine and Rehabilitation
- American Association of Neurological Surgeons
- American Society of Anesthesiologists
- American Society of Neuroradiology
- American Society of Regional Anesthesia and Pain Medicine
- American Society of Spine Radiology
- Congress of Neurological Surgeons
- International Pain and Spine Intervention Society
- North American Neuromodulation Society
- North American Spine Society
- Society for Interventional Radiology
- Washington State Society of Anesthesiologists

"Information in this report is not a substitute for sound clinical judgement."

- Aggregate Analytics, Inc. Health Technology Assessment September 2023

Ten published guidelines support SCS use in a subset of patients

NANS
NORTH AMERICAN NEUROMODULATION SOCIETY

2019 HHS Best Practice Task Force on Pain

U.S. Department of Health & Human Services
CMS, Military Health, Military Health, Academia, Community Practice

- SCS Recommended for Chronic Intractable Pain
  - Failed Medical Management & Conservative Care
  - SCS Favorable Impact on Opioid Use
- Muti-Disciplinary Multi-Modal Approach Encouraged

Medicare has a longstanding National Coverage Determination (NCD) for electrical nerve stimulators **(160.7)** that includes specific criteria for coverage, which are as follows: The implantation of the stimulator is used only as a late resort for patients with chronic intractable pain;

2019 HHS Best Practice Report: https://www.hhs.gov/opioids/prevention/pain-management-options/index.html

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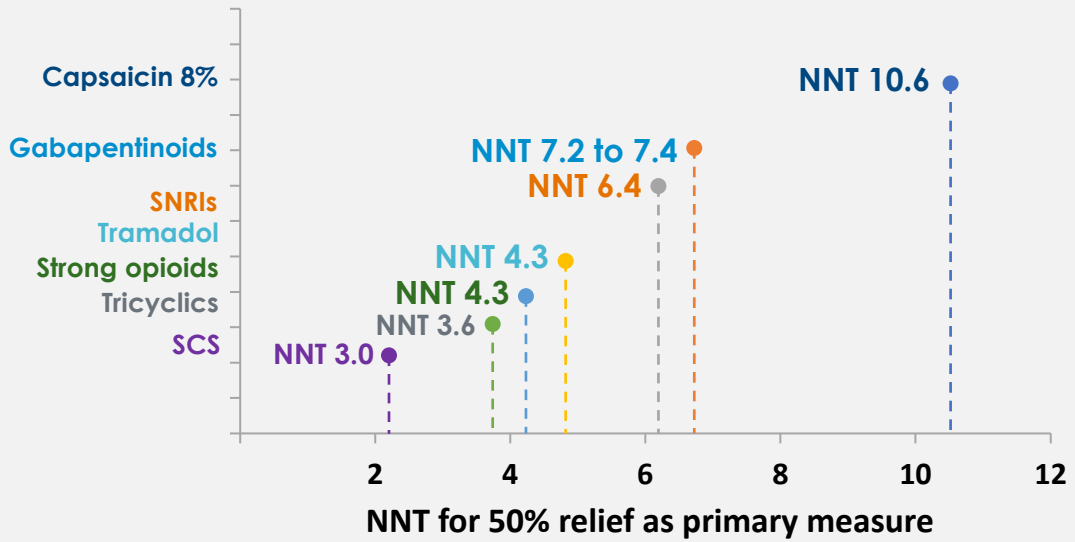
NORTH AMERICAN NEUROMODULATION SOCIETY

Spinal Cord Stimulation Prescribed Following Conservative Medical Management

Reduction or Elimination of Opioid Medications Aligned to Washington Population Health Objectives

Commonly Prescribed Medications
NNT= Numbers Needed to Treat



In meta-analysis of 96 randomized trials involving (N>26K), opioids and the comparators (tricyclic antidepressants, nonsteroidal anti-inflammatory medication, anticonvulsants, cannabinoids, or usual care) had minimal impact on pain, and functioning.

-Busse et al JAMA 2018

- Finnerup et al. Pharmacotherapy for Neuropathic Pain in Adults: A Systematic Review and Meta-Analysis. Lancet 2015:14,162-73
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NORTH AMERICAN NEUROMODULATION SOCIETY

Muti-Society Recommendation for SCS Coverage
Washington State Healthcare Authority

- AAI Technology Assessment Seriously Flawed with Apparent Bias
- Spinal Cord stimulation is within Community Standards of Care, Recommended through Guidelines, Government & Public Health Authorities
- High Quality Published Evidence Support HCA Coverage Consistent with National & Regional Health Plans
- Timely & Equitable Access to Spinal Cord Stimulation for FBSS, CRPS I / II and Diabetic Peripheral Neuropathies Are Recommended for Washington State Employees, Medicaid Beneficiaries, Workers Compensation & Liability Programs Administered by the State of Washington

NANS
NORTH AMERICAN NEUROMODULATION SOCIETY

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

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1 Applicant information

First name: Julie

Middle initial:

Last name: Pilitsis

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Boston Scientific	1375	✓ Self	Family
B	medtronic	2320	✓ Self	Family
B	medical device business services	2632.50	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

I publish frequently on SCS outcomes and also have a NIH grant on SCS technology- NIH U44NS115111.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

As President of NANS, I am ultimately tasked with overseeing our Guidelines Committee which is working on SCS guidelines.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

As President of NANS and President Elect of the American Society for Stereotactic and Functional Neurosurgery, I have the responsibility to advocate for patients to obtain access to therapies they need, including SCS.

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

10/17/2023

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

SCS Safety & Inequalities in Pain Medicine

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Medical Director of Pain Medicine
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Ontario Health Technology Assessment Series 2005; Vol. 5, No. 4

Spinal Cord Stimulation for Neuropathic Pain

An Evidence-Based Analysis

Figure 2: Incidences of Technical Complications of Spinal Cord Stimulation at 1 and 2 Years (63)

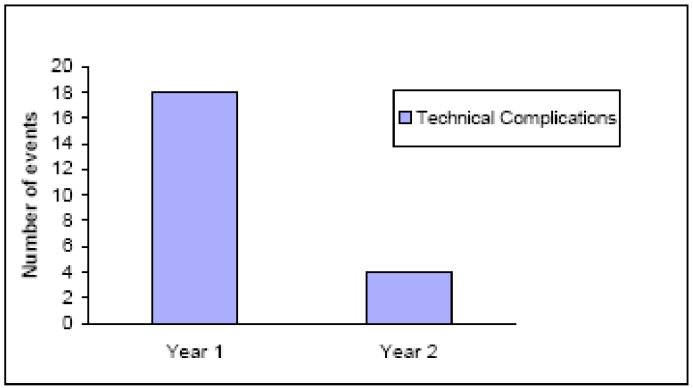

Table 6: Spinal Cord Stimulation Technical Failures and Procedural Complications

Complication	Incidence, %
Lead migration	13.2
Infection	3.4
Hematoma	0.3
Paralysis	0.03
Cerebrospinal fluid leak	0.3
Unwanted stimulation	2.4
Pain over implant	0.9
Allergic reaction	0.1
Skin erosion	0.2
Lead breakage	9.1
Hardware malfunction	2.9
Loose connection	0.4
Battery failure	1.6
Other	1.4

PAIN MANAGEMENT

BEST PRACTICES

PAIN MANAGEMENT BEST PRACTICES INTER-AGENCY TASK FORCE REPORT

Updates, Gaps, Inconsistencies, and Recommendations

FINAL REPORT

Inequality in IPM

2.7.8 Health Disparities in Racial and Ethnic Populations, Including African-Americans, Hispanics/Latinos, American Indians, and Alaska Natives

Considerable evidence exists documenting health disparities in racial and ethnic minority populations, particularly substantial disparities in the prevalence, treatment, progression, and outcomes of pain-related conditions.[386] These disparities in care are attributed to factors related to social disadvantage as well as factors within health systems.[387] Health disparities contributing to suboptimal pain management in these special populations may be related to such factors as barriers to accessing health care, lack of insurance, discrimination, lack of a PCP, lack of child care, a lower likelihood to be screened or receive pain treatment, and environmental barriers that impede effective self-management. Effective strategies and plans to address these issues specifically in these disparate communities are necessary to address these gaps to improve patient outcomes.

ORIGINAL ARTICLE

Socioeconomic Disparities in the Utilization of Spinal Cord Stimulation Therapy in Patients with Chronic Pain

Vwaire Orhurhu,MD, MPH*; Catherine Gao,BA†; Emeka Agudile,MBBS, MPH, ScD‡; Wendy Monegro,RN§; Ivan Urits,MD¶; Mariam Salisu Orhurhu,MD, MPH*; Dare Olatoye,MD**; Omar Viswanath,MD††,‡‡,§§; Sameer Hirji,MD¶¶; Mark Jones,MD¶; Anh Ngo,MD, MBA***,†††; Christopher Aiudi,MD, PharmD*; Thomas Simopoulos,MD¶; Jatinder Gill,MD¶

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(onlinelibrary.wiley.com) DOI: 10.1111/ner.13373

Racial and Socioeconomic Disparities in Spinal Cord Stimulation Among the Medicare Population

Mark R. Jones, MD[1]; Vwaire Orhurhu, MD, MPH[2]; Brian O'Gara, MD, MPH[3]; Ethan Y. Brovman, MD, MPH[4]; Nikhilesh Rao MBA[5]; Stephanie G. Vanterpool, MD, MBA[6]; Lawrence Poree, MD, PhD[7]; Amitabh Gulati, MD[8]; Richard D. Urman, MD, MBA[9]

ABSTRACT

Introduction: Spinal cord stimulation (SCS) is used in the treatment of many chronic pain conditions. This study investigates racial and socioeconomic disparities in SCS among Medicare patients with chronic pain.

Materials and Methods: Patients over the age of 18 with a primary diagnosis of postlaminectomy syndrome (ICD-10 M96.1) or chronic pain syndrome (ICD-10 G89.4) were identified in the Center for Medicare and Medicaid Services (CMS) Medicare Claims Limited Data Set. We defined our outcome as SCS therapy by race and socioeconomic status. Multivariable logistic regression was used to determine the variables associated with SCS.

Results: We identified 1,244,927 patients treated between 2016 and 2019 with a primary diagnosis of postlaminectomy syndrome (PLS) or chronic pain syndrome (CPS). Of these patients, 59,182 (4.8%) received SCS. Multivariable logistic regression analysis revealed that, compared with White patients, Black (OR [95%CI], 0.62 [0.6–0.65], $p < 0.001$), Asian (0.66 [0.56–0.76], $p < 0.001$), Hispanic (0.86 [0.8–0.93], $p < 0.001$), and North American Native (0.62 [0.56–0.69], $p < 0.001$) patients were significantly less likely to receive SCS. In addition, patients who were dual-eligible for Medicare and Medicaid were significantly less likely to receive SCS than those eligible for Medicare only (OR = 0.38 [95% CI: 0.37–0.39], $p < 0.001$).

Conclusions: This study suggests that racial and socioeconomic disparities exist in SCS among Medicare and Medicaid patients with PLS and CPS. Further work is required to elucidate the complex etiology underlying these findings.

Amputation as an Unusual Treatment for Therapy-Resistant Complex Regional Pain Syndrome, Type 1

Babak K. Kashy, MD,[1] Alaa A. Abd-Elsayed, MD, MPH,[2] Ehab Farag, MD, FRCA,[3] Maria Yared, MD,[3] Roya Vakili, MD,[4] Wael Ali Sakr Esa, MD, PhD[3]

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Background: Complex regional pain syndrome, type 1 (CRPS-1) causes severe pain that can be resistant to multiple treatment modalities. Amputation as a form of long-term treatment for therapy-resistant CRPS-1 is controversial.

Case Report: We report the case of a 38-year-old man who failed all treatment modalities for CRPS-1, including medication, steroid injections, and spinal cord stimulator implantation. Below-the-knee amputation to relieve intractable foot and ankle pain resulted in a favorable outcome for this patient.

Conclusion: Select patients with severe CRPS-1 who are unresponsive to all forms of treatment for pain may benefit from amputation as a last option for relief of suffering. Larger studies are needed to prove the efficacy of amputation.

Keywords: *Amputation, complex regional pain syndrome–type 1, reflex sympathetic dystrophy*

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Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 71 / No. 3
November 4, 2022

CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022

WASHINGTON STATE HEALTHCARE AUTHORITY

TIMELY & EQUITABLE ACCESS TO SPINAL CORD STIMULATION

Public Meeting Summary Comments
17 November 2023

Nilesh Patel, MD MBA
Board Certified Anesthesiology & Pain Management
on Behalf of SCS Manufacturers

Abbott Boston Scientific BIOTRONIK Medtronic nevro saluda MEDICAL

OVERWHELMING CLINICAL EVIDENCE FOR SPINAL CORD STIMULATION

Novel Waveforms & Platforms Now Consistently Achieving 80% Reduction in Pain

Evolution of Waveforms and SCS Platforms

North: Level 1 RCT demonstrating cost effectiveness & superiority of conventional SCS vs re-operation for failed back surgery syndrome (FBSS)

Grider: Level 1, based on RCTs (RR>50%, After HD, Lumina 3D, subperception waveforms)

Thomson: **PROCO** RCT demonstrating efficacy of 1–10 kHz SCS and importance of neural dose adjustment

Kapural: RCT of **10 kHz SCS**, demonstrating efficacy of conventional SCS and superiority of high frequency

Deer: SUNBURST RCT demonstrating efficacy of conventional SCS and superiority of BURST SCS

North: WHISPER RCT demonstrating efficacy of conventional SCS and superiority of multi-modal SCS

Mekhail: RCT of **CL-SCS**, 79% responder rate with CL-SCS & superiority to tonic stim

Fishman: RCT of **Differential Targeted Multiplexed (DTM) stim**, demonstrating efficacy of conventional SCS and superiority of DTM

Mekhail: EVOKE-RCT demonstrating efficacy of conventional SCS and superiority of closed-loop SCS

2007 **2009** **2011** **2013** **2015** **2017** **2019** **2021** **2023**

Kumar: **PROCESS** RCT demonstrating superiority of conventional SCS to CMM for FBSS

Frey: Level 2 (RR=Responder rates ~40%-50%)

Taylor: Cost effectiveness of SCS in failed back surgery patients

Farber: Cost effectiveness of SCS demonstrated in failed back surgery patients

Hoelscher: Cost effectiveness of SCS in low back pain

Wallace: COMBO RCT on combination SCS demonstrating responder rates of 84% and 85% at 1 and 2 year follow up, and high level of functional improvement

Petersen: RCT of 10 kHz SCS vs Conservative Medical Management (CMM) for **Diabetic Neuropathy**, 90% responder rate

Rauck: RELIEF Registry, demonstrating long term safety and effectiveness of SCS in a real world multicenter cohort

Increasing Responder Rates from 50% → 80%+

SCS WELL SUPPORTED BY LEVEL I – V PEER REVIEWED PUBLISHED CLINICAL & ECONOMIC EVIDENCE

Programming Parameters Optimized to Meet Intended Use

- U.S. Food & Drug Administration PMA-Approved Technologies
- Randomized Controlled Clinical Trials
- Strong Body of Level I – V Publications Proving Safety, Effectiveness & Durability of Treatment for FBSS, CRPS I/II, DPN
- Proven Cost Effective
- Covered by Medicare (NCD 160.7), Medicaid, Commercial (Including Commercial WA State Members), Military and Workers Compensation Plans Across the United States

HTCC COVERAGE RECOMMENDATIONS

Enable Timely & Equitable Access to SCS for FBSS, CRPS I/II & DPN Indications

- FDA PMA Approved Platforms Enabling Personalized Healthcare, as Deemed Appropriate by the Clinician
- SCS Proven: Large Body of Peer Reviewed & Published Level I-V Evidence
- Consistent with Current Community Standards of Care
- Equitable Access Aligned to Washington State Policy, Historic Decisions and public Health Objectives

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SUMMARY REFERENCES

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1 Applicant information

First name: nileshkumar

Middle initial:

Last name: patel

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	full time employee of Boston Scientific	NA	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

No

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

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Signature

Date

Octr 21 2023

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Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions
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Instructions specific to HTCC applicants
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1 Applicant information

First name: Ashwini

Middle initial:

Last name: Sharan

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B,C	Medtronic employee		✓ Self	Family
B	Physician, Thomas Jefferson University		✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

No

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

I have many publications on SCS but not on policy - but relating to opioid use - ie: North RB, Sharan AD. Does SCS Help Reduce Opioid Usage?. Pain Med. 2021 Apr 20;22(4):772-773. doi: 10.1093/pm/pnab091. PubMed PMID: 33749797 and Sharan AD, Riley J, Falowski S, Pope JE, Connolly AT, Karst E, Dalal N, Provenzano DA. Ass

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

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Signature

Date

10/16/23

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1 Applicant information

First name: Todd

Middle initial:

Last name: Davis

Phone number:

Email:

2 Financial interests

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D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Saluda Medical Payroll as Employee		✓ Self	Family
C	Saluda Medical Stock	40000	Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Submitted a comment letter to WAHCA realted to the draft SCS assessment.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

NO

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

NO

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Signature

Date

10/9/2023

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Washington State Health Care Authority
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Olympia, WA 98504-2712

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1 Applicant information

First name: Allen

Middle initial:

Last name: Burton

Phone number:

Email:

2 Financial interests

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List amounts totaling $1,000 or more from a single source.
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E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Employee of Abbott 9/2015-ongoing	Salary	✓ Self	Family
A	Abbott Stock Annual Grant 9/2015-ongoing	>100k	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Authored numerous peer-reviewed publications about various neuromodulation therapies and outcomes including the use of neuromodulation for various disease states, FDA-IDE studies on various neuromodulation therapies including DRG stimulation, high-frequency stimulation and BurstDR Stimulation

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

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Signature [redacted]

Date

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Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Overview

Washington Spinal Cord Stimulator Workgroup

Steven Stanos, DO

Medical Director, Swedish Pain Services; Executive Medical Director, Rehabilitation and Performance Medicine

Providence SWEDISH

UNIVERSITY of WASHINGTON

SCS Evidence Report Limitations

Washington Spinal Cord Stimulator Workgroup

Brett R. Stacey
Professor, Anesthesiology & Pain Medicine
Division Chief, Pain Medicine
University of Washington

Spinal Cord Stimulation

Electrodes in the posterior epidural space deliver electrical energy

Interactive trial/clinical test before permanent implant

Traditional SCS = pre-2015: success associated with added sensation/paresthesia/tingling overlapping pain area

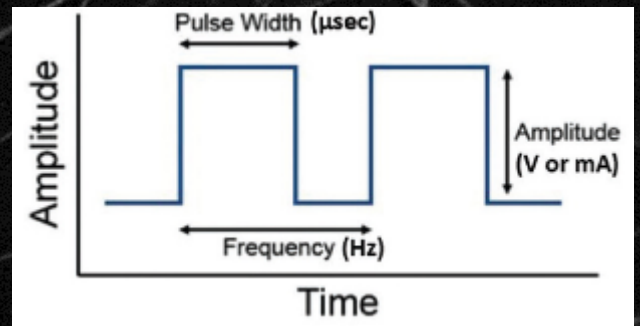
1965 Gate Control Theory and Dorsal Column Activation

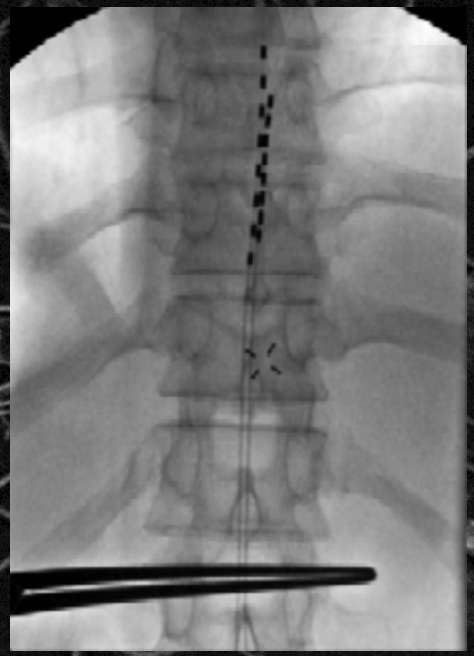
Many parameters optimized

Amplitude = intensity/power

Frequency Traditional range of ~20-200 Hz

Pulse width– 100-500 µs





Final Evidence Report Clinically Outdated

"…pain may be masked by the tingling and vibratory sensations of paresthesia, which occur with dorsal column stimulation, as successful pain reduction is dependent on complete overlap of the paresthesia with the painful region"

Citing a 25-year-old reference[1]

"Traditional SCS systems, which are still the most widely used…"

References from 2005 and 2007[2,3]

1. Holsheimer J, Barolat G. Spinal geometry and paresthesia coverage in spinal cord stimulation. Neuromodulation : journal of the International Neuromodulation Society 1998;1:129-36. 2. North RB, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. Neurosurgery 2005;56:98-106; discussion -7. 3. Kumar K, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179-88.

Both statements are inaccurate and outdated

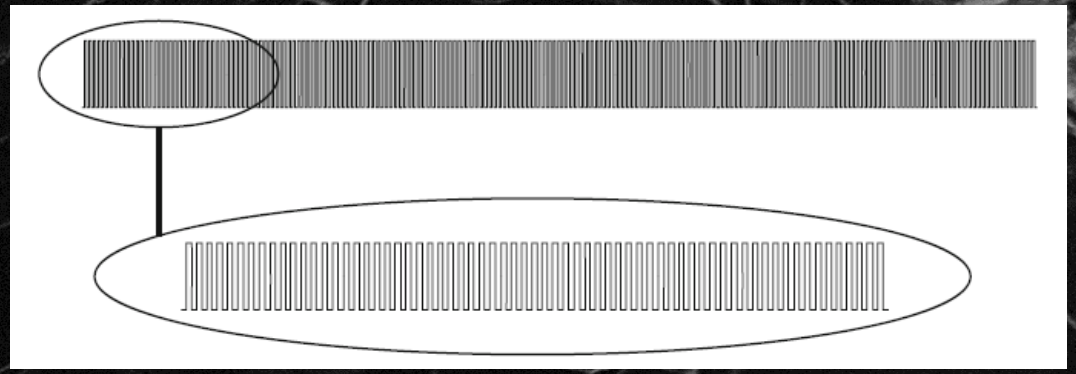
SCS mechanism of action (MOA) evolution with superior outcomes means older studies need to receive less emphasis

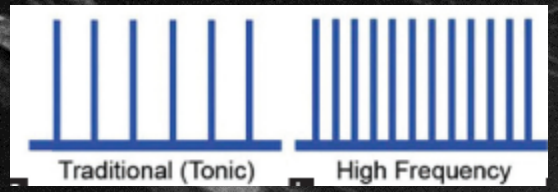
We need attention to clinical and technical details of the studies, in addition to study design

Spinal Cord Stimulation

Since 2015 new paradigms with no added sensation and new neuroanatomic targets:

<u>High frequency</u>: kHz range, 10,000 Hz most studied, proprietary



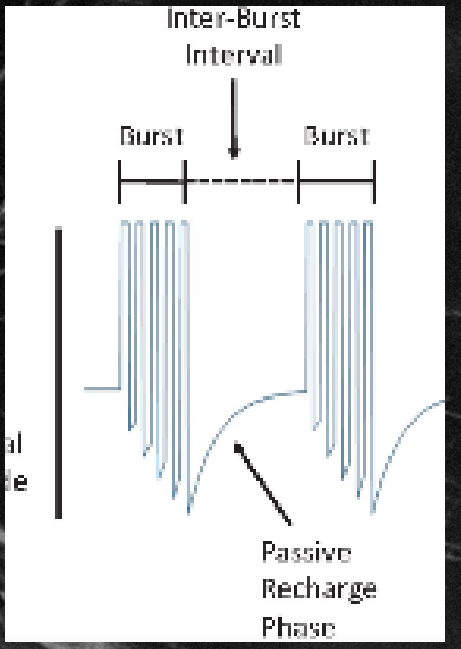


Caylor, Jacob, et al *Bioelectronic Medicine,* (2019)

Spinal Cord Stimulation

Since 2015 new paradigms with no added sensation and new neuroanatomic targets:

<u>Pattern:</u> BurstDR® -five pulses @ 500 Hz, per second, passive recharge

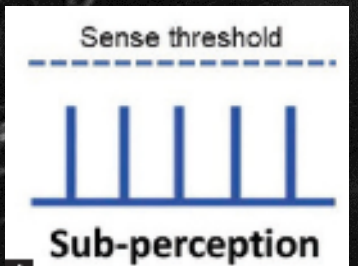


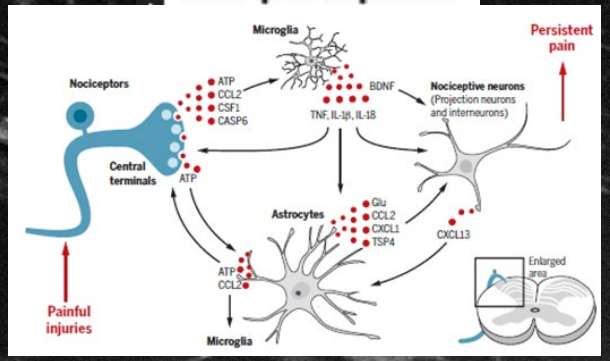
Kirketeig,et al.
Pain Medicine,
(2019)

Spinal Cord Stimulation

Since 2015 new paradigms with no added sensation and new neuroanatomic targets:

High-dose and other sub-perception programming strategies



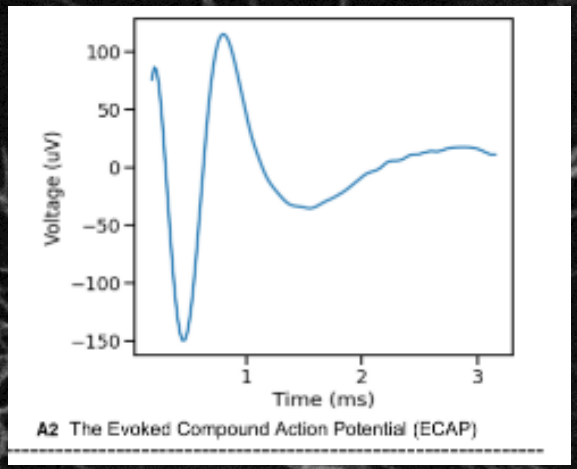


Ji et al., *Science,* (2016)

Spinal Cord Stimulation

Since 2015 new paradigms with no added sensation and new neuroanatomic targets :

Evoked compound action potential (ECAP)-controlled closed-loop SCS: adjusts output based on spinal cord response 50 times/second



Mekhail et al. *Regional Anesthesia & Pain Medicine*, (2023)

New mechanisms, science, and technology: Superior to pre-2015 SCS

These have different MOA, not tied to a distracting sensation

Largest SCS studies with superior outcomes reflect these advances

Implanted systems now use these technologies

Newer data and technologies should be the focus

The Final Evidence Report

"Information in this report is not a substitute for sound clinical judgment."

Focus on "best evidence" which appropriately includes sham and placebo controlled prospective randomized trials

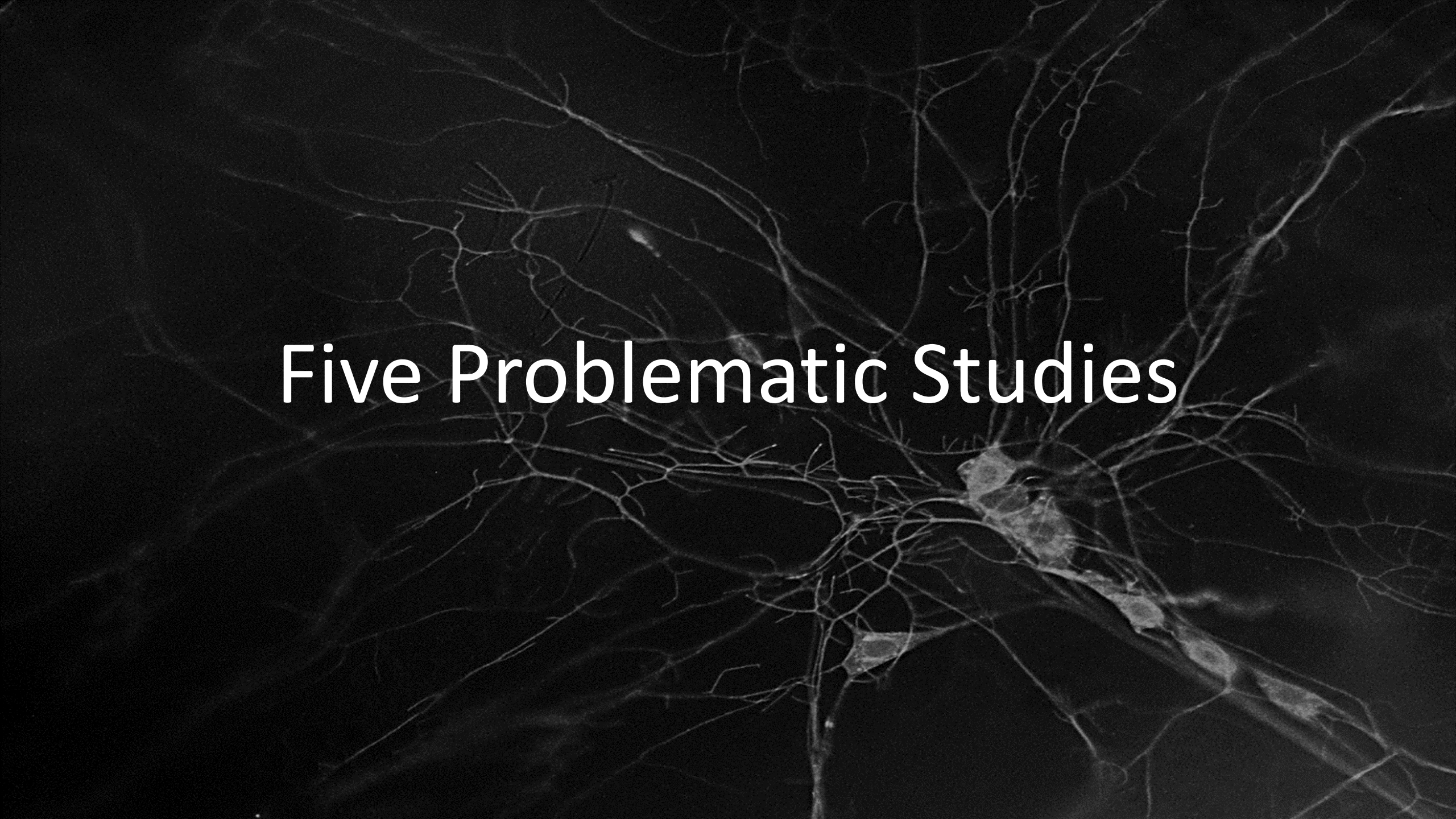
The Final Evidence Report

"Information in this report is not a substitute for sound clinical judgment."

Unfortunately, the SCS vs Sham studies prioritized by AAI to meet their methodological standard for evidence reporting for failed back surgery syndrome have clinical and technical flaws that should invalidate them from data analysis.

The 4th SCS vs Sham study for Complex Regional Pain Syndrome has shortcomings

- But still a positive study



Five Problematic Studies

Hara, et al. Rated as “good” with “moderate strength of evidence”
The only trial rated this highly in the report
Unusual “burst” pattern vs placebo

5.1.1 Strength of Evidence Summary: Efficacy Results from Crossover Trials comparing SCS with sham (placebo) in patients with FBSS or persistent radicular pain following low back surgery

Outcome	Crossover phases, time	Studies N (randomized)	Serious Risk of Bias	Serious Inconsistency	Serious Indirectness	Serious Imprecision	SCS vs. Sham Effect estimate (95% CI) Conclusion	Quality (SoE)
Function: ODI (0-100 scale)	2, 12-week phases per intervention	1 RCT (N=50) Hara	No	Unknown	No	No	Burst vs. sham **Mean, 95%CI** 34.0 (95% CI 30.0 to 38.1) vs. 35.4 (95% CI 31.3 to 39.4) **Δ from baseline** -10 (95% CI -14 to 7.2) vs. -9.3 (95% CI -12.7 to -5.9) **MD in change scores:** -1.3 (95% CI -3.9 to 1.3, p=0.32) Conclusion: No difference in functional improvement between burst SCS and sham	⊕⊕⊕◯ MODERATE
Back pain VAS or NRS (0-10 scale)	2, 12-week phases per intervention	Burst vs. Sham 1 RCT (N=50) Hara 2022	No	Unknown	No	No	Burst vs. sham **Mean, 95%CI** 5.9 (95% CI 5.3 to 6.4) vs. 6.1 (95% CI 5.6 to 6.6) **MD**, −0.2 (95% CI −0.7 to 0.2), p=0.32 Conclusion: No difference in back pain improvement between burst SCS and sham	⊕⊕⊕◯ MODERATE

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 2022;328:1506-14.

Problems with Hara study

The study does not meet standards of CMS or any insurer in the state of Washington:

- Trial/test period first with “tonic stimulation” (sensation/paresthesia) – not Burst
  - What does a “successful” trial mean if that is not what is used at implant?
- “Successful” trial = 2-point reduction in NRS leg pain or 30% reduction (per supplement 2)
  - NOT 50% relief of pain as required by all insurers
- After implant:
  - 40-Hz burst with 4 spikes, reduced amplitude of 50-70% vs Sham, crossover design
    - The published study protocol calls for a different burst pattern, the change is not explained
  - No adjustment of the stimulation based on patient response – not optimized in any way = not reasonable or appropriate

Problems with Hara Study

Why use a MOA at implant that has not been given a trial?

- Similar to assuming diabetes outcomes are the same with metformin and GLP-1 agonists
- Not consistent with standards for Placebo RCTs of SCS[1,2]

This burst pattern = 40 hz, 4 spikes, at reduced amplitude has no evidence of efficacy

- Not recommended by the manufacturer nor available on current systems
- Shown to be ineffective in RCT with placebo control[3]
- Patients subjected to placebo vs ineffective treatment = clinically irrelevant/invalid

1. Katz N, Dworkin RH, North R, et al. Research design considerations for randomized controlled trials of spinal cord stimulation for pain: Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials/Institute of Neuromodulation/International Neuromodulation Society recommendations. Pain. 2021;162(7):1935-1956. doi:10.1097/j.pain.0000000000002204
2. Duarte RV, McNicol E, Colloca L, Taylor RS, North RB, Eldabe S. Randomized placebo-/sham-controlled trials of spinal cord stimulation: a systematic review and methodological appraisal. Neuromodulation. 2020;23(1):10-18. doi:10.1111/ ner.13018
3. Eldabe S, Duarte R, Gulve A, et al. Analgesic efficacy of “burst” and tonic (500 Hz) spinal cord stimulation patterns: a randomized placebo-controlled crossover study. *Neuromodulation*. 2021;24(3):471-478. doi:10.1111/ner.13321

The Other Sham/Placebo FBSS Studies: major limitations

FROM THE DRAFT EVIDENCE REPORT:

- Al-Kaisy 2018: "Conclusion: Based on adjusted estimates there were no differences in pain improvement between the different frequencies and sham. Adjusted and unadjusted effect estimates are imprecise. The unadjusted effect estimate suggests moderate improvement with 5882 Hz vs. sham but doesn't account for repeated measures of patients"
- Sokol 2020: "No difference between SCS frequencies and sham based on adjusted estimates. Most estimates are below the threshold for a small effect and imprecision is noted."

The report is correct, these studies are deficient. In addition, they have clinical validity problems.

Al-Kaisy, et al. 2018

24 subjects, Randomized, sham-controlled, double blind crossover study with sham, 1200 Hz, 3030 Hz, and 5882 Hz

- No devices in the United States offer standard 3030 Hz or 5882 Hz programming

- Only positive outcome in a frequency not routinely available in the United States

CONCLUSION: Don’t include a study of stimulation not available to patients in Washington State.

Al-Kaisy A, Palmisani S, Pang D, et al. Prospective, Randomized, Sham-Control, Double Blind, Crossover Trial of Subthreshold Spinal Cord Stimulation at Various Kilohertz Frequencies in Subjects Suffering From Failed Back Surgery Syndrome (SCS Frequency Study). Neuromodulation : journal of the International Neuromodulation Society 2018;21:457-65.

Sokal, et al. 2020

"Semi-double-blind, placebo controlled, four period (4x2weeks) crossover trial"

Sham vs 1kHz vs LF tonic vs "Clustered tonic"

- 18 non-excluded patients.
  - Under powered to demonstrate meaningful differences in 4 treatments
- The study mixes "failed back surgery syndrome" and complex regional pain syndrome patients together
- 5 patients had NO SCS TRIAL before permanent implant
- 18 non-excluded patients.
  - Under powered to demonstrate meaningful differences in 4 treatments

2 week periods with no washout between them; inadequate to assess full effect or limit carry-over or reflect change in chronic conditions

Sokal P, Malukiewicz A, Kieronska S, et al. Sub-Perception and Supra-Perception Spinal Cord Stimulation in Chronic Pain Syndrome: A Randomized, Semi-Double-Blind, Crossover, Placebo-Controlled Trial. J Clin Med 2020;9.

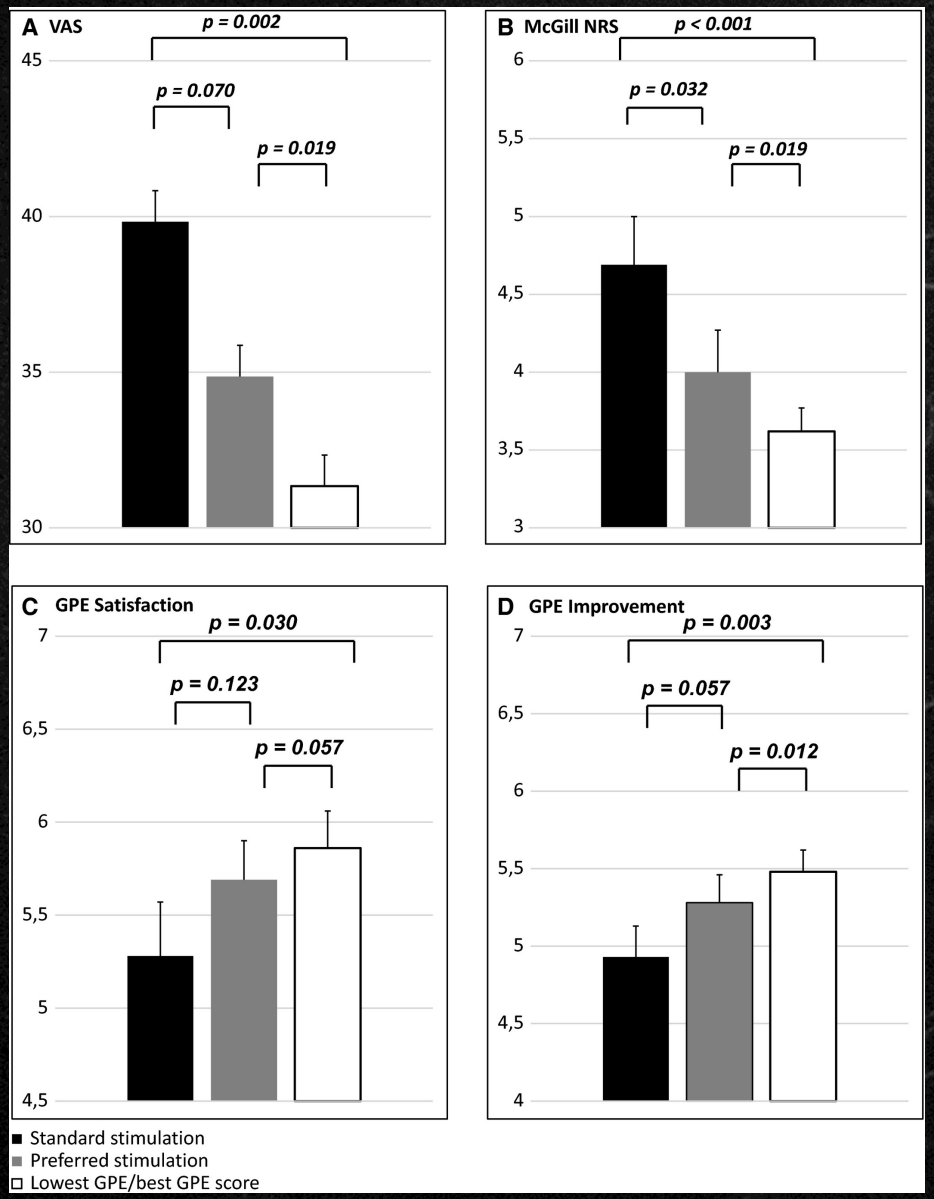
Data From These Three Studies Must Be Set Aside

Sham/Placebo vs Ineffective SCS programming sheds no light on the use of SCS

SCS parameters not being used clinically should not impact clinical care

An underpowered trial with mixed populations and SCS techniques with short treatment periods should not impact care decisions

Kriek, et al. Placebo Controlled Crossover CRPS



CRPS = complex regional pain syndrome = severe pain and sensitivity

- 40Hz, 500Hz, 1200Hz, BurstDR, placebo
- 33 implanted: 3 months 40Hz conventional; then 5 periods, 2 weeks each, 2 day wash out.
- "… patients have a preference for different SCS setting…"
  - Reflects need for personalized programming

All active modalities superior to placebo

Kriek N, Groeneweg JG, Stronks DL, de Ridder D, Huygen FJ. Preferred frequencies and waveforms for spinal cord stimulation in patients with complex regional pain syndrome: A multicentre, double-blind, randomized and placebo-controlled crossover trial. European journal of pain (London, England) 2017;21:507-19.

Turner/Hollingworth: An old study of a challenging subgroup = Injured Workers

- Rated as a “good quality cost effectiveness study”
  - “population-based controlled cohort” = not randomized
- “Context of workers’ compensation” with older technology
- Higher rate of SCS trial failure than other trials
- Lack of generalizability from workers’ compensation patients: “does not necessarily imply ineffectiveness in other settings”

Turner JA, Hollingworth W, Comstock BA, Deyo RA. Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Pain 2010;148:14-25. Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: an observational study in a workers' compensation population. Spine 2011;36:2076-83. Munoz G, Feigin G, Kara J, Bhatia A. Is Workers' Compensation Setting

Turner/Hollingworth: An old study of a challenging subgroup = Injured Workers

Old technology, poor patient selection, special population = minimal impact on our 2023 decisions for all HCA patients

Turner JA, Hollingworth W, Comstock BA, Deyo RA. Spinal cord stimulation for failed back surgery syndrome: outcomes in a workers' compensation setting. Pain 2010;148:14-25.
Hollingworth W, Turner JA, Welton NJ, Comstock BA, Deyo RA. Costs and cost-effectiveness of spinal cord stimulation (SCS) for failed back surgery syndrome: an observational study in a workers' compensation population. Spine 2011;36:2076-83.

Some things to build on

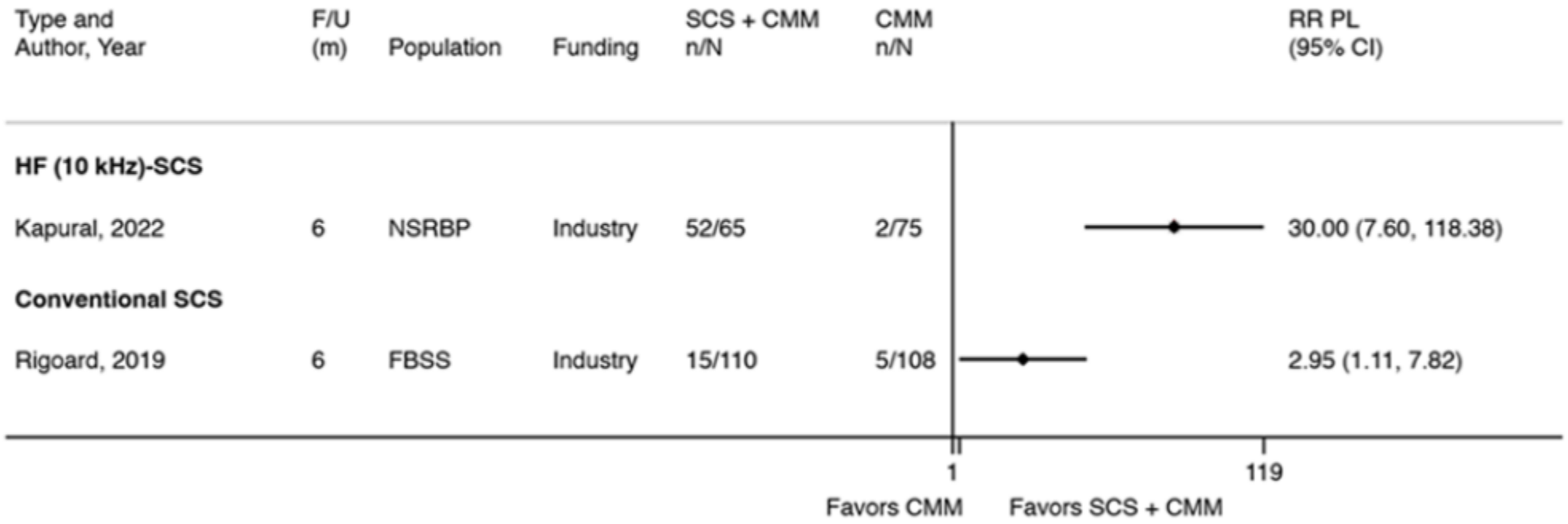
For the three main conditions:

- CRPS (complex regional pain syndrome)– at least one good study reviewed– there are others
- PDN– at least one good study reviewed– there are others
- FBSS– report focus on clinically flawed placebo/sham studies– other studies need to be the focus

The clear separation in data in many of the Figures in the Evidence Report:

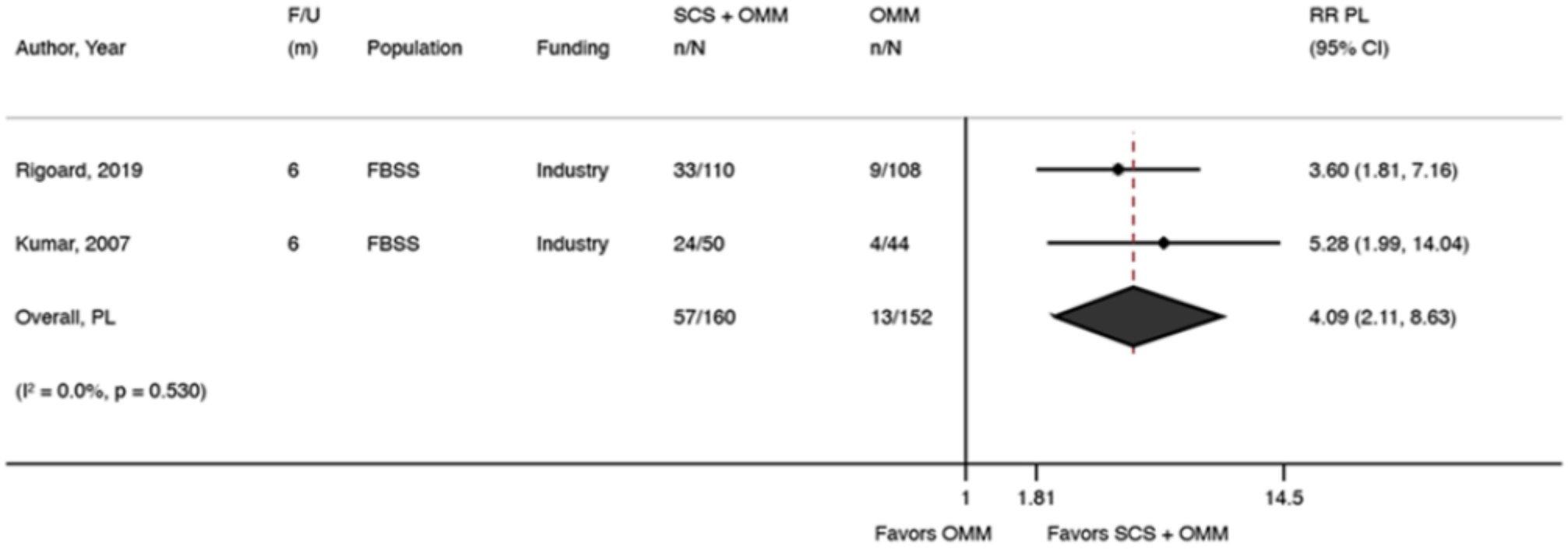
The Evidence Report: Positive Signals

Figure 2. Low back pain responders (≥50% reduction in LBP on the VAS/NPRS): SCS versus CMM for chronic back pain



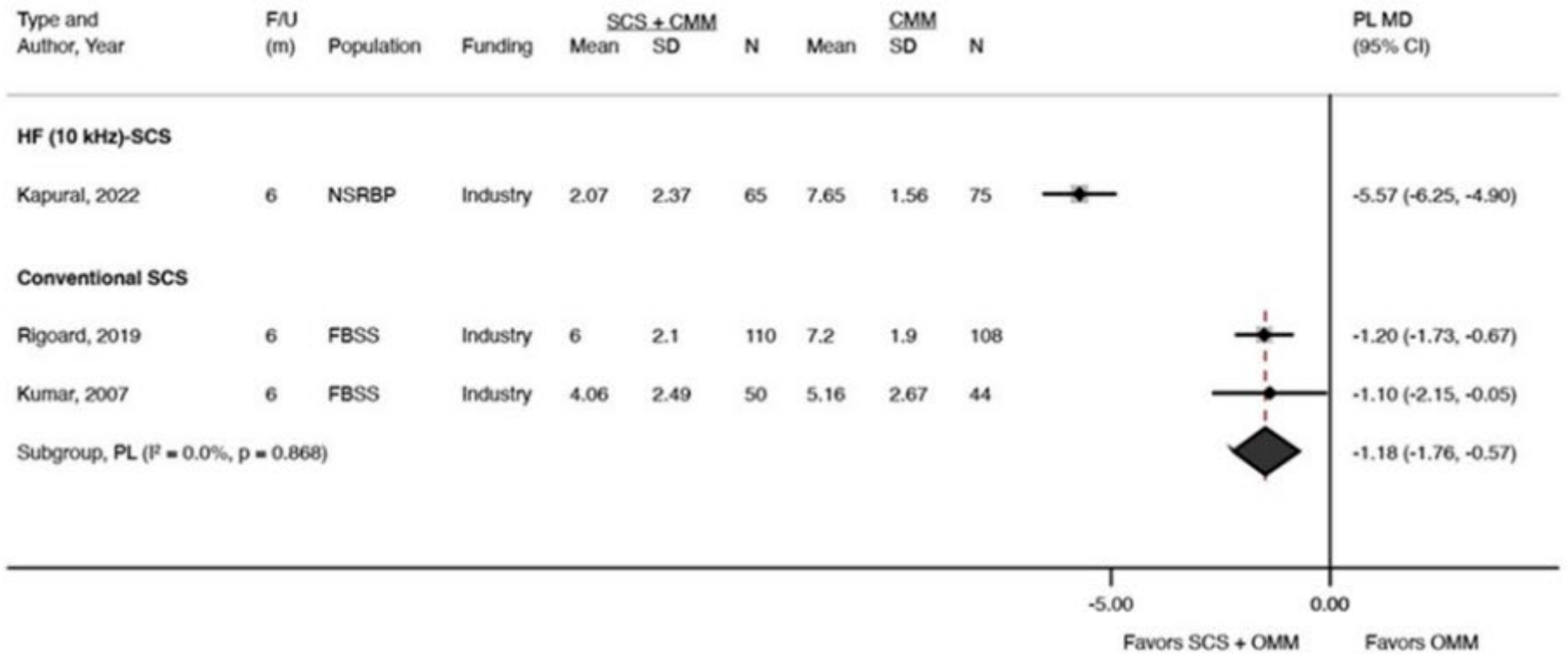
The Evidence Report: Positive Signals

Figure 3. Leg pain responders (≥50% reduction in LBP on the VAS/NPRS): SCS versus CMM for chronic back pain



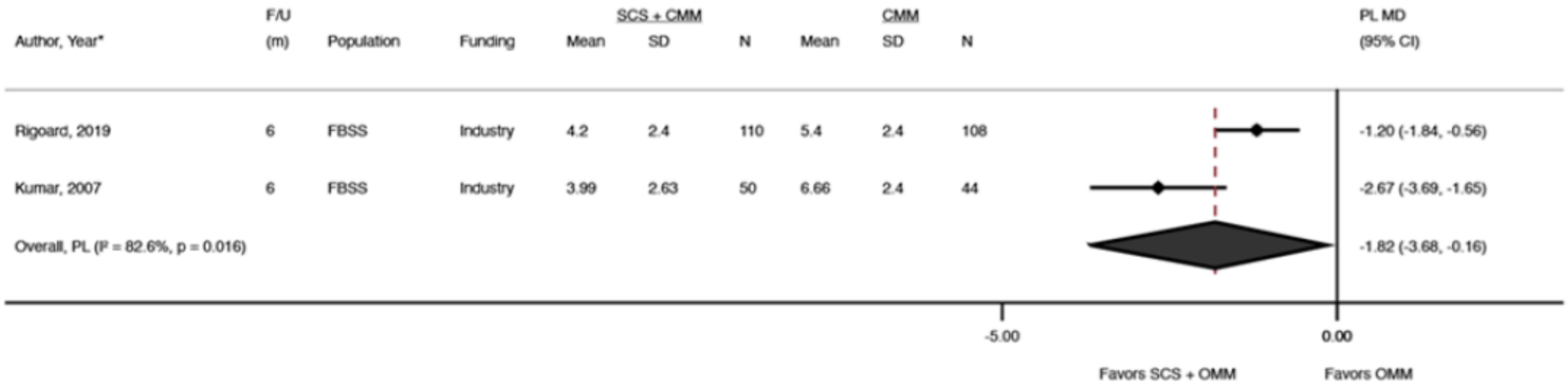
The Evidence Report: Positive Signals

Figure 4. Back pain scores (VAS or NPRS, 0-10 scale): SCS versus CMM for chronic back pain



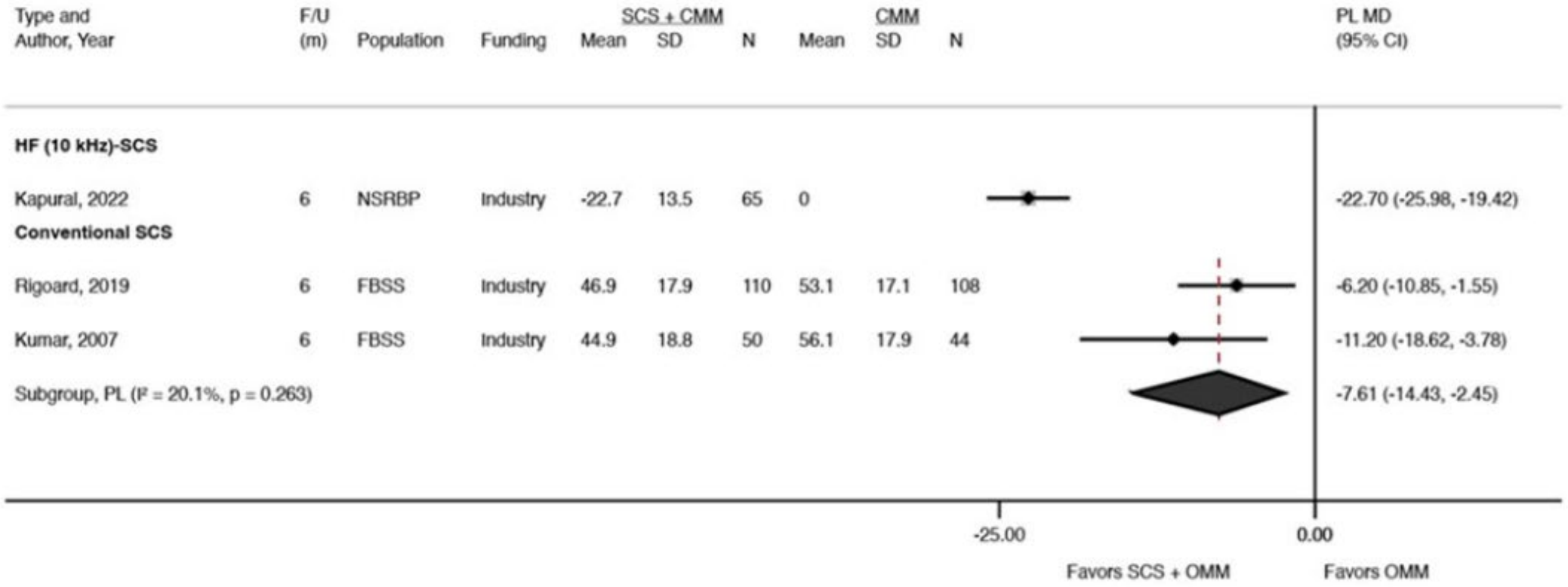
The Evidence Report: Positive Signals

Figure 5. Leg pain scores (VAS or NPRS, 0-10 scale): SCS versus CMM for chronic back pain



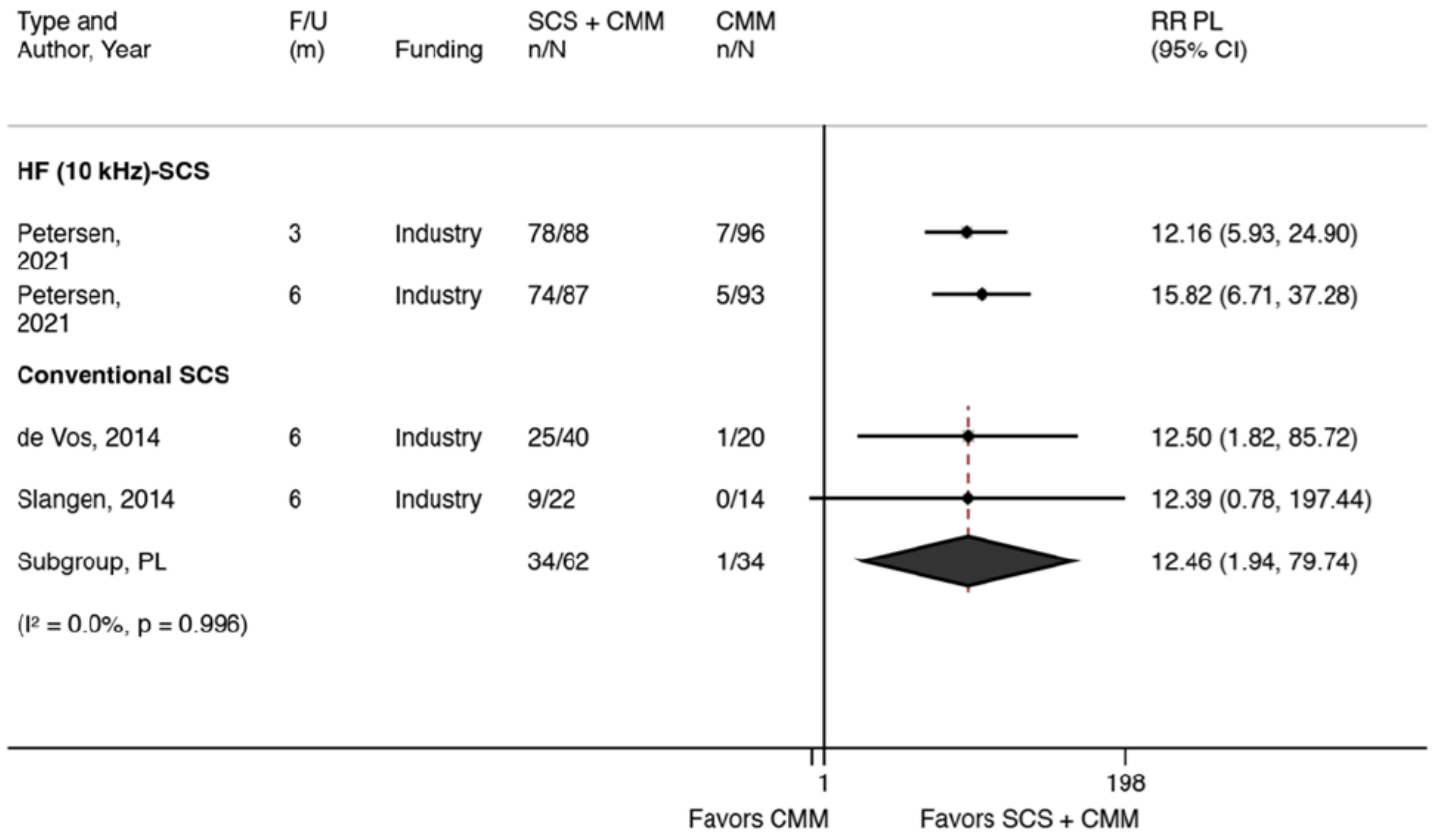
The Evidence Report: Positive Signals

Figure 6. Function scores (ODI, 0-100 scale): SCS versus CMM for chronic back pain



The Evidence Report: Positive Signals

Figure 9. Lower Extremity Pain Responders (≥50% reduction on VAS or NRS): SCS versus CMM for PDN



The Evidence Report: Positive Signals

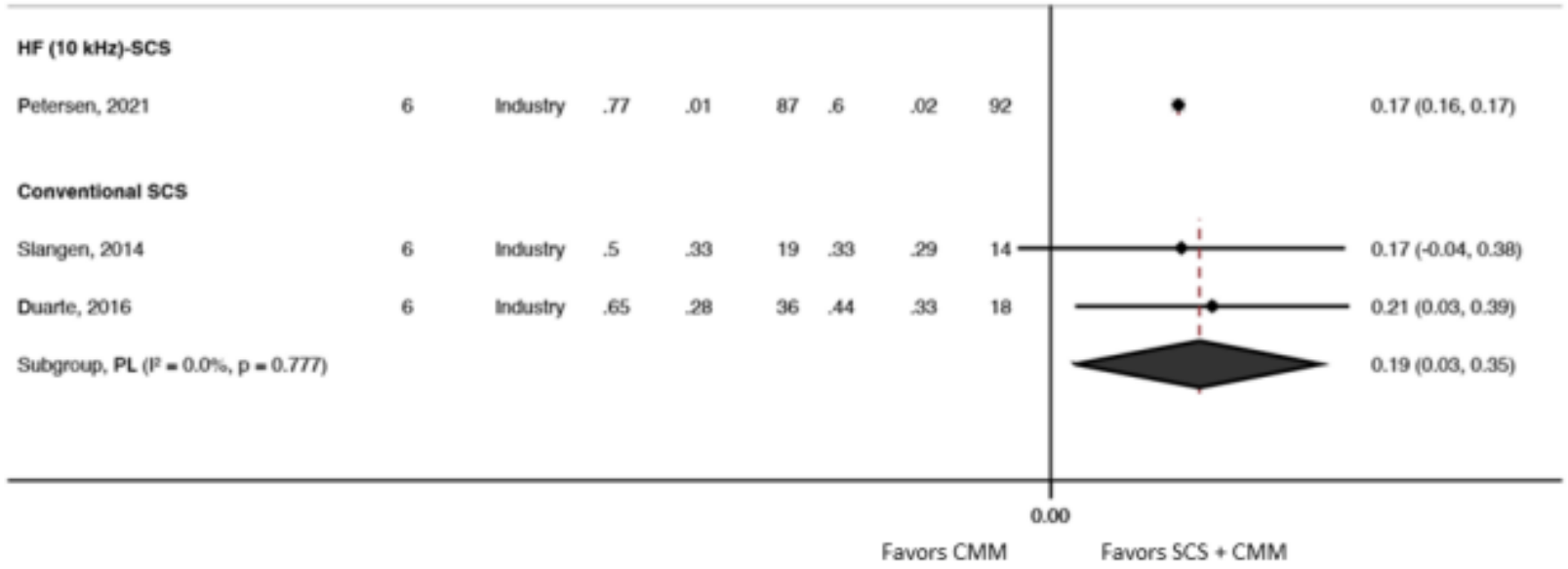
Figure 10. LE pain scores (VAS or NRS, 0-10 scale): SCS versus CMM for PDN

Type and Author, Year	F/U (m)	Population	Funding	SCS + CMM Mean	SCS + CMM SD	SCS + CMM N	CMM Mean	CMM SD	CMM N	PL MD (95% CI)
HF (10 kHz)-SCS										
Petersen, 2021	3	PDN	Industry	1.7	.2	87	6.55	.2	93	-4.85 (-4.91, -4.79)
Petersen, 2021	6	PDN	Industry	1.7	.2	87	6.9	.2	93	-5.20 (-5.26, -5.14)
Conventional SCS										
Slangen, 2014	3	PDN	Industry	3.5	2.4	22	6.7	1.8	14	-3.20 (-4.58, -1.82)
Slangen, 2014	6	PDN	Industry	4	2.9	22	6.5	1.9	14	-2.50 (-4.07, -0.93)
de Vos, 2014	6	PDN	Industry	3.1	2.8	40	6.7	2.1	20	-3.60 (-4.86, -2.34)

The Evidence Report: Positive Signals

Figure 11. EQ-5D index scores (-0.224 to 1 scale): SCS versus CMM for PDN

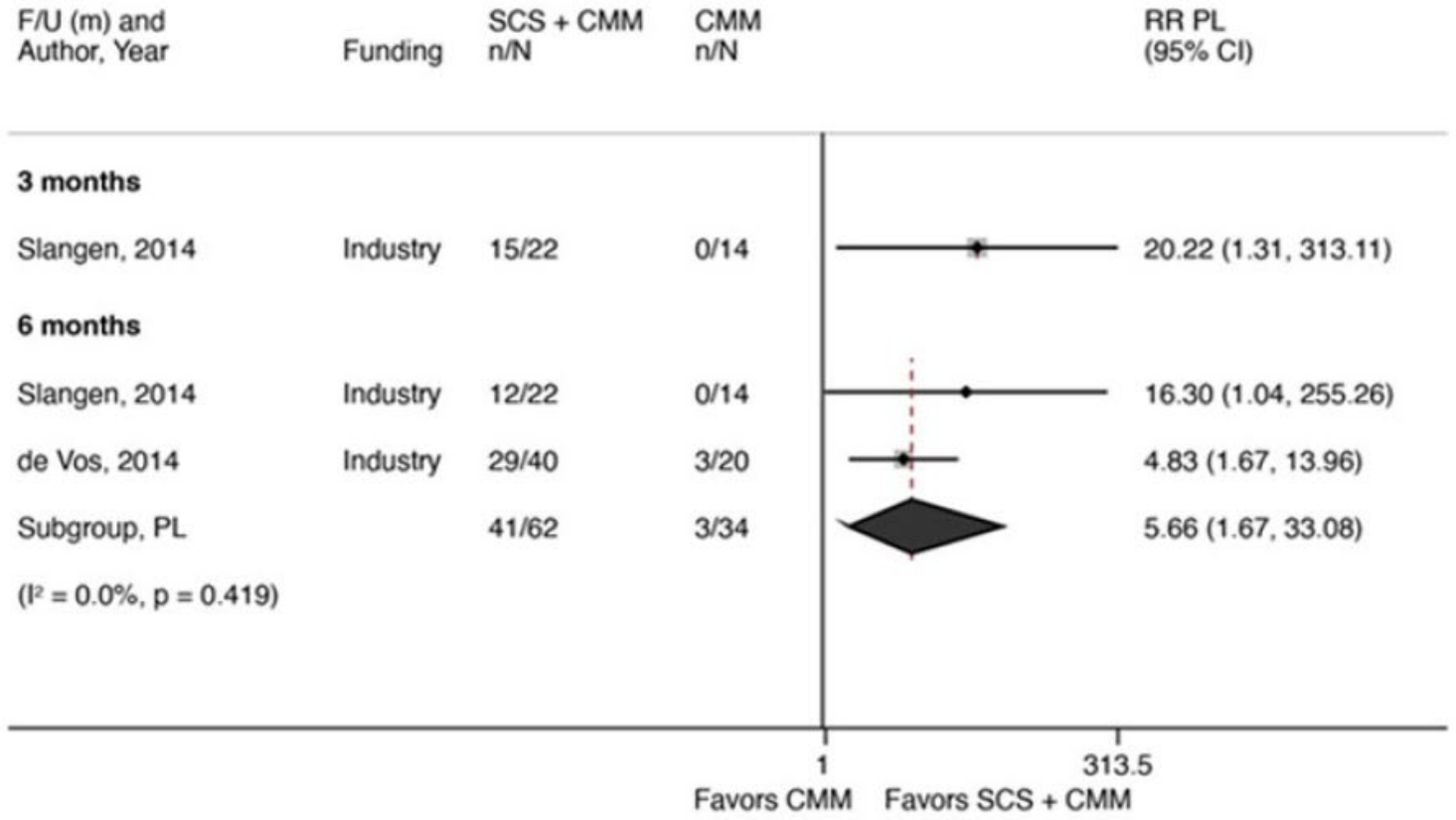
Type and Author, Year	F/U (m)	Funding	SCS + CMM Mean	SCS + CMM SD	SCS + CMM N	CMM Mean	CMM SD	CMM N	PL MD (95% CI)
HF (10 kHz)-SCS									
Petersen, 2021	6	Industry	.77	.01	87	.6	.02	92	0.17 (0.16, 0.17)
Conventional SCS									
Slangen, 2014	6	Industry	.5	.33	19	.33	.29	14	0.17 (-0.04, 0.38)
Duarte, 2016	6	Industry	.65	.28	36	.44	.33	18	0.21 (0.03, 0.39)
Subgroup, **PL** (I^2 = 0.0%, p = 0.777)									0.19 (0.03, 0.35)



CI = Confidence interval; CMM = Conventional medical management; F/U = Follow-up; HF = High frequency; kHz = Kilohertz; m = months; MD = Mean difference; PL = Profile likelihood; SCS = Spinal cord stimulation; SD = Standard deviation.

The Evidence Report: Positive Signals

Figure 13. Patient global impression of change: SCS versus CMM for PDN



P 106

The Final Evidence Report

"Information in this report is not a substitute for sound clinical judgment."

The report inappropriately excludes powerful and larger studies of current technology: "Comparisons of different types/modalities of SCS."

- This type of evidence has been used in prior HTCC coverage decisions
- It needs to be included in the decision process

Fact: Spinal Cord Stimulation is established therapy for selected patients and conditions

- Therefore, it is a valid comparator

We are asking the committee to focus on studies of the best technology

- Ignore invalid studies per HCA guidelines
- Discount clinically irrelevant older studies
- Focus on larger, newer studies of current technology with appropriate selection criteria
- With these steps, the evidence clearly supports SCS using contemporary technology for FDA approved indications
- Place appropriate “guard rails” around SCS
  - Carefully selected patients with recalcitrant high impact pain
  - Limited set of diagnoses
  - Assure SCS includes new stimulation paradigms

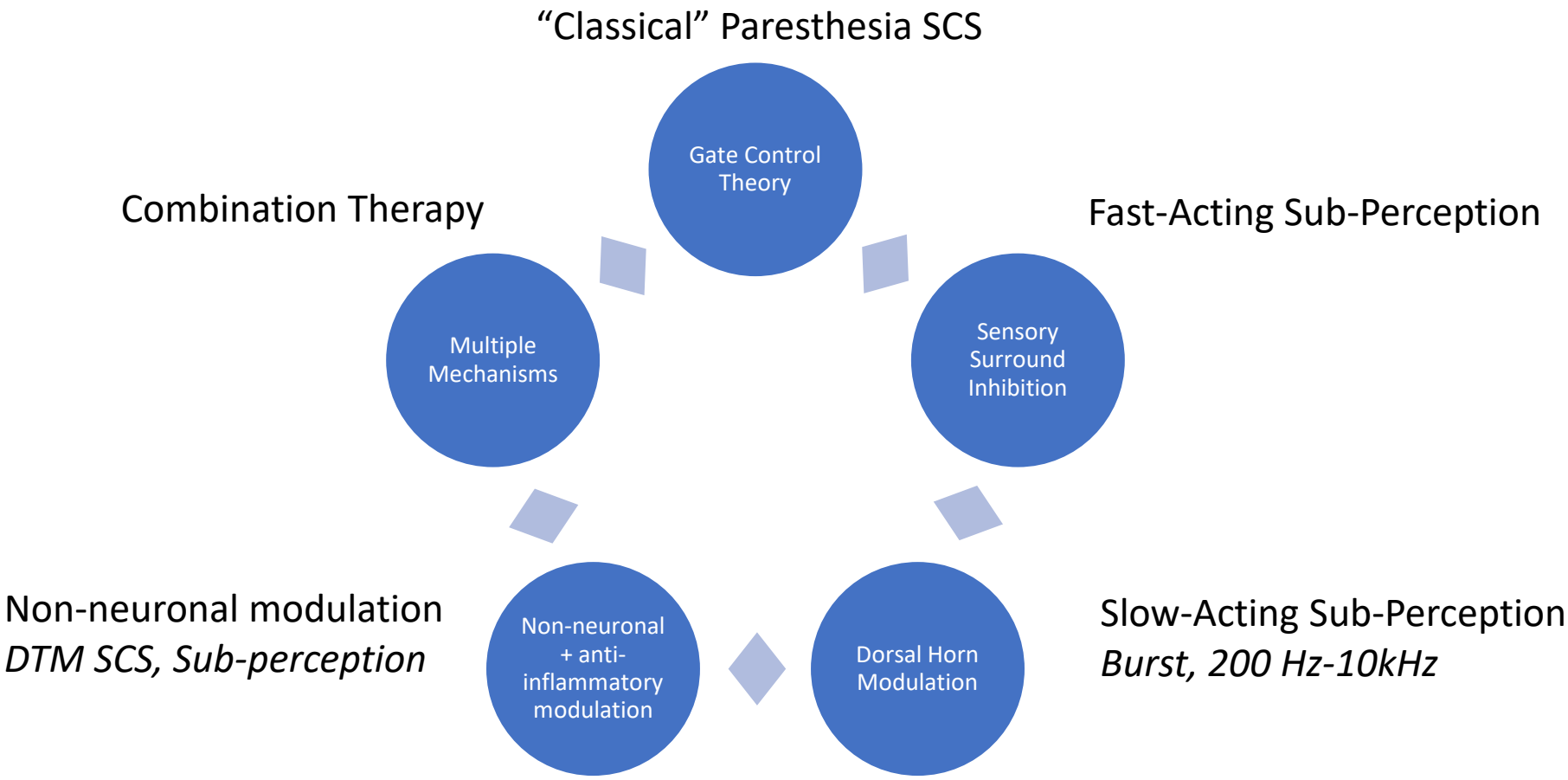
Updated Literature Review of Spinal Cord Stimulation

Fangfang Xing, MD
Swedish Department of Rehabilitation and Pain Medicine
Swedish Providence Medical Center
University of Washington Pain Fellowship Preceptor
Seattle WA

Providence SWEDISH

UNIVERSITY of WASHINGTON

Multiple mechanisms of action now elucidated for spinal cord stimulation, which has led to improved technology and patient outcomes



Washington State Health Care Authority

In response to the HTCC request for specific meeting comments

- Evidence not reviewed but available from peer-reviewed publications.

Petersen etc al. JAMA Neurology 2021
Petersen etc al. DiabetesResClinPract2022
Mekhail etc al. Lancet Neurology 2020
Mekhail etc al. JAMA Neurology 2022
Kapural etc al. Anesthesiology 2015
Canos-Verdecho etc al. Neuromodulation 2021

- Study design issues.

Large studies
Currently used technologies
Appropriate SCS treatment protocols,
Up to 24 months of follow-up

- Criticality of outcomes.

High quality studies, high certainty of clinical relevance

- Interpretations of the evidence cited in the technology review.

Al-kaisy et al. 2018, Sokol 2020

Hara etc al. 2020

- Study design issues.

Small and short studies, methodologically flawed, antiquated technology

Methodologically flawed, waveform not used in clinical practice

- Criticality of outcomes.

Low quality studies, low certainty of clinical relevance

The Aggregate Analytics report excludes key comparator studies

We must look at comparator studies for 4 important reasons

We must look at comparator studies because they present the best quality evidence

JAMA Neurology | Original Investigation

Petersen etc al. JAMA Neurology 2021

Mekhail etc al. JAMA Neurology 2022

THE LANCET
Neurology

Mekhail etc al. Lancet Neurology 2020 (EVOKE RCT)

The HTCC gives the greatest weight to:

- The evidence it determines to be the most valid and reliable.
- The nature and source of the evidence.
- The empirical characteristics of the studies or trials upon which the evidence is based.
- The consistency of the outcome with comparable studies; recency (date of information); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias.

We must look at comparator studies for ethical reasons

"Trapped" 2022 Yaman Ibrahim

"The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s)"

- World Medical Association's Declaration of Helsinki

We must look at comparator studies because the HCA cares

Washington State Health Care Authority

[Clinical committee meetings and decisions | Washington State Health Care Authority]

- Size of the possible health effect from the technology compared to the existing standard of care.

We must look at comparator studies because there is HTCC precedent

Health Technology Clinical Committee
FINAL Findings and Decision

SBRT – adopted July 21, 2023

Number and coverage topic:

20230623A – Stereotactic Body Radiation Therapy

HTCC coverage determination:

SBRT is a **covered benefit with conditions** for treatment of localized prostate cancer non-small cell and small cell lung cancer, pancreatic adenocarcinoma, oligometastatic disease, hepatocellular carcinoma, and cholangiocarcinoma.

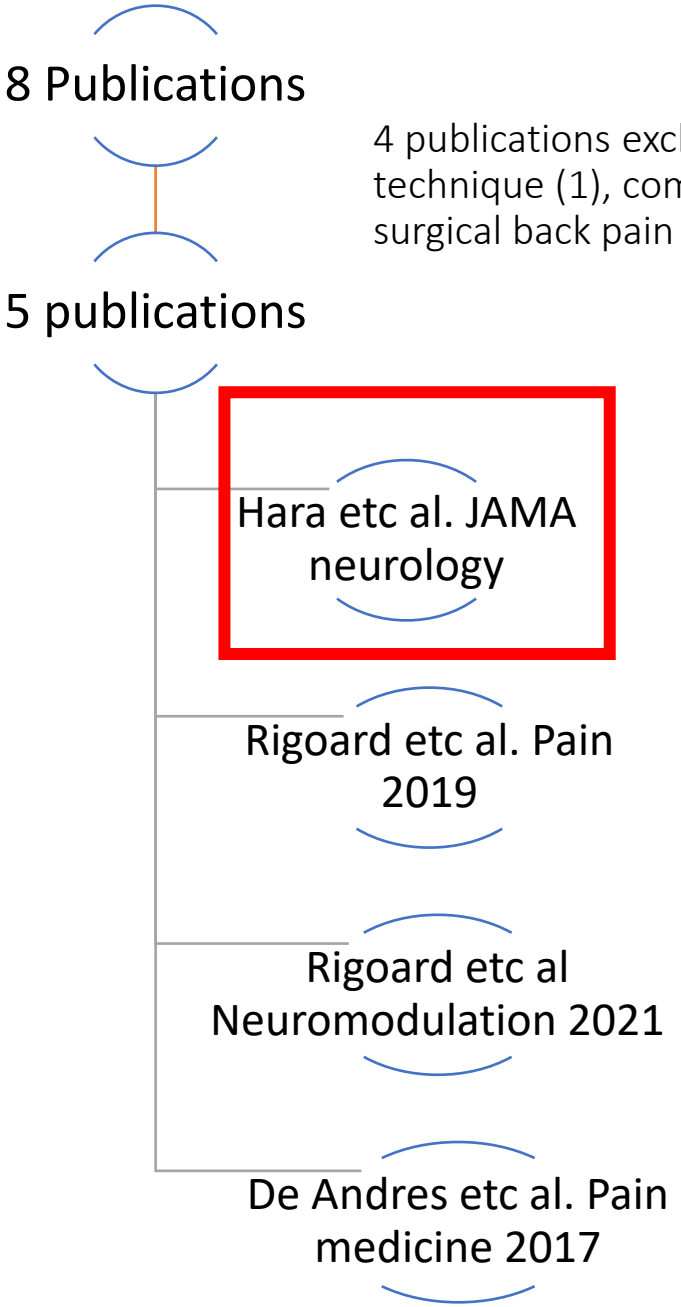
Key Questions 1 and 2

Based on the studies included in this review, we conclude that SBRT:

- May be similarly or more effective than other options for individuals with localized prostate cancer (very low to moderate certainty of evidence [CoE], based on 3 RCTs and 7 comparative NRSs);
- May be similarly or more effective than radiation therapy for inoperable stage II non-small cell lung cancer (NSCLC; low CoE, based on 1 comparative NRS) or in combination with pembrolizumab than pembrolizumab alone for advanced NSCLC (low to moderate CoE, based on 1 RCT). SBRT also appears to be similarly or more effective than conventional radiation therapy (cRT) for people with lung metastases (very low to low CoE, based on 4 comparative NRSs) or large cell neuroendocrine carcinoma (LCNEC) of the lung (low CoE, based on 2 comparative NRSs). In general, surgery appears to be more effective than SBRT for resectable lung cancer (very low to low CoE, based on 10 comparative NRSs);
- In combination with nivolumab and ipilimumab, may be as effective as nivolumab and ipilimumab for Merkel cell carcinoma (low CoE, based on 1 RCT);
- May be less effective than ablation (radiofrequency ablation [RFA], microwave, or cryoablation) or surgery for stage 1 renal cell carcinoma (low CoE, based on 1 comparative NRS);

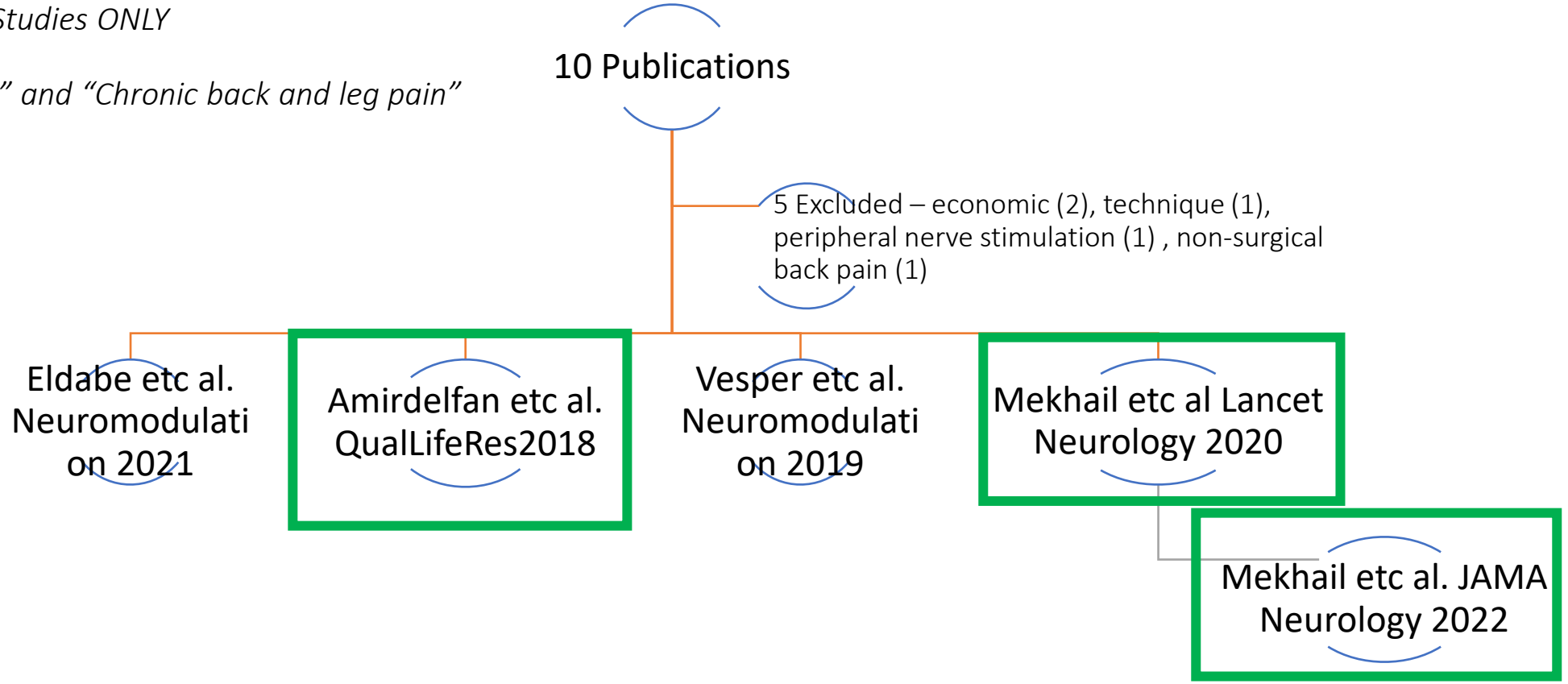
We performed a literature search for failed back surgical syndrome

Pubmed Search performed 10/13/2023
Randomized Controlled Studies ONLY
2017-2023
"Spinal Cord Stimulation" and "Failed Back Surgical syndrome"



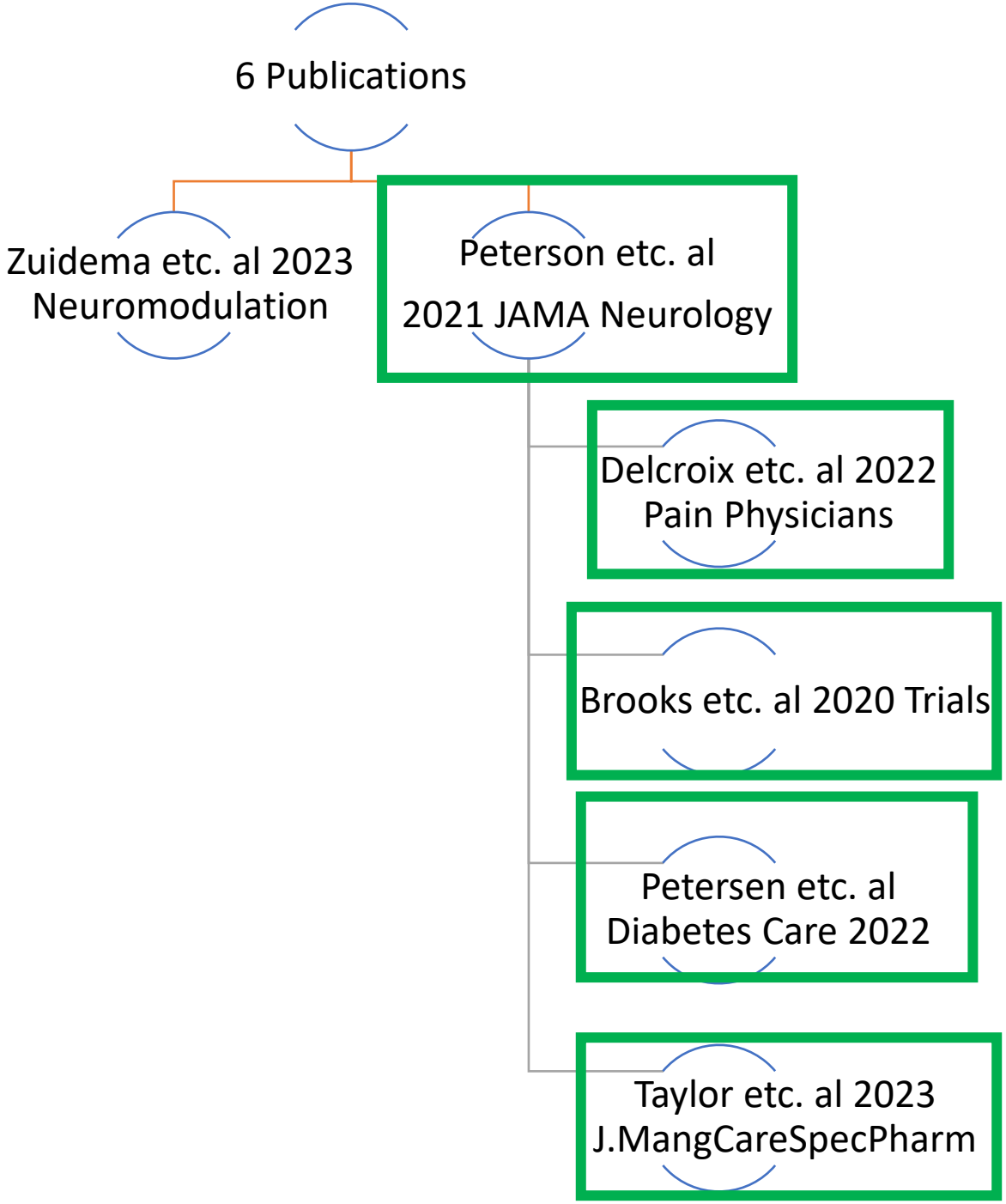
We performed a literature search for persistent neuropathic pain after spine surgery

Pubmed Search performed 10/13/2023
Randomized Controlled Studies ONLY
2017-2023
"Spinal Cord Stimulation" and "Chronic back and leg pain"



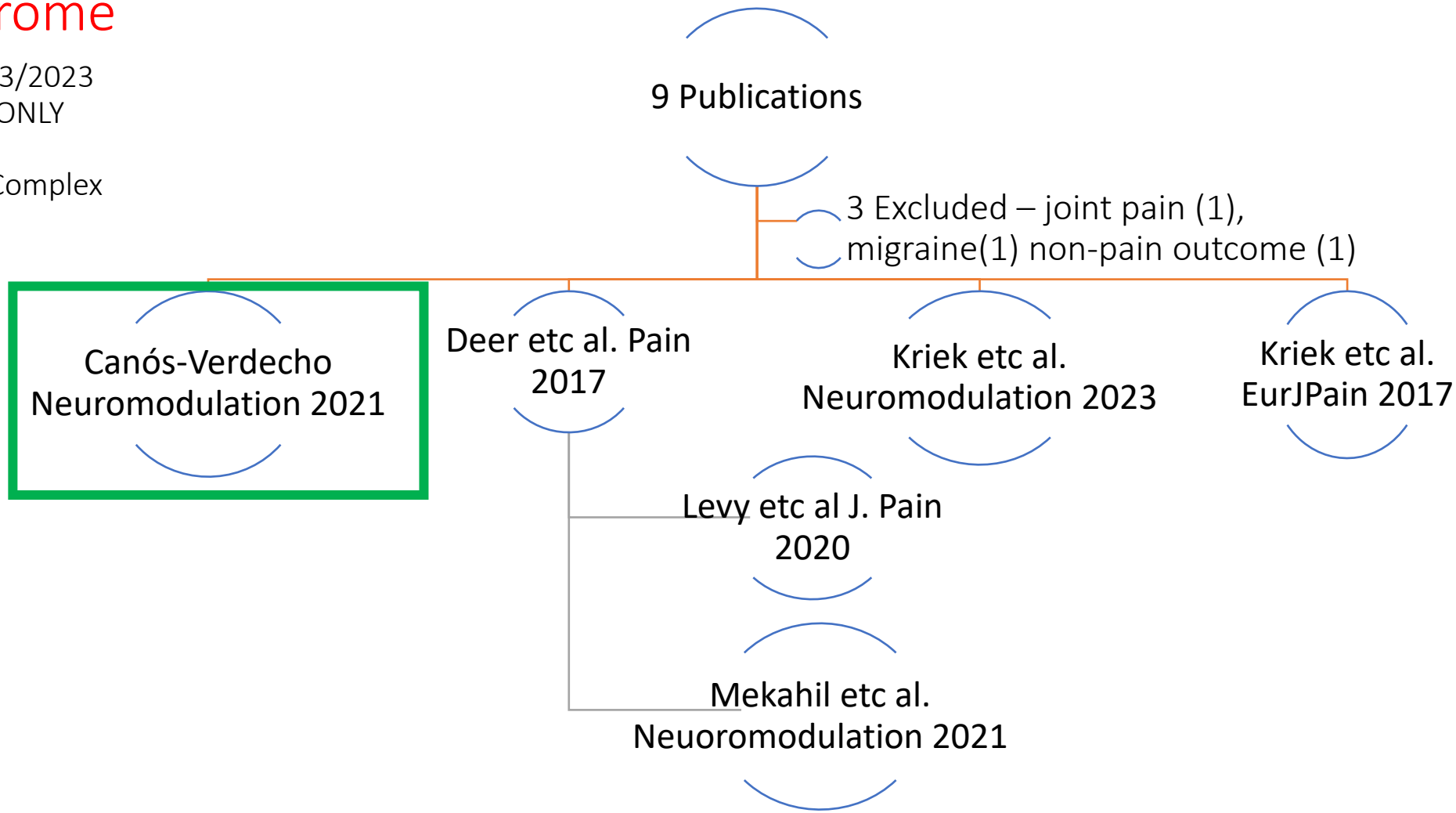
We performed a literature search for painful diabetic neuropathy

Pubmed Search performed 10/13/2023
Randomized Controlled Studies ONLY, 2017-2023 “Spinal Cord Stimulation” and “Painful Diabetic Neuropathy”



We performed a literature search for complex regional pain syndrome

Pubmed Search performed 10/13/2023
Randomized Controlled Studies ONLY
2017-2023
“Spinal Cord Stimulation” and “Complex Regional Pain Syndrome”



9 publications from 4 primary RCTs of the 33 studies present the best available evidence

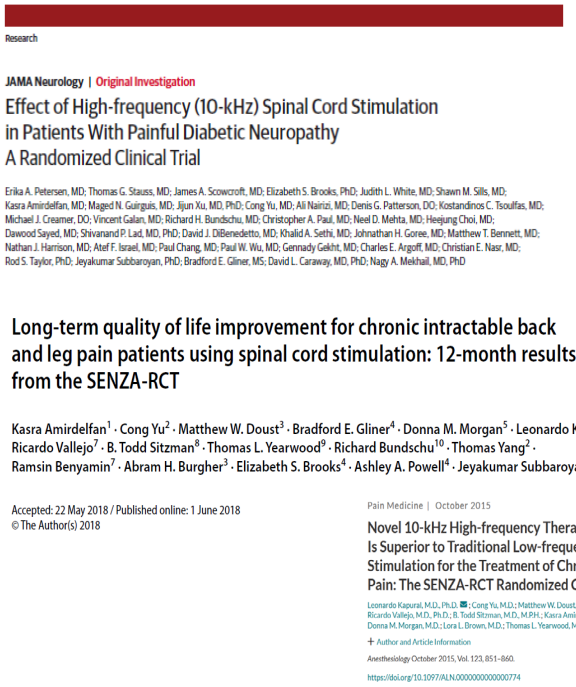
4 Primary RCTs

(1) **Mekhail etc al. Lancet Neurology 2020 (EVOKE RCT)**

(2) **Kapural etc al. Anesthesiology 2015 (SENZA)**

(3) **Petersen etc al. JAMA Neurology 2021**

(4) **Canos-Verdecho etc al. Neuromodulation 2021**



Research

JAMA Neurology | Original Investigation

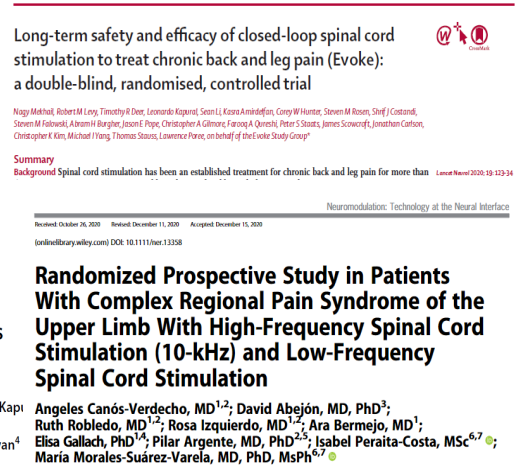
Effect of High-frequency (10-kHz) Spinal Cord Stimulation in Patients With Painful Diabetic Neuropathy
A Randomized Clinical Trial

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

Long-term quality of life improvement for chronic intractable back and leg pain patients using spinal cord stimulation: 12-month results from the SENZA-RCT

Kasra Amirdelfan[1] · Cong Yu[2] · Matthew W. Doust[3] · Bradford E. Gliner[4] · Donna M. Morgan[5] · Leonardo Kapu
Ricardo Vallejo[7] · B. Todd Sitzman[8] · Thomas L. Yearwood[9] · Richard Bundschu[10] · Thomas Yang[2] ·
Ramsin Benyamin[7] · Abram H. Burgher[3] · Elizabeth S. Brooks[4] · Ashley A. Powell[4] · Jeyakumar Subbaroyan[4]

Accepted: 22 May 2018 / Published online: 1 June 2018
© The Author(s) 2018



Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial

Nagy Mekhail, Robert M Levy, Timothy R Deer, Leonardo Kapural, Sean Li, Kasra Amirdelfan, Corey W Hunter, Steven M Rosen, Shrif J Costandi, Steven M Falowski, Abram H Burgher, Jason E Pope, Christopher A Gilmore, Farooq A Qureshi, Peter S Staats, James Scowcroft, Jonathan Carlson, Christopher K Kim, Michael J Yang, Thomas Stauss, Lawrence Poree, on behalf of the Evoke Study Group*

Summary

Background Spinal cord stimulation has been an established treatment for chronic back and leg pain for more than

Lancet Neurol 2020; 19: 123–34

Neuromodulation: Technology at the Neural Interface

Received: October 26, 2020 Revised: December 11, 2020 Accepted: December 15, 2020

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13358

Randomized Prospective Study in Patients With Complex Regional Pain Syndrome of the Upper Limb With High-Frequency Spinal Cord Stimulation (10-kHz) and Low-Frequency Spinal Cord Stimulation

Angeles Canós-Verdecho, MD[1,2]; David Abejón, MD, PhD[3]; Ruth Robledo, MD[1,2]; Rosa Izquierdo, MD[1,2]; Ara Bermejo, MD[1]; Elisa Gallach, PhD[1,4]; Pilar Argente, MD, PhD[2,5]; Isabel Peraita-Costa, MSc[6,7]; María Morales-Suárez-Varela, MD, PhD, MsPh[6,7]

Pain Medicine | October 2015

Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial FREE

Leonardo Kapural, M.D., Ph.D. ✉; Cong Yu, M.D.; Matthew W. Doust, M.D.; Bradford E. Gliner, M.S.; Ricardo Vallejo, M.D., Ph.D.; B. Todd Sitzman, M.D., M.P.H.; Kasra Amirdelfan, M.D.; Donna M. Morgan, M.D.; Lora L. Brown, M.D.; Thomas L. Yearwood, M.D., Ph.D.; ... Show more

+ Author and Article Information

Anesthesiology October 2015, Vol. 123, 851–860.

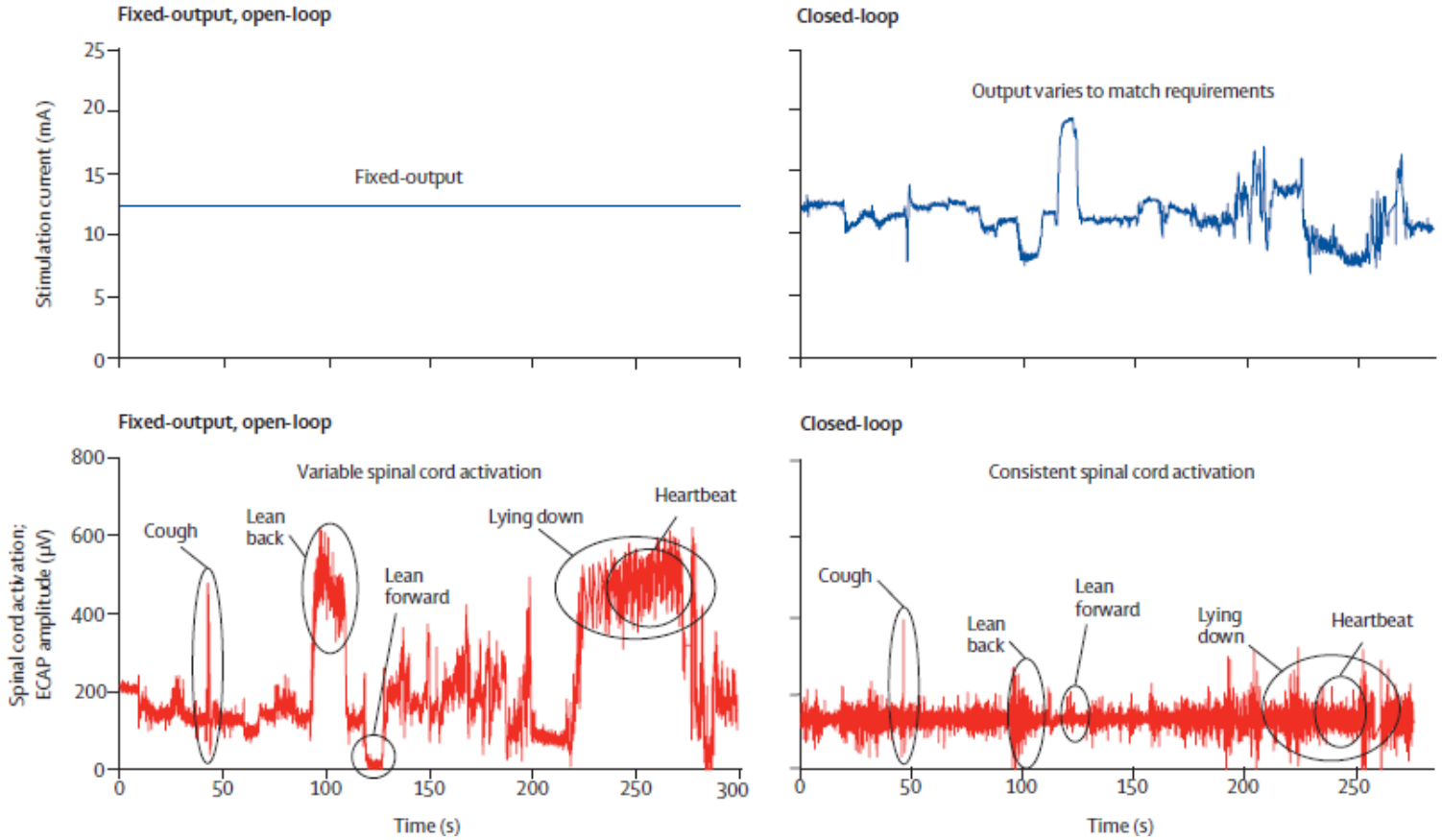
https://doi.org/10.1097/ALN.0000000000000774

Advantages of these 4 Primary RCTs

- **Randomized clinical trials across multiple sites**
- **Large Studies**
- **Clinical treatments reflect modern day methods for use of SCS**
- **Patients with no prior SCS experience**
- **Compared to standard of pain care**
- **12-24 months of follow up**
- **High quality journals – JAMA, Lancet, Anesthesiology**

(1) EVOKE RCT – Closed-loop technology uses real time spinal cord monitoring to adjust spinal cord stimulation dosing

THE LANCET
Neurology



More stable physiological response with closed loop treatment

(1) EVOKE RCT- Closed-loop technology leads to improved patient outcomes in patients with persistent neuropathic pain following back surgery

THE LANCET Neurology

- 61% traditional vs 83% traditional with closed loop had >50% reduction in pain
- Improved ODI, POMS, PSQI, EQ-5D-5L and SF-12
- Opioid reduction
- Benefits durable through 24 months *(Mekhail etc al. JAMA Neurology 2022)*

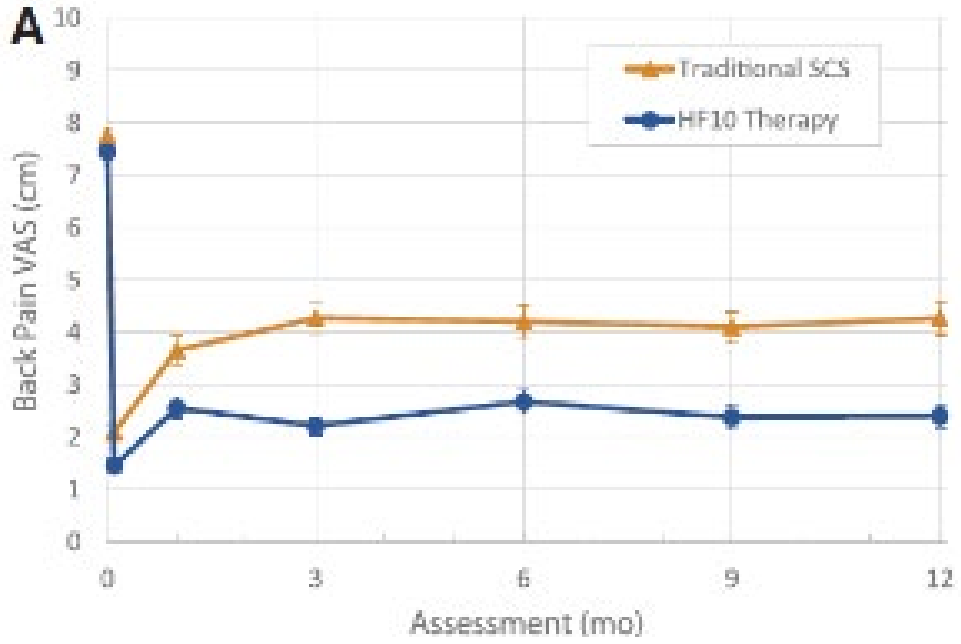
	3 months				12 months	
	Closed-loop group	Open-loop group	Difference (95% CI)	p value	Closed-loop group	Open-loop group
VAS percentage change from baseline*†‡						
Overall pain	73·8% (28·0)	59·4% (35·8)	14·4% (3·0 to 25·8)	0·013	72·3% (29·0)	56·2% (38·5)
Back pain (hierarchical secondary outcome)	72·1% (29·4)	57·5% (36·4)	14·6% (2·9 to 26·3)	0·015§	69·4% (30·6)	54·0% (39·5)
Leg pain (hierarchical secondary outcome)	76·8% (28·3)	67·8% (35·5)	9·0 (–2·4 to 20·4)	0·0006¶	72·9% (31·0)	62·1% (37·5)
VAS responder rates*‖						
Overall pain ≥50% reduction (primary outcome)	51/62 (82%)	38/63 (60%)	21·9% (6·6 to 37·3)	0·0052§	49/59 (83%)	36/59 (61%)
Back pain ≥50% reduction (hierarchical secondary outcome)	50/62 (81%)	36/63 (57%)	23·5% (7·8 to 39·2)	0·0033§	47/59 (80%)	34/59 (58%)
Leg pain ≥50% reduction	50/62 (81%)	43/63 (68%)	12·4% (–2·7 to 27·5)	0·0020¶	49/59 (83%)	36/59 (61%)
VAS high responder rates*‖						
Overall back and leg pain ≥80% reduction (hierarchical secondary outcome)	36/62 (58%)	27/63 (43%)	15·2% (–2·1 to 32·5)	0·0023¶	33/59 (56%)	22/59 (37%)

(2) SENZA RCT – New 10-kHz stimulation technology improved both back and leg pain better than tonic stimulation

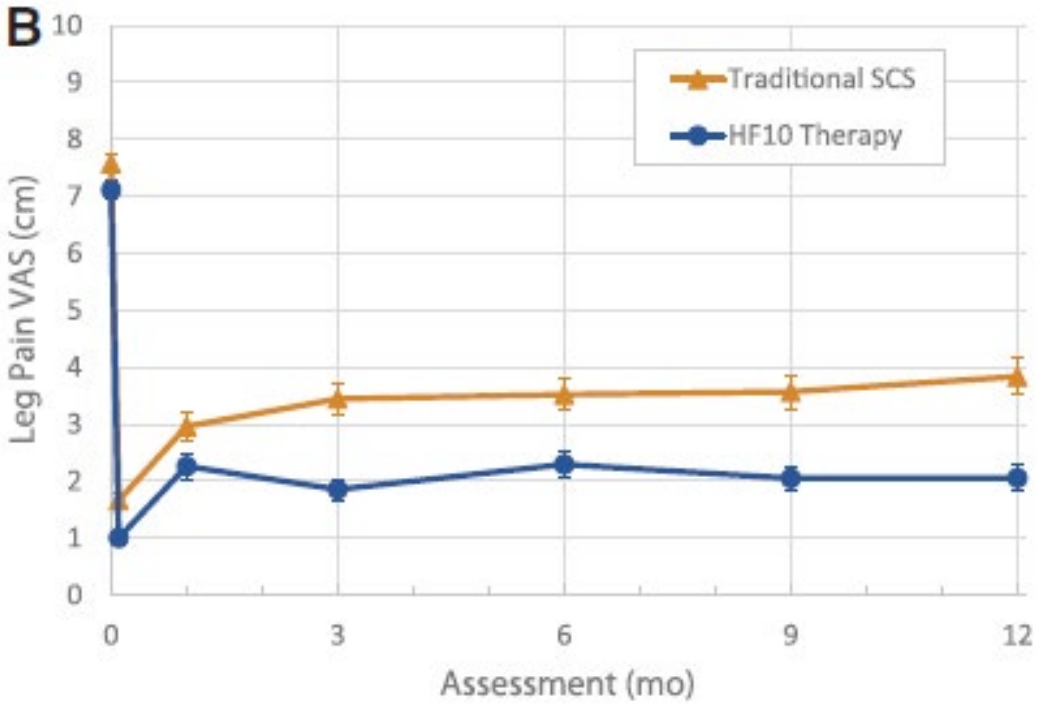
ANESTHESIOLOGY
Trusted Evidence: Discovery to Practice®

Primary Outcome (>50% pain relief)

44% traditional vs 67% 10-kHz decrease in back pain, 12 months



49% traditional vs 70% 10-kHz decrease in leg pain, 12 months

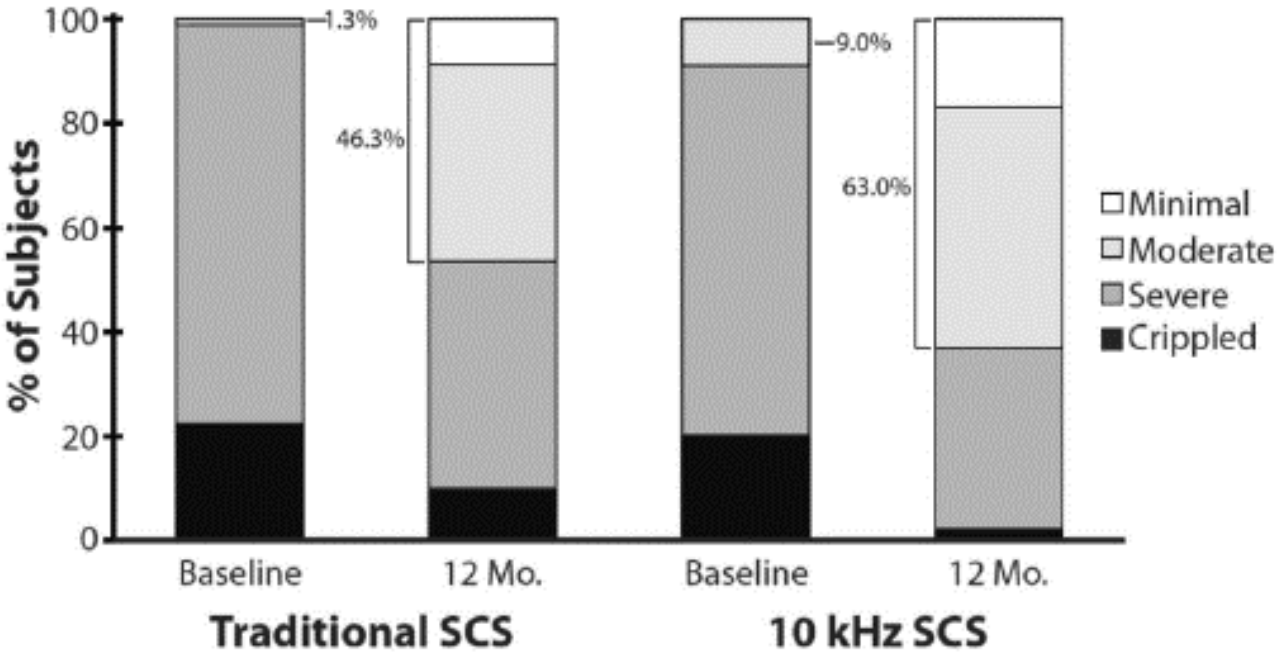


(2) SENZA RCT – New 10-kHz stimulation technology improved multiple functional domains in patients with persistent neuropathic pain following back surgery more than tonic stimulation

ANESTHESIOLOGY
Trusted Evidence: Discovery to Practice®

- Improvement in ODI, GAF, patient satisfaction, SF-MPQ2, GIC, Sleep
- 26% traditional vs. 35% 10-kHz opioid reduction

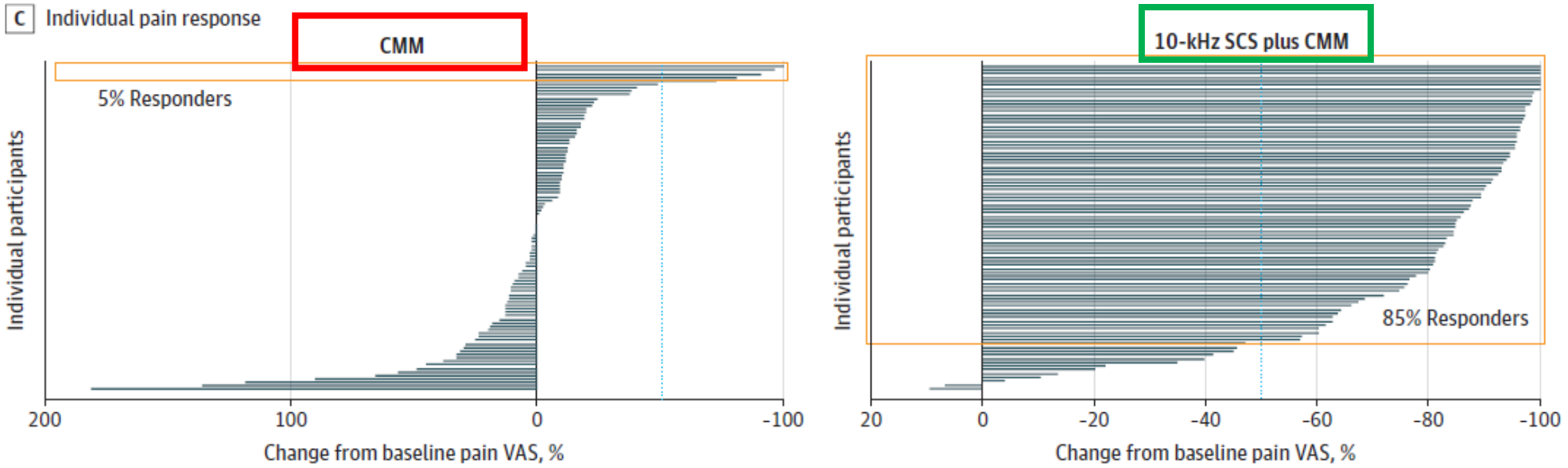
Oswestry Disability Index



(3) Petersen etc al. RCT –10 kHz spinal cord stimulation improved pain in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

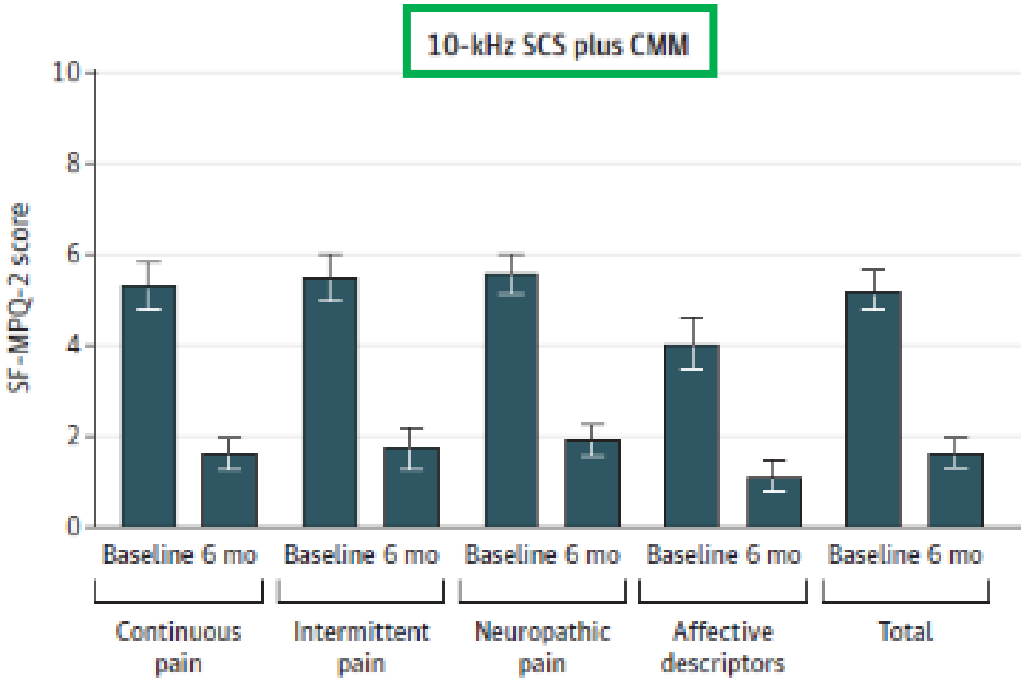
Primary Outcome (>50% pain reduction)

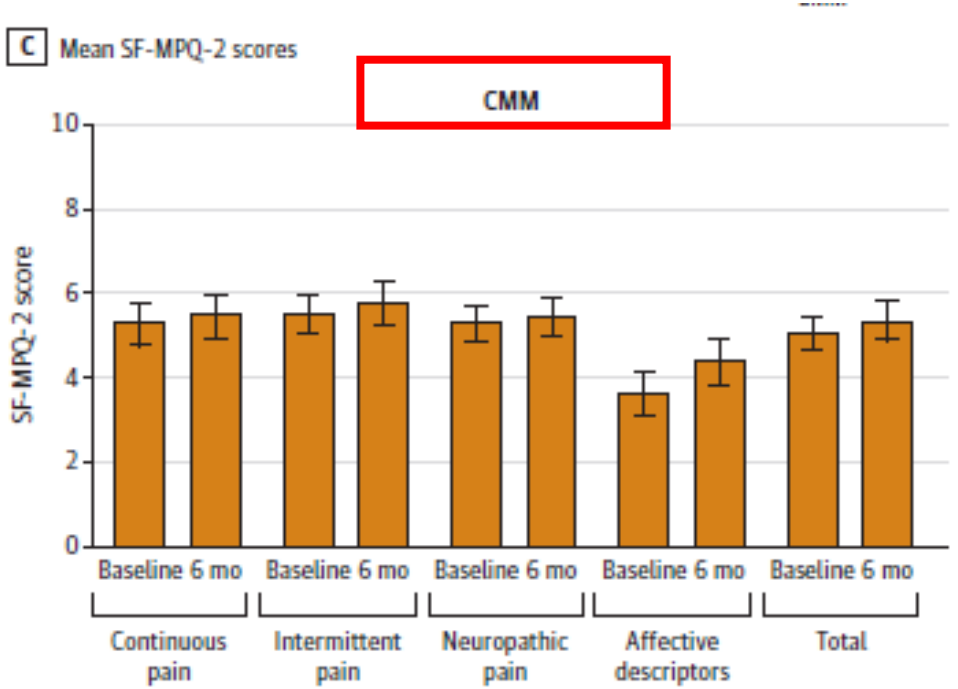


85% SCS + CMM vs. 5% CMM >50% pain relief
Sustained through 24 months (*Petersen etc al. DiabetesResClinPract2022*)

(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved pain descriptors in patients with diabetic neuropathy while conventional management did not

JAMA Neurology | Original Investigation



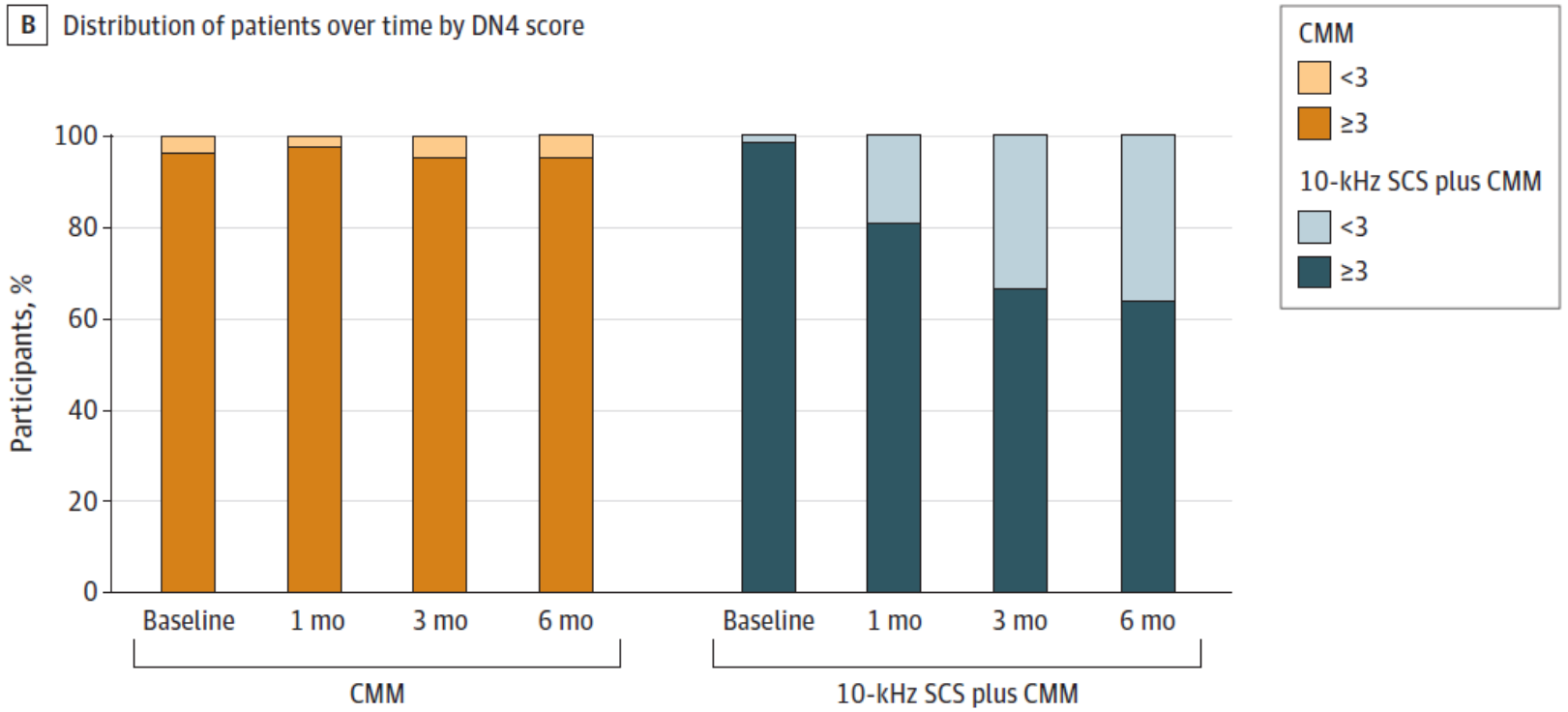


SCS improved SF-MP-Q-2

(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved descriptors of neuropathic pain in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

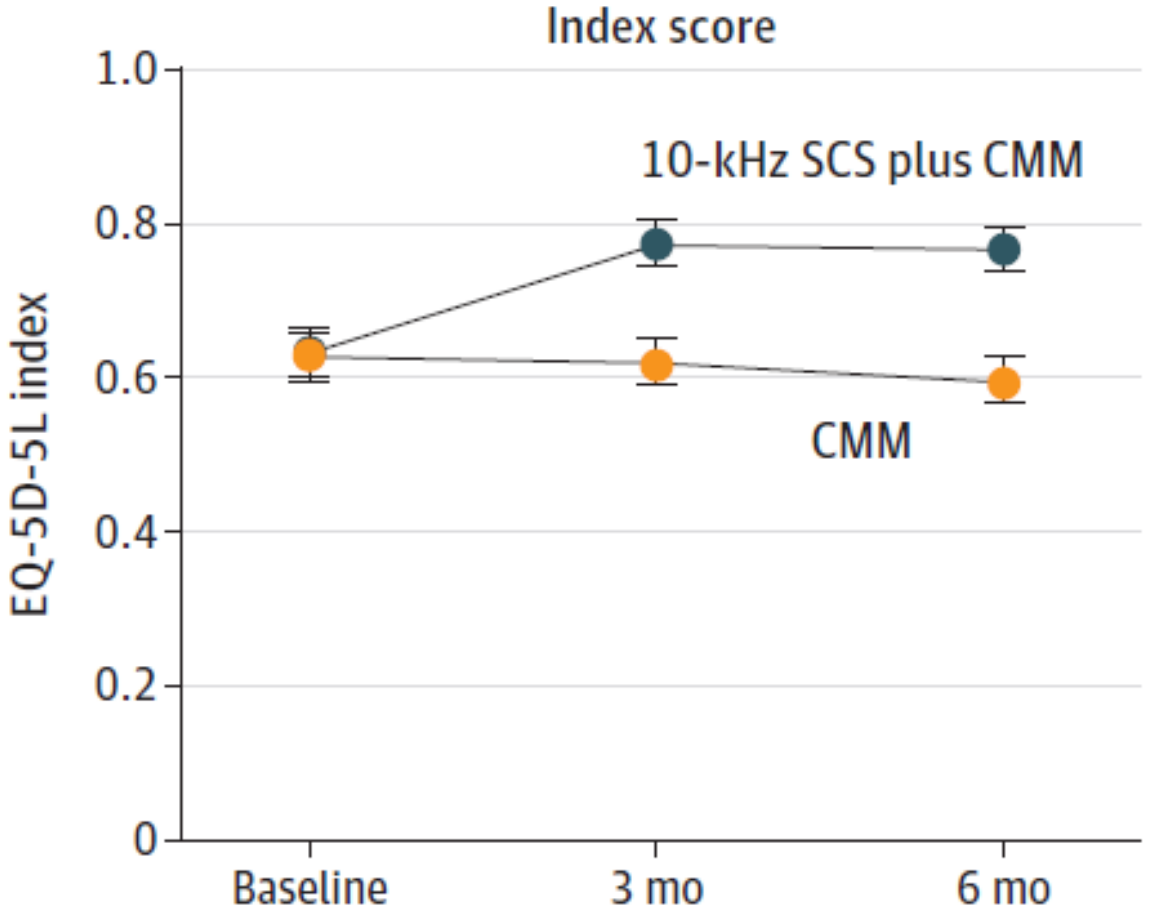
SCS improved DN4



(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved multi-faceted functional measures in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

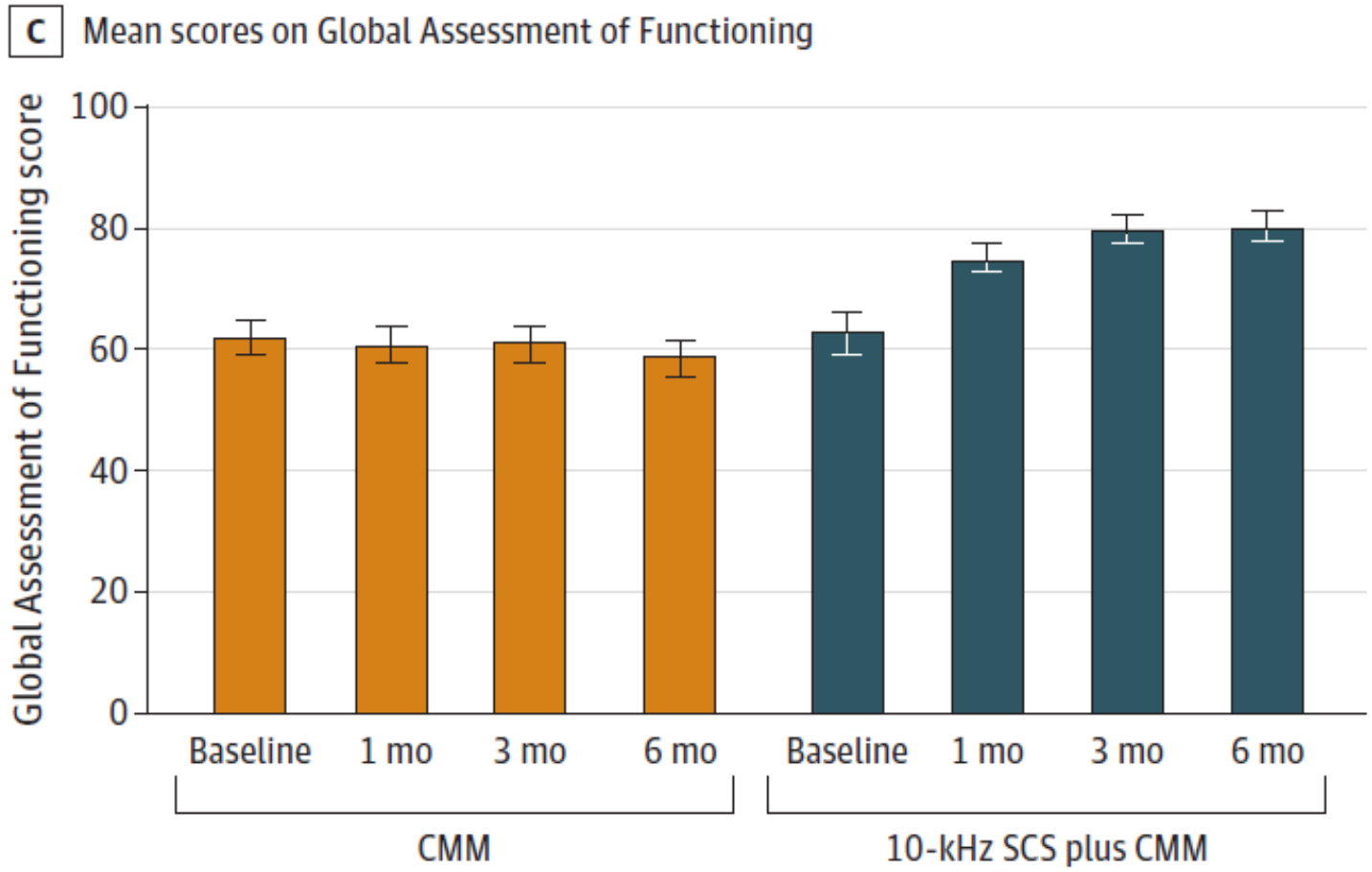
SCS improved EQ-5D-5L



(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved global functioning in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

SCS improved global functioning

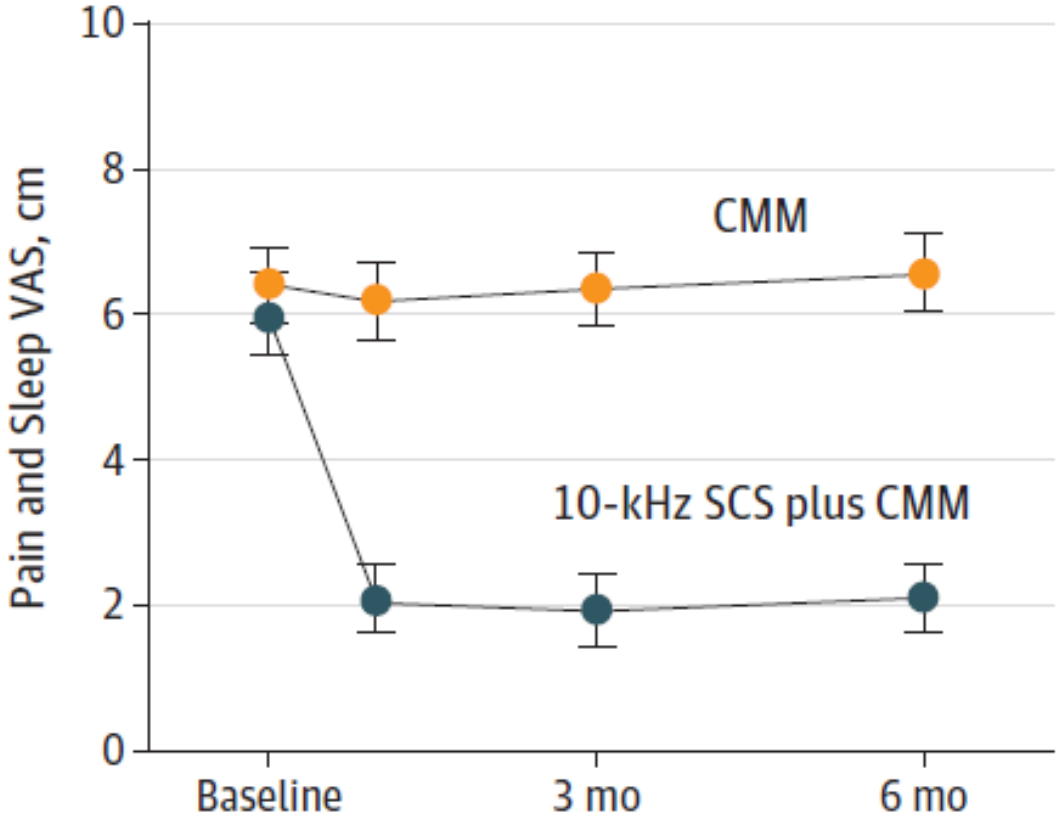


(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved sleep in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

SCS improved sleep

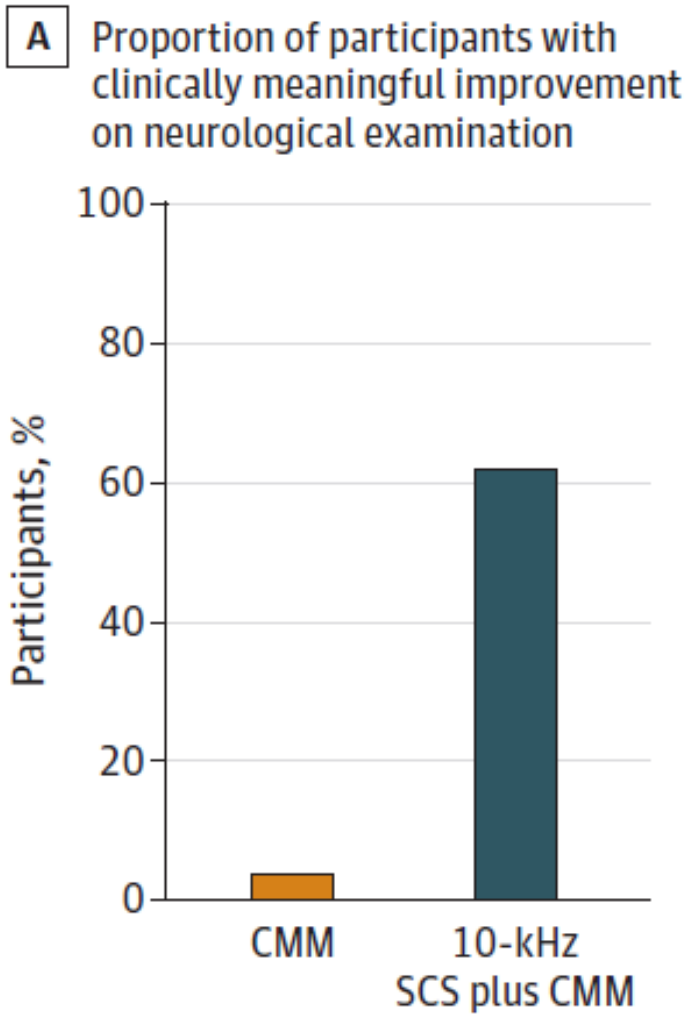
B Mean scores on the Pain and Sleep Questionnaire



(3) Petersen etc al RCT –10 kHz spinal cord stimulation improved the neurological examination in patients with diabetic neuropathy while conventional medical management did not

JAMA Neurology | Original Investigation

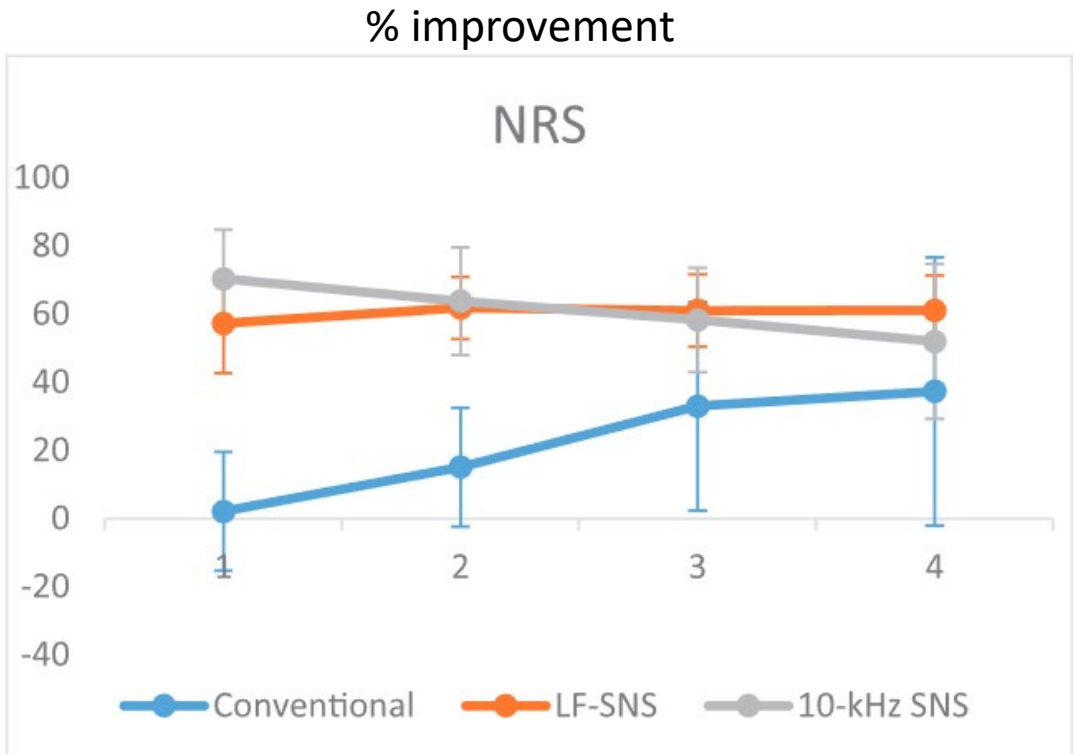
SCS improved the neurological examination
This is an area of active clinical research



(4) Canos Verdecho etc–10 kHz spinal cord stimulation and tonic stimulation improved pain and neuropathic descriptors in patients with complex regional pain syndrome better than conventional management

Neuromodulation
Technology at the Neural Interface
Editor-in-Chief: Robert M. Levy, MD, PhD

10 kHz stimulation and traditional stimulation improved pain scores at 12 months



(4) Canos Verdecho etc–10 kHz spinal cord stimulation and tonic stimulation improved sleep and functioning in patients with complex regional pain syndrome better than conventional management

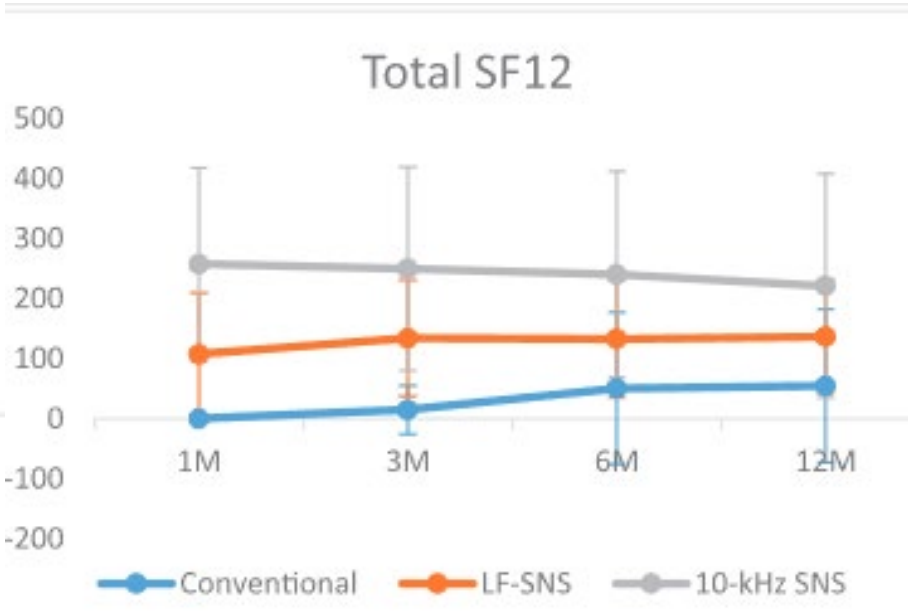
Neuromodulation
Technology at the Neural Interface
Editor-in-Chief: Robert M. Levy, MD, PhD

10 kHz and traditional stimulation improved MOS-SS better than conventional management

10 kHz stimulation improved Total SF12 better than traditional stimulation

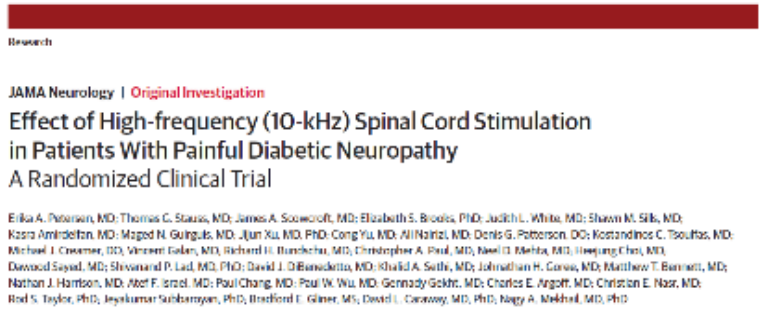
Traditional stimulation improved SF 12 better than conventional management

% improvement



Spinal cord stimulation is a safe procedure with a low risk of infection

JAMA Neurology | Original Investigation



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 C. 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; Jun Xu, MD, PhD; Cong Yu, MD; Ali Nairizi, MD; Denis G. Patterson, DO; Konstandinos 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. Barnett, 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 Subbaraya, PhD; Bradford E. Gliner, MS; David L. Caraway, MD, PhD; Nagy A. Mekhail, MD, PhD

No deaths, disability, long term neurological injury

5.6% wound complication rate despite high-risk diabetic patients

THE LANCET Neurology

Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial

*Nagy Mekhail, Robert M Levy, Timothy R Deer, Leonardo Kapural, Sean Li, Kasra Amirdelfan, Corey W Hunter, Steven M Rosen, Shrif J Costandi, Steven M Falowski, Abram H Burgher, Jason E Pope, Christopher A Gilmore, Faroog A Qureshi, Peter S Staats, James Scowcroft, Jonathan Carlson, Christopher K Kim, Michael I Yang, Thomas Stauss, Lawrence Poree, on behalf of the Evoke Study Group**

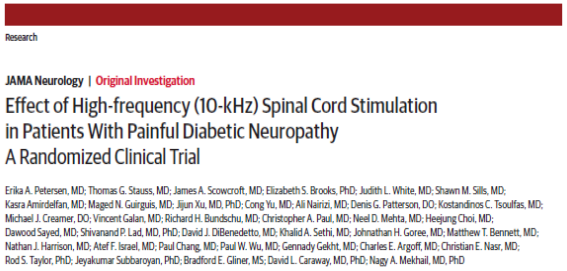
No deaths, disability, or long-term neurological injury

2% of patients with infection or serious device failure

Most common and well-known risks are pocket pain and lead migration

“Guardrails” against overutilization

Clinical Evidence



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

Long-term quality of life improvement for chronic intractable back and leg pain patients using spinal cord stimulation: 12-month results from the SENZA-RCT

Kasra Amirdelfan[1] · Cong Yu[2] · Matthew W. Doust[3] · Bradford E. Gliner[4] · Donna M. Morgan[5] · Leonardo Kapu
Ricardo Vallejo[7] · B. Todd Sitzman[8] · Thomas L. Yearwood[9] · Richard Bundschu[10] · Thomas Yang[2] ·
Ramsin Benyamin[7] · Abram H. Burgher[3] · Elizabeth S. Brooks[4] · Ashley A. Powell[4] · Jeyakumar Subbaroyan[4]

Accepted: 22 May 2018 / Published online: 1 June 2018
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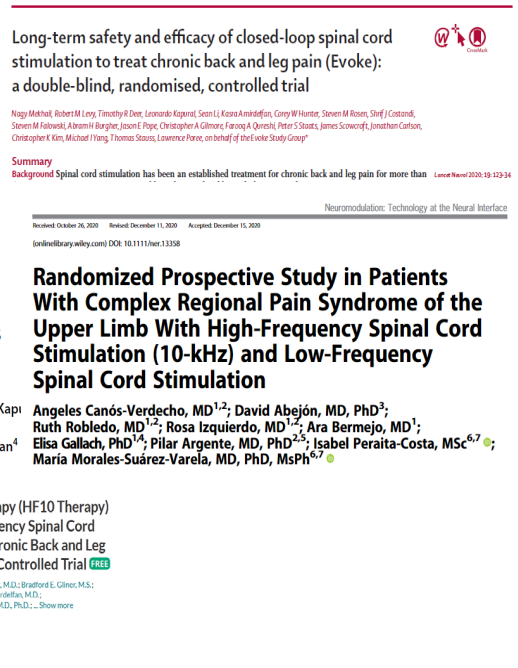

Long-term safety and efficacy of closed-loop spinal cord stimulation to treat chronic back and leg pain (Evoke): a double-blind, randomised, controlled trial

Nagy Mekhail, Robert M Levy, Timothy R Deer, Leonardo Kapural, Sean Li, Kasra Amirdelfan, Corey W Hunter, Steven M Rosen, Shrif J Costandi, Steven M Falowski, Abram H Burgher, Jason E Pope, Christopher A Gilmore, Farooq A Qureshi, Peter S Staats, James Scowcroft, Jonathan Carlson, Christopher K Kim, Michael I Yang, Thomas Stauss, Lawrence Poree, on behalf of the Evoke Study Group*

Summary

Background Spinal cord stimulation has been an established treatment for chronic back and leg pain for more than

Lancet Neurol 2020; 19: 123–34

Neuromodulation: Technology at the Neural Interface

Received: October 26, 2020 Revised: December 11, 2020 Accepted: December 15, 2020

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13358

Randomized Prospective Study in Patients With Complex Regional Pain Syndrome of the Upper Limb With High-Frequency Spinal Cord Stimulation (10-kHz) and Low-Frequency Spinal Cord Stimulation

Angeles Canós-Verdecho, MD[1,2]; David Abejón, MD, PhD[3]; Ruth Robledo, MD[1,2]; Rosa Izquierdo, MD[1,2]; Ara Bermejo, MD[1]; Elisa Gallach, PhD[1,4]; Pilar Argente, MD, PhD[2,5]; Isabel Peraita-Costa, MSc[6,7]; María Morales-Suárez-Varela, MD, PhD, MsPH[6,7]

Pain Medicine | October 2015

Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial FREE

Leonardo Kapural, M.D., Ph.D. ✉; Cong Yu, M.D.; Matthew W. Doust, M.D.; Bradford E. Gliner, M.S.; Ricardo Vallejo, M.D., Ph.D.; B. Todd Sitzman, M.D., M.P.H.; Kasra Amirdelfan, M.D.; Donna M. Morgan, M.D.; Lora L. Brown, M.D.; Thomas L. Yearwood, M.D., Ph.D.; ... Show more

+ Author and Article Information

Anesthesiology October 2015, Vol. 123, 851–860.

https://doi.org/10.1097/ALN.0000000000000774

Clinical Expertise

Clinical Reasoning and Best Practices
Accurate Diagnoses
Thoughtful Patient Selection
Right SCS Treatment

Oversight

Center for Medicare and Medicaid Services (CMS)
National Care Determination (NCD)

FDA Approved Indications

Local Coverage Determination

Washington Health Care Authority

Core recommendations for coverage

- FDA indicated diagnoses
- Quantitative pain scale indicating moderate-severe pain despite conservative treatments (physical therapy, medications, biopsychosocial approaches, other less invasive procedures) or for whom theses alternatives are deemed clinically unsuitable
- Appropriate medical evaluation to determine and optimize procedural safety
- Multidisciplinary evaluation including psychological to evaluate readiness for procedure
- SCS Trial 5-14 days
- SCS implant only after trial with >50% pain reduction and improvement as measured by a validated functional outcome tool

Washington State Health Care Authority

In response to HTCC request for specific meeting comments

- Evidence not reviewed but available from peer-reviewed publications.

Petersen etc al. JAMA Neurology 2021
Petersen etc al. DiabetesResClinPract2023
Mekhail etc al. Lancet Neurology 2020
Mekhail etc al. JAMA Neurology 2022
Kapural etc al. Anesthesiology 2015
Canos-Verdecho etc al. Neuromodulation 2021

- Study design issues.

Large studies, currently used technologies, appropriate SCS treatment protocols, up to 24 months of follow-up

- Criticality of outcomes.

High quality studies, high certainty of clinical relevance

- Interpretations of the evidence cited in the technology review.

Al-kaisy et al. 2018, Sokol 2020

Hara etc al. 2020

- Study design issues.

Small and short studies, methodologically flawed, antiquated technology

Methodologically flawed, waveform not used in clinical practice

- Criticality of outcomes.

Low quality studies, low certainty of clinical relevance

Conclusions

- Ignore invalid studies per HCA guidelines
- Discount clinically irrelevant older studies
- Focus on larger, newer studies of current technology with appropriate selection criteria
- **With these steps the evidence clearly supports SCS using contemporary technology for FDA approved indications**
- Place appropriate “guardrails” around SCS
  - Carefully selected patients with recalcitrant high impact pain
  - Limited set of diagnoses
  - Assure SCS includes new stimulation paradigms

Appendix

Recommended guideline for Failed Back Surgical Syndrome

- Persistent neuropathic limb pain +/- back pain following spinal surgery for which additional surgical treatment would not be appropriate. Recommend interdisciplinary collaboration with surgical expertise.
- >18 yo, quantitative pain scale indicating moderate-severe pain, intractable pain despite conservative treatments (physical therapy, medication trials) > 6 months
- Appropriate medical evaluation to determine and optimize procedural safety
- Multidisciplinary evaluation including psychological to evaluate readiness for procedure
- SCS Trial 5-14 days
- SCS implant only after >50% pain reduction and improvement as measured by a validated functional outcome tool

Recommended guideline for Painful Diabetic Neuropathy

- Symptoms and signs of peripheral nerve dysfunction in a diabetic patient after the exclusion of other causes
- >18 yo, quantitative pain scale moderate-severe pain, >12 months of conservative treatment including 2+ pharmacologic agents
- Appropriate medical evaluation to determine and optimize procedural safety
- Multidisciplinary evaluation including psychological to evaluate readiness for procedure
- SCS Trial 5-14 days
- SCS implant only after >50% pain reduction and improvement as measured by a validated functional outcome tool

Recommended guideline for Complex Regional Pain Syndrome I and II

- Diagnosis of complex regional pain syndrome by Budapest Criteria
- CRPS II diagnosis also must have evidence of injury to a named nerve
- >18 yo, quantitative pain scale indicating moderate-severe pain, >6 months of conservative treatment including 2+ pharmacologic agents, physical therapy
- Appropriate medical evaluation to determine and optimize procedural safety
- Multidisciplinary evaluation including psychological to evaluate readiness for procedure
- SCS Trial 5-14 days
- SCS implant only after >50% pain reduction and improvement as measured by a validated functional outcome tool

Terms and Definitions

- Paresthesia-based stimulation – can also be called “tonic” or “traditional.” Clinical response whereby an additional tingling or paresthesia overlaps the patient’s area of pain using low frequency waveforms. Modern day technologies improve this technology e.g. closed-loop stimulation.
- Paresthesia-free stimulation – Clinical response whereby a patient feels no additional tingling or paresthesia, just pain relief. Stimulation treatments such as high frequency (10-kHz) or burst stimulation patterns are examples.
- Closed-loop stimulation – Any spinal cord stimulation technology that incorporates real time neurophysiologic monitoring (such as evoked compound actions potentials) to help determine stimulation parameters, thereby personalizing spinal cord stimulation treatment

Terms and Definitions

- Trial of Spinal Cord Stimulation (percutaneous) – This allows a patient to try spinal cord stimulation first before making the decision to surgically implant a device. A percutaneous trial accounts for the vast majority of trial procedures and does NOT require a surgical incision. This procedure is performed like a spinal injection whereby temporary neurostimulator leads are introduce into the epidural space using only a needle. The leads are simply taped (like a pain epidural for delivery of newborns) onto the patient. The leads are pulled after the trial period and the patient is then evaluated for appropriateness for spinal cord stimulator implantation. The trial neurostimulator leads are discarded and not used for the final implantation. If the trial worked, the device is surgically implanted at a later date.
- Trial of Spinal Cord Stimulation (surgical) – A surgical method for trialing spinal cord stimulation. A neurosurgeon places a “paddle” lead surgically (laminectomy) in the operating room. The patient then goes home to trial the device. After completion of the trial, the patient is taken directly to the operating room to either remove the paddle lead (if the trial did not work) or implant a battery along with the existing paddle lead (if the trial did work).

Terms and Definitions

- VAS – Visual analogue score – Pain score along continuum with the aid of descriptors or visuals
- NRS – Numerical Rating Scale – numerical pain scale
- ODI – Oswestry Disability Index. questionnaire examines the level of disability in 10 everyday activities of daily living: Pain intensity, Personal care, Lifting, Walking, Sitting, Standing, Sleeping, Sex (if applicable), Social, travel
- POMS – Profile of Mood States- Scale measuring frequency of mood states eg friendly, tense, angry, worn out
- PSQI – Pittsburg Quality Index – measures quantity and quality of sleep
- EQ-5D-5L - Descriptive system comprising five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems.

Terms and Definitions

- SF-12 -8 domains – Limitations to physical activity, Limitations to social activity, Limitations in usual role activities, bodily pain, general mental health, limitations because of emotional problems, vitality, general health perceptions
- SF-MP-Q-2 - 22 different descriptors of pain and each item is rated based on a 0-10 scale with 0 equal to no pain and 10 equal to the worst pain ever during the past week. The total score is calculated by summing 22 individual scores. SF-MPQ-2 comprises of 4 parts including Continuous (throbbing pain, cramping pain, gnawing pain, aching pain, heavy pain, tender), Intermittent (shooting pain, stabbing pain, sharp pain, splitting pain, electric-shock pain, piercing), Neuropathic (hot-burning pain, cold-freezing pain, pain caused by light touch, itching, tingling or "pins and needles", numbness), and Affective (tiring-exhausting, sickening, fearful, punishing-cruel) subscales

Terms and Definitions

- DN4 - Questions about burning, painful cold, electric shocks, tingling pins, needles. Hypoesthesia to touch pinprick. Descriptors and exam consistent with neuropathic pain
- GAF –Global Assessment of Functioning – 0-100 scale assessing how psychological symptoms, mood impacts quality of life and psychosocial functioning
- MOS-SS –Medical Outcomes Study Sleep Scale- six factors: sleep initiation, maintenance, respiratory problems, quantity, perceived adequacy, and somnolence.

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care J-UJthority

Instructions

This conflict of interest (COi) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.

Those wishing to provide public comment at HTCC meetings are also requested to complete this COi form, but are not required to do so.

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1 Applicant information

First name: **Brett**

Middle initial:

Last name: **Stacey**

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List **amounts totaling** $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

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Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

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E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

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Category (A-G)	Source of income and date	Amount	Recipient	
			Self	Family
C	Nevro IIS Study: Functional Outcomes in SCS Tha	0	Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Some time ago:
Cohen SP , Wallace M, Rauck RL, Stacey BR. Unique aspects of clinical trails of invasive therapies for chronic pain. PAIN reports. 2019 May 1;4(3). doi: 10.1097/PR90000000000000687. PMID: 31583336Dworkin R, O'Connor

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

See above AND : 2005-2008 International Association for the Study of Pain Neuropathic Pain Special Interest Group, Clinical Guidelines Committee

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

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To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature [redacted]

Date

Download this form and send the completed version to shtap@hca.wa.gov.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

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Washington State Health Care Authority

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1 Applicant information

First name: Paul

Middle initial:

Last name: DeJulio

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
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G. Receiving honoraria.

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			Self	Family
			Self	Family
			Self	Family
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Signature

[redacted]

Date

10/12/23

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1 Applicant information

First name: Paul

Middle initial:

Last name: Dreyfuss

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
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Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
D	Oakworks for 2022, 2023 Royalties for a spine pos	20,000.00	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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No

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No

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No

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Signature

Date

10.11.2023

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Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State A // Health Caref,uthority

Instructions

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Applicant information

First name:

Emilie

Middle initial:

Last name:

Jones

Phone number:

[redacted]

Email:

[redacted]

Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

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F. Participating in a speakers bureau.

G. Receiving honoraria.

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			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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No

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[redacted]

Date

10/17/2023

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1 Applicant information

First name: Katherin

Middle initial:

Last name: Peperzak

Phone number: [redacted]

Email: [redacted]

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
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1 Applicant information

First name: Jiang

Middle initial:

Last name: Wu

Phone number: [redacted]

Email: [redacted]

2 Financial interests

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1 Applicant information

First name: Peter

Middle initial:

Last name: Lee

Phone number:

Email:

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Spinal Cord Stimulators for Chronic Pain: Re-review

Presentation to
Washington State Health Care Authority
Health Technology Clinical Committee

Andrea C. Skelly, PhD, MPH
Erika D. Brodt, BS

November 17, 2023

Report prepared by:
Andrea C. Skelly, Erika D. Brodt
Dakota Riopelle, Shay Stabler-Morris,
Mark Junge, Asmaa Khariji Watson

Internal clinical, methods review: Roger Chou
Clinical experts/peer review: Carl Noe, Kim Mauer

Aggregate Analytics

2010 Report

- Evidence base: 3 RCTs (2 FBSS, 1 CRPS-I) across 7 publications, 1 prospective NRSI (FBSS, open Washington state workers' compensation claims), 6 case series (safety)
- Findings:
  - SCS superior to conventional therapies (CMM, physical therapy or reoperation) in the shorter term for pain relief but benefits decreased with time, no difference vs. controls longer term but data were sparse.
  - Evidence on function and QOL was sparse and inconsistent
  - Revision surgery and side effects were not uncommon through 5-year f/u
  - No trials compared SCS with sham/placebo

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Re-Review Rationale and Topic Refinement

- Rationale: Additional evidence and technical advances related to use of SCSs, including use of high frequency and burst stimulation available since the prior report.
- Topic Refinement:
  - Public comment to topic nomination, draft key questions/scope and a petition to HTAP were reviewed, considered, and discussed with HTAP as was input from clinical experts prior to finalization of KQ and PICOTS scope. All suggested citations were evaluated against the final PICOTS for possible inclusion.
- Clinical input on specific clinical questions was obtained throughout report development; internal clinical and methods review was done as was clinical peer review of the draft report.

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Background

Chronic Pain

- **Chronic pain**
  - Pain that persists for several months (typically ≥3 months) or for longer than anticipated
  - Substantially interferes with ADLs (e.g., work, social, personal); can lead to depression, anxiety and trouble sleeping; overall loss in QoL
  - Conditions in this review: Back pain (FBSS, NSRBP), peripheral diabetic neuropathy (PDN), complex regional pain syndrome (CRPS)
- **Approx. 51.6 million U.S. adults (21%) currently affected by chronic pain; 17.1 million (7%) experience high-impact chronic pain**
  - LBP is most common: ~13% of U.S. adults; PDN: 8.7-14.6 million; CRPS: 200,000/yearly
- **Healthcare costs**
  - As high as $635 billion a year, which is more than the yearly costs for cancer, heart disease, and diabetes.

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Included Conditions and SCS

Back pain

- FBSS: generalized disorder usually characterized by chronic pain in the lower back and/or legs that persists or recurs following anatomically successful spinal surgery
- NSRBP: chronic refractory back pain that does not respond to CMM in patients with no history of spine surgery and who are not candidates for spine surgery

CRPS

- The presence of severe prolonged pain of without clear origin that occurs in the arm or leg, usually after injury; Pain is often disproportionate to inciting event

Neuropathy

- Intense and persistent pain caused by nerve damage (e.g., from uncontrolled diabetes)

SCS

- **SCS** considered only after CMM has failed, typically used in addition to other therapies; treats rather than cures
- **SCS** may provide pain relief, improve QoL and function, reduce pain medication use

Spinal Cord Stimulation

- **Uses pulsed electrical energy sent to the spinal cord to manage pain**
- **Mechanisms of action not fully understood; thought to provide relief by modifying and masking pain signals before they reach the brain**
- **FDA approved**
  - A number of currently approved devices, 6 manufacturers (Appendix K)
  - Indications (some device dependent): chronic intractable pain in the trunk and/or limbs, radicular syndromes, FBSS, CRPS, PDN, arachnoiditis, other; refractory to CMM, would not benefit from additional surgery
  - Contraindications: failed trial stimulation (i.e., ineffective pain relief), poor surgical candidates, cardiac pacemaker, uncontrolled bleeding or coagulopathy, untreated mental health issues, psychological comorbidities, SUD
  - CMS/most payers require screening (physical and psychological) and diagnosis by a multidisciplinary team and demonstration of pain relief with a temporarily implanted system (i.e., trial stimulation).

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Spinal Cord Stimulation (cont.)

- **3 main components:** implantable pulse generator (IPG) with a battery, a lead wire with electrodes (8-32) (cylindrical or paddle), remote control that controls device and settings.
- **SCS systems** involve percutaneous implantation of electrode leads into the epidural space above the spine cord; IPG typically implant under the skin the abdominal or buttock region.
- "**Conventional" SCS** devices use a low-frequency current to replace the pain sensation with a mild tingling feeling (i.e., paresthesia); others use **high-frequency (HF)** (e.g., 10 kHz) or **burst** pulses to mask the pain with no tingling feeling.
- Input from our clinical experts suggests substantial heterogeneity in devices, modes of operation and parameters used across usual clinical practice.
- **SCS-specific risks described**: undesirable changes in stimulation; epidural hemorrhage, hematoma, infection, spinal cord compression and/or paralysis; CSF leak; seroma; persistent pain at electrode/stimulator site; paralysis, weakness, numbness below level of implantation, battery failure/leakage, lead migration, allergic reaction, IPG migration or local skin erosion.

Image: SSED from PMA P010032/S189

Questions and Scope

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Key Questions

When used in adult patients who have failed other treatment options for pain related to FBSS, chronic back pain, CRPS, or peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia):

1. What is the evidence of short and long-term **effectiveness** of SCS **compared with** medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?
2. What is the evidence of the **safety** of SCS compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?
3. What is the evidence that SCS has **differential efficacy or safety** issues in sub-populations of interest
4. What is the evidence of **cost-effectiveness** of SCS compared with other medical or surgical options that do not include neuromodulation?

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PICO Scope: Inclusion Criteria

- **Population**
  - Adults who had not been previously treated with SCS with one of the following conditions: chronic low back pain, failed back surgery syndrome with low back pain and significant radicular pain, complex regional pain syndrome, peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia
- **Intervention**
  - FDA-approved SCS system (permanently implanted pulse generator systems and radiofrequency receiver systems)
- **Comparator**
  - Medical and/or surgical treatment (appropriate to condition) that does not include comparison of SCS methods/devices or other neuromodulation devices
- **Outcomes**
  - Primary: Function, pain, opioid use, AEs or harms (***SOE on these only***)
  - Economic: Cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcome)

PICO Scope: Inclusion Criteria

- **Study Design**
  - Key Questions 1: RCTs will be the primary focus; prospective high quality **comparative** nonrandomized studies of intervention (NRSI) with concurrent controls that control for confounding will be considered.
  - Key Question 2: RCTs and NRSIs designed specifically to evaluate harms/adverse events that are rare or occur long-term (including case series).
  - Key Question 3: RCTs which present results for both intervention and comparator such that they are stratified on patient or other characteristics of interest and test for interaction.
  - Key Question 4: Formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies).
- **Publication**
  - Studies published in English in peer reviewed journals or publicly available FDA reports, published HTAs; KQ 4 full/formal economic studies published after those in the prior HTA

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Methods

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Systematic Review Process

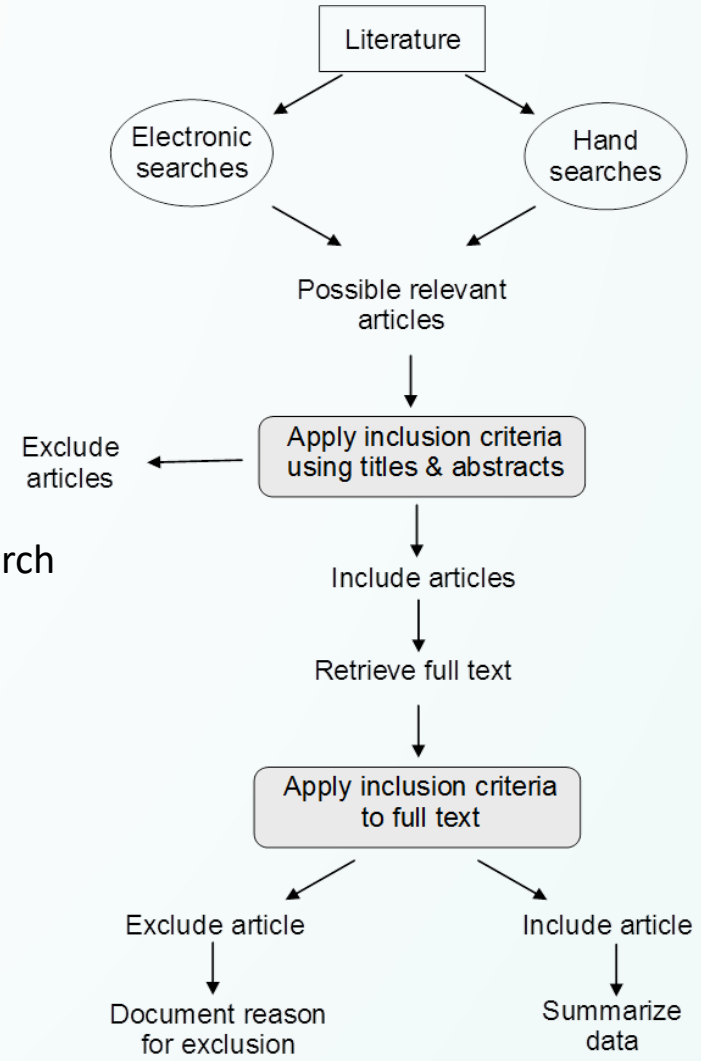
Methodological Standards:
AHRQ, IOM/NASEM, Cochrane

Topic Refinement
- Key questions
- Scope (inclusion/exclusion)
  - Population
  - Intervention
  - Comparators
  - Outcomes
  - Timing
  - Studies
  - Setting
- Preliminary Search

Finalization/Work Plan

Role of Clinical Experts

Formal, Structured Search



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Quality (Risk of Bias) Assessment

Predefined criteria used to assess individual studies based on study design and methods (AHRQ, Cochrane); independent, dual assessment

Rating	Description and Criteria
Good	• **Low ROB, most criteria for methodologic quality are met** and results generally considered valid • Valid methods for selection, inclusion, and treatment allocation; report similar baseline characteristics in different treatment groups; clearly describe attrition and have low attrition; appropriate means for preventing bias and use of appropriate analytic methods
Fair	• **Some study flaws: May not meet all criteria for good quality**, but no flaw is likely to cause major bias that would invalidate results; the study may be missing some information making it difficult to assess limitations and potential problems**. This is a broad category; results from studies may or may not be valid**.
Poor	• **Significant flaws that imply methodologic biases of various kinds that may invalidate results**; most criteria for a good quality study are not met and/or "fatal flaws" in design, analysis or reporting are present; large amounts of missing information; discrepancies in reporting; or serious problems with intervention delivery

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Individual Studies: Risk of Bias –Appendix E

Study Methods Criteria (areas for possible downgrade)

Parallel RCTs

- Random sequence generation
- Statement of allocation concealment
- Intent-to-treat analysis
- Blinding (patients, providers, assessors)
- Groups comparable at baseline
- Complete follow-up of >80% ,
- <10% difference in follow-up between groups
- Reported specified outcomes

Cross-over RCTs (random sequence, concealment, blinding)

- Group comparability baseline/first period
- Washout, mitigation of carryover or carryover effect test
- Completeness of outcome data
- Correlated data analysis

Individual Studies: Risk of Bias

Study Methods Criteria (areas for potential downgrade)

Nonrandomized Studies of Intervention (Observational)

- Patient sampling (random, consecutive) from the same underlying population
- Groups comparable at baseline on key prognostic factors
- Blind, independent assessment of outcomes/analysis
- Follow-up of >80%
- <10% difference in follow-up between groups
- Prespecified outcomes
- Accurate measurement methods
- Follow-up duration reasonable for investigated events
- Controlling for possible confounding
    - Multivariate analysis, matching (including propensity)

*case series are considered at high risk of bias

Strength of Evidence (SoE)- is not the same thing as study risk of bias

SoE for <u>overall body of evidence</u> for primary outcomes is assessed based on:

- **Risk of bias**: the extent to which the individual included studies protect against bias
  - Appropriate randomization
  - Allocation concealment
  - Intention to treat analysis
  - Blind assessment of outcomes
  - Adequate follow-up (≥80%) and <10% follow-up difference between groups
  - Controlling for confounding
- **Consistency**: degree to which estimates across studies of a specific outcome are similar in terms of effect direction, magnitude, range.
- **Directness**: whether the evidence is directly related to patient health outcomes. NOTE: None were considered indirect.
- **Precision**: level of certainty (variability) surrounding the effect estimates.
- **Publication/report bias**: selective reporting or publishing.

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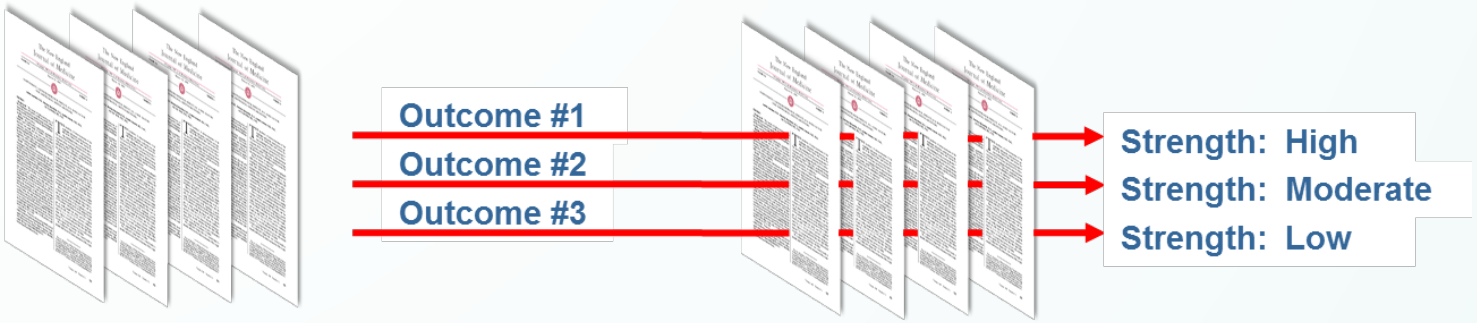
Systematic Review Process

Studies meeting eligibility criteria
- Efficacy: RCTs
- Harms: RCTs, observational studies
- Economic studies (SOE not done)

Risk of Bias Appraisal (Study)
Good, Fair, or Poor
Synthesis/analysis

Overall Strength of Evidence Determination (GRADE/AHRQ)



Strength of Evidence Ratings	
High	Very confident that effect is true.
Moderate	Moderately confident.
Low	Limited confidence.
Insufficient	No evidence or no confidence in effect.

Aggregate Analytics

Magnitude of Effects (Appendix J)

Slight/Small	Moderate	Large/Substantial
Pain		
5–10 points on a 0-to 100-point VAS or the equivalent	>10–20 points on a 0-to 100-point VAS or the equivalent	>20 points on a 0-to 100-point VAS or the equivalent
0.5–1.0 points on a 0-to 10-point numerical rating scale or the equivalent	>1–2 points on a 0-to 10-point numerical rating scale or the equivalent	>2 points on a 0-to 10-point numerical rating scale or the equivalent
Function		
5–10 points on the ODI	>10–20 points on the ODI	>20 points on the ODI
Pain or function		
1.2 to 1.4 RR/OR	1.5 to 1.9 RR/OR	≥2.0 RR/OR

Based on mean between-group differences for continuous scores

Small effects may be below published thresholds for clinically meaningful effects. However, for some patients, a small improvement in pain or function may be important.

Effects below the threshold for small were categorized as no effect (similar between groups)

Results

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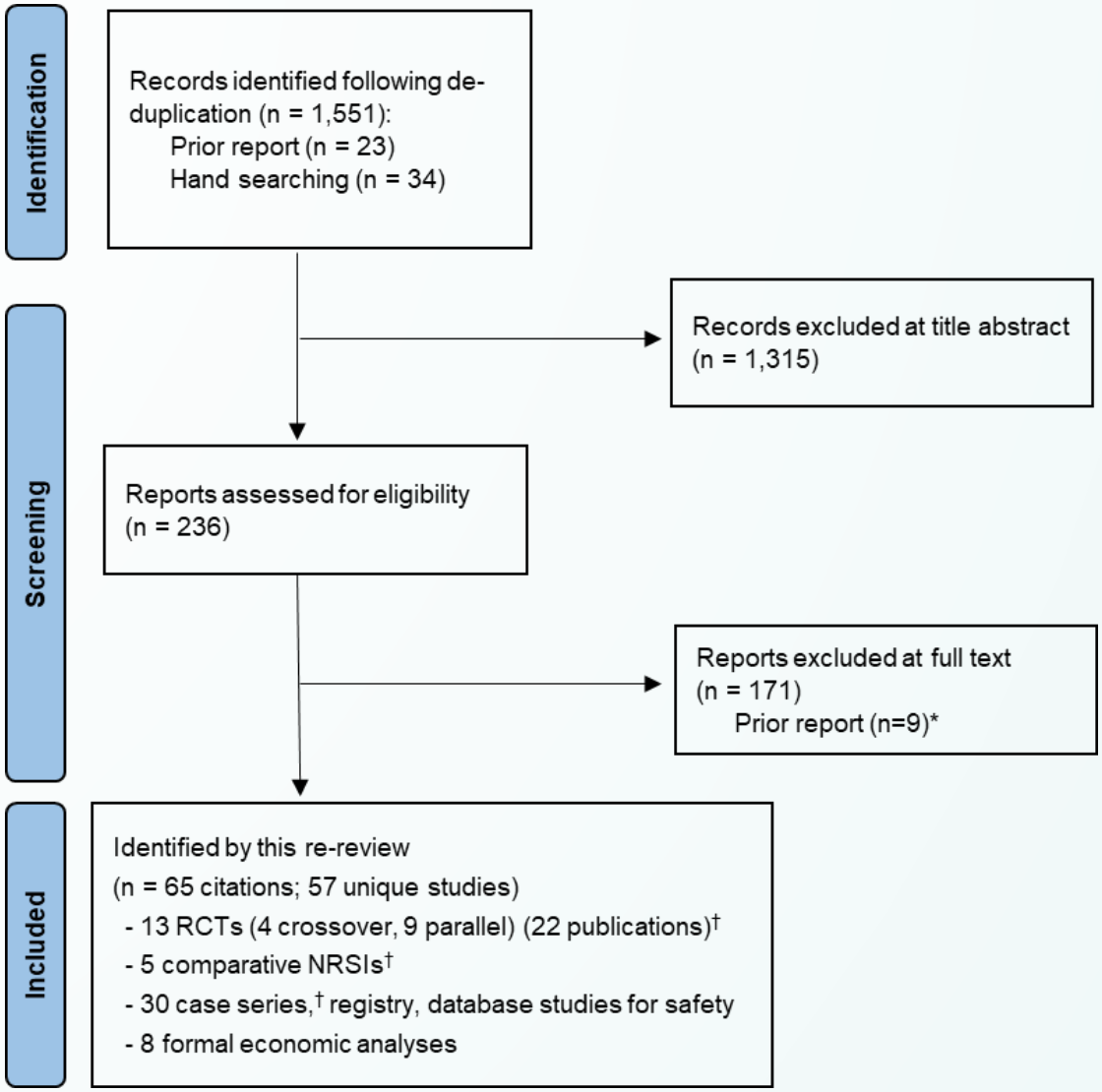
Included Literature

- **Literature search**
  - PubMed, Embase, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews searched 2010 to June 6, 2023
  - Dual abstract review
  - Dual full text review
  - Conference abstracts, non-English-language articles, duplicate publications that did not report different data or follow-up times, white papers, editorials, narrative reviews, preliminary reports, and incomplete economic evaluations excluded



†3 parallel RCT (in 7 publications), 1 prospective comparative NRSI, 6 case series carried over from prior report.

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Overview of Evidence Base

Condition	No. RCTs (Pubs.)	RCT Industry Funded	No. Comp NRSI	No. Case series for safety
FBSS or Nonsurgical refractory back pain				
TOTAL:	7 (10)	5	5	n/a
PAINFUL DIABETIC NEUROPATHY				
TOTAL:	3 (7)	3	0	n/a
COMPLEX REGIONAL PAIN SYNDROME				
TOTAL:	3 (5)	1	0	n/a
TOTAL OVERALL				
– ***Crossover RCTs***	**4**	**50% (2/4)**		
– ***Parallel RCTs***	**9 (18)**	**78% (7/9)**		
– ***NRSIs***			**5**	**30**

Aggregate Analytics

Key Question (KQ) 1: Effectiveness

Primary outcomes:
Pain, Function, Opioid use

Aggregate Analytics

KQ 1 Overview of Evidence Base: Chronic back pain

Condition Intervention vs. Comparator	No. RCTs (Pubs.)	RCT Industry Funded	No. Comp NRSI	No. Case series for safety
CHRONIC BACK PAIN				
Failed back surgery syndrome				
*Crossover trials**				
SCS (Various)† vs. Sham	3	1	n/a	n/a
Parallel trials				
Conventional SCS vs. CMM	2 (5)	2	4	n/a
Conventional SCS vs. Reoperation	1	1	1	n/a
Nonsurgical refractory back pain				
*Parallel trials**				
HF (10 kHz)-SCS vs. CMM	1	1	0	n/a
TOTAL:	7 (10)	5	5	n/a

Crossover trials: Various frequencies and/or modes of operation(e.g., burst) compared with each other and sham (placebo)

Aggregate Analytics

Patient and Intervention Characteristics:
SCS vs. Placebo
(Crossover trials, back pain)

3 crossover RCTs (1 industry funded), 3 publications, N=84 analyzed

- Mean age 50.4 years (range 48 to 57)
- Female: 37.9% (range 14% to 54%)
- Pain duration at least 6 months
- 2 trials required failed conventional medical management
- Trials did not provide details on multidisciplinary evaluation
- All trials excluded individuals with psychological comorbidities
- All trials excluded individuals with substance use disorders
- All patients were implanted and randomly assigned to phases with different SCS programs including a variety of SCS settings (HF-SCS, LF-SCS, burst SCS, cluster activated SCS, etc.) and a placebo/sham setting
- Heterogeneity across studies: populations studied, SCS methods, reporting

Aggregate Analytics

KQ 1 - Chronic back pain: SCS vs. Sham; Crossover trials

	Al-Kaisy 2018 (FAIR)	Hara 2022 (GOOD)	Sokal 2020 (POOR)
Screening	Yes (NOS)	Yes (NOS)	Yes (NOS)
N enrolled	53	65	23*
N, SCS trial complete	36	61	16*
Trial threshold	≥50% pain reduction	≥2 pt NRS reduction -leg pain	≥50% reduction
Permanent implant	92% (33/36)	82% (50/61)	18*
Same device/mode	Unclear	No†	Unclear
N random, analyzed	30, 24	50, 42	18, 18*
Comorbidities	NR	64%	NR
Condition, diagnosis	FBSS (NOS)	Lumbar surgery, radicular pain	FBSS 78% (NOS)
Prior surgery	Yes, (NOS)	Median: 2 (1-3), diskectomy 76%, Fusion 26%, Decompression 22%	Yes (FBSS, NOS)
Active Treatments	1200 Hz, 3030 Hz, 5882 Hz	Burst- 40 HZ, 50% to 70% paresthesia perception threshold	LF: 40-60 Hz, HF (1000 Hz), cluster tonic
Sham	IPG discharge; no stim	No stimulation	IPG deactivated
N Tx periods/length	4 (3 wks)	2 (12 wks)	4 (2 wks)
Washout period	No	Unclear/No	No
Check period effects	Yes	No	No
1st Phase data	NR	NR	NR
Co-intervention, medications	NR	Daily pain meds (baseline) Overall: 64% Opioids: 36%,	Model estimates, Timing NR: Opioids: 49%, NSAIDS: 72%
Funding	Industry	Non-industry	None

Aggregate Analytics

KQ 1 Chronic back pain – SCS vs. Sham, cross-over trials
FUNCTION

Outcome	Crossover phases, time	Studies N (randomized)	SCS vs. Sham Effect estimate (95% CI) Conclusion	Quality (SoE)
Function: ODI (0-100 scale)	2, 12-week phases per intervention Burst vs. Sham SCS	1 RCT (N=50) Hara	M**ean, 95%CI** 34.0 (95% CI 30.0 to 38.1) vs. 35.4 (95% CI 31.3 to 39.4) **MD in change scores:** -1.3 (95% CI -3.9 to 1.3, p=0.32) **Conclusion**: Similar functional improvement between burst SCS and sham	⊕⊕⊕◯ MODERATE (unknown consistency)

Patients: Persistent radicular pain following low back surgery

KQ 1 Chronic back pain, SCS vs. Sham, cross-over trials: Pain

Outcome	Crossover phases, time	Studies N (randomized)	SCS vs. Sham Effect estimate (95% CI) Conclusion	Quality (SoE)
Back pain VAS or NRS (0-10 scale)	2, 12-week phases per intervention	Burst vs. Sham 1 RCT (N=50) Hara 2022 Persistent radicular pain after surgery	**MD**, −0.2 (95% CI −0.7 to 0.2), p=0.32 **<u>Conclusion</u>: Similar back pain improvement between burst SCS and sham**	⊕⊕⊕◯ MODERATE (unknown consistency)
	For 4, 3-week phases (over 12 weeks)	Multiple frequencies (1200 Hz, 3030 Hz, 5882 Hz) vs. sham 1 RCT (N=24) Al-Kaisy 2018 FBSS	**MD (95%CI) from author data** 1200 Hz vs. Sham: MD -0.32 (-1.59 to 0.94) 3030 Hz vs. Sham: MD -0.26 (-1.58 to 1.06) **5882Hz vs. Sham:** **MD-1.61 (-2.67 to -0.55) CI calculated from p-value** MD (95%CI) Calculated by Cochrane* 1200 Hz vs. Sham: MD -0.32 (-2.17 to 1.54) 3030 Hz vs. Sham: MD -0.26 (-2.1 to 1.63) 5882 Hz vs. Sham: MD-1.61 (-3.48 to 0.26) **<u>Conclusion</u>: Insufficient evidence to draw firm conclusions**.	⊕◯◯◯ INSUFFICIENT (ROB, unknown consistency, imprecision)

Aggregate Analytics

KQ 1 Chronic back pain, SCS vs. Sham, cross-over trials: Pain

Outcome	Crossover phases, time	Studies N (randomized)	SCS vs. Sham Effect estimate (95% CI) Conclusion	Quality (SoE)
Leg pain (0-10 scale)	2, 12-week phases per intervention	Burst vs. Sham 1 RCT (N=50) Hara 2022	MD, −0.2 (95% CI −0.7 to 0.2), p=0.32 **Conclusion:** Similar leg pain improvement between burst SCS and sham	⊕⊕◯◯ LOW (unknown consistency, imprecision)
	For 4, 3-week phases (over 12 weeks)	Multiple frequencies (1200 Hz, 3030 Hz, 5882 Hz) vs. sham 1 RCT (N=24) Al-Kaisy 2018 FBSS	Mean (SD or CI) Sham: 2.51 (NR) 1200 Hz: 2.37 (NR) 3030 Hz: 2.20 (NR) 5882 Hz: 1.81 (NR) P across groups = 0.367 **Conclusion:** Evidence insufficient to draw conclusions	⊕◯◯◯ INSUFFICIENT (ROB, unknown consistency, imprecision)
VAS Pain (NOS, 0-10 scale)	4, 2-week periods per intervention	1 RCT (N=18) Sokal 2020 FBSS	**Adjusted MD (95%CI)*** 1000 Hz: -0.17 (-0.77 to 0.43) LF tonic: -0.99 (-2.25 to 0.27) Cluster tonic: -0.03(-1.06 to 1.0) **Conclusion:** Evidence from this poor-quality trial is insufficient.	⊕◯◯◯ INSUFFICIENT (ROB -2, unknown consistency, imprecision)

Patient and Intervention Characteristics:
SCS vs. CMM/Reoperation (Parallel Trials, FBSS and NSRBP)

4 RCTs (4 industry funded), 6 publications, N=577

- Mean age 47.9 years (range 38 to 54)
- Female: 56.8% (range 48.7% to 60.6%)
- Pain duration ranged from 6.7 years to 8.3 years
- 3 trials used conventional SCS, 1 trial used 10 kHz HF-SCS
- 3 trials compared SCS vs. CMM, 1 trial compared SCS vs. Reoperation
- 2 trials required failed conventional medical management
- 2 trials used multidisciplinary evaluation
- 3 trials excluded individuals with psychological comorbidities
- 2 trials excluded individuals with substance abuse disorders
- Patients randomized to SCS underwent trial; if successful trial patients had permanent implant.
- All trials allowed patients to cross over to SCS after 6 months.
- Heterogeneity in populations studied and SCS devices/methods

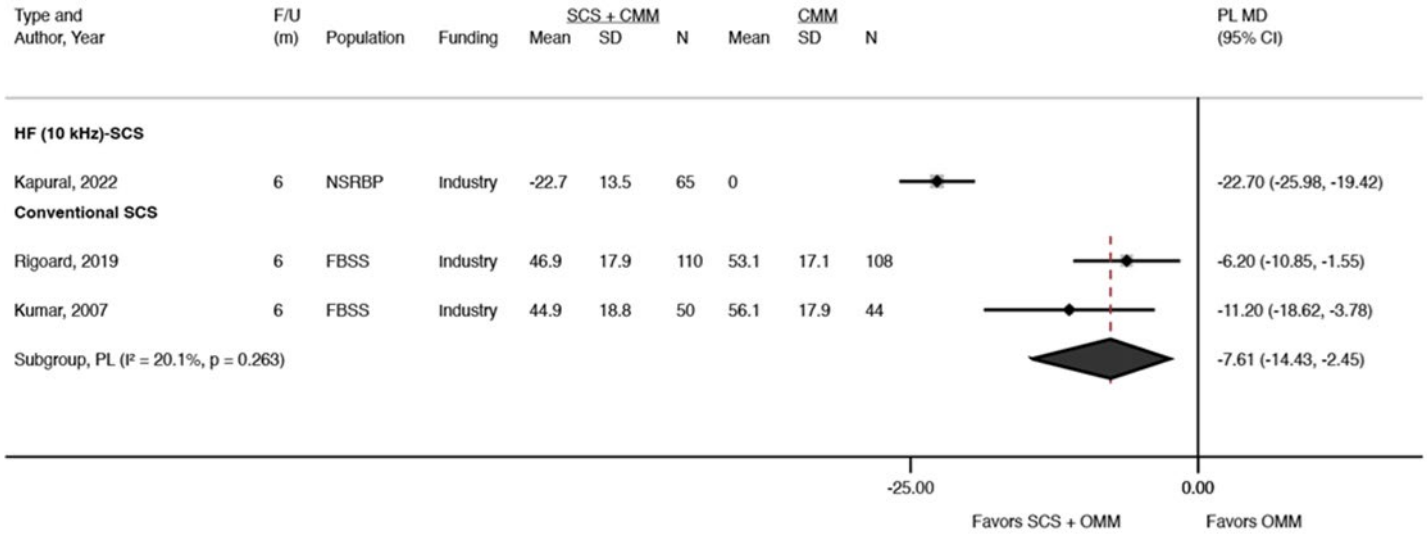
Aggregate Analytics

KQ 1 Chronic back pain – SCS vs. CMM, Parallel Trials
Function – ODI Responders and ODI scores

Function - ODI Responder

Author, year	Definition	Timing	10 kHz SCS % (n/N)	CMM % (n/N)	RR (95% CI)	Conclusion SOE
Kapural, 2022 **NSRBP** **HF (10 kHz) SCS** **PP analysis**	≥10 point reduction in ODI score (0-100)	1 mos.	67.7% (46/68)	8.1% (6/75)	8.45 (3.86, 18.54)	**Large improvement** **SOE: LOW** *Downgrades*: RoB, Imprecision
		3 mos.	80.9% (55/68)	12.0% (9/75)	6.74 (3.61, 12.58)	
		6 mos.	78.5% (51/65)	4.0% (3/75)	18.75 (6.13, 57.31)	

Function - ODI Scores (0-100 scale): Different SCS and population



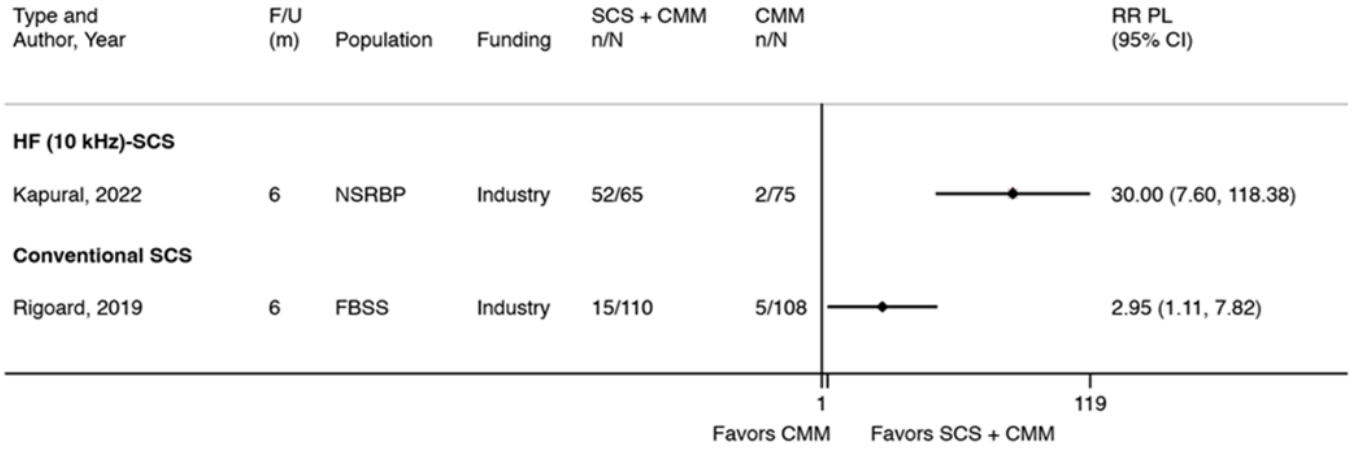
HF SCS:
Large improvement
MD -22.7 (-26.0, -19.4)

Conv. SCS:
Small improvement
MD -7.6 (-14.5, -2.5), I^2=20%

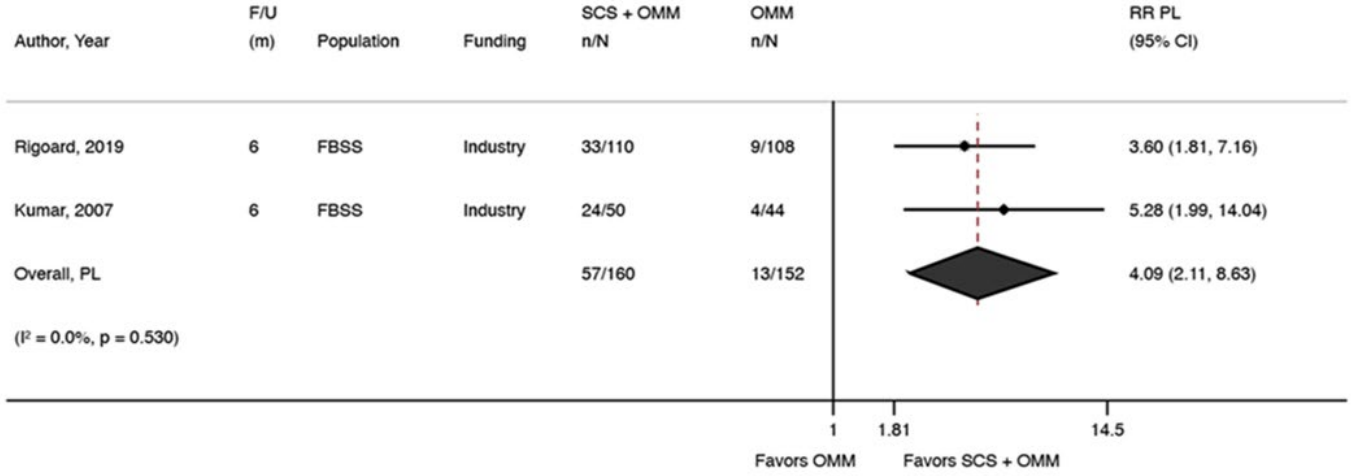
SOE: LOW
(RoB, Imprecision)

KQ 1 Chronic back pain – SCS vs. CMM, Parallel Trials
Pain Responders (≥ 50% decrease, 0-10 VAS)

Back Pain Responders



Leg Pain Responders (Conventional SCS)



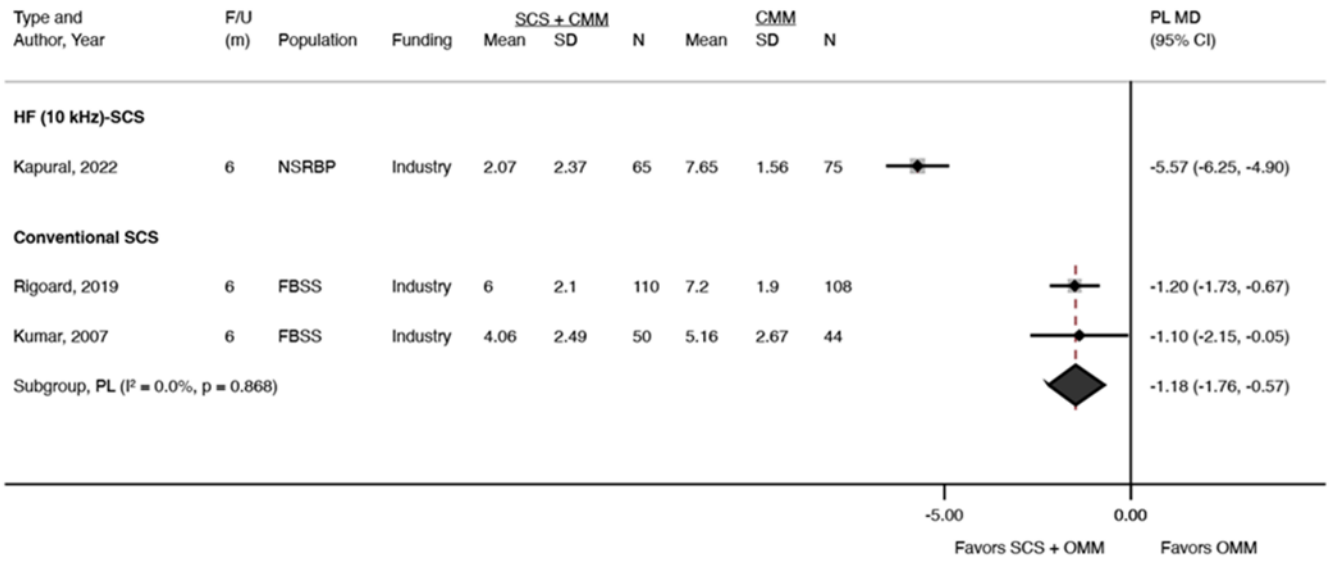
Large improvement (both outcomes) for both HF and Conv.

Same conclusion at 3 months (back pain, 1 RCT, HF SCS; leg pain, 1 RCT, conv. SCS)

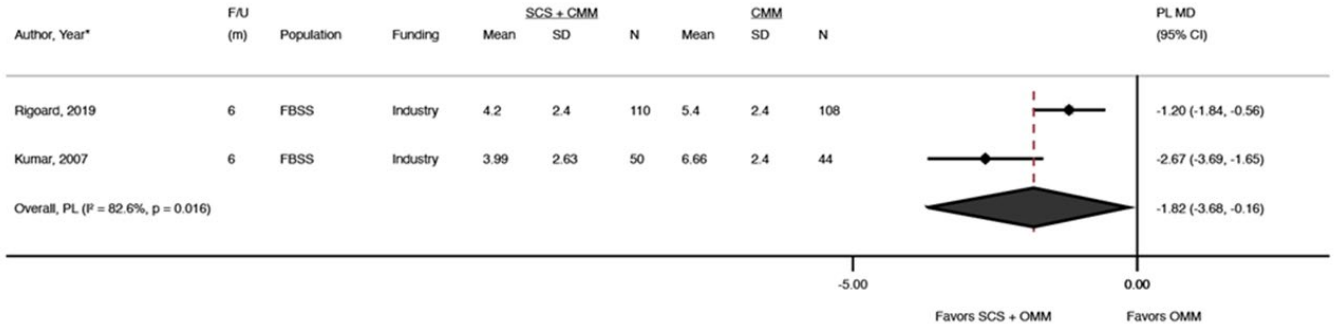
SOE: LOW for all (RoB, Imprecision)

KQ 1 Chronic back pain – SCS vs. CMM, Parallel Trials
Pain Scores (0-10 VAS)

Back Pain



Leg Pain (Conv. SCS)



Back Pain

HF SCS: Large improvement

Conv. SCS: Moderate improvement

3 months: Same conclusion in HF SCS trial; small improvement in 1 Conv. SCS trial

SOE: LOW (RoB, imprecision)

Leg Pain

Pooled MD -1.8 (-3.7, -0.16), I^2=83%, Moderate improvement

Substantial heterogeneity, diff. in patient populations

SOE: LOW (RoB, Imprecision)

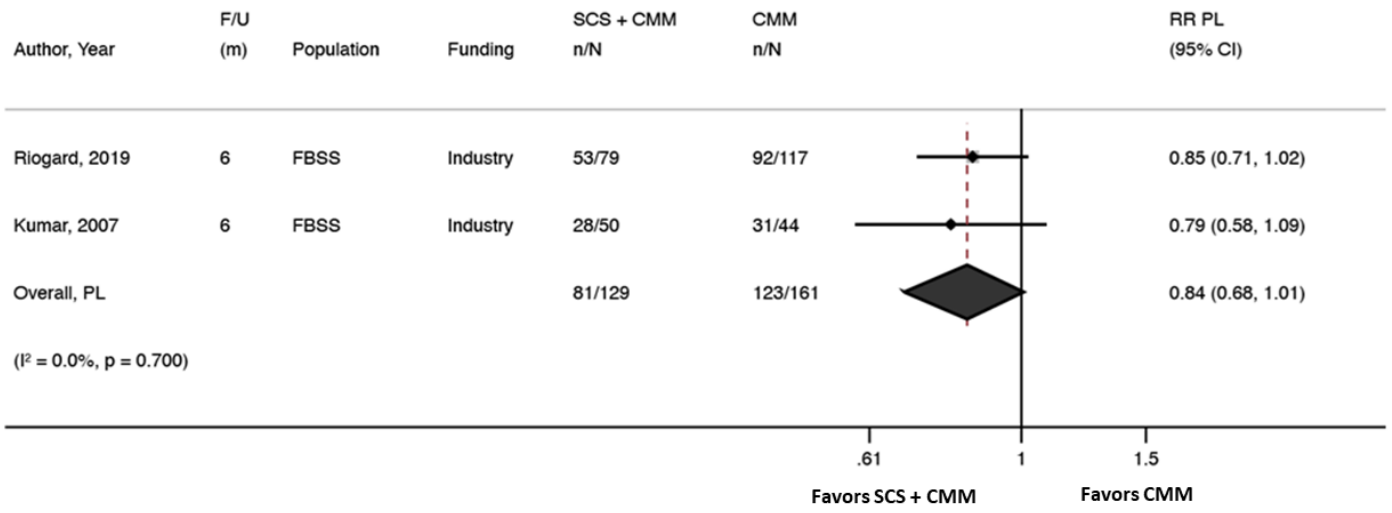
KQ 1 Chronic back pain – SCS vs. CMM, Parallel Trials
Opioid use

Change in Opioid Use (HF 10 kHz SCS)

Author, year	Outcome	10 kHz SCS % (n/N)	CMM % (n/N)	RR (95% CI)
Kapural, 2022 NSRBP 6 months PP analysis	Stopped use	22% (16/65)	0% (0/75)	NC, p<0.05
	Decreased use	44% (27/65)	17% (13/75)	2.40 (1.35 to 4.25)
	Increased use	6% (4/65)	49% (37/75)	0.12 (0.05 to 0.33)

Substantially more **HF SCS** patients decreased or stopped opioid use; substantially fewer increased opioid use

Proportion Using Opioids (Conv. SCS)

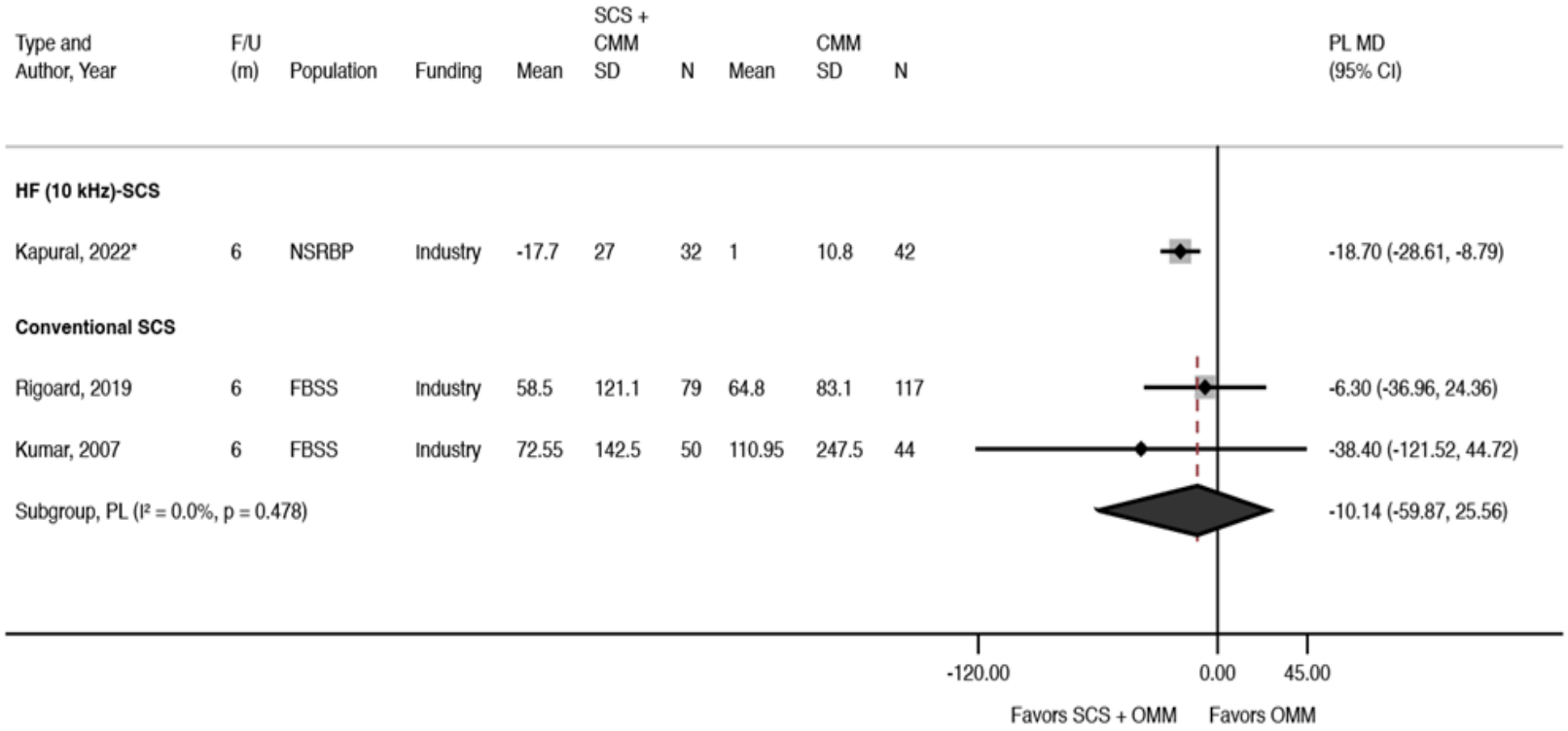


Small decrease in the likelihood of continued opioid use with **Conv. SCS**

SOE: LOW for all (RoB, Imprecision)

KQ 1 Chronic back pain – SCS vs. CMM, Parallel Trials
Opioid use

Mean daily MME dose (mg)



HF SCS: Stat. significant reduction in mean MME dose, clinical significance unclear (**SOE: Low**, ROB, imprecision)

Conv. SCS: Similar between groups (**SOE: Insufficient,** RoB, Inconsistency, Imprecision)

KQ 1 Chronic back pain – SCS vs. Reoperation

All evidence considered **INSUFFICIENT** to draw conclusions (ROB, unknown consistency, imprecision)

1 small (N=45), fair-quality RCT, FBSS
SCS associated with a:

- Large increase in the likelihood of achieving treatment success (pain relief ≥ 50% and patient satisfied)
- Moderate increase in likelihood of being on a stable or decreased dose of opioids versus reoperation

Aggregate Analytics

KQ 1 Overview of Evidence Base: Painful Diabetic Neuropathy

Condition Intervention vs. Comparator	No. RCTs (Pubs.)	RCT Industry Funded	No. Comp NRSI	No. Case series for safety
PAINFUL DIABETIC NEUROPATHY				
*Parallel trials**				
HF (10 kHz)-SCS vs. CMM	1 (3)	1	0	n/a
Conventional SCS vs. CMM	2 (4)	2	0	n/a
TOTAL:	3 (7)	3	0	n/a

Aggregate Analytics

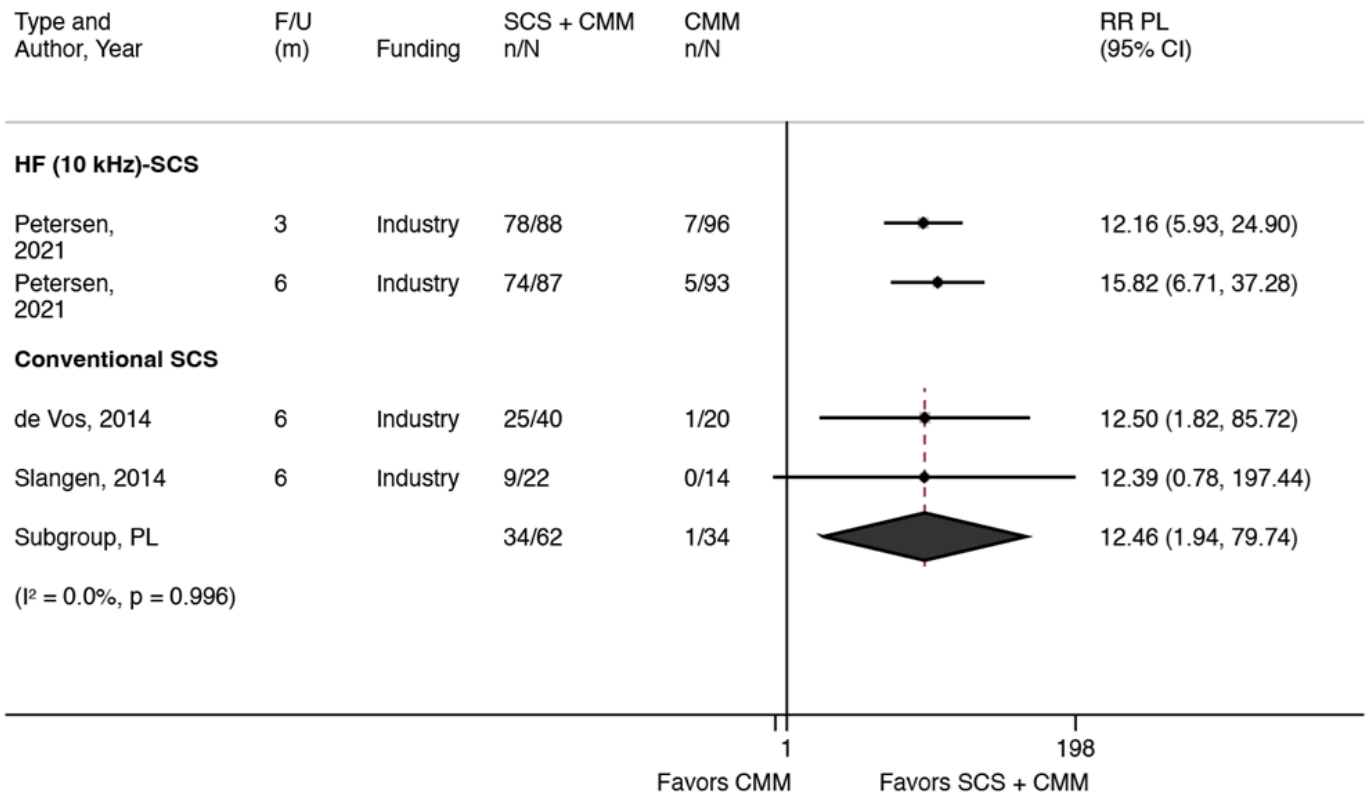
Patient and Intervention Characteristics:
SCS vs. CMM (PDN)

3 RCTs (3 industry funded), 7 publications, N=312

- Mean age 60.2 years (range 57 to 61)
- Female: 54.5% (range 33% to 63%)
- Pain duration ranged from 5.5 years to 7 years
- All trials used conventional SCS
- All trials required failed conventional medical management
- 1 trials used multidisciplinary evaluation
- All trials excluded individuals with psychological comorbidities
- All trials excluded individuals with substance abuse disorders
- Patients randomized to SCS underwent trial; if successful trial patients had permanent implant.
- All trials allowed patients to cross over to SCS after 6 months.

Aggregate Analytics

KQ 1 PDN – SCS vs. CMM, Parallel RCTs
Pain responders (≥50% reduction in LE pain on VAS/NRS, 0-10)



Large increase in the likelihood of achieving LE pain response for all:

HF SCS:
3 and 6 months

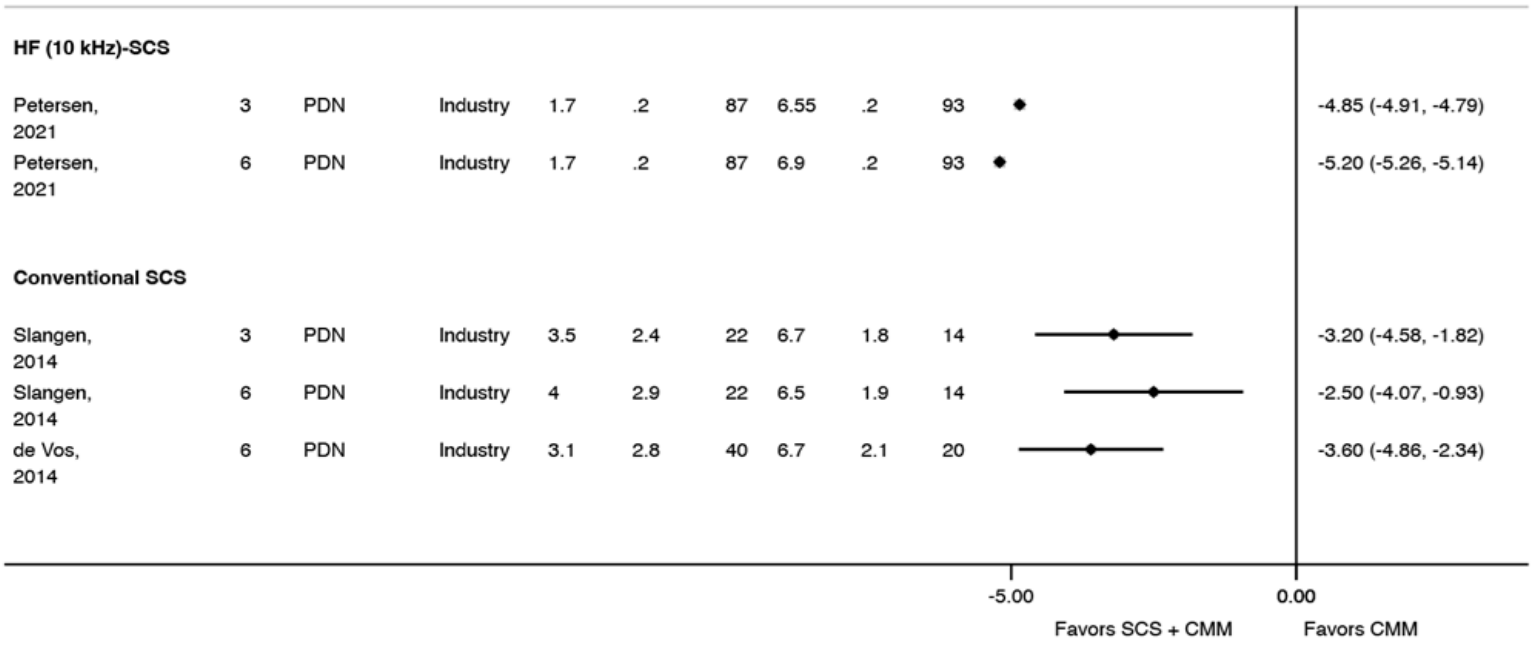
Conv. SCS:
6 months, pooled RR 12.5 (1.9, 79.7), I^2=0%

SOE LOW for all
(RoB, Imprecision)

Aggregate Analytics SOE

KQ 1 PDN – SCS vs. CMM, Parallel RCTs
LE pain scores (VAS/NRS 0-10)

Type and Author, Year	F/U (m)	Population	Funding	SCS + CMM Mean	SCS + CMM SD	SCS + CMM N	CMM Mean	CMM SD	CMM N	PL MD (95% CI)
HF (10 kHz)-SCS										
Petersen, 2021	3	PDN	Industry	1.7	.2	87	6.55	.2	93	-4.85 (-4.91, -4.79)
Petersen, 2021	6	PDN	Industry	1.7	.2	87	6.9	.2	93	-5.20 (-5.26, -5.14)
Conventional SCS										
Slangen, 2014	3	PDN	Industry	3.5	2.4	22	6.7	1.8	14	-3.20 (-4.58, -1.82)
Slangen, 2014	6	PDN	Industry	4	2.9	22	6.5	1.9	14	-2.50 (-4.07, -0.93)
de Vos, 2014	6	PDN	Industry	3.1	2.8	40	6.7	2.1	20	-3.60 (-4.86, -2.34)



6 months: pooled MD -3.2 (-4.5 to -1.7), I^2=12.7%

- Both types of SCS associated with a large improvement in LE pain scores at 3 months (1 RCT each) and 6 months (1 RCT, HF SCS; 2 RCTs, Conv. SCS)
- **SOE: LOW for all** (RoB, Imprecision)

Aggregate Analytics

KQ 1 PDN – SCS vs. CMM, Parallel RCTs
Opioid Use

1 RCT (N=60), Conventional SCS (+ CMM) vs. CMM, 6 months

Similar between groups:

- Proportion taking opioids:
  37.5% (15/40) vs. 55.0% (11/20); RR 0.68 (95% CI 0.39 to 1.20)
- Medication Quantification Scale III scores
  MD -2.4 (95% CI -7.08 to 2.28)

SOE: LOW for both outcomes (RoB, Imprecision)

Aggregate Analytics

KQ 1 Overview of Evidence Base: Complex Regional Pain Syndrome (CRPS)

Condition Intervention vs. Comparator	No. RCTs (Pubs.)	RCT Industry Funded	No. Comp NRSI	No. Case series for safety
COMPLEX REGIONAL PAIN SYNDROME				
Crossover trials[*]				
SCS[‡] vs. Sham	1	1	n/a	n/a
Parallel trials[*]				
HF (10 kHz)-SCS vs. CMM	1	0	0	n/a
Conventional SCS vs. CMM	1	0	0	n/a
Conventional SCS vs. PT	1 (3)	0	0	n/a
TOTAL:	3 (5)	1	0	n/a

Aggregate Analytics

Patient and Intervention Characteristics: SCS vs. PT/CMM (CRPS, Parallel); SCS vs. Sham (CRPS, Crossover)

2 RCTs (0 industry funded), 4 publications; 1 crossover RCT (industry), N=95

- Mean age 42.5 years (range 38 to 49)
- Female: 54.5% (range 14% to 78%)
- Pain duration ranged from at least 12 months to 38 months
- 1 trial used conventional SCS+PT vs. PT alone, 1 trial used LF-SCS vs. CMM, crossover trial used LF-SCS, HF-SCS, burst SCS, and placebo
- All trials required failed conventional medical management
- All trials used multidisciplinary evaluation
- 1 trials excluded individuals with psychological comorbidities
- 2 trials excluded individuals with substance abuse disorders
- **Parallel RCTs**, patients implanted with SCS devices after successful trial. One trial allowed patients to cross over to PT at trial failure; the other allowed cross-over at 6 months.
- **Crossover RCT**, patients randomly assigned to different SCS settings (HF-SCS, LF-SCS, burst SCS, etc.) and a sham/placebo setting; Trial included a 2-day washout between settings.

Aggregate Analytics

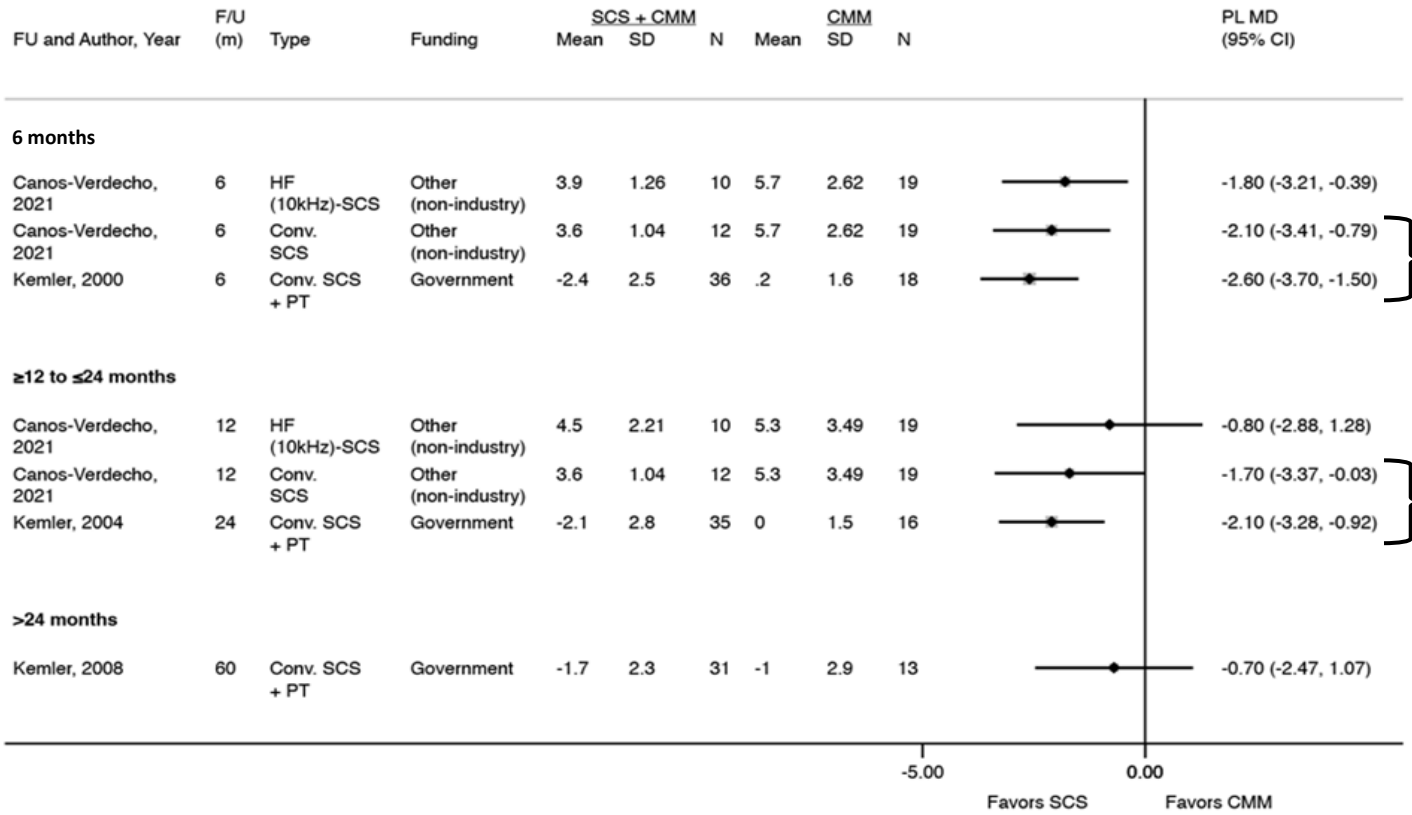
KQ 1 CRPS – SCS vs. CMM, Parallel RCTs
Function scores (ODI, 0-100)

			Mean (SE)			MD (95% CI)	
Author, year	**Outcome**	**Timing**	**10 kHz SCS (n=10)**	**Conv. SCS (n=12)**	**CMM (n=19)**	**10 kHz SCS vs. CMM**	**Conv. SCS vs. CMM**
Canos-Verdecho, 2021 ***Poor-quality*** **ITT analyses**	ODI (0-100, worst)	*Baseline*	*65.0 (6.6)*	*58.5 (4.3)*	*32.4 (4.4)*	*32.6 (25.76, 39.44)*	*26.1 (20.56, 31.64)*
		3 mos.	29.4 (3.4)	17.3 (3.0)	31.5 (4.4)	-2.1 (-5.66, 1.46)	-14.2 (-18.81, -9.59)
		6 mos.	31.20 (3.6)	16.8 (3.0)	22.9 (4.5)	8.3 (4.54, 12.06)	-6.1 (-10.77, -1.43)
		12 mos.	33.2 (4.8)	17.0 (3.0)	22.0 (4.7)	11.2 (6.23, 16.17)	-5.0 (-9.79, -0.21)

Evidence from one poor-quality trial was INSUFFICIENT to draw conclusions

Aggregate Analytics

KQ 1 CRPS – SCS vs. CMM, Parallel RCTs
Pain scores (VAS/NRS 0-10)



Conv. SCS: 6 months, pooled MD -2.39 (-3.39 to -1.34), I^2=0%

Conv. SCS: 12-24 months, pooled MD -1.97 (-3.08 to -0.77), I^2=0%

- **HF (10 kHz) SCS, 1 poor-quality RCT:** Moderate improvement at 6 mos., similar at 12 mos. *(**SOE: INSUFFICIENT,** ROB, unknown consistency, imprecision)*

- **Conv. SCS, 1 fair-, 1 poor-quality RCT:** Large (6 mos.) and moderate (12-24 mos.) improvement, similar at 60 mos. *(**SOE: LOW** based on fair-quality trial)*

KQ 1 CRPS – SCS vs. Placebo (Crossover trial)

Evidence from one poor-quality trial was INSUFFICIENT to draw conclusions

Outcome	SCS type	SCS Mean (SD)	Sham Mean (SD)	MD, (95% CI unadjusted)	MD, (95% CI adjusted) O'Connell – Cochrane
Primary Outcomes					
VAS Pain (0-10)	40 Hz	3.98 (2.53)	6.37 (1.89)	-2.39 (-3.57 to -1.22)	-2.39 (-4.35 to -0.43)
	500 Hz	4.01 (2.66)		-2.36 (-3.58 to -1.15)	Not calculated
	1200 Hz	4.29 (2.58)		-2.08 (-3.27 to -0.89)	-2.08 (-4.1 to -0.06)
	Burst	4.798 (2.82)		-1.58 (-2.84 to -0.31)	-1.5 (-3.79 to 0.65)
McGill NRS Average pain (0-10)	40 Hz	4.70 (2.15)	7.07 (1.51)	-2.37 (-3.35 to 1.39)	NR
	500 Hz	5.10 (2.42)		-1.97 (-3.03 to -0.91)	NR
	1200 Hz	5.31 (2.48)		-1.76 (-2.84 to -0.68)	NR
	Burst	5.66 (2.64)		-1.41 (-2.54 to -0.28)	NR

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Key Question (KQ) 2: Safety

Aggregate Analytics

KQ 2: Safety and Adverse events
Evidence from trials – SOE Low

Low SOE for the following AE categories reported in RCTs:

- **Any SCS related AE:** 12.4% to 17.6% within 6 months (2 RCTs, Ns = 102 and 113) and 24.1% to 32.1% between 12-24 months (3 RCTs, Ns 84 to 174) in parallel group RCTs; 18% in 1 cross-over trial (N=50)

- **SCS-related AEs requiring surgery**: 11.8% to 16.7% at 6 months (Ns 24 and 102) and from 23.8% to 37.5% at 12-24 months (Ns, 24 to 102) in 2 parallel group RCTs

- **Withdrawal due to AEs** similar for SCS and CMM within 6 months of implant; substantial imprecision in estimates noted.

KQ 2: Safety and Adverse events
Evidence across study designs: SOE Low or moderate

- **Device-related events (SOE low for all):**

  <u>Most common</u>
  - Any IPG device explantation: 1.4% to 25.2%
  - Any IPG revision or replacement: 0.9% to 22%
  - IPG removal for inadequate pain relief, loss of efficacy, lack of efficacy, inadequate benefit: 0% to 20.3%
  - Any lead/electrode replacement or revision: 3.4% to 17.9% (1 small trial excluded)
  - Lead failure or migration (surgery not specified): 0.9% to 9.5%
  - Lead fracture or failure: 1.1% to 15.8%

  <u>Less common</u>
  - IPG removal for infection (1% to 5%) or infect or dehiscence (2.5% to 4.8%)
  - IPG revision or removal due to IPG displacement or migration: 0.5% to 1.2%
  - Serious infection (deep, fatal, leading to revision, removal, or hospitalization): 1.4% to 6%; reported within 30 days 0.9%
- **Unintentional durotomy 6% (3/50); CSF leak, dural tear 0.6% to 0.7%**
- **Neurologic injury** (deficit, paralysis, intraspinal abscess): 0% to 4% (SOE Moderate)

KQ 2: Safety and Adverse events
Evidence across study designs: SOE Insufficient

- **RCTs (parallel group and crossover)**
  - Mortality
  - Any SCS-related AE requiring surgery long term (60 months)
  - Any serious SCS-related AE
  - Withdrawal due to AE (NOS)
  - 1 small trial in CRPS: serious AE, Electrode dislocation or reconfiguration, unable to attain comfortable paresthesia, SCS parameter concerns
- **Across study designs (for NRSI, studies of >100 pts)**
  - IPG removal due to malfunction
  - Allergic reaction or anaphylaxis
  - AE requiring hospitalization

Aggregate Analytics

Key Question (KQ) 3: Differential efficacy or safety

No Evidence

Key Question (KQ) 4: Cost effectiveness

(Overall SOE is not done for economic studies)

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KQ 4: Cost effectiveness – new studies

8 full new economic studies, 5 industry funded, 2 US-based

- **Back pain, 2 US-based studies –mixed results**
  - FBSS: Cost effectiveness study in Workers Compensation population (good quality)
    - SCS not cost-effective at common WTP thresholds vs. pain clinic referral or UC, 24-month time-horizon
    - Applicability to other populations unclear
  - Nonsurgical refractory back pain (NSRBP):
    - CUA of 10kHz SCS + CMM vs. CMM (poor quality)
    - Base case: SCS cost-effective vs. CMM at 6 months, modeling excluded initial SCS and procedure costs; Inclusion of these costs - ICER <$200K/QALY at 6 months, $100K/QALY at 12 months, cost-effectiveness at ~2.1 years
    - Unclear modeling of AEs, limited sensitivity analyses

KQ 4: Cost effectiveness – new non-US studies

- FBSS, 4 CUAs outside of US (3 good quality, 1 poor):
  - SCS + CMM cost-effective vs. CMM (3 studies) and vs. reoperation (1 study
  - Limitations: time-horizons beyond available clinical data, unclear modeling of long-term benefits and complications. Not all included initial SCS trial or implantation procedure costs; effectiveness assumptions unclear
- CRPS, 3 good quality CUAs
  - SCS + CMM was more cost-effective than CMM alone based on usual willingness to pay thresholds
  - All note concern about lack of high-quality long-term data on benefits, harms, and costs to support long-term modeling but modeled 15-20 year.
  - Modeling of AEs unclear
- PDN, 1 good quality CUA
  - SCS was not cost-effective short term due to substantial initial SCS cost; SCS considered more effective; Cost-effectiveness sensitive to baseline cost imbalances; the impact of imputing missing data was unclear.
- Applicability of non-US studies to US system unclear

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Summary of Findings

Summary: KQ1
Chronic Back Pain, SCS vs. Sham, Crossover Trials

Measure	SCS type(s)	≤3 months	>3 to <12 months	≥12 months
Chronic radiculopathy				
Function: ODI (0-100)	Burst	No evidence	Similar, 1 RCT (SOE: Moderate)	No evidence
VAS back pain (0-10)	Burst	No evidence	Similar, 1 RCT (SOE: Moderate)	No evidence
VAS leg pain (0-10)	Burst	No evidence	Similar, 1 RCT (SOE: Low)	No evidence
FBSS				
Function (any measure)	Various frequencies	No evidence	No evidence	No evidence
VAS back pain (0-10)	1200 Hz 3030 Hz 5882 Hz	Insufficient*	No evidence	No evidence
VAS leg pain (0-10)	1200 Hz 3030 Hz 5882 Hz	Insufficient	No evidence	No evidence
VAS pain, NOS (0-10)	1000 Hz LF tonic Cluster tonic	Insufficient	No evidence	No evidence

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*Favors SCS unless otherwise indicated

Summary: KQ1
FBSS (with radiculopathy*): Conventional SCS vs. CMM – Parallel Trials

Measure	3 months	6 months	≥12 months (comparative)
FBSS with radiculopathy,* Conventional SCS			
LBP Responders (≥50% on VAS/NPRS)	No evidence	Large increase, 1 RCT (N=218) SOE: Low	No evidence
Leg Pain Responders (≥50% on VAS/NPRS)	Large increase, 1 RCT (N=94) SOE: Low	Large increase, 2 RCTs (N=312) SOE: Low	No evidence
LBP pain scores (VAS/NPRS, 0-10)	Small, 1 RCT (N=94) SOE: Low	Moderate, 2 RCTs (N=312) SOE: Low	No evidence
Leg pain scores (VAS/NPRS, 0-10)	Large, 1 RCT (N=94) SOE: Low	Moderate, 2 RCTs (N=312) SOE: Low	No evidence
Function Responders (≥10-pt. reduction, ODI)	No evidence	No evidence	No evidence
Function scores (ODI, 0-100)	No evidence	Small, 2 RCTs (N=312) SOE: Low	No evidence
Proportion of patients still using opioids	No evidence	Small decrease, 2 RCTs (N=290) SOE: Low	No evidence
Opioid use: mean MME dose	No evidence	2 RCTs (N=312) SOE: Insufficient	No evidence

Favors SCS unless otherwise noted

*1 RCT, patients with leg pain greater than back pain; the other, patients with back pain greater than leg pain

Summary: KQ1
NSRBP, HF (10 kHz) SCS vs. CMM – Parallel Trials

Measure	3 months	6 months	≥12 months (comparative)
Nonsurgical Refractory Back Pain (NSRBP), HF (10 kHz) SCS			
LBP Responders (≥50% on VAS/NPRS)	Large increase, 1 RCT (N=159) SOE: Low	Large increase, 1 RCT (N=140) SOE: Low	No evidence
Leg Pain Responders (≥50% on VAS/NPRS)	No evidence	No evidence	No evidence
LBP pain scores (VAS/NPRS, 0-10)	Large, 1 RCT (N=143) SOE: Low	Large, 1 RCT (N=140) SOE: Low	No evidence
Leg pain scores (VAS/NPRS, 0-10)	No evidence	No evidence	No evidence
Function Responders (≥10-pt. reduction, ODI)	Large, 1 RCT (N=143) SOE: Low	Large, 1 RCT (N=140) SOE: Low	No evidence
Function scores (ODI, 0-100)	No evidence	Large, 1 RCT (N=140) SOE: Low	No evidence
Proportion of patients who stopped or decreased opioids	No evidence	Large increase, 1 RCT (N=140) SOE: Low	No evidence
Opioid use: mean MME dose	No evidence	1 RCT (N=74) SOE: Insufficient	No evidence

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Favors SCS unless otherwise noted

Summary: KQ1
FBSS, SCS vs. Reoperation – Parallel Trials

Evidence from one poor quality RCT (N=60) was INSUFFICIENT to draw conclusions

Measure	Mean 2.9 years
Treatment success (≥50% pain improvement and patient satisfaction)	Large, 1 RCT (N=45)
Opioid use: % taking a stable or decrease dose	Moderate, 1 RCT (N=45)

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Summary: KQ1
PDN, SCS vs. CMM – Parallel Trials

Measure	3 months	6 months	≥12 months (comparative)
Conventional SCS			
LE Responders (≥50% on VAS/NPRS)	No evidence	Large increase, 2 RCTs (N=96) SOE: Low	No evidence
LE Pain scores (VAS/NPRS, 0-10)	Large, 1 RCT (N=36) SOE: Low	Large, 2 RCTs (N=96) SOE: Low	No evidence
Opioid use: Proportion of patients still taking opioid; MSQ II scores	No evidence	Similar, 1 RCT (N=60) SOE: Low	No evidence
HF (10 kHz) SCS			
LE Responders (≥50% on VAS/NPRS)	Large increase, 1 RCT (N=184) SOE: Low	Large increase, 1 RCT (N=184) SOE: Low	No evidence
LE Pain scores (VAS/NPRS, 0-10)	Large, 1 RCT (N=180) SOE: Low	Large, 1 RCT (N=180) SOE: Low	No evidence
Opioid use	No evidence	No evidence	No evidence

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*Favors SCS unless otherwise noted

Summary: KQ1
CRPS, SCS vs. CMM or Sham

Parallel Trials: SCS vs. CMM

	3 months	6 months	12-24 months	60 months (comparative)
Conventional SCS				
Pain scores (VAS/NRS, 0-10)	Large, 2 RCTs (N=85) SOE: Low	Large, 2 RCTs (N=85) SOE: Low	Moderate, 2 RCTs (N=82) SOE: Low	1 RCT (N=44) SOE: Insufficient
Function scores (ODI, 0-100)	Moderate, 1 RCT (N=31) SOE: Low	Small, 1 RCT (N=31) SOE: Low	Small, 1 RCT (N=31) SOE: Low	No evidence
HF (10 kHz) SCS				
Pain scores (VAS/NRS, 0-10)	1 RCT (N=29) SOE: Insufficient	1 RCT (N=29) SOE: Insufficient	1 RCT (N=29) SOE: Insufficient	No evidence
Function scores (ODI, 0-100)	1 RCT (N=29) SOE: Insufficient	1 RCT (N=29) SOE: Insufficient	1 RCT (N=29) SOE: Insufficient	No evidence

Crossover Trial: SCS vs. Sham

Measure	SCS type(s)	≤3 months	>3 to <12 months	≥12 months
VAS pain (NOS) (0-10)	40 Hz 500 Hz 1200 Hz Burst SCS	Insufficient	No evidence	No evidence
McGill NRS average pain (0-10)		Insufficient	No evidence	No evidence

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*Favors SCS unless otherwise indicated

Summary: KQ 1b
Harms and Safety of SCS

- Substantial heterogeneity in classification, reporting, lack of consistency in definitions and severity description
- SCS-related AEs common, substantial range of event frequencies
- RCTs (SOE Low)
  - Any SCS-related AE: 12.4% to 17.6% (6 months), 24.1% to 32.1% (12-24 months)
  - SCS-related, requiring surgery: 11.8% to 16.7% (6 months), 23.8% to 37.5% (12-24 months)
  - Withdrawal due to AE: similar within 6 months
- Across designs, most common (SOE: Low)
  - Any IPG device explantation: 1.4% to 25%
  - Any IPT revision or replacement: 0.9% to 22%
  - IPG removal-inadequate relief, loss of efficacy, lack of efficacy, inadequate benefit: 3% to 20%
  - Any lead/electrode replacement or revision: 3.4% to 20.8%
  - Lead fracture or failure: 1.1% to 15.8%

Summary: KQ 1b
Harms and Safety of SCS

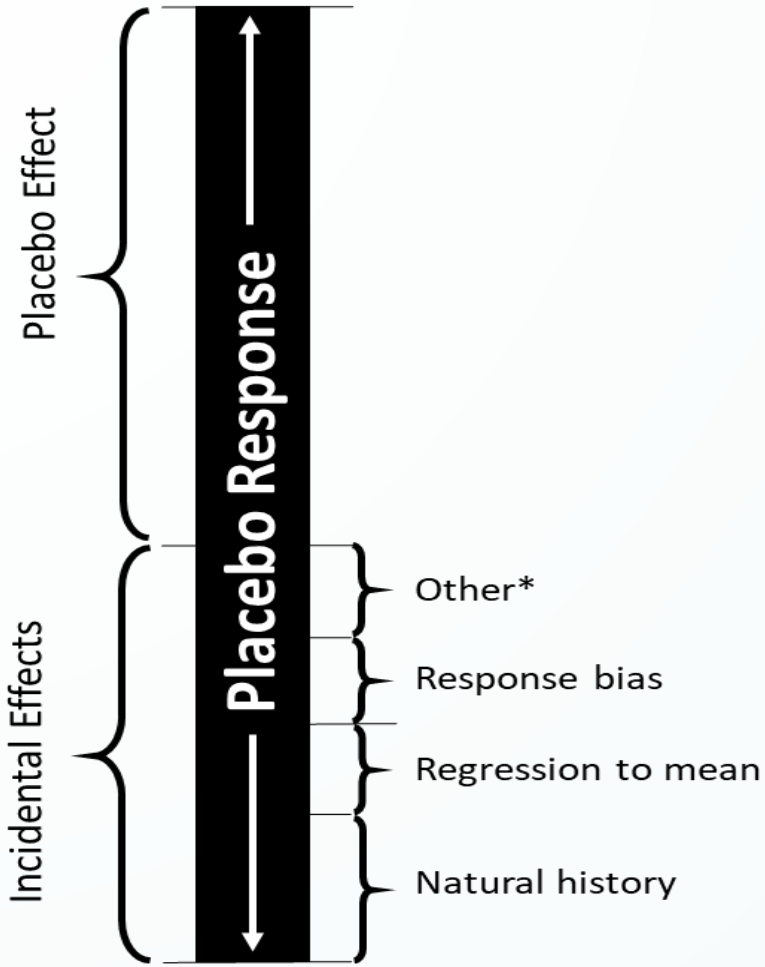
- Across designs, less common (SOE Low)
  - Lead failure or migration (surgery not specified): 0.9% to 9.5%
  - IPG removal for infection (1% to 5%) or infect or dehiscence (2.5% to 4.8%)
  - Serious infection (deep, fatal, leading to revision, removal, or hospitalization): 0% to 6%
  - Unintentional durotomy 6% (3/50)
- Across designs, least common (SOE low unless noted)
  - IPG revision, removal for IPG displacement or migration: 0.5% to 1.2%
  - Serious infection reported within 30 days 0.9%
  - CSF leak, dural tear 0.5% to 0.7%
  - Neurologic injury (deficit, paralysis, intraspinal abscess): 0% to 4% (SOE Moderate)

KQ 4: Cost-effectiveness

- Only 2 U.S.-based full economic studies
  - One good quality cost-effectiveness study in Workers Compensation population with FBSS found SCS is not cost effective at common WTP thresholds
  - One poor quality CUA in patients with NSRBP reported that SCS was cost-effective vs. CMM alone in modeling that did not include costs for initial SCS procedure costs for base case and would be cost-effective within 2.1 years when these were included in the model.
- Non-U.S. based full economic studies, mostly good quality
  - In patients with FBSS 4 studies reported SCS+ CMM was cost effective vs. CMM alone; one also reported SCS + CMM was cost-effective versus reoperation.
  - In patients with CRPS, 3 studies reported SCS + CMM was more cost-effective than CMM alone.
  - SCS not cost effective in one study in patients with PDN
- Limitations: time horizon in the absence of long-term data, limited sensitivity analyses, assumptions regarding effectiveness, modeling of AEs; unclear applicability of non-US studies

Considerations

Placebo Response



*such as diet, exercise, sleep, stress, support structure, physical or psychological treatment

- Total response attributable to placebo (or sham) administration
- Includes proportion of response that would be likely to occur even without treatment (i.e., incidental effects)
- Placebo effect is the proportion of improvement (or worsening) that remains after controlling for incidental effects

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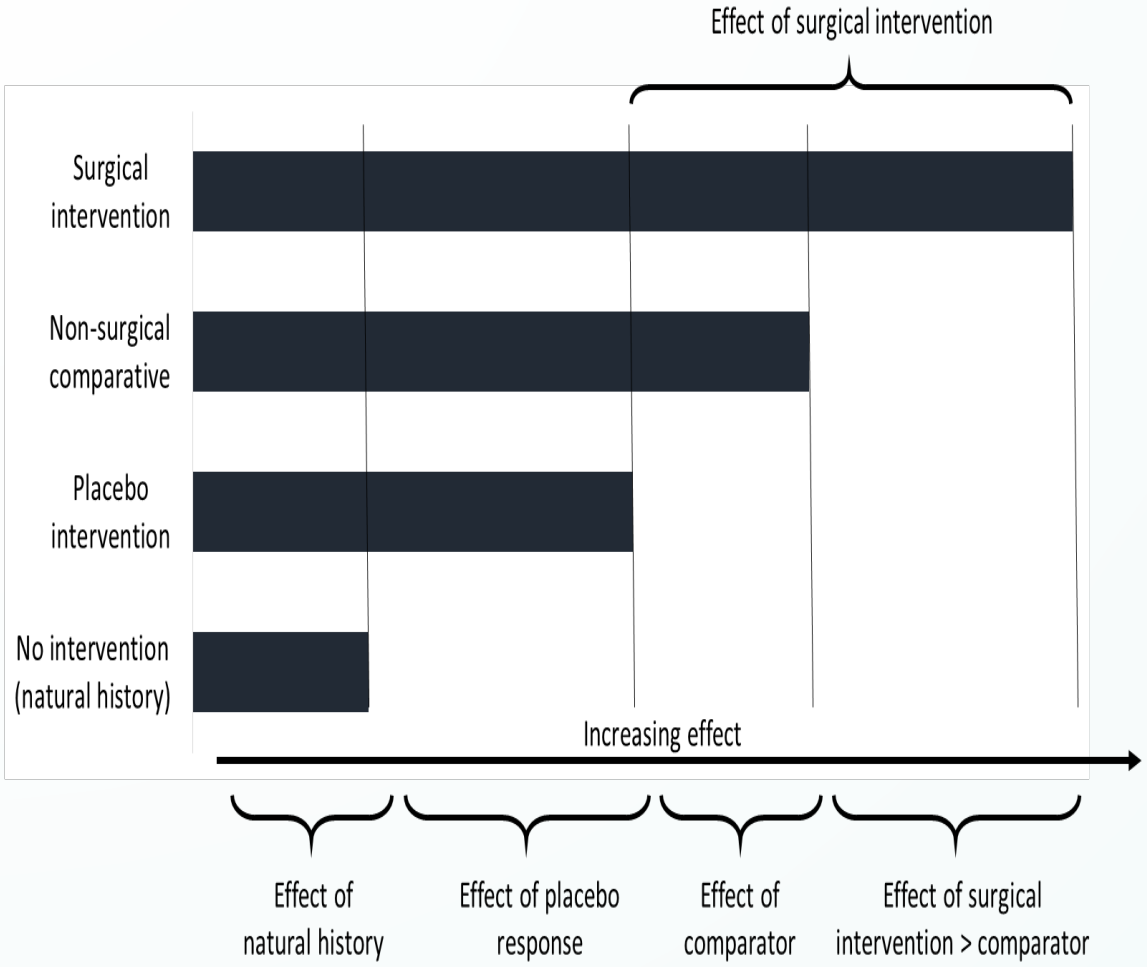
Dettori, JR, et. al. Global Spine Journal Vol. 9(6) 680-683

Conceptual contribution of effects following an intervention



- Treatment response is more than the effect of a given treatment: culture, presentation and ceremony around the treatment and expectation of provider and patient impact outcome
- The placebo response heightens the significance of having a comparative group to evaluate treatment effectiveness; case series should rarely be interpreted as supporting treatment effectiveness

Dettori, JR, et. al. Global Spine Journal Vol. 9(6) 680-683

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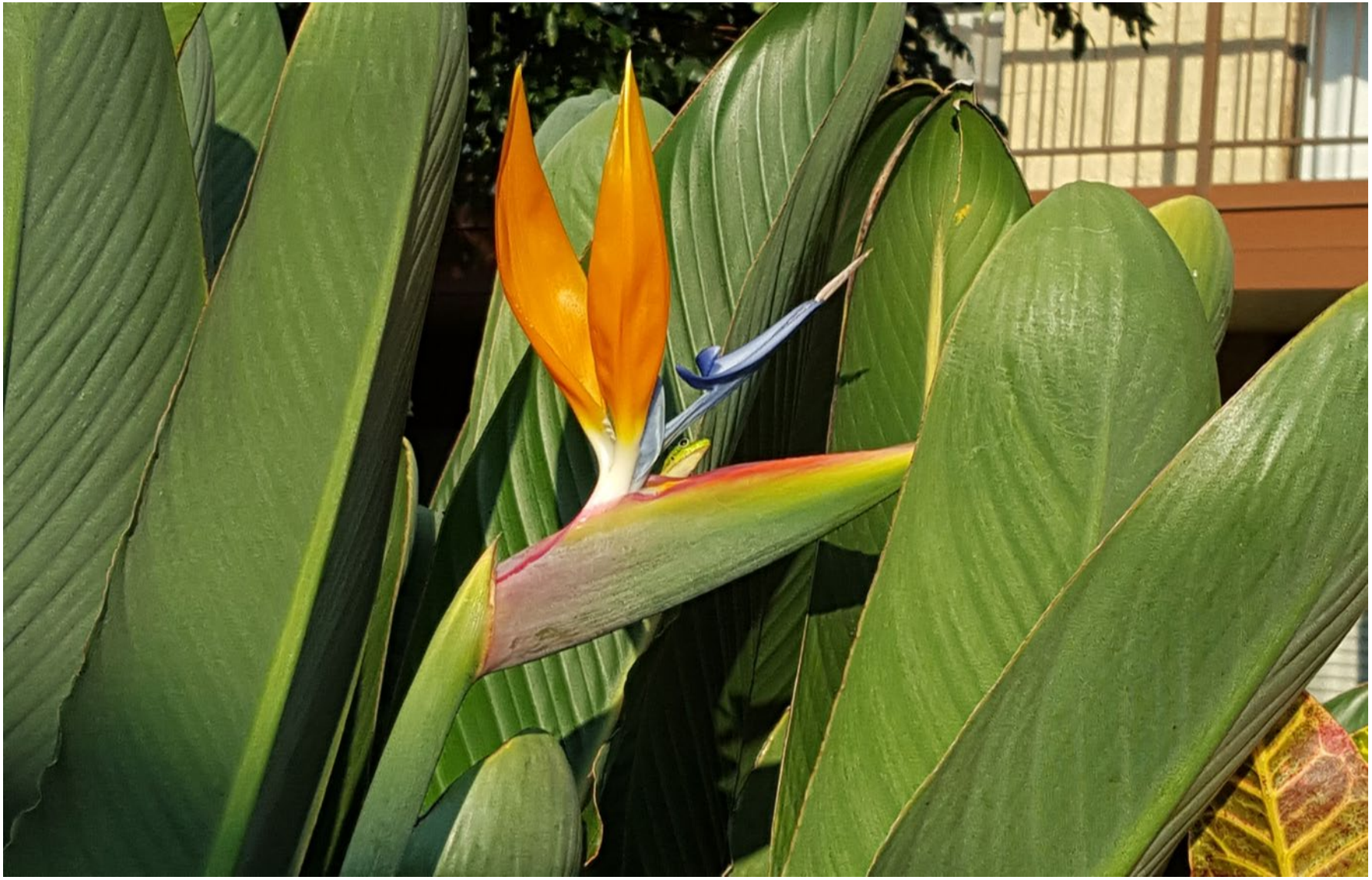
Considerations

- Effect magnitude varied depending on comparator (sham, CMM).
- Effects may at least in part be due to lack of patient blinding, expectation of benefit and other non-specific effects as well as an intervention.
- Heterogeneity in patient populations, SCS (types, delivery, parameters), CMM components and concurrent medications across studies is noted.
- Our clinical experts suggest that it is unclear how comparable or applicable the parameters used in the RCTs are to usual clinical practice, that there is likely substantial heterogeneity in what is used clinically; SCS delivery parameters are tailored to the patient.
- Substantial lack of precision in effect estimates, particularly when effect sizes were large for some outcomes may call into question the stability of effect size estimates, decreasing confidence in them consistency across single studies is unknown.

Considerations

- Impact of the following is unclear: Lack of an adequate washout period between SCS modes and sham, potential for carryover effects from prior phases, and potential for breaking of patient blinding for some modes of operation (e.g., switching from high frequency to low frequency conventional).
- Some studies may have been underpowered to detect uncommon or rare AEs or differences in effectiveness; heterogeneity in classification, description of severity, reporting of AEs is noted.
- Applicability: Most patients failed CMM, were selected following multidisciplinary assessment including psychological evaluation, (specific thresholds, standards not described); most had a positive response to trial SCS prior to permanent implant.
- Definitions, criteria related to FBSS and NSRBP not well described.
- Economic study limitations: Time horizons modeled, limited sensitivity analyses, inconsistent modeling of SCS procedure costs and AEs, support for assumptions regarding effectiveness and harms especially long term are unclear.

Questions?



HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the

task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Any adverse event		
AEs requiring surgery		
Withdrawal due to AEs		
Durotomy		
Neurologic injury		
Death		
Allergic reaction		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Pain (VAS, NRS etc)		
Function (ODI, etc)		
Opioid use		
ODI		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	**Less** Less cost effective	**Equivocal**	**More** More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is *insufficient* to make a conclusion about whether the health technology is *safe, efficacious, and cost-effective*;
- Evidence is *sufficient* to conclude that the health technology is *unsafe, ineffectual, or not cost-effective*
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for all indicated conditions*;
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for some conditions or in some situations*

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	**Covered unconditionally**	**Covered with conditions**

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

The report "identified no Medicare national coverage determination on the use of SBRT or any local coverage determinations that apply to the state of Washington."

Medicare Coverage

[see page 60 of final report]

- **Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**
  NCD – Electrical Nerve Stimulators (160.7) - There are two types of implantations covered by this instruction: Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered. Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

Clinical Practice Guidelines
[see page 19-24 of final report]

Guideline	Year	Evidence Base	Recommendation	Rating/Strength of Recommendation
American Society of Regional Anesthesia and Pain Medicine	2023	NR	• In patients with chronic low back pain and/or leg pain, limb ischemia due to peripheral vascular disease, painful diabetic neuropathy, and/or CRPS type I or II a trial of SCS should be performed prior to a definitive SCS implant.	• Moderate (US Preventative Services Task Force rating)
Dutch Quality of Healthcare Institute	2022	NR	• Given the high initial costs and the invasiveness, the scientific committee has followed the general rule that primarily more conservative therapies should be used to treat the complaints. If there is insufficient effect and/or if relevant, too many side effects, neurostimulation can be advised. • **FBSS**: In the case of insufficient effect on conservative treatments, minimally invasive treatment can be considered. Treatment with epidural injections with local anesthesia and possibly corticosteroids in a PSPS (FBSS) in which there is scar pain can be considered. In a PSPS (FBSS) in which the neuropathic and/or nociplastic pain is prominent, a pulsed radio frequency of a nerve root can be considered. • **CRPS**: Based on the available literature, combined with the expert opinion, the Scientific Committee recommends considering the following conservative treatments before applying neurostimulation. In the case of insufficient effect on conservative treatments, minimally invasive treatment can be considered. In upper extremity CRPS where vasomotor dysregulation is prominent, a thoracic block(T2–3) with local anesthetic and corticosteroids can be considered. In a residual CRPS situation in which neuropathic and/or nociplastic pain is prominent, a low dose of intravenous ketamine therapy can be considered. • **PDPN**: Based on the available literature, combined with the expert opinion, the Scientific Committee recommends considering conservative treatments before applying neurostimulation. In the case of insufficient effect of conservative treatments, minimally invasive treatment can be considered. Transcutaneous electrical nerve stimulation can	NR

			be considered for a PDPN in which pain is the main focus. In the case of a PDPN in which vasomotor dysregulation is prominent, a sympathetic blockade can be considered.	
European Academy of Neurology	2016	• **Post-surgical chronic leg and back pain (CBLP)**: Spinal cord stimulation added to conventional medical management versus conventional management alone or versus reoperation in post-surgical CBLP: 2 RCTs • **CRPS and PDN**: Spinal cord stimulation added to conventional medical management versus conventional management alone in CRPS and PDN: 2 or 3 RCTs	• **CBLP**: There is weak recommendation for the use of SCS added to conventional medical management versus conventional medical management and for the use of SCS as an alternative to reoperation in post-surgical CBLP • **CRPS and PDN**: There is weak recommendation for the use of SCS added to conventional medical management versus conventional medical management in PDN and CRPS I	• **CBLP**: Moderate (GRADE) • **CRPS and PDN**: Low (GRADE)
Dutch Orthopedic Association and the Dutch Neurosurgical Society	2015	• 2 RCTs	• FBSS: Neuromodulation is recommended for patients with FBSS who have pronounced leg pain and for whom conservative therapy has provided insufficient or no effect.	• **FBSS**: Based on the lack of a scientific conclusion and these other considerations, the task force developed the following positive recommendation for practice (because effectiveness is demonstrated in various RCTs, and the benefits clearly outweigh the risks and burdens)

American Society of Interventional Pain Physicians	2013	• 2 RCTS, 12 NRSIs	• **FBSS**: SCS is indicated in chronic low back pain with low-er extremity pain secondary to FBBS, after exhausting multiple conservative and interventional modalities.	• **FBSS**: The evidence is fair for spinal cord stimulation (SCS) in managing patients with failed back surgery syndrome (FBSS)
Neuropathic Pain Special Interest Group	2013	• **FBSS**: 2 RCTs • **CRPS type I**: 1 RCT, 1 SR, 1 Guideline • **CRPS type II**: NR • **PDN**: 1 NRSI	• **FBSS**: SCS is effective in treating FBSS • **CRPS type I**: SCS is effective in treating CRPS type I • **CRPS type II**: Very limited evidence • **PDN:** Weak evidence with small, positive case series with large effects in refractory DPN over long-term follow-up	• **FBSS**: Quality of evidence: Moderate; Strength of recommendation: Weak • **CRPS type I**: Quality of evidence: Moderate; Strength of recommendation: Weak • **CRPS type II:** Quality of evidence: Low; Strength of recommendation: Inconclusive • **PDN**: Quality of evidence: Low; Strength of recommendation: Inconclusive
Canadian Pain Society	2012	• 2 RCTs, 1 SR, 1 Guideline	• **FBSS**: In patients with FBSS who are not candidates for corrective surgery and who have failed conservative therapy, a SCS trial should be considered • **CRPS**: In patients with CRPS who are not candidates for corrective surgery and who have failed conservative therapy, a SCS trial should be considered	• **FBSS**: Level of evidence: Good; Rating of recommendation: B • **CRPS**: Level of evidence: Good; Rating of recommendation: B
Neuromodulation Access Therapy Coalition	2008 (Incorrectly noted in Deer, 2014)	• 8 RCTs	• SCS is effective in treating chronic neuropathic pain	NR
National Institute for Health and Care Excellence Technology appraisal guidance [TA159],	2008 (Original) 2014 Re-review	• 11 RCTs (3 RCTs in people with neuropathic pain due to FBSS)	• SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain of at least 50mm on a 0–100mm VAS for at least six months despite appropriate conventional medical management, and who have had a successful trial of stimulation.	• NR; no overall description of level of evidence in guideline document. • The Committee noted that only a small

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin *[2008 original assessment included in prior review]* *See Table 5 for device-specific evaluations by NICE*		• 8 RCTs in patients with ischaemic pain, 4 of which were for treatment of angina	• SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed. • When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with SCS. Tests to assess pain and response to SCS should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted. • If different SCS systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered. **2014 Re-review Decision**: The implementation section updated to clarify that spinal cord stimulation is recommended as an option for treating chronic pain of neuropathic or ischemic origin. Nothing new that affects the recommendations in this guidance was identified. This guidance will be reviewed if there is new evidence that is likely to change the recommendations.	number of clinical trials had been identified and that relatively small numbers of people were included in these studies. The Committee accepted that there was some uncertainty about how the effects of pain treatments were sustained over time, but concluded that benefits could be sustained for at least up to 5 years in pain of neuropathic origin (for FBSS, CRPS)

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination
Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no or unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

Washington State Health Care Authority

FINAL Key Questions

Spinal Cord Stimulation

Background

Chronic pain is a leading cause of disability and is an immense public health challenge. Pain is chronic when it occurs for extended periods (usually defined as >3 months), and can affect other aspects of an individual's health and function, including physical, emotional, social, and mental, often leading to a loss in quality of life[1-6]. Treatment of chronic pain aims to improve function and quality of life in addition to pain relief. Primary treatments include disease and injury-specific treatments such as nerve root decompression or reoperation, and other therapies such as pharmaceuticals, physical therapy, behavioral and psychological therapies, and neurostimulation therapies such as transcutaneous nerve electrical stimulation (TENS). Spinal cord stimulation (SCS) may be considered for moderate or severe pain that does not respond to standard therapies. A 2020 U.S. Food and Drug Administration (FDA) communication estimated that 50,000 SCS devices are implanted annually.[7]

SCS was developed in the 1960's based on the Melzack and Wall's gate-control theory and has been used to treat a number of chronic pain issues.[8,9] Mechanisms of pain relief using SCS are not completely understood, although current theories suggest stimulation occurs through a pulse delivering a specific current to dorsal fibers which interfere with or suppress the transmission of pain signals between nerves and the brain.[10-12] Originally, pain relief through parameter changes were completely dependent on user input. Open loop and closed loop systems have been described. *Open loop* (OL) systems ignore external stimuli, such as movement of the spinal cord, heart rate, and respiration.[13,14] In contrast, *closed loop* (CL) systems automatically adapt and modify stimulator settings in response to patient position and activity in real time, maintaining stimulation within an individualized therapeutic range.[13,14] Further details on the mechanism of SCS systems have been described in great detail elsewhere.[11,12,15]

SCS systems involve percutaneous implantation of electrode leads into the epidural space until they reach the dorsal column of the spinal cord. Currently, 16 FDA approved SCS devices are available. Approved musculoskeletal indications generally include Failed Back Surgery Syndrome (FBSS), Complex regional pain syndrome (CRPS) Types I and II, intractable low back pain and leg pain. Other indications include epidural fibrosis, degenerative disc disease, and arachnoiditis. Some SCS devices are approved for treatment of diabetic neuropathy. In 2016 the FDA gave premarket approval (PMA) to the first generation of devices implanted onto the dorsal root ganglion (DRG) of the posterior root to treat CRPS type I or type II, reflex sympathetic dystrophy and causalgia.[16-18] Compared with SCS devices, in which leads are implanted into the epidural space, DRG leads enter the epidural space, exit the neuroforamina, and stimulate the adjacent DRG, potentially providing more focused pain relief through specific targeting, as well as decreased paresthesia.[11,19]

The pulse frequency used in SCS, measured in hertz (Hz), can be adjusted to meet the needs of individual pain thresholds.[11,12] Traditional SCS systems are considered "low-frequency", typically defined as 30 Hz to 200 Hz, but may be as low as 10 Hz or high as 1200 Hz.[12] Low-frequency SCS is often associated with paresthesia, a feeling of tingling or buzzing that is perceived differently depending on the individual, which may or may not bring discomfort. "High frequency" (also referred to as "paresthesia free") SCS systems, often defined as greater than 200 Hz, produce stimulations that are

typically unperceivable by patients, and may be preferred.[20] Currently, the highest frequency available is 10,000 Hz. Additionally, in 2016 the FDA approved a clinician application for SCS systems that provide stimulation in "bursts" rather than constant rates (referred to as tonic stimulation or burst stimulation), which may provide greater relief at lower frequencies.[21-24]

Topic Background

A Health Technology Assessment (HTA) on SCS was performed in 2010 and reviewed by the Washington Health Technology Assessment Program (HTAP). The prior report focused on evidence for the effectiveness of and complications for traditional SCS (dorsal column) in patients with chronic neuropathic pain. Signal updates were performed in 2014, 2016, and 2018, all of which concluded that there was not substantial, high-quality new evidence comparing SCS with medical or surgical interventions that did not involve neuromodulation (e.g., SCS, DRG stimulators, peripheral nerve neuromodulation) to trigger an updated report. The HTAP is interested in re-evaluation of spinal cord stimulation as additional evidence on technical advances related to use of SCSs, including use of high frequency and burst stimulation, may be available. Dorsal root ganglion stimulators will not be included in this review, given differences in lead placement compared with traditional SCS. This is consistent with the scope of the prior report. The proposed assessment update will be restricted to devices approved by the FDA for management of the FDA-approved conditions related to neuropathic and non-neuropathic musculoskeletal pain as described in the PICOTS (Table 1). Comments from the public posting of the KQ and PICOTS and consultation with the HTAP were considered for finalization of the Key Questions and scope.

Final Key Questions and Scope

Key Questions (KQ)
When used in adult patients who have failed other treatment options for pain related to failed back surgery syndrome, chronic back pain, complex regional pain syndrome, or peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia):

Key Question 1:
What is the evidence of short and long-term effectiveness of spinal cord stimulation compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?

Key Question 2:
What is the evidence of the safety of spinal cord stimulation compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?

Key Question 3:
What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub-populations of interest?

Key Question 4:
What is the evidence of cost-effectiveness of spinal cord stimulators compared with other medical or surgical options that do not include neuromodulation?

Table 1. Draft PICOTS Scope

Study Component	Inclusion	Exclusion

Participants	Adults with one of the following: • chronic low back pain, failed back surgery syndrome (low back pain and persistent, significant radicular pain following surgery), complex regional pain syndrome, peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia) Special populations/factors of interest: Sex, age, psychological or psychosocial co-morbidities, diagnosis or pain type, provider type, setting or other provider characteristics, health care system type, including worker's compensation, Medicaid, state, employees	• Children, patients <18 years old • Patients with prior use of SCS • Patients who are pregnant • All other pain conditions (e.g., cancer pain, chronic refractory anginal pain, heart failure, critical limb ischemia, peripheral vascular pain, pain at end of life, MS, fibromyalgia, headache, trigeminal neuralgia, chronic pancreatitis, chronic pelvic pain, chronic abdominal pain, post-stroke pain • Studies in which < 75% of patients have chronic musculoskeletal or neuropathic pain or other included pain conditions
Intervention	FDA-approved spinal cord stimulation (permanently implanted pulse generator systems and radiofrequency receiver systems)	• Temporarily implanted spinal cord stimulation devices • Neurostimulation of other parts of the nervous system (e.g., peripheral nerves, deep brain), dorsal root ganglion stimulation • Transcutaneous electrical nerve stimulation (TENs) • Non-FDA approved devices (unless final, phase III trial) • Intrathecal pumps
Comparators	Medical and/or surgical treatment (appropriate to condition) that does not include comparison of SCS methods/devices or other neuromodulation devices	• Comparisons of SCS devices • Comparison of SCS combined with other interventions vs. the other intervention alone • Comparisons of different types/modalities of SCS (e.g., comparisons of low versus high frequency, burst vs. tonic, etc.)
Outcomes	**Primary Outcomes (SOE)** • Function • Pain • Opioid use • **Complications** and adverse effects (e.g., procedural complications and technical failures, harms, infection, revision, removal, painful paresthesia or loss of paresthesia, mortality, serious adverse events) **Secondary outcomes (No SOE)**	• Non-clinical outcomes • Non-validated measures • Intermediate outcomes • Return to work

	• Health-related quality of life (HR-QoL) • Anxiety and depression • Patient satisfaction • Global perceived effect (GPE)/global impression of change	
Setting	Any	
Study design	• RCTs will be the primary focus; prospective high quality comparative nonrandomized studies of intervention (NRSI) with concurrent controls that control for confounding will be considered if RCTs are not available; question 3 is limited to RCTs • NRSIs including case series designed to evaluate harms with at least 5 years follow-up, or which report on rare harms for question 2 will be considered. • Formal cost-effectiveness analyses assessing initial placement and replacement will be considered for question 4	• Case reports • Case series (for KQ1, 3, 4) • Case series not designed to evaluate harms, those with < 5 years follow-up for question 2 unless they report on rare harms outcomes • Non-clinical studies (e.g., animal studies) • Studies with N < 10 patients total or < 10 per group • Studies not reporting on primary outcomes or harms
Publication	• Studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports • Full formal economic analyses (e.g., cost-utility analyses) published in English in an HTA, or in a peer-reviewed journal published after those represented in previous HTAs	• Abstracts, editorials, letters, books, conference proceedings • Studies without abstracts available online • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • Studies reporting on the technical • aspects spinal cord stimulation • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions/publications • Other types of economic evaluations (e.g., costing studies, cost-minimization analyses, cost-benefit analyses)

DRGS = Dorsal Root Ganglion Stimulation; FDA = Food and Drug Administration; GPE = Global perceived effect; HFSCS = High-frequency spinal cord stimulation; HR-QoL = Health-related quality of life; HTA = Health Technology Assessment; MS = multiple sclerosis; NRSI = Non-randomized studies of interventions; RCT = Randomized Control Trial; SCS = Spinal cord stimulator; SOE = Strength of Evidence; TENS = Transcutaneous electrical nerve stimulation.

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