Evolving concepts and controversies in spinal cord stimulation

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Disclosures

Richard B. North, MD

Research support to Johns Hopkins University and Sinai Hospital (former employers, 1974-2013) and to nonprofit Neuromodulation Foundation, Inc. (unpaid officer), 2007 – present: Abbott, Boston Scientific, Medtronic, Nevro, Stimwave

Royalty – Abbott

1967

electrical inhibition of pain: *experimental evaluation*

C. NORMAN SHEALY,* M.D.
NORMAN TASLITZ, Ph.D.
J. THOMAS MORTIMER, M.E.
DONALD P. BECKER, M.D.
Cleveland, Ohio†

RECENT neurophysiologic studies have raised the possibility of electrical inhibition of pain. Electronarcosis has been widely investigated[1,52] but no previous attempts are known of application of inhibiting currents to the spinal cord. Wall[53] demonstrated that activity in large peripheral sensory nerve fibers carrying nonpainful impulses inhibits in the spinal cord subsequent activity from the smallest fibers considered essential to pain conduction. Melzack and Wall[54] suggested using this knowledge to suppress pain. Mechanical surface activation of the nonpainful large fibers, such as rubbing or vibration, however, is not practical for prolonged use. Furthermore, it is probable that such stimuli must be applied to a wide area to block pain effectively from even a small focus.

Unfortunately, most "intractable" pain arises from diffusely involved structures. Thus it seems reasonable to concentrate on stimulation of the dorsal columns, where large fibers are compactly arranged, or of the anterolateral spinal cord where small fibers predominate.

Using the tegmental and medullary r
cording sites first described by Collins ar
Randt[3,55] (fig. 1) one finds a prolonged a
ter discharge (PSAD) upon electrical te
anic stimulation of a peripheral nerve abov
delta threshold. This response lasts fro
500 msec. to many seconds. It has prev
ously been demonstrated that most of th
after discharge is elicited by stimulation
C fibers, although a small early componer
comes from delta.[3,27]

When the whole nerve stimulus respons
is compared with isolated C stimulus r
sponse, however, the isolated C response
found to be of greater amplitude than th
response to whole nerve stimulation.[3] Ele
trical stimulation of skin through two sul
cutaneous needles at current intensity su
ficient to elicit pain in man (greater tha
40 volts) also elicits prolonged small fib
after discharge in cats. Similarly, PSA
can be evoked by pinching a paw with a h
mostat, by heat sufficient to produce tissu
damage, and by subcutaneous injection
noxious substances. Nonpainful mechanic
stimuli such as hair movement, deep rubbin

*A preliminary report of Dr. Shealy's first successful clinical application of this technic will appear in the July–August 1967 issue of *Anesthesia and Analgesia—Current Researches*.—Ed.

†Division of Neurosurgery and Department of Anatomy, Western Reserve University School of Medic and University Hospitals, Cleveland, Ohio. Dr. Shealy's present address: Gundersen Clinic, Ltd., La Crosse, Wisconsin.

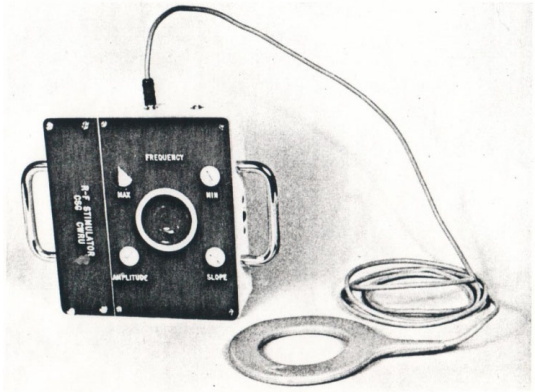


Figure D14. Variable frequency transmitter-stimulator used on patient R. W.

Shealy March 24, 1967

Mortimer 1968 PhD thesis

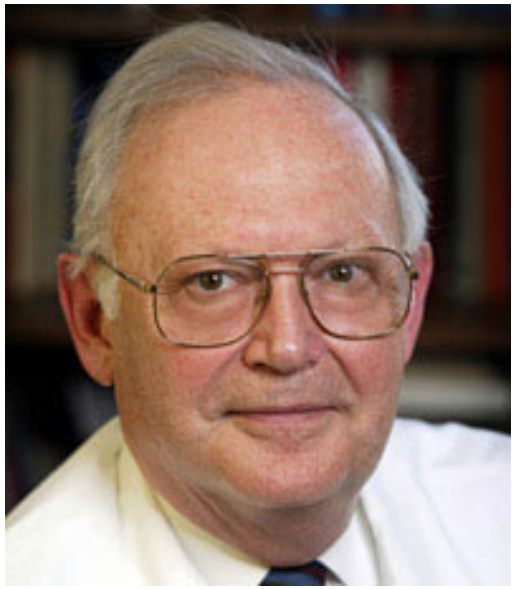
Implantable stimulator development

1959

Cardiac pacemaker (rechargeable) - Elmqvist

Johns Hopkins Department of Neurosurgery

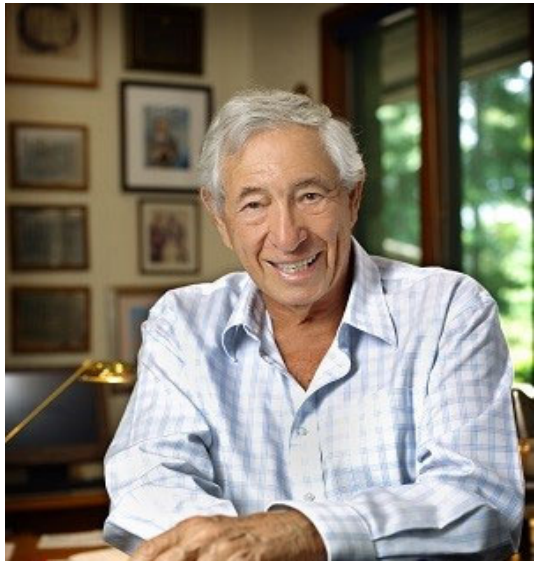
1973



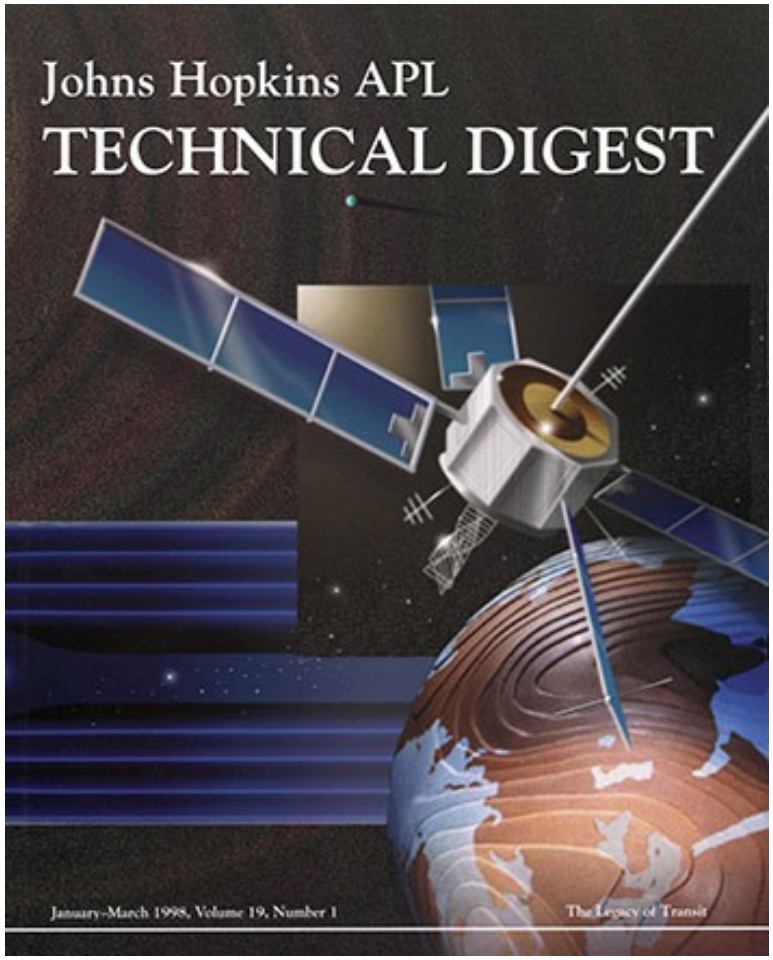
Donlin M. Long, MD, PhD
Professor and Chairman
1973 ff

JHU Applied Physics Laboratory

1973



Robert E. Fischell, D. Sc.
Director, Satellite Development



JHU/APL rechargeable pacemaker

1973

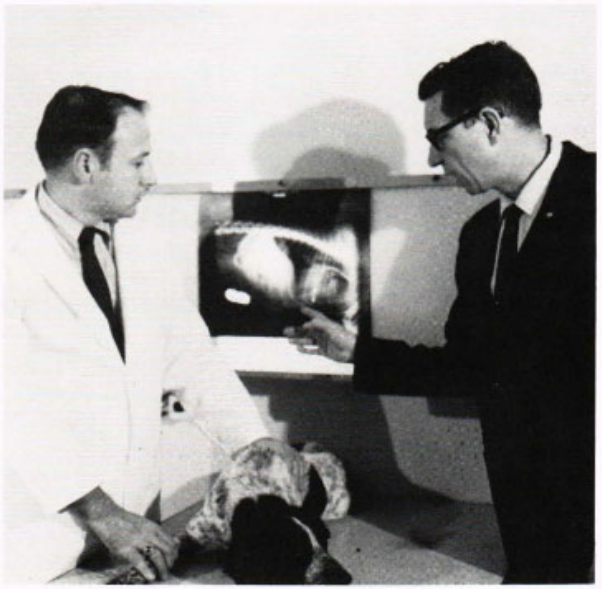


Figure 4. Dr. Lewis and the author discussing the location of the pacemaker and stimulating electrodes that were regulating the heartbeat of a laboratory dog.

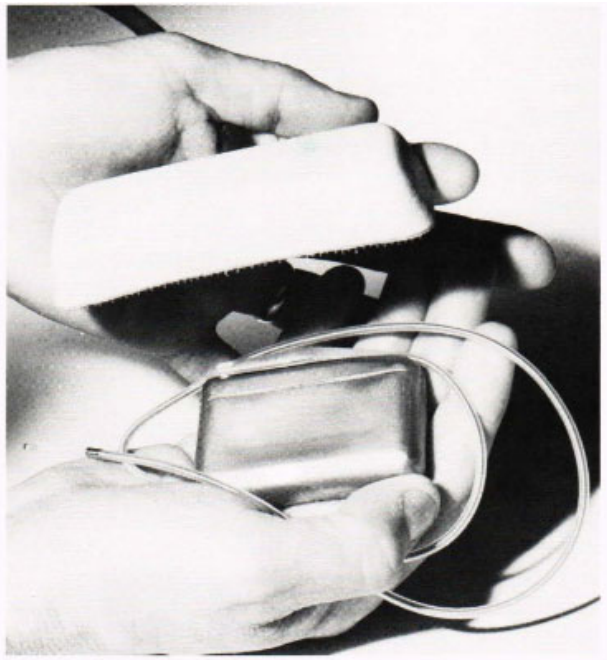


Figure 5. The Johns Hopkins Rechargeable Pacemaker shown in close proximity to the charging head.

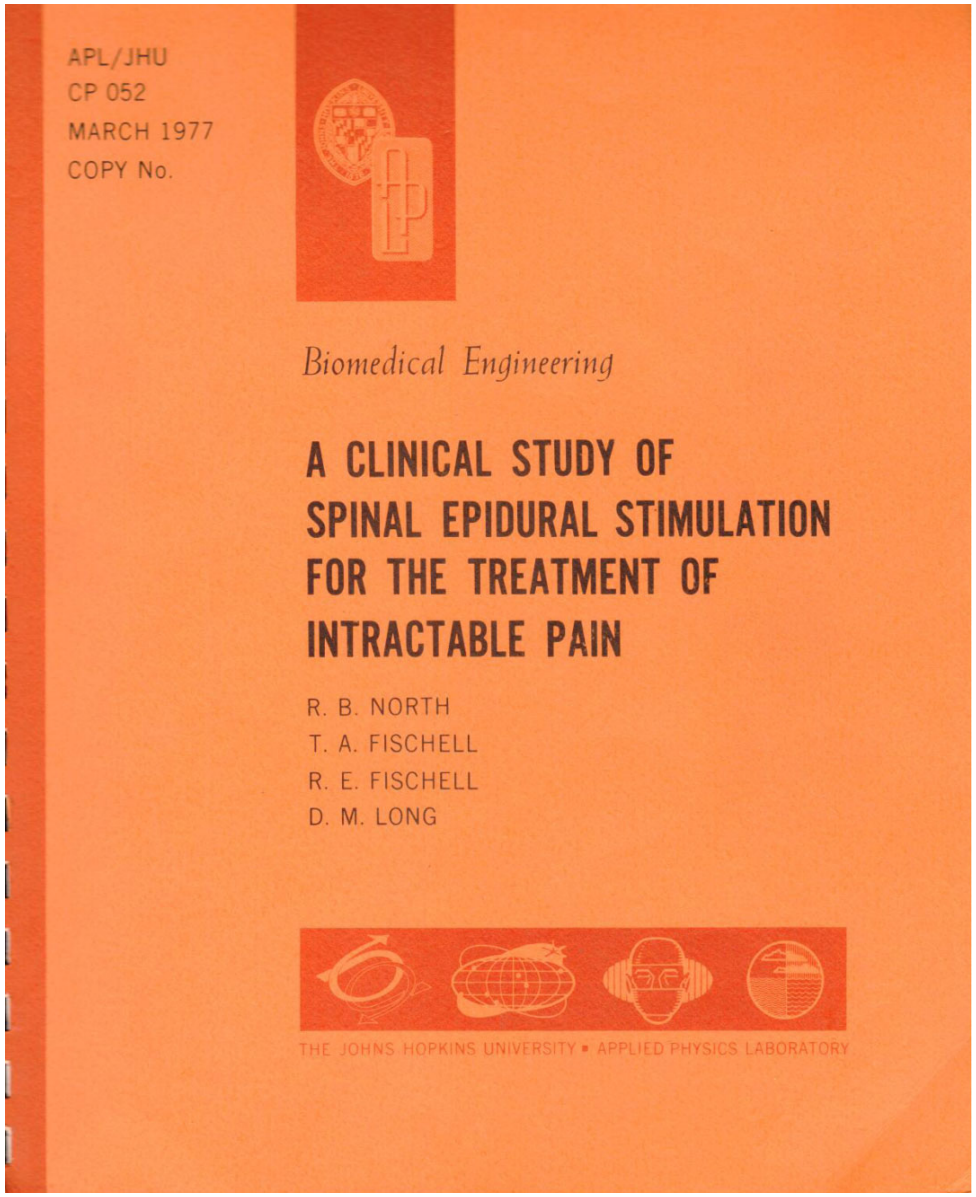
4/26

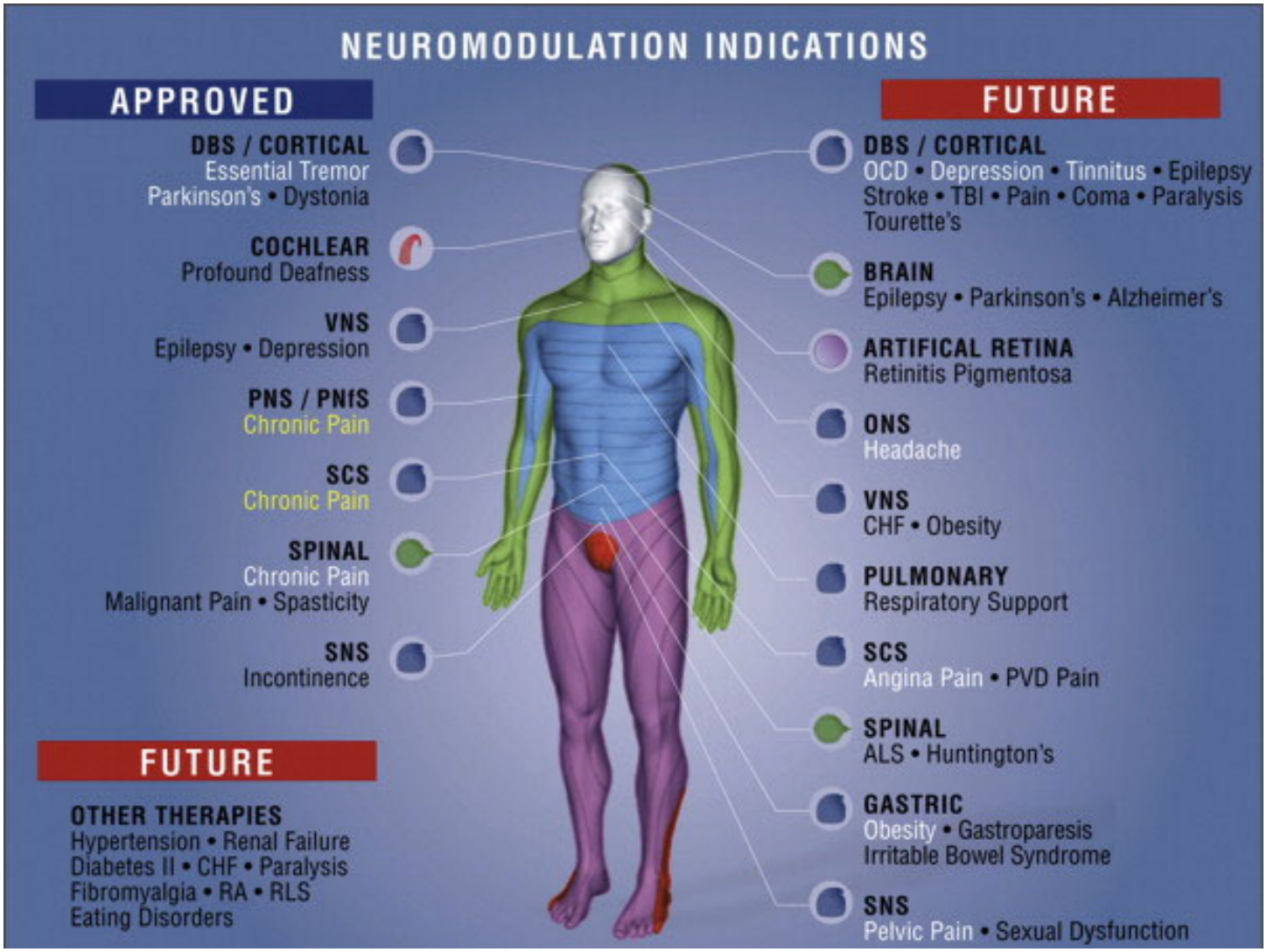
"I don't trust those new-fangled battery-powered pacemakers."

Internal (battery) power

- PRO
  - Always available (viz., cardiac pacing)
  - No antenna required during use
    - although remote control still required
- CON
  - Surgical replacement when depleted
    - Compromise settings and usage
  - Failure modes (and thus FDA Class)
    - Runaway
    - Battery leakage
  - Bulky implant

1977


APL/JHU
CP 052
MARCH 1977
COPY No.
Biomedical Engineering
A CLINICAL STUDY OF SPINAL EPIDURAL STIMULATION FOR THE TREATMENT OF INTRACTABLE PAIN
R. B. NORTH
T. A. FISCHELL
R. E. FISCHELL
D. M. LONG
THE JOHNS HOPKINS UNIVERSITY ▪ APPLIED PHYSICS LABORATORY



http://ars.els-cdn.com

JHU/APL rechargeable stimulator

1979

Figure 11. Dr. Donlin M. Long (right) adjusting the electrical stimulation parameters for the first Human Tissue Stimulator patient.

First battery powered SCS implant

1981

Totally (or fully) implanted (??)

"IPG"

- Implanted pulse generator (?) *or*
- **Internally powered generator**

vs.

- Externally powered generator
  - aka "radiofrequency" or "wireless"

Wireless technology and implanted devices

Power

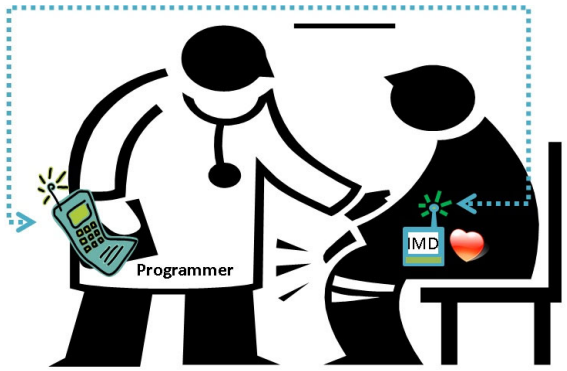
- Real time
- Recharge battery

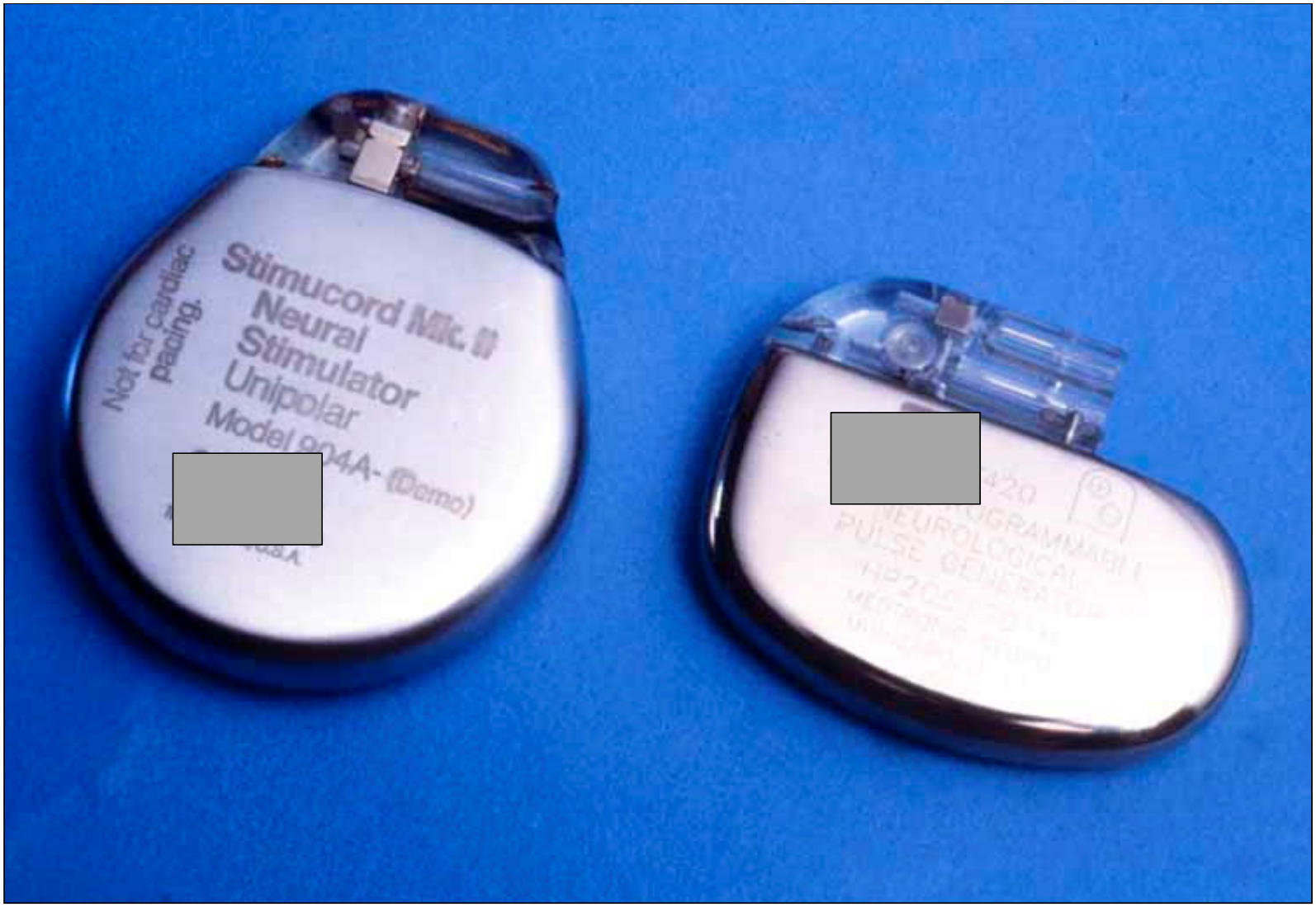
Telemetry

- Handshake - security
- Implant or biometric data

Command

- Control parameters
- Implant ID



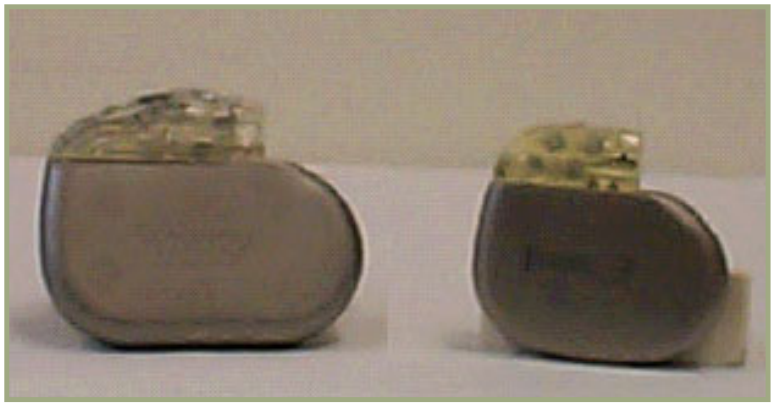


[redacted] 1981

[redacted] 1982


MULTI–PROGRAMMABLE
NEUROLOGICAL
PULSE GENERATOR
QT1100045R

Primary cell capacity



83g
51cc

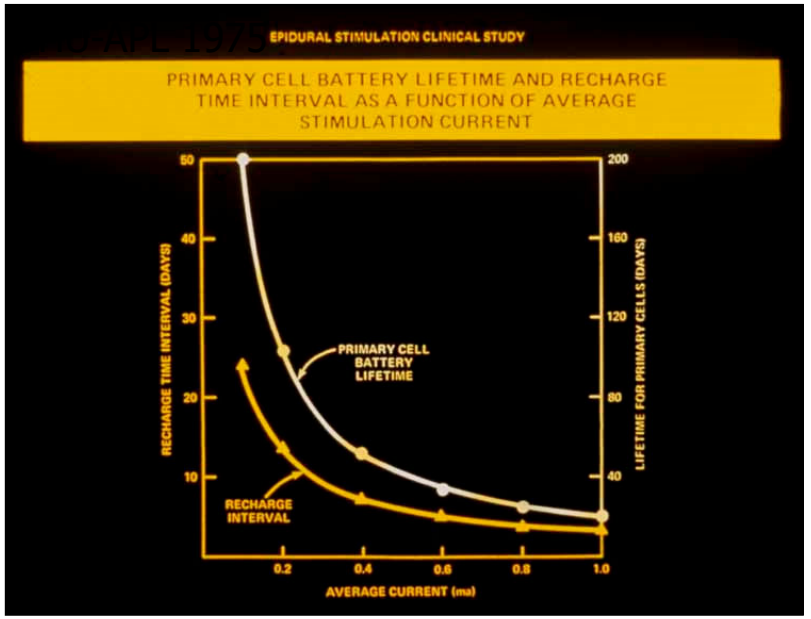
42g

Hybrid RF/primary cell

1990

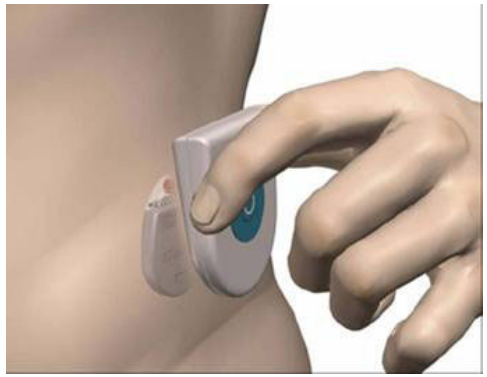
Rechargeable cell power
vs. primary cell

- PRO
  - Surgical replacement deferred
  - Less bulk, as smaller cell adequate
  - Power availability
- CON
  - Recharging
    - Inconvenience
    - Noncompliance – might compromise battery life
    - Overheating?



[redacted]

Spinal Cord Stimulation System



- Charging Made Simple
  - Portable- cordless & lightweight
  - Charge on the go
  - Stimulation on while charging
  - Charge every couple of days or every couple of weeks-as patient prefers

IMAGINE the Possibilities™

(now [redacted]) 2004

Cost $C = (1 + x)(y) \Sigma_{(n = 0 \text{ to } z)} \{[(1 + i) / (1 + d)]^{nb}\}$

Patient Determinants of Lifetime Cost (C)

- b: Battery Life in years
  - Differs between primary and rechargeable cells
  - Battery life is directly proportional to (24 hours/ usage)

- z: # of re-implantations required over lifetime = (Treatment time) / (battery life in years)
  - Base case Treatment Time = estimated patient lifespan based on gender-age actuarial tables.

Cost

Retrospective Clinical Research Report

Journal of INTERNATIONAL MEDICAL RESEARCH

Journal of International Medical Research
49(8) 1–16

DOI: 10.1177/03000605211038457
journals.sagepub.com/home/imr
SAGE

Spinal cord stimulation: a real-world data analysis on outcomes and differences between rechargeable and non-rechargeable implantable pulse generators

Thorsten Luecke[1], Harald Kuhlmann[2,3], Melanie May[4], Marius Petermann[4], Berit Libutzki[4,5] and Gunnar Jäehnichen[6]

Abstract

Objective: In this analysis, we examined differences between rechargeable and non-rechargeable spinal cord stimulation (SCS) devices in patients with pain.

Methods: We conducted a retrospective, longitudinal claims data analysis using a German research database comprising 5 million statutory insured patients (2012–2017). Outcomes of demographics, patient pathways, and health care resource utilization (HCRU) in patients with initial SCS were collected.

Results: Of 150 patients in the database, 73 (49%) received a rechargeable device and 77 (51%) a non-rechargeable device. The average age was 62.5 years (51% female and 49% male patients). A significant decrease over a 3-year follow-up was observed in analgesic prescriptions (−18%), number of patient visits to a physician, and number of patients who were hospitalized. HCRU-related figures for patients with non-rechargeable neurostimulators increased in the last follow-up year whereas the group receiving rechargeable neurostimulators showed a steady decrease.

Cost

Anesth Pain Med. 2020 February; 10(1):e100308. doi: 10.5812/aapm.100308.

Published online 2020 March 4. **Research Article**

A Cost-Consequence Analysis Examining the Differences Between Non-Rechargeable and Rechargeable Systems

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Abstract

Background: Spinal cord stimulation (SCS) is an effective treatment option to relieve chronic intractable pain, and failed back surgery syndrome (FBSS) is a key indication.
Objectives: The objective of the current study was to analyze the cost consequences of using non-rechargeable (NR)-SCS and rechargeable (R)-SCS.
Methods: Real data taken from a review of 86 patients were used to simulate costs and review which patients might have benefitted more from R-SCS. Calculations were made to see what is the impact from a monetary point of view.
Results: On average, NR-SCS devices lasted for 58 months (M). Only 14 patients were not eligible to receive an R-SCS implant. We found that using R-SCS batteries would save up to €56.322 on average over a patient's life expectancy, which means a saving of 43% compared to using NR-SCS systems. In our analysis, we found that if R-SCS implants were used instead of NR-SCS batteries, a saving of €5,735,334.23 over patients' life expectancy would be made, which represented a 63% saving to the public health system. We found that R-SCS was cost-beneficial from second year compared to NR-SCS, saving up to 70% when patients are implanted for 9 years.
Conclusions: This cost-consequences analysis suggests that R-SCS implants are more cost-beneficial than NR-SCS systems in well-selected patient candidates for this type of treatment.

Keywords: Spinal Cord Stimulation, Rechargeable SCS IPG, Non-Rechargeable SCS IPG, Cost-Benefit, Cost-Consequences

"Cost"

Neuromodulation: Technology at the Neural Interface

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https://doi.org/10.1016/j.neurom.2022.04.046

Clinical Longevity of 106,462 Rechargeable and Primary Cell Spinal Cord Stimulators: Real World Study in the Medicare Population

Timothy R. Deer, MD[1]; Jason E. Pope, MD[2]; Steven M. Falowski, MD[3]; Julie G. Pilitsis, MD, PhD[4]; Corey W. Hunter, MD[5]; Allen W. Burton, MD[6]; Allison T. Connolly, PhD[6]; Paul Verrills, MD[7]

ABSTRACT

Introduction: Spinal cord stimulators (SCS) are available with either primary cell (PC) or rechargeable cell (RC) batteries. Although RC systems are proposed to have a battery longevity upward of nine years, in comparison with four years for PC systems, there are few studies of longevity of SCS in the real world.

Materials and Methods: This was an observational, nonrandomized, retrospective study of Medicare beneficiaries who received neurostimulator implants in the outpatient hospital. This study used Medicare fee-for-service claims data from 2013 to 2020. The clinical longevity of the implantable pulse generator (IPG), defined as the duration from implant until removal for any reason, was compared between PC and RC devices. Life distribution analysis was used to approximate device lifespan. The secondary analysis separated removals into explant or replacements. The statistics were adjusted for relevant clinical covariates.

Results: A total of 25,856 PC and 79,606 RC systems were included in the study. At seven years after implant, 53.8% of PC IPGs and 55.0% of RC IPGs remained in use. The life distribution modeling analysis projected a median lifespan of 8.2 years for PC and 9.0 years for RC devices. The rate of explant was lower for PC devices (19.2%) than for RC devices (22.0%, hazard ratio (HR) = 0.96, $p = 0.082$), whereas the rate of replacements was higher for PC devices (33.7%) than for RC devices (29.5%, HR = 1.31, $p < 0.001$). An analysis of the battery type used in device replacements showed an increasing adoption of PC devices over time.

Conclusions: This large, retrospective, real-world analysis of Medicare claims data demonstrated that the clinical longevity of neurostimulator devices is similar for PC and RC batteries. In the past, clinicians may have defaulted to RC devices based on the assumption that they provided extended battery life. Considering this longevity data, clinicians should now consider the choice between PC and RC devices based on other individual factors pertinent to the patient experience and not on purported longevity claims.

Computer-controlled, patient interactive SCS

Jacqueline North, age 3, 1990

Flexibility

NEUROMODULATION: TECHNOLOGY AT THE NEURAL INTERFACE

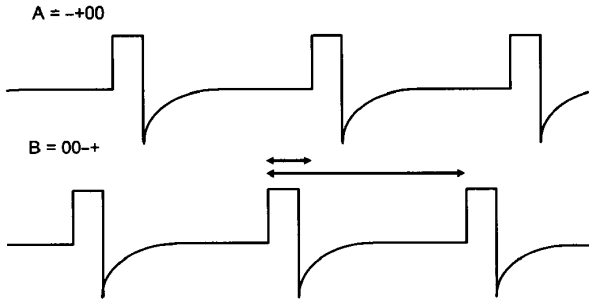
Volume 10 • Number 4 • 2007
http://www.blackwell-synergy.com/loi/ner

ORIGINAL ARTICLE

Spinal Cord Stimulation With Interleaved Pulses: A Randomized, Controlled Trial

Richard B. North, MD* • David H. Kidd, MA* • John Olin, PA-C* • Jeffrey M. Sieracki, PhD* • Marc Boulay, PhD†

*Department of Neurosurgery, Johns Hopkins University School of Medicine, Baltimore, MD; and †Department of Population and Family Health Sciences, Johns Hopkins University Bloomberg School of Public Health, Baltimore, MD, USA

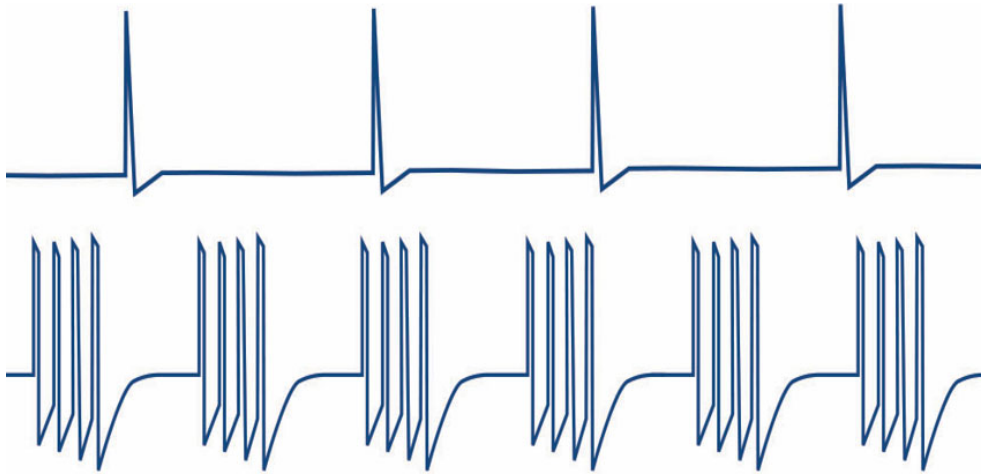


"increased pain-paresthesia overlap [with]

1) up to 1500 Hz interleaved pulses
2) frequency doubling“

Flexibility

Tonic vs. burst

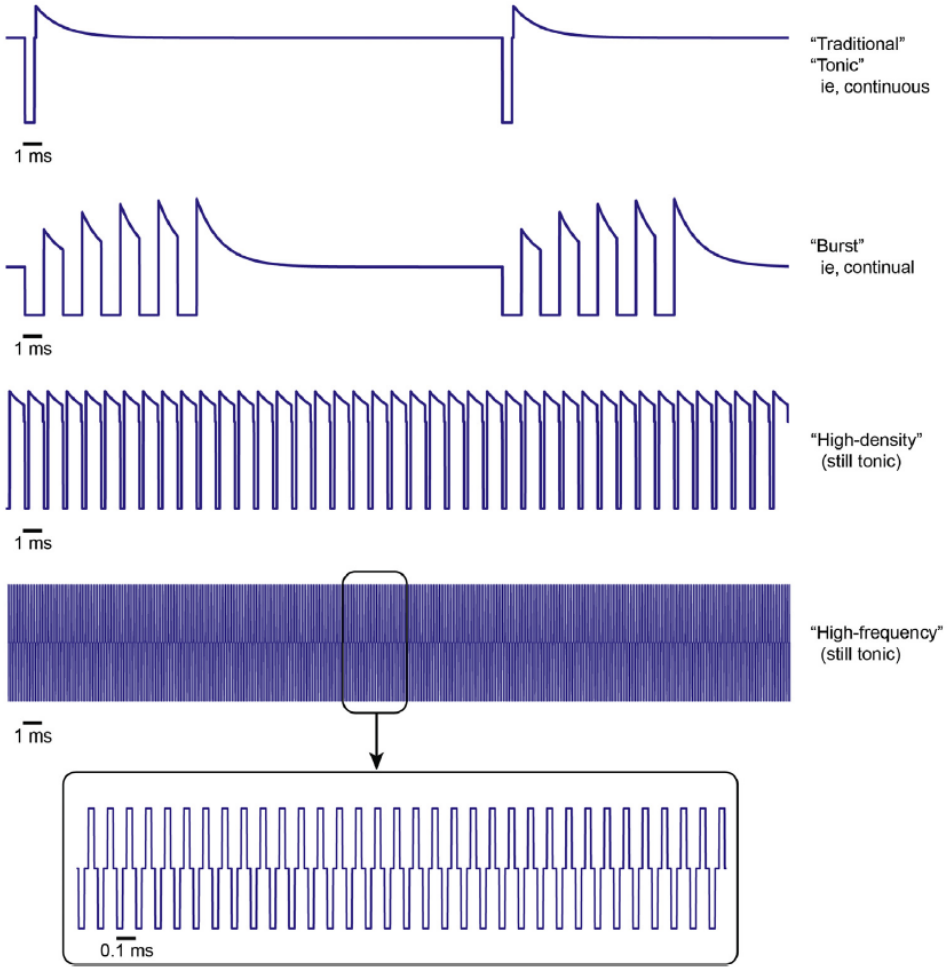


"Traditional"
"Tonic"
i.e., continuous

"Burst"
i.e., continual

Flexibility

Tonic vs. burst; “high” dose/frequency



ECAP-controlled closed-loop versus open-loop SCS for the treatment of chronic pain: 36-month results of the EVOKE blinded randomized clinical trial

Nagy A Mekhail ,[1] Robert M Levy,[2] Timothy R Deer ,[3] Leonardo Kapural,[4] Sean Li,[5] Kasra Amirdelfan,[6] Jason E Pope,[7] Corey W Hunter,[8] Steven M Rosen,[9] Shrif J Costandi ,[1] Steven M Falowski,[10] Abram H Burgher,[11] Christopher A Gilmore,[12] Farooq A Qureshi,[13] Peter S Staats,[5] James Scowcroft,[14] Tory McJunkin,[15] Jonathan Carlson,[16] Christopher K Kim,[3] Michael I Yang,[17] Thomas Stauss,[18] Erika A Petersen,[19] Jonathan M Hagedorn ,[20] Richard Rauck,[12] Jan W Kallewaard,[21,22] Ganesan Baranidharan,[23] Rod S Taylor,[24] Lawrence Poree,[25] Dan Brounstein,[26] Rui V Duarte ,[26,27] Gerrit E Gmel,[26] Robert Gorman,[26] Ian Gould,[26] Erin Hanson,[26] Dean M Karantonis,[26] Abeer Khurram,[26] Angela Leitner,[26] Dave Mugan,[26] Milan Obradovic,[26] Zhonghua Ouyang,[26] John Parker,[26] Peter Single,[26] Nicole Soliday,[26] The EVOKE Study Group

BMJ

Mekhail NA, *et al*. *Reg Anesth Pain Med* 2023;**0**:1–9. doi:10.1136/rapm-2023-104751

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https://doi.org/10.1016/j.neurom.2021.10.010

Glossary of Neurostimulation Terminology: A Collaborative Neuromodulation Foundation, Institute of Neuromodulation, and International Neuromodulation Society Project

Richard B. North, MD[1]; Scott F. Lempka, PhD[2]; Yun Guan, MD, PhD[3,4]; Ellen L. Air, MD, PhD[5]; Lawrence R. Poree, MD, PhD[6]; Jane Shipley, BA[1]; Jeffrey Arle, MD, PhD[7]; Philippe Rigoard, MD, PhD[8]; Simon Thomson, MBBS[9]

ABSTRACT

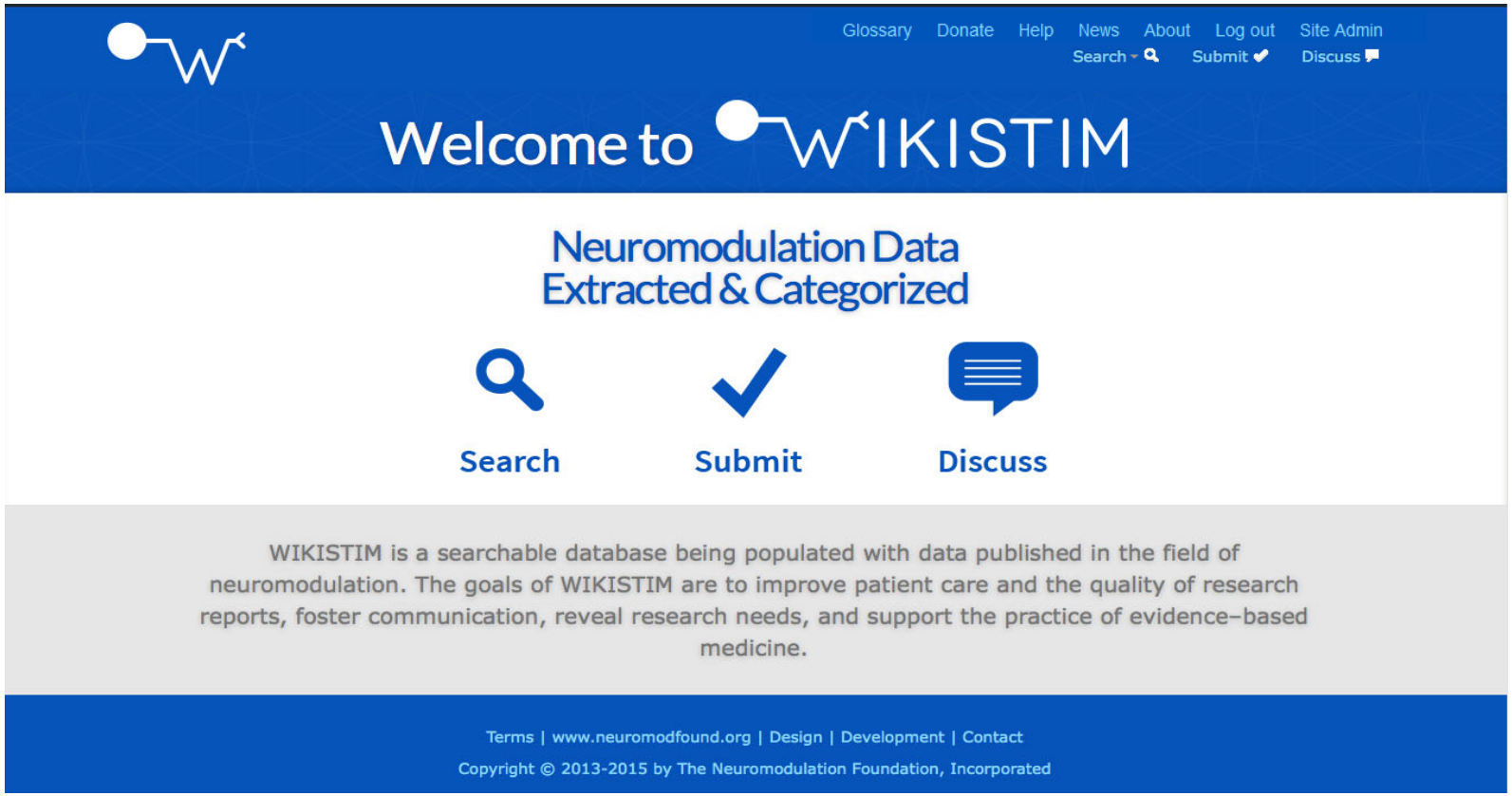
Objective: Consistent terminology is necessary to facilitate communication, but limited efforts have addressed this need in the neurostimulation community. We set out to provide a useful and updated glossary for our colleagues and prospective patients.

Materials and Methods: This collaborative effort of the Neuromodulation Foundation (NF), the Institute of Neuromodulation (IoN), and the International Neuromodulation Society (INS) expands a glossary first published in 2007 for spinal cord stimulation. Peripheral nerve, dorsal root ganglion, deep brain, and motor cortex stimulation have been added to our scope. Volunteers from the collaborating entities used a nominal group process, consensus development panels, and the Delphi technique to reach consensus on inclusion and definition of terms. We created a glossary suitable for print and for expansion on the websites of the collaborating entities, which will offer the possibility of explaining definitions for a general audience. We excluded proprietary and brand names but included terms that have attracted proprietary interest without becoming brands or trademarks. We made an effort to be inclusive while also being concise and economical with space.

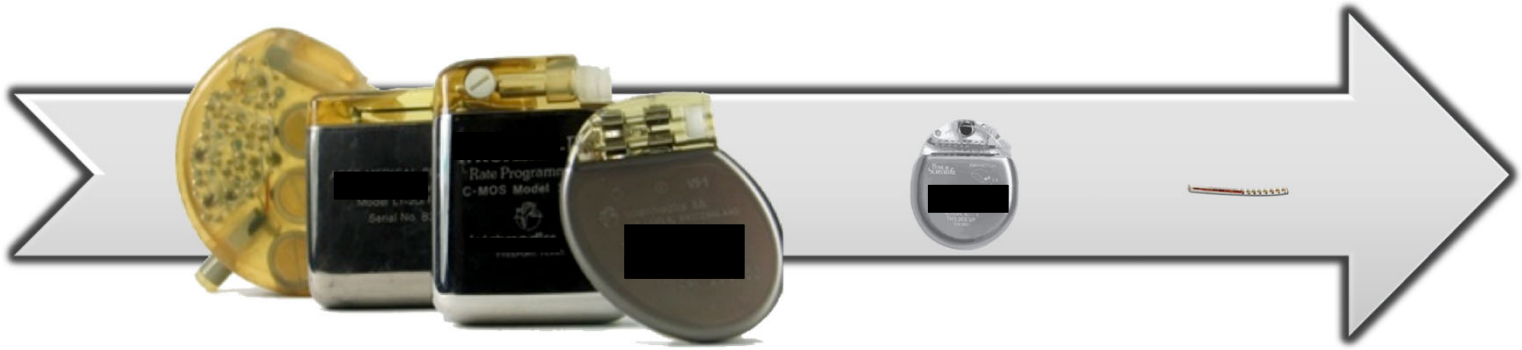
Results: We identified and defined 91 terms for this print edition and created an accompanying list of acronyms. As appropriate, we provided figures to illustrate the definitions.

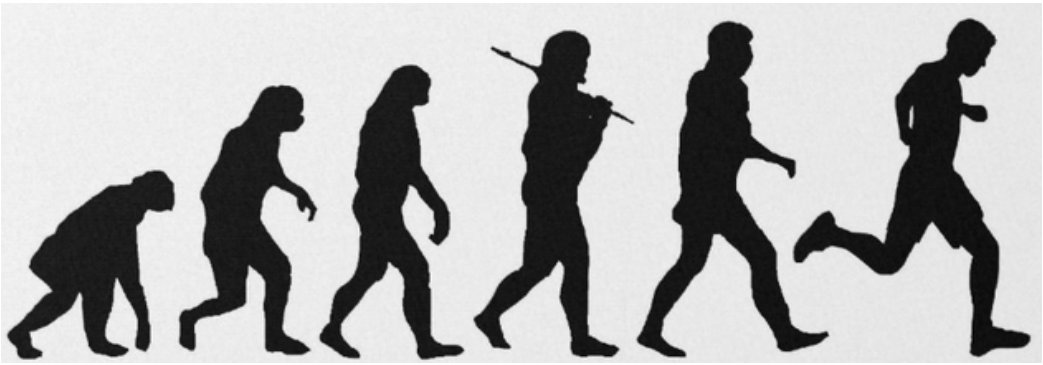
Conclusions: Although we refer to the glossary presented herein as the print edition, it can of course be viewed and searched electronically. NF, IoN, and INS will continue to collaborate on expanded web editions that can include hyperlinks for internal and external navigation. We believe this glossary will benefit our growing field by facilitating communication and mitigating inappropriate use of neurostimulation terms.

www.wikistim.org



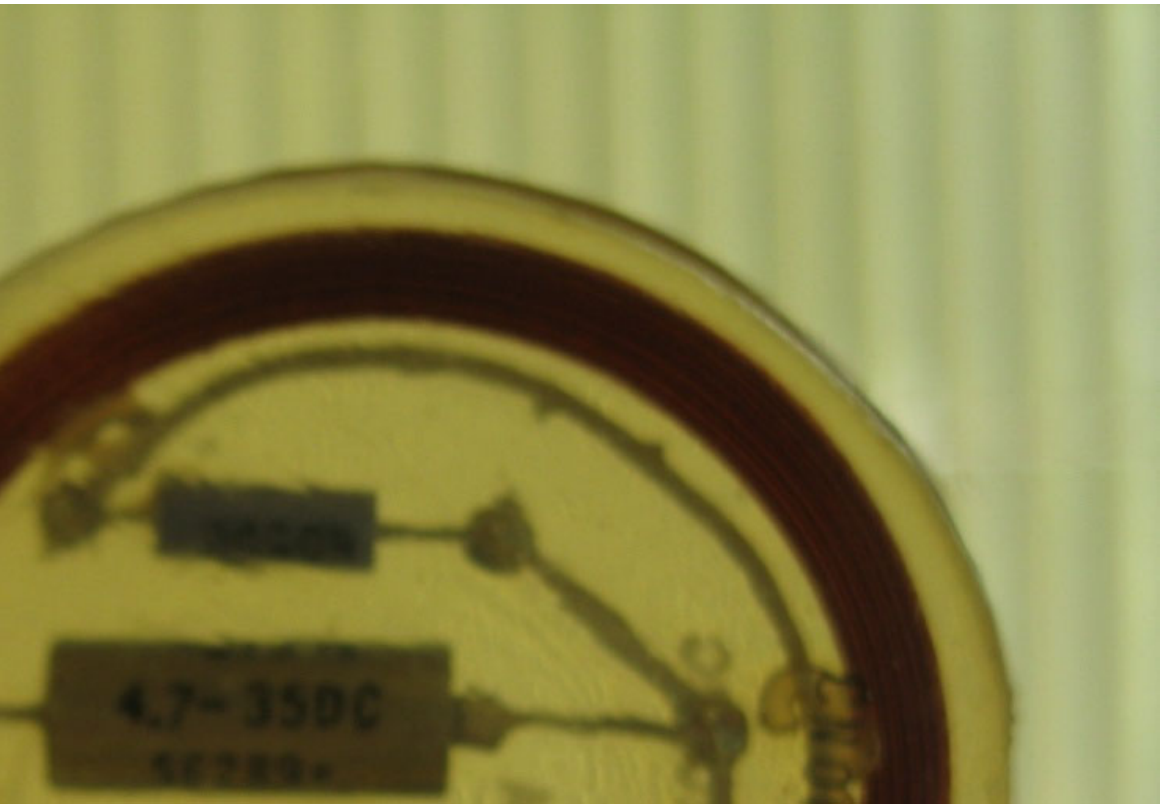
Evolving technology





Wireless technology scale

RF (inductive coupling), 1962



Microwave (electrical coupling), 2014

Wired vs. wireless (PNS, DBS in particular)

Wired IPG System

- IPG bulk requires placement on trunk (DBS, PNS)
  - Reliability suffers
    - Crossing mobile joints (neck, limbs)
    - Adding extension cables and connectors, tethering points
- Pocket pain

Wireless ASIC System

- Receiver integral with electrode assembly can be “out on a limb”
    - wearable transmitter in cuff, sleeve, eyeglasses, cap, jewelry, etc.
- MRI compatibility
- Single stage implant facilitated

Mobility

United States Patent [19]
Fischell et al.

[11] **Patent Number: 6,006,124**
[45] **Date of Patent: Dec. 21, 1999**

[54] **MEANS AND METHOD FOR THE PLACEMENT OF BRAIN ELECTRODES**

[75] Inventors: **Robert E. Fischell**, Dayton; **Richard B. North**, Baltimore, both of Md.

[73] Assignee: [redacted], Fair Haven, N.J.

[21] Appl. No.: **09/071,055**

[22] Filed: **May 1, 1998**

[51] **Int. Cl.**[6] **A61B 5/04**; A61N 1/05

[52] **U.S. Cl.** **600/378**; 607/116

[58] **Field of Search** 600/377, 378; 604/175; 606/129, 130; 607/116, 139

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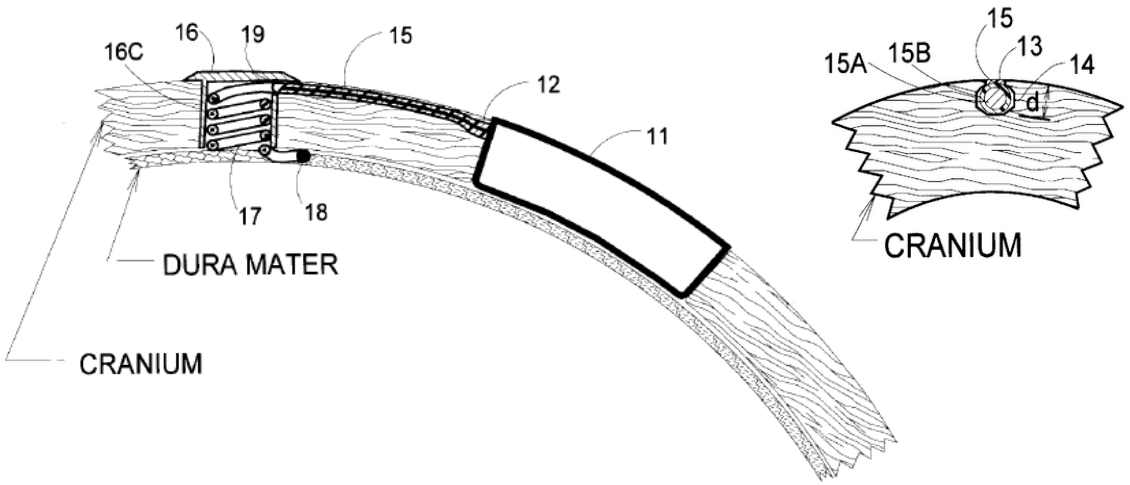
5,865,842	2/1999	Knuth et al.	607/116

Primary Examiner—Lee Cohen

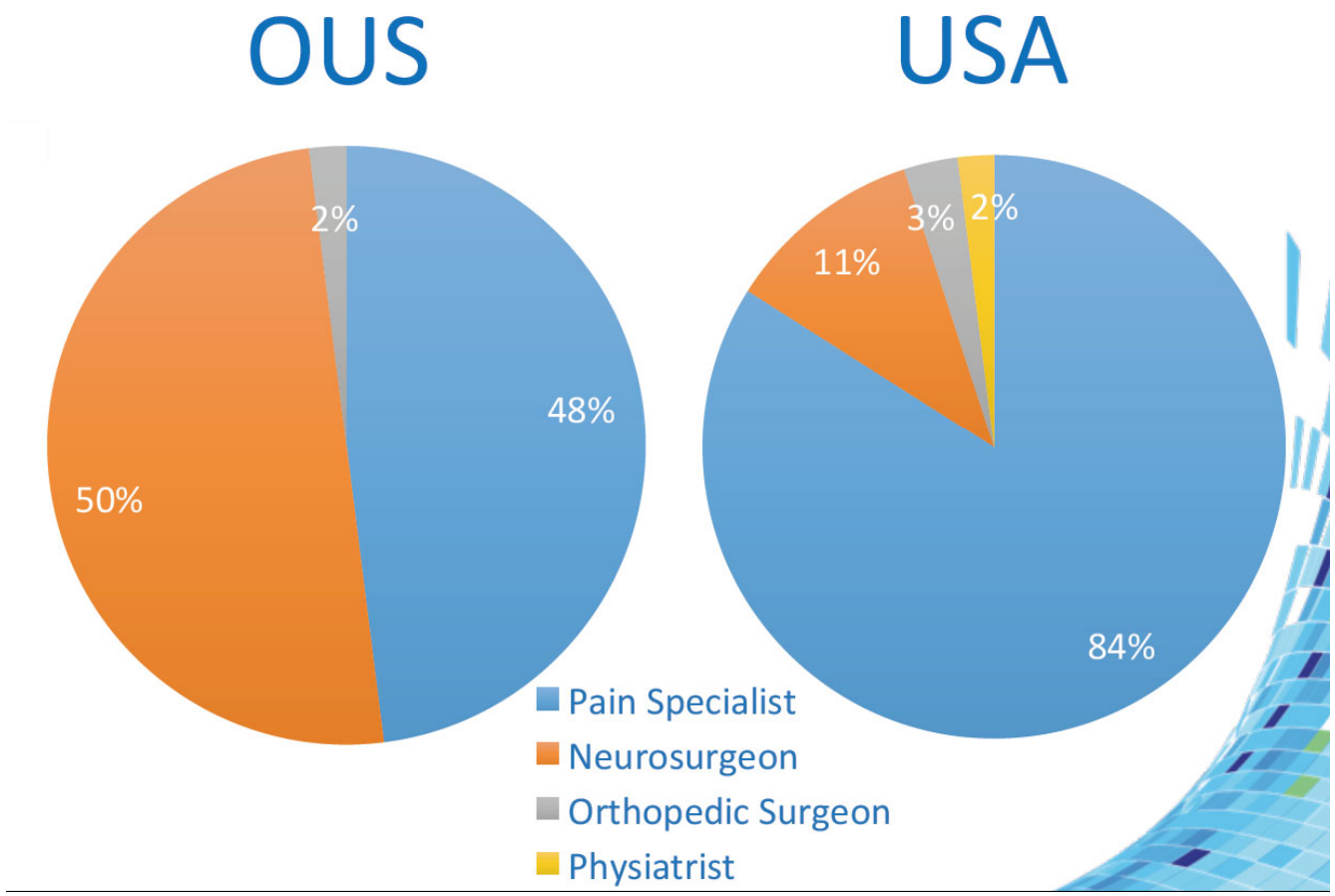
[57] **ABSTRACT**

Disclosed are a means and a method for the placement of insulated electrical wires beneath the human scalp in such a way that they will experience no flexing after implantation thus disallowing wire breakage. Specifically, this intracranial system uses wires to connect a control module containing various electronic systems to brain electrodes. These wires are placed in grooves that are made by a surgeon in an outer portion of the patient's cranium by means of a specially shaped burr rotated at high speed by means of a router. At the end of the groove, the surgeon would drill a burr hole in the cranium at the site where a brain electrode is to be placed. A distal portion of each electrical wire would be in the form of a helical coil; one helical coil would be placed in each burr hole. The grooves and burr holes could be filled with an adhesive filler type of material to form a smooth outer surface for the cranium. Also, a special cap could be placed over the burr hole. The function of the cap would be to form a smooth outer surface for the cranium. The electrodes at the end of the wires could be placed at various locations such as deep into the brain, on the brain surface, or in close proximity to the brain.

11 Claims, 4 Drawing Sheets



SCS Implanter Specialties 2017



Source:

Pain

Neuromodulation: Technology at the Neural Interface

Received: March 30, 2017 Revised: May 19, 2017 Accepted: June 2, 2017

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12637

Pocket Pain and Neuromodulation: Negligible or Neglected?

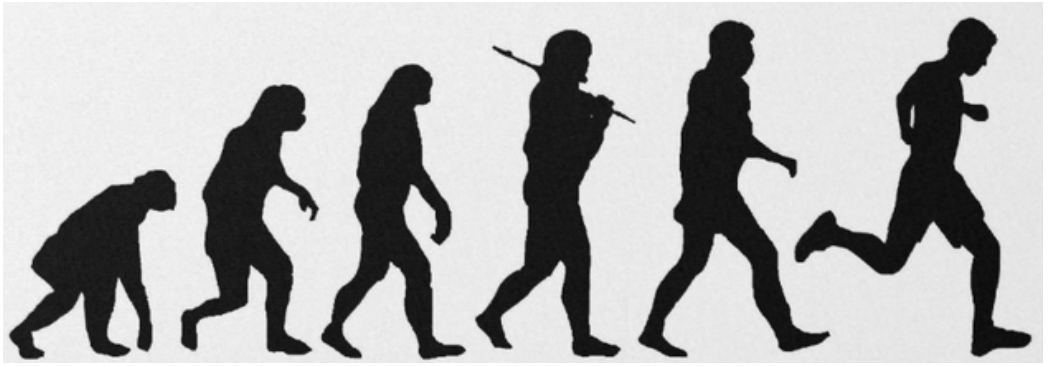
Sofie Dietvorst, MD*†1; Thomas Decramer, MD*†1; Robin Lemmens, MD, PhD‡; Bart Morlion, MD, PhD§; Bart Nuttin, MD, PhD*†; Tom Theys, MD, PhD*†

Objectives: Pain encountered at the site of the implantable pulse generator (IPG) after invasive neuromodulation is a well-known and important complication. The reported incidence of implant site pain is variable, ranging between 0.4 and 35%. Implant site pain has never been systematically studied and no treatment guidelines are available.

Material and Methods: We performed an observational study (study registration number mp05728) on the incidence and the determining factors of implant site pain, the subjective rating of intensity by sending questionnaires ($n = 554$) to our cohort of neuromodulation patients with IPGs. The number of revision surgeries and explants due to implant site pain were also analyzed.

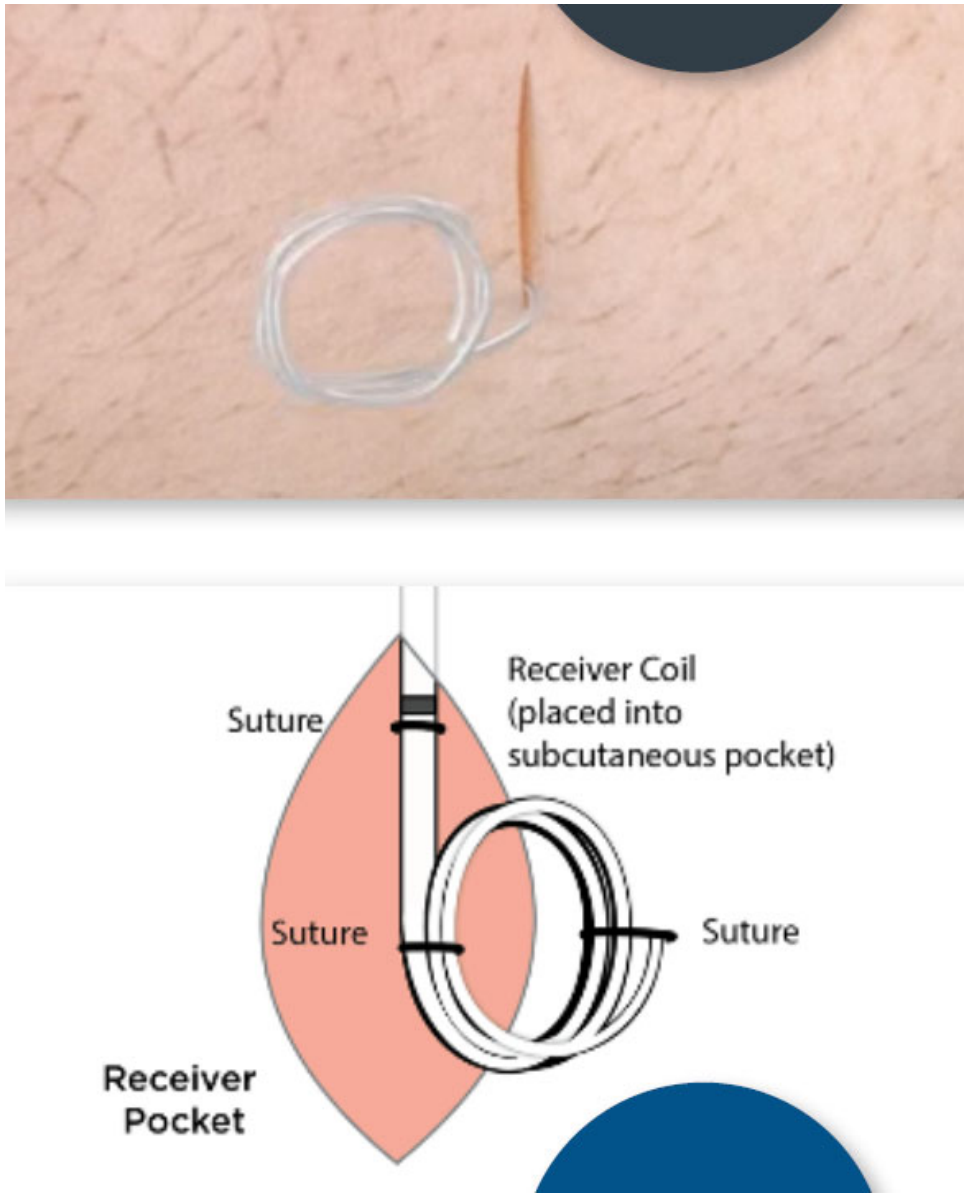
Results: Total response rate was 50% ($n = 278$). Pain patients suffered significantly ($p < 0.05$) more often from IPG site pain than other patients undergoing neuromodulation therapies. Up to 64% of patients undergoing spinal cord stimulation reported IPG site discomfort or pain. Severe pocket pain was found in up to 8% of patients. No association was found between other variables (age, BMI, duration of follow-up, gender, smoking, number of pocket surgeries) and implant site pain.

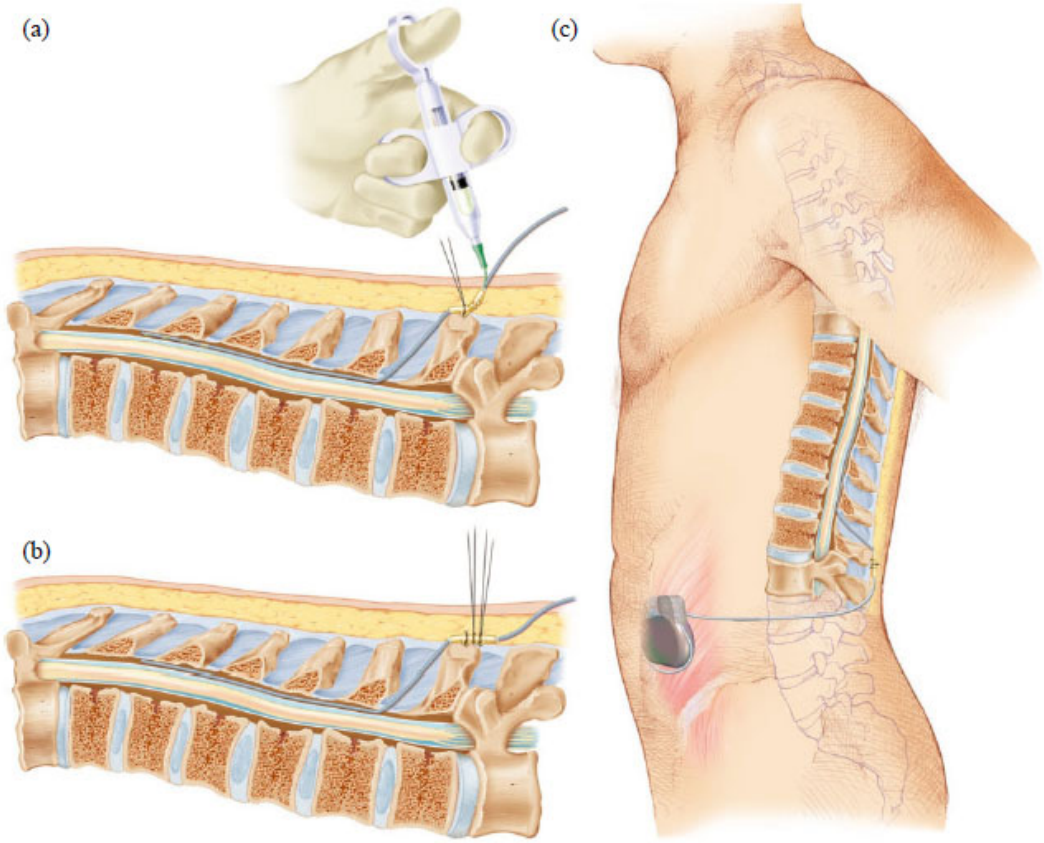
Conclusion: Pocket pain represents an important problem after invasive neuromodulation and is more prevalent in pain patients. We believe further technological improvements with miniaturized IPGs will impact the incidence of pocket pain and could even obviate the need for an IPG pocket.



Neurostimulator Miniaturization

“Receiver”


Receiver Coil
(placed into
subcutaneous pocket)
Suture
Suture
Suture
Receiver
Pocket



Neuromodulation 2014; 17: 670–677

Cost

Received: October 29, 2019 Revised: December 16, 2019 Accepted: January 2, 2020

(onlinelibrary.wiley.com) DOI: 10.1111/ner.13102

Cost-Effectiveness Model Shows Superiority of Wireless Spinal Cord Stimulation Implantation Without a Separate Trial

Richard B. North, MD*; Harish S. Parihar, PhD RPh†; Shawn D. Spencer, PhD RPh†; Arthur F. Spalding, MBA‡; Jane Shipley, BA*

Objective: We evaluated the cost-effectiveness of wireless spinal cord stimulation (Wireless SCS) with single stage "direct to permanent" implantation vs. screening with temporary electrodes and an external pulse generator followed by implantation of a system for long-term use (IPG SCS).

Materials and Methods: We created a cost model that takes a 2019 United States (U.S.) payer perspective and is based on IPG SCS cost models for subjects with chronic back and/or leg pain. Our six-month decision tree includes the screening trial period (success ≥50% relief) and leads to various levels of pain relief with or without complications for IPG SCS and Wireless SCS and without complications for conventional medical management (CMM). Every three months in the follow-on 15-year Markov model (with costs and quality-adjusted life years discounted 3.5% annually), subjects remain stable or transition to deteriorated health or death. Subjects who fail SCS receive CMM. After 60 Markov cycles, a 100,000-sample simulation reveals the impact of maximum willingness-to-pay (WTP) from $10,000 to $100,000 per quality-adjusted life year on net monetary benefit (NMB). Sensitivity analyses considered the impact of the Wireless SCS screening success rate, Wireless SCS device cost, and IPG SCS device longevity.

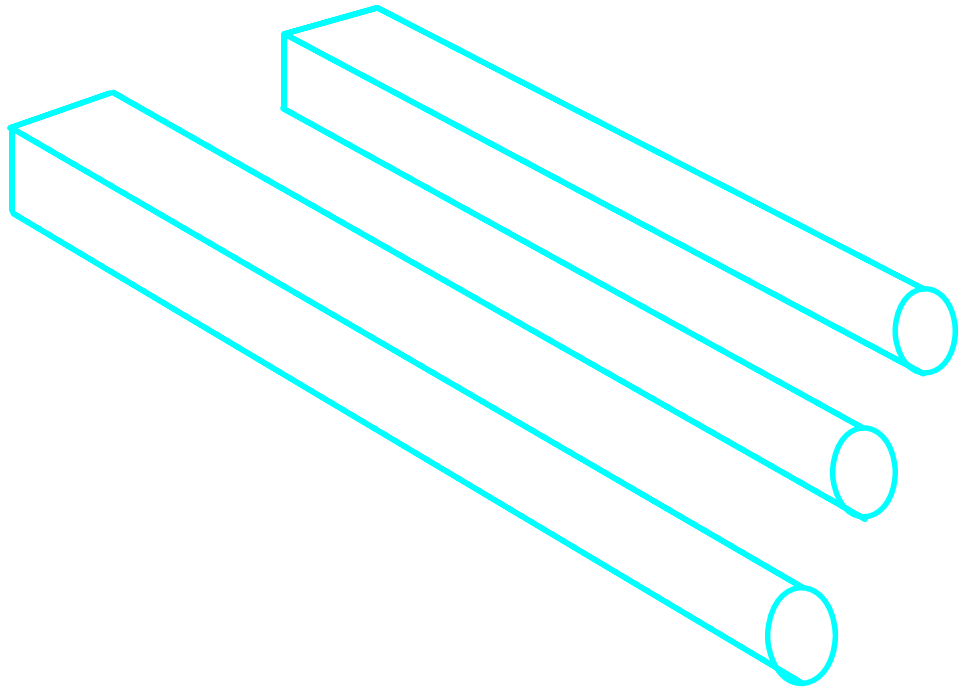
Results: Compared with IPG SCS, Wireless SCS offers higher clinical effectiveness at a lower cost and a higher NMB for our WTP thresholds and is, thus, dominant. Wireless SCS is also cost-effective compared with CMM. Results remain robust with 1) Wireless SCS screening success rates as low as 85% (dominant), 2) the cost of the Wireless SCS devices as high as $55,000 (cost-effective), and 3) IPG SCS devices lasting 12 years (dominant).

Conclusions: In this model, compared with IPG SCS or with CMM, Wireless SCS is a superior strategy.

Keywords: Cost-effectiveness, modeling study, SCS health economics, spinal cord stimulation, wireless SCS

Conflict of Interest: The nonprofit Neuromodulation Foundation which employs Ms. Shipley, and of which Dr. North is an unpaid officer, has received grants and/or consulting income from Abbott (formerly St. Jude), Boston Scientific, Medtronic, Nevro, Nuvectra, and Stimwave. Dr. North has received royalties from Abbott and Nuvectra and consulting income from Nuvectra and Stimwave; his spouse has equity in Stimwave. Drs. Parihar and Spencer are consultants to TAMM Net, which has a contractual agreement with Stimwave. Mr. Spalding is the owner of TAMM Net.

IPG vs. wireless



Smaller

Cheaper

Better

"Pick any two."

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Medicare Coverage Database

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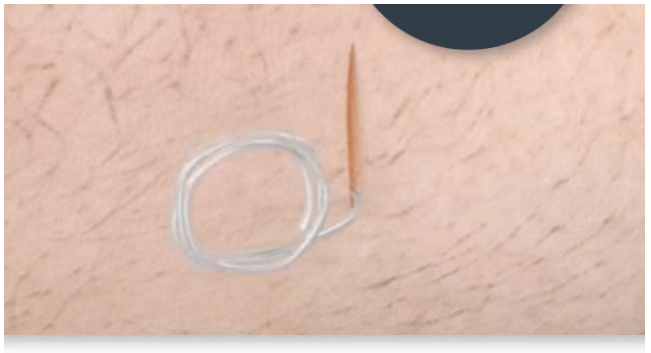
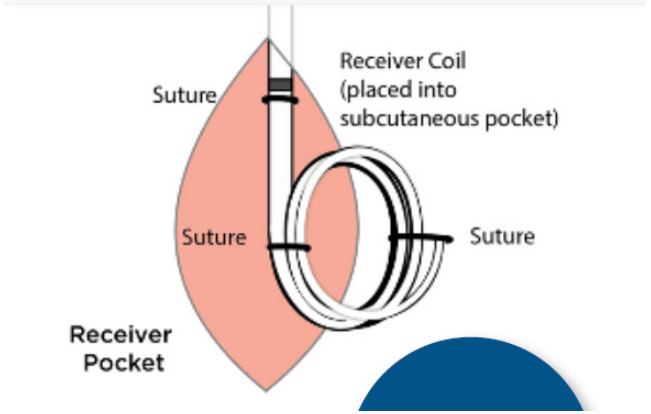
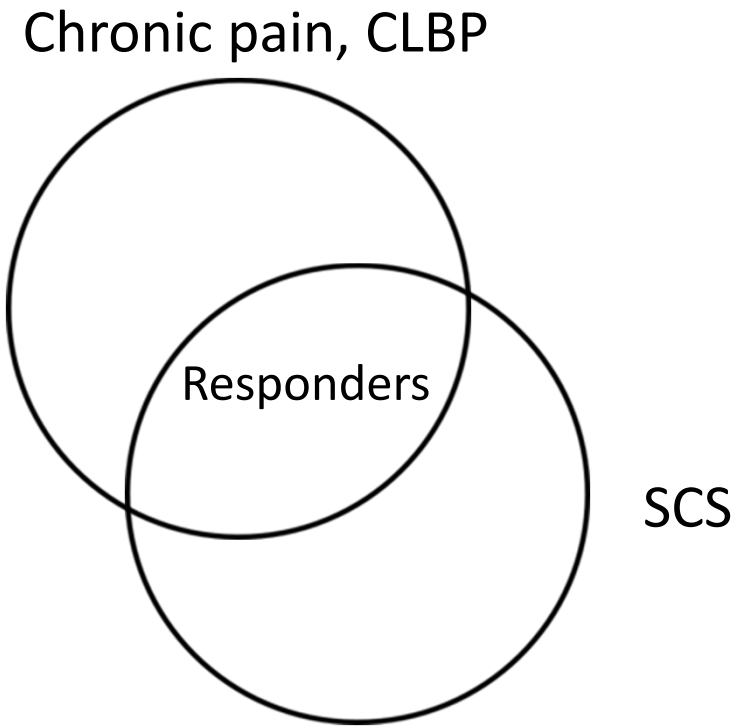
Billing and Coding

Code	Description
61885	INSERTION OR REPLACEMENT OF CRANIAL NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER, DIRECT OR INDUCTIVE COUPLING; WITH CONNECTION TO A SINGLE ELECTRODE ARRAY
64553	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; CRANIAL NERVE
64555	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)
64561	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; SACRAL NERVE (TRANSFORAMINAL PLACEMENT) INCLUDING IMAGE GUIDANCE, IF PERFORMED
64569	REVISION OR REPLACEMENT OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY, INCLUDING CONNECTION TO EXISTING PULSE GENERATOR
64570	REMOVAL OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY AND PULSE GENERATOR
64575	INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)
64581	INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; SACRAL NERVE (TRANSFORAMINAL PLACEMENT)
64585	REVISION OR REMOVAL OF PERIPHERAL NEUROSTIMULATOR ELECTRODE ARRAY
64590	INSERTION OR REPLACEMENT OF PERIPHERAL OR GASTRIC NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER, DIRECT OR INDUCTIVE COUPLING

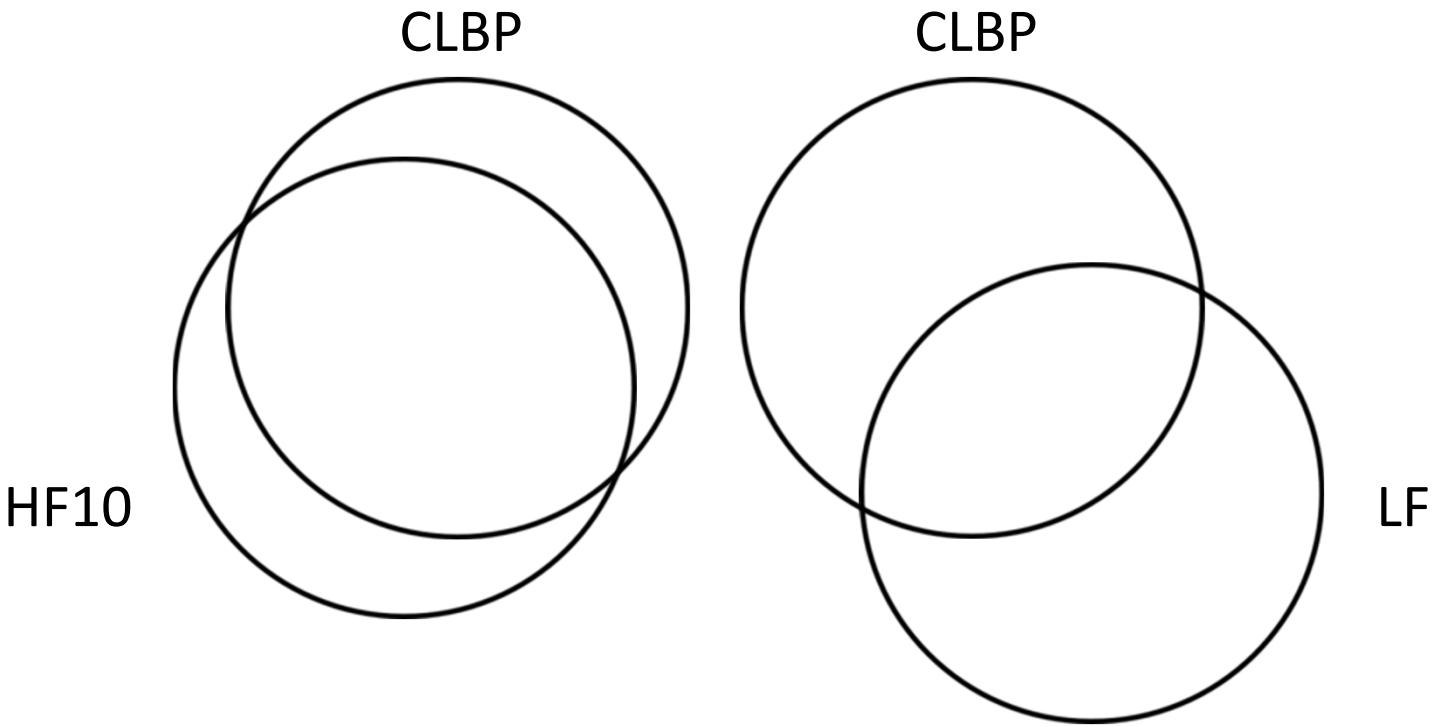
}?



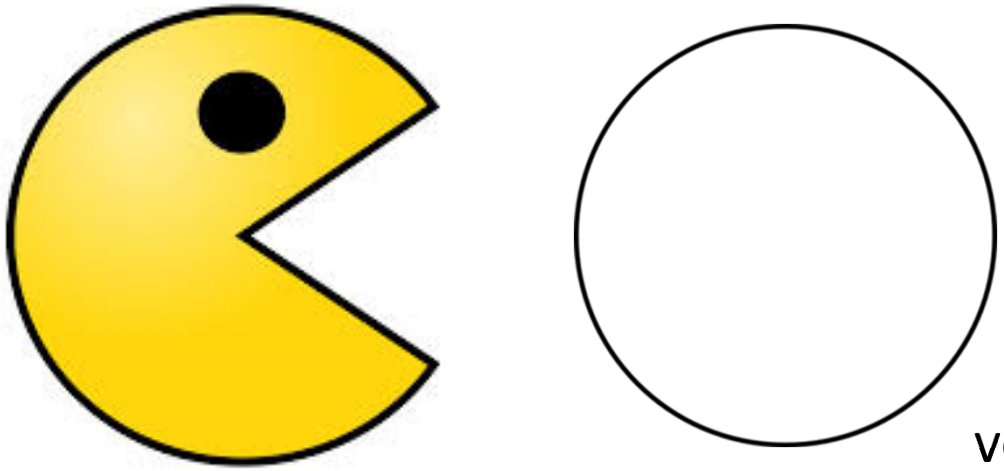


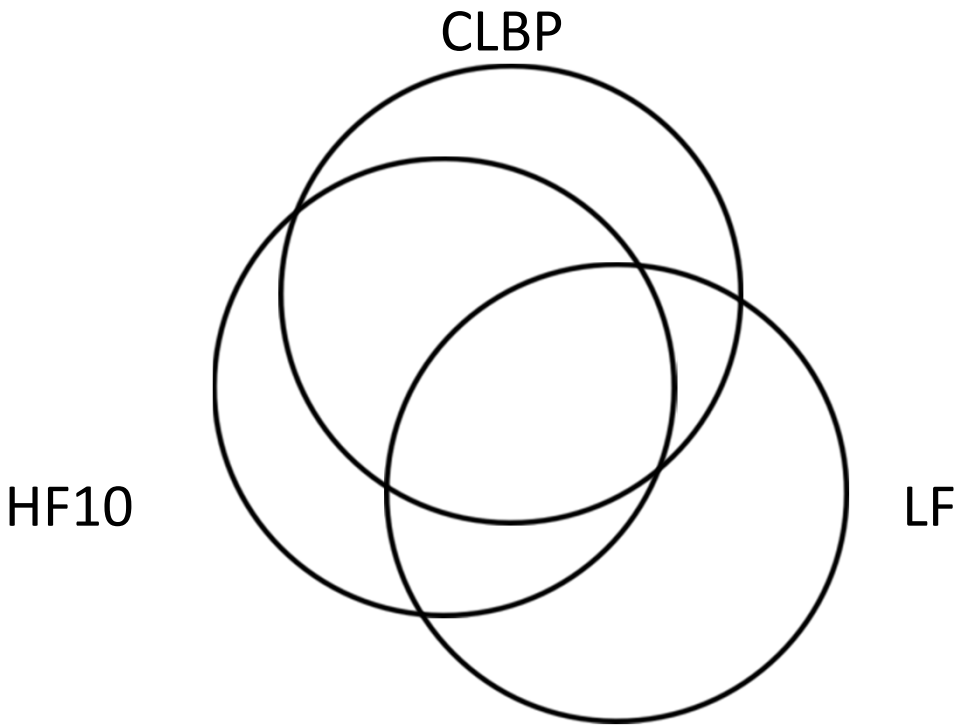


Shealy 1967 ff . . .

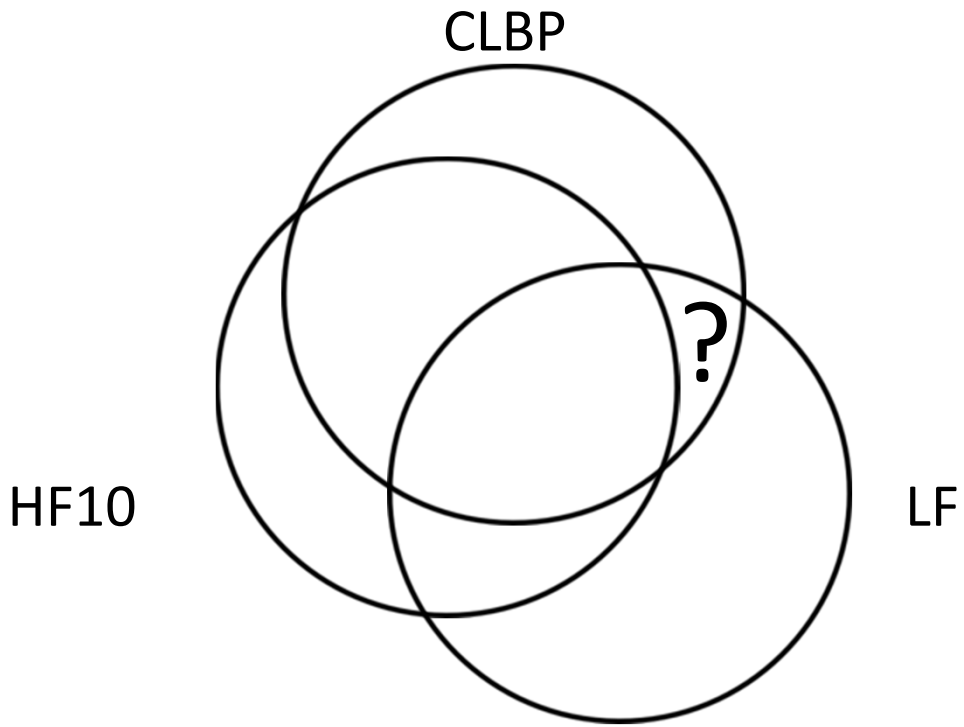


Kapural 2015 RCT – “superiority“

HF10  versus LF

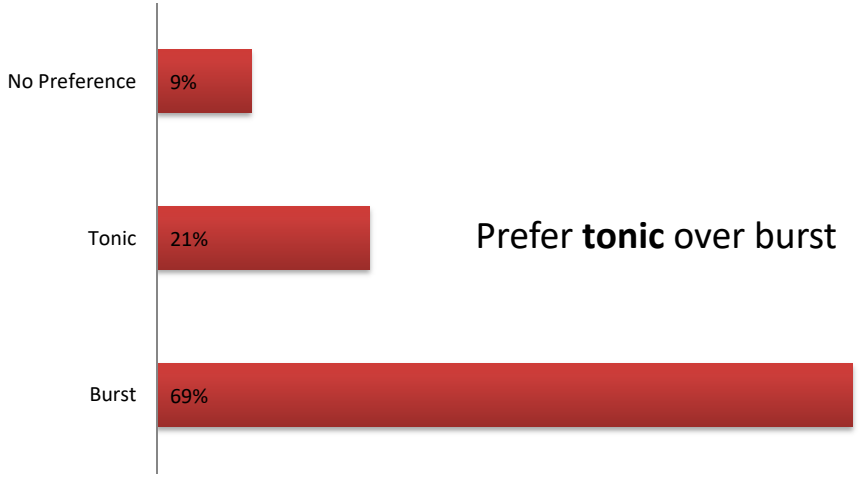


Crossover ?



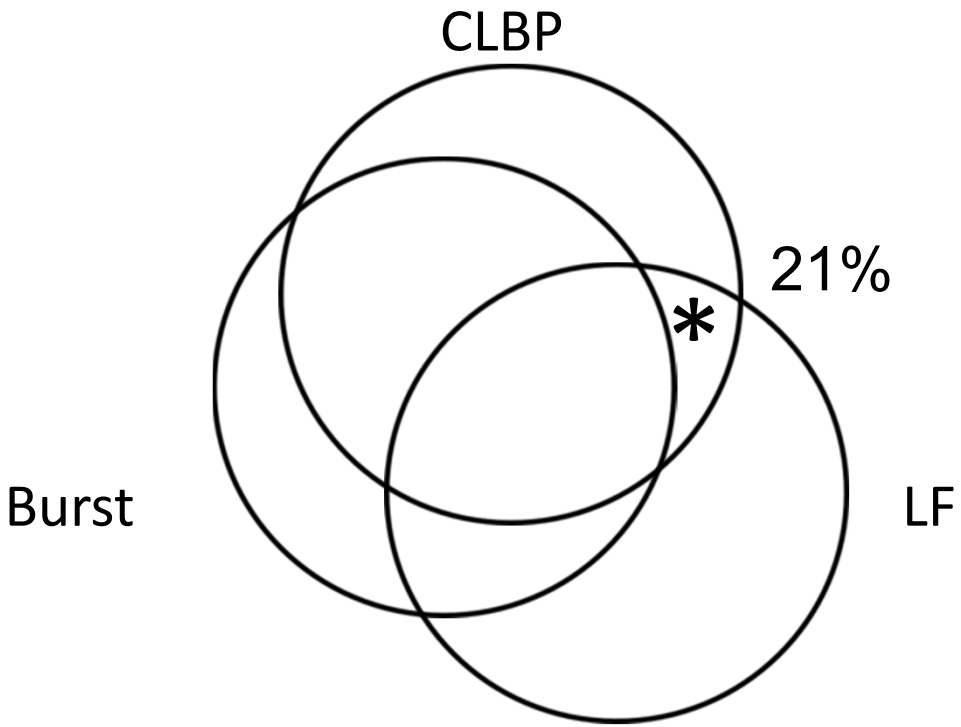
Crossover ?

Preferred therapy type: Percentage of patients



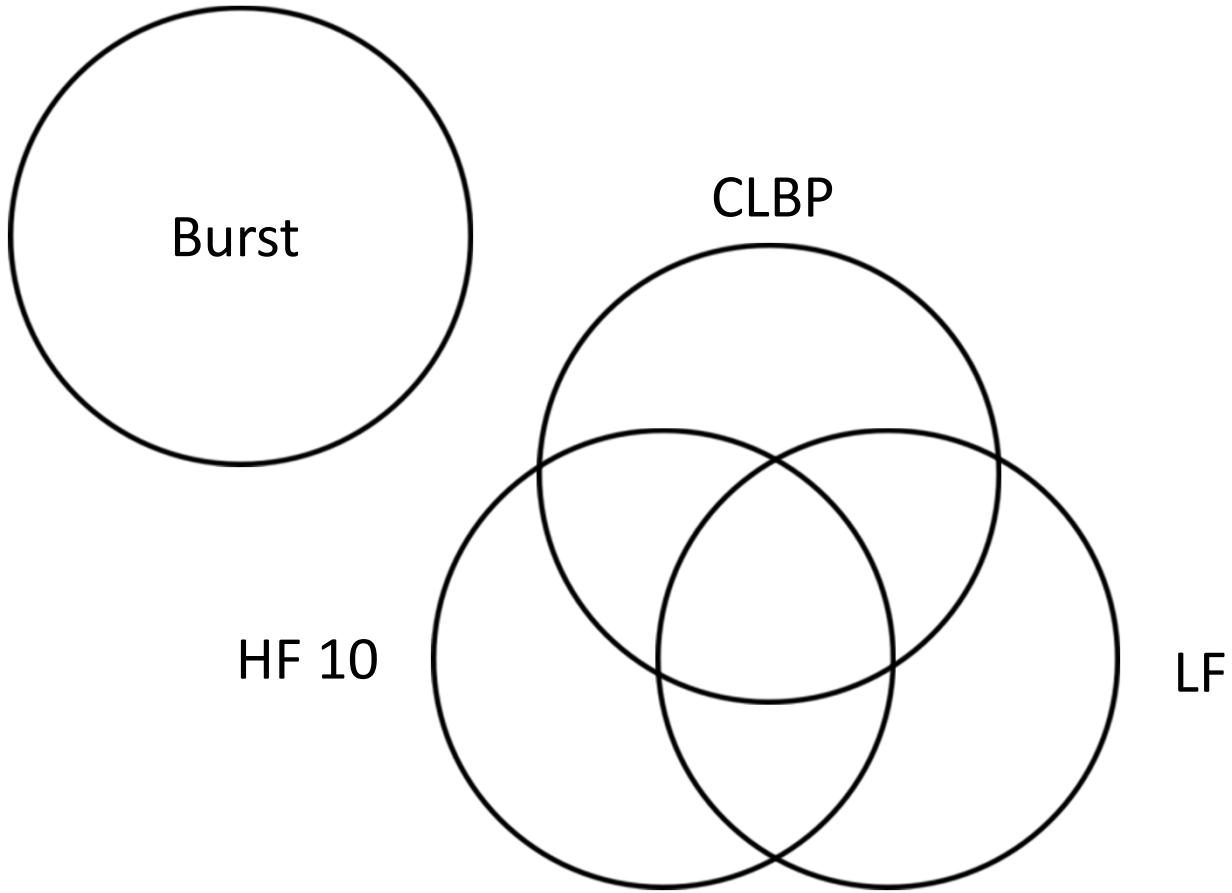
(N=85)

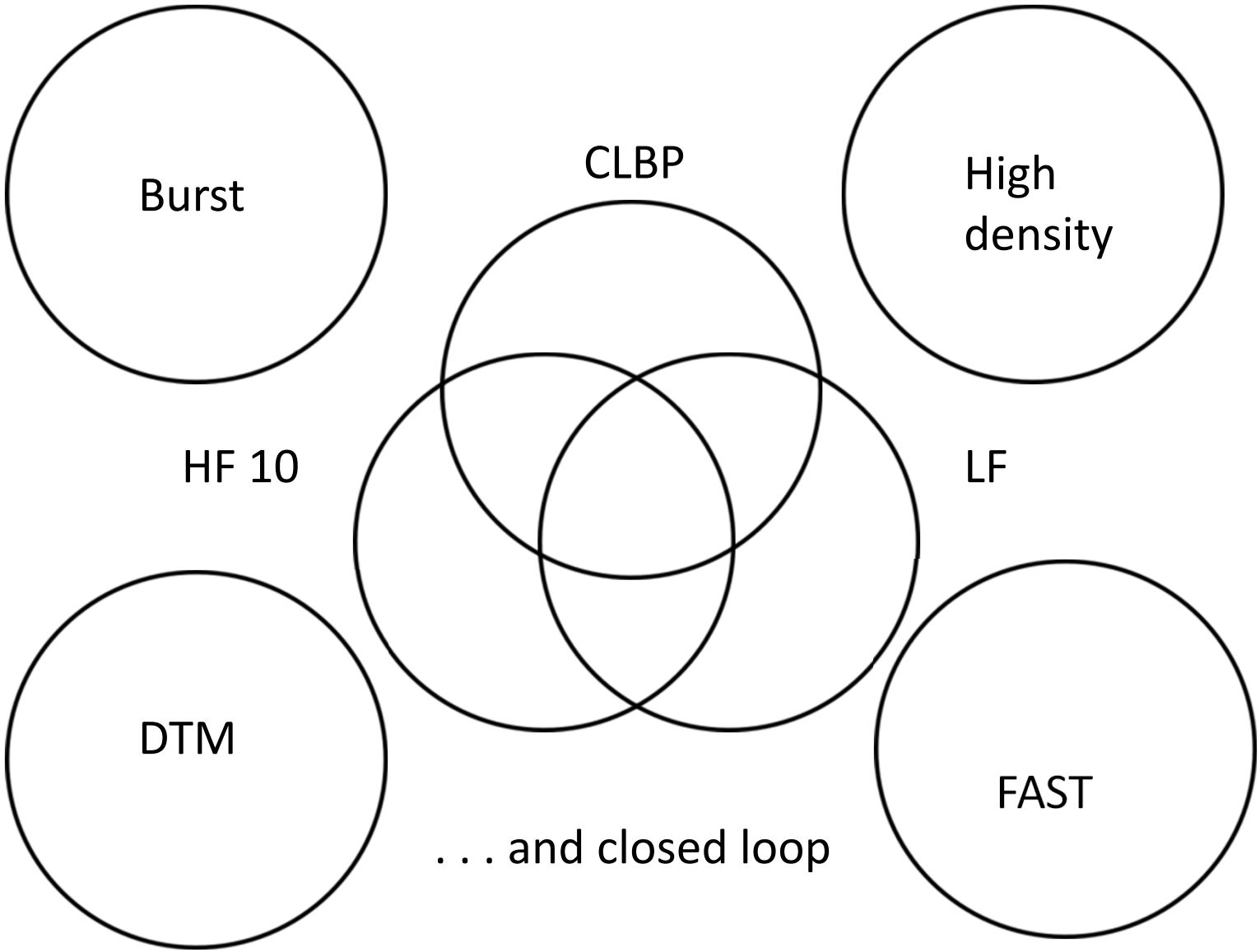
Deer, 2015



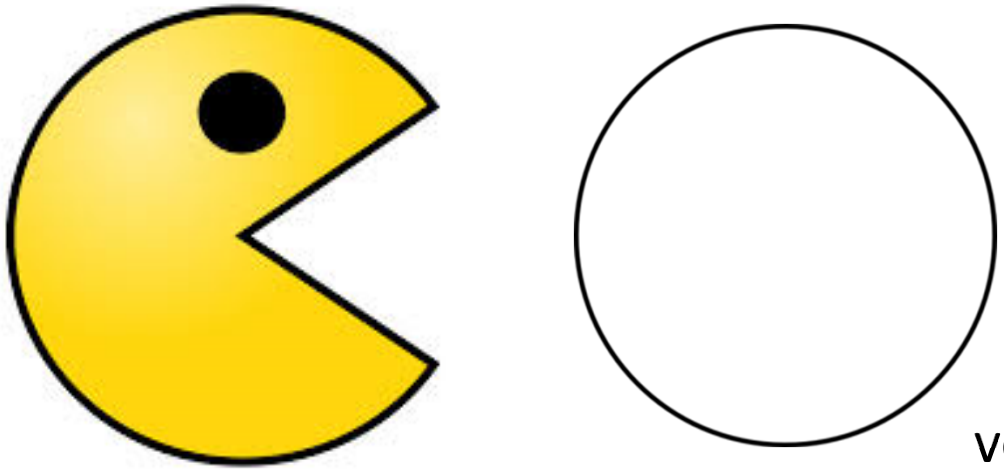
Crossover – burst (mixed frequency)

Dual purpose device


Burst
CLBP
HF 10
LF


Burst
CLBP
High density
HF 10
LF
DTM
FAST
. . . and closed loop

Wassily Kandinsky, Several Circles (1926)



HF10,
burst,
HD,
DTM,
FAST,
PSP

versus LF

Zero sum ?

Multi-purpose device

October 23, 2001

New SCS waveforms

"Superior" to traditional

Complementary vs. competitive

Multipurpose devices needed, subject to

- IP and engineering constraints

Caution re study designs and comparators

- "Evidence based medicine"
- SCS is **no longer a single treatment entity**

2015

JAMA and EBM

1992 **Evidence-Based Medicine**

A New Approach to Teaching the Practice of Medicine

Evidence-Based Medicine Working Group

1993 **Users' Guides to the Medical Literature**

I. How to Get Started

Andrew D. Oxman, MD, MSc; David L. Sackett, MD, MSc; Gordon H. Guyatt, MD, MSc;
for the Evidence-Based Medicine Working Group

2000 **Users' Guides to the Medical Literature**

XXV. Evidence-Based Medicine: Principles for Applying the Users' Guides to Patient Care

JAMA and EBM

1994

Article

December 28, 1994

A Proposal for Structured Reporting of Randomized Controlled Trials

Erik Andrew, PhD; Aslam Anis, PhD; Tom Chalmers, MD; et al

» Author Affiliations

JAMA. 1994;272(24):1926-1931. doi:10.1001/jama.1994.03520240054041

JAMA and SCS

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Search

This database comprises citation information on 3056 reports that report primary data on spinal cord stimulation (SCS) as well as relevant study protocols. Of these entries, 135 have been completely or partially abstracted in WIKISTIM format. We believe the citation list is comprehensive. Latest update for content January 11, 2023; next content update is scheduled for February 9, 2023. Latest update of "epub" citations December 2, 2022; next epub citation update is scheduled for March 2023.

Please note that entries beginning with accented authors' names might not appear in standard alphabetical order in the list of papers.

Searchable SCS Papers

SCS Data Categories

JAMA | Search

Sort By: Publication Date

Use the checkboxes to select multiple papers: Export to CSV

JAMA and SCS

2022

Original Investigation

October 18, 2022

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

A Randomized Clinical Trial

Sozaburo Hara, MD[1,2]; Hege Andresen, RN, MSc[1,2,3]; Ole Solheim, MD, PhD[1,2]; et al

» Author Affiliations

JAMA. 2022;328(15):1506-1514. doi:10.1001/jama.2022.18231

Research

JAMA | Original Investigation

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

A Randomized Clinical Trial

Sozaburo Hara, MD; Hege Andresen, RN, MSc; Ole Solheim, MD, PhD; Sven M. Carlsen, MD, PhD; Terje Sundstrøm, MD, PhD; Greger Lønne, MD, PhD; Vetle V. Lønne, MD; Kristin Taraldsen, PT, PhD; Erling A. Tronvik, MD, PhD; Lise R. Øie, MD, PhD; Agnete M. Gulati, MD, PhD; Lisa M. Sagberg, RN, PhD; Asgeir S. Jakola, MD, PhD; Tore K. Solberg, MD, PhD; Øystein P. Nygaard, MD, PhD; Øyvind O. Salvesen, MSc, PhD; Sasha Gulati, MD, PhD

IMPORTANCE The use of spinal cord stimulation for chronic pain after lumbar spine surgery is increasing, yet rigorous evidence of its efficacy is lacking.

OBJECTIVE To investigate the efficacy of spinal cord burst stimulation, which involves the placement of an implantable pulse generator connected to electrodes with leads that travel into the epidural space posterior to the spinal cord dorsal columns, in patients with chronic radiculopathy after surgery for degenerative lumbar spine disorders.

DESIGN, SETTING, AND PARTICIPANTS This placebo-controlled, crossover, randomized clinical trial in 50 patients was conducted at St Olavs University Hospital in Norway, with study enrollment from September 5, 2018, through April 28, 2021. The date of final follow-up was May 20, 2022.

INTERVENTIONS Patients underwent two 3-month periods with spinal cord burst stimulation and two 3-month periods with placebo stimulation in a randomized order. Burst stimulation consisted of closely spaced, high-frequency electrical stimuli delivered to the spinal cord. The stimulus consisted of a 40-Hz burst mode of constant-current stimuli with 4 spikes per burst and an amplitude corresponding to 50% to 70% of the paresthesia perception threshold.

MAIN OUTCOMES AND MEASURES The primary outcome was difference in change from baseline in the self-reported Oswestry Disability Index (ODI; range, 0 points [no disability] to 100 points [maximum disability]; the minimal clinically important difference was 10 points) score between periods with burst stimulation and placebo stimulation. The secondary outcomes were leg and back pain, quality of life, physical activity levels, and adverse events.

RESULTS Among 50 patients who were randomized (mean age, 52.2 [SD, 9.9] years; 27 [54%]

Visual Abstract

Supplemental content

CONCLUSIONS AND RELEVANCE Among patients with chronic radicular pain after lumbar spine surgery, spinal cord burst stimulation, compared with placebo stimulation, after placement of a spinal cord stimulator resulted in no significant difference in the change from baseline in self-reported back pain–related disability.

The Sydney Morning Herald

This was published 5 months ago

Insurers call for ban on spinal cord stimulator subsidies after new trial

Liam Mannix

October 27, 2022 — 12.30pm

KEY POINTS

- Private health insurers and an independent scientist are calling on Medicare to stop funding spinal cord stimulators.
- The expensive devices are designed to interfere with nerve signals to treat stubborn pain conditions.
- New evidence suggests they are no better than a placebo for a key pain condition.

WIKISTIM.ORG

See ABOUT WIKISTIM

NEWSLETTER #109 NOVEMBER 2022

SCS, JAMA, and EBM

Between 1992 and 2000, the “Evidence-Based Medicine (EBM) Working Group" published 31 papers in the Journal of the American Medical Association (JAMA) to address the critical question, “What is the best evidence for making clinical decisions?” and JAMA has continued to publish important papers in the field of EBM. Until this month, however, as a search of WIKSTIM's list of SCS citations sorted by journal will readily confirm, JAMA (the parent journal) had never published a paper reporting primary spinal cord stimulation (SCS) data and neither had any of the 17 co-authors of a new paper by Hara et al. As detailed in its WIKISTIM abstract, Hara’s paper follows many of the important principles of EBM, but it follows them in such a way that we and our colleagues have begun a dialogue questioning the study’s validity, its ethics, and JAMA’s decision to publish it.

WIKISTIM.ORG

See ABOUT WIKISTIM

NEWSLETTER #109 NOVEMBER 2022

SCS, JAMA, and EBM

SCS is not a single entity, and its overall efficacy should not be called into question by a single, foreseeably negative study. The champions of EBM surely would frown upon this. [Guyatt 2000]
As is often the case, we are left wondering *cui bono*—the authors? the journal? certainly not the study participants who didn't receive optimal therapy and certainly not other patients in pain seeking relief through SCS.

JAMA

To the Editor: Spinal Cord Burst Stimulation vs Placebo Stimulation for Patients With Chronic Radicular Pain After Lumbar Spine Surgery

Nasir Hussain, MD,MSc
Vwaire Orhurhu, MD
Ryan D'Souza, MD

Laxmaiah Manchikanti, MD
Mahendra Sanapati, MD
Joshua Hirsch, MD

Akash Goel, MD, MPH
Michael Leong, MD
Harsha Shanthanna, MBBS, PhD

Simon Thomson, MBBS
Jan Willem Kallewaard, MD, PhD
Kliment Gatzinsky,MD, PhD

Corey W. Hunter,MD
Joshua Rosenow, MD
Marc Russo, MBBS, DA
On behalf of: ASA, AAPM, AANS, ASPN, CNS, INS, NANS

Sam Eldabe MD[1]
Christopher Gilligan MD[2]
Rod S. Taylor PhD[3]
Kiran V. Patel MD[4,5]
Rui V. Duarte PhD[6,7]

EDITORIAL

Pain Practice. 2022;00:1–2.

Issues in design, conduct, and conclusions of JAMA's Hara et al.'s randomized clinical trial of spinal cord burst stimulation versus placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery

Neuromodulation: Technology at the Neural Interface
Received: December 7, 2022 Accepted: December 13, 2022
https://doi.org/10.1016/j.neurom.2022.12.006

LETTER TO THE EDITOR

Randomized Trial of Spinal Cord Stimulation in Chronic Pain: A Critical Review

Philippe Rigoard, MD, PhD[1,2,3]; Konstantin Slavin, MD[4,5]

LETTER TO THE EDITOR

Dirk De Ridder, MD, PhD
University of Otago Surgical Sciences, Dunedin, Otago, New Zealand

Semantic Confusion Risks Undermining the Science of Spinal Cord Stimulation

INS response to the Recent JAMA Article on Spinal Cord Stimulation

Marc A. Russo, MBBS DA (UK) FANZCA FFPMANZCA
President, International Neuromodulation Society

JAMA and SCS

2022

Original Investigation

ONLINE FIRST

November 28, 2022

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

Sanket S. Dhruva, MD, MHS[1,2,3]; Jaime Murillo, MD[4]; Omid Ameli, MD, DrPH[5]; et al

» Author Affiliations

JAMA Neurol. Published online November 28, 2022. doi:10.1001/jamaneurol.2022.4166

JAMA Neurology | Original Investigation

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

Sanket S. Dhruva, MD, MHS; Jaime Murillo, MD; Omid Ameli, MD, DrPH; Pamela E. Morin, MBA; Donna L. Spencer, PhD; Rita F. Redberg, MD, MSc; Ken Cohen, MD

IMPORTANCE Spinal cord stimulators (SCSs) are increasingly used for the treatment of chronic pain. There is a need for studies with long-term follow-up.

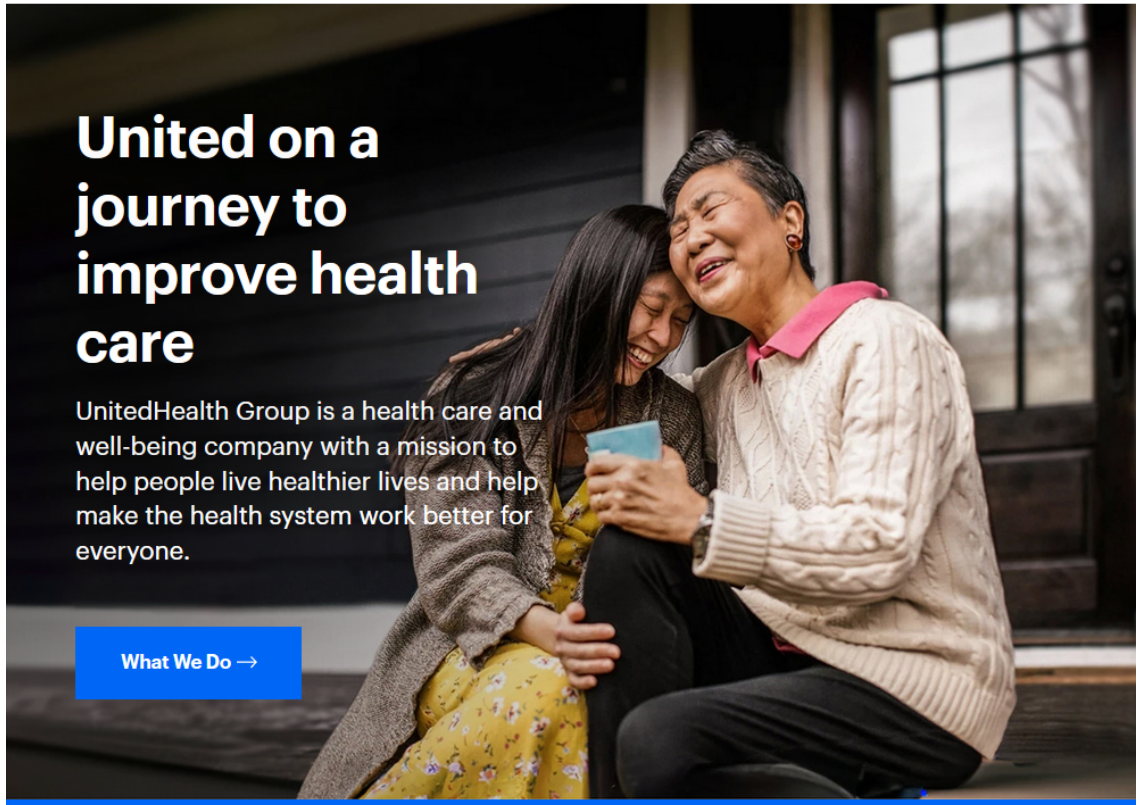
OBJECTIVE To determine the comparative effectiveness and costs of SCSs compared with conventional medical management (CMM) in a large cohort of patients with chronic pain.

DESIGN, SETTING, AND PARTICIPANTS This was a 1:5 propensity-matched retrospective comparative effectiveness research analysis of insured individuals from April 1, 2016, to August 31, 2018. This study used administrative claims data, including longitudinal medical and pharmacy claims, from US commercial and Medicare Advantage enrollees 18 years or older in Optum Labs Data Warehouse. Patients with incident diagnosis codes for failed back surgery syndrome, complex regional pain syndrome, chronic pain syndrome, and other chronic postsurgical back and extremity pain were included in this study. Data were analyzed from February 1, 2021, to August 31, 2022.

Conflict of Interest Disclosures: Dr Dhruva reported receiving grants from Arnold Ventures; research funding from the Greenwall Foundation, the Department of Veterans Affairs, the National Evaluation System for Health Technology Coordinating Center, the US Food and Drug Administration, and the National Institute for Health Care Management; and serving on the Institute for Clinical and Economic Review California Technology Assessment Forum. Dr Murillo reported being an employee and stockholder of UnitedHealth Group and being a full-time employee of Optum Labs UnitedHealth Group outside the submitted work. Dr Ameli reported being a full-time employee of Optum Center for Research and Innovation and Optum Labs during the conduct of the study. Ms Morin reported being a full-time employee of Optum Labs during the conduct of the study and purchasing UnitedHealth Group stock as an employee. Dr Spencer was a full-time employee of Optum Labs during the conduct of the study and reported purchasing stock in UnitedHealth Group as an employee. Dr Redberg reported receiving grants from Arnold Ventures and Greenwall Foundation outside the submitted work; and serving on the Institute for Clinical and Economic Review California Technology Assessment Forum. Dr Cohen reported being an employee of Optum Center for Research and Innovation and Optum Labs. No other disclosures were reported.

Funding/Support: This study was supported by Arnold Ventures (Drs Dhruva and Redberg).

UNITEDHEALTH GROUP



United on a journey to improve health care

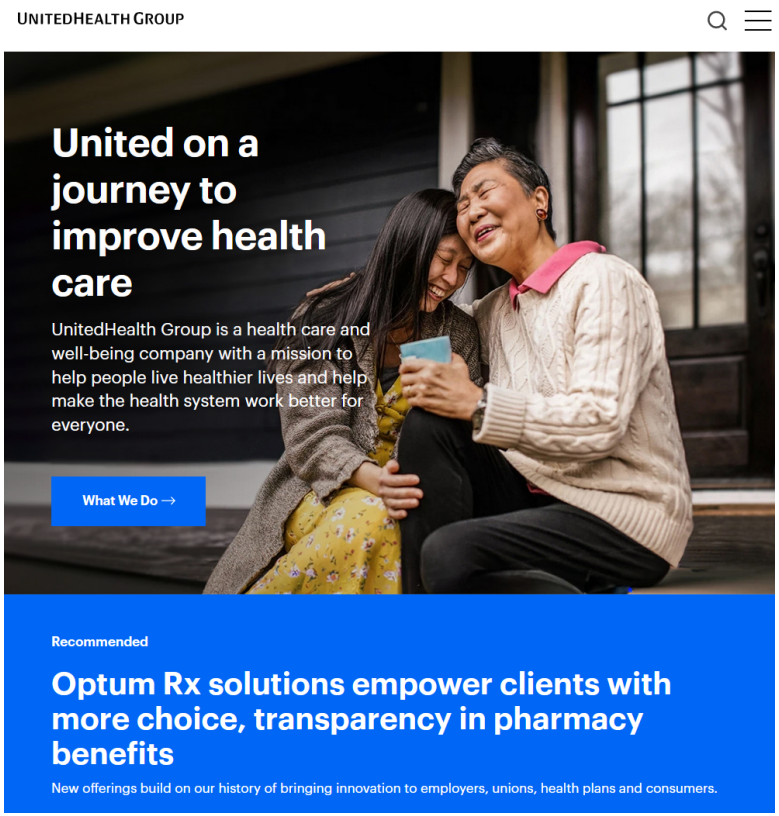
UnitedHealth Group is a health care and well-being company with a mission to help people live healthier lives and help make the health system work better for everyone.

What We Do →

Recommended

Optum Rx solutions empower clients with more choice, transparency in pharmacy benefits

New offerings build on our history of bringing innovation to employers, unions, health plans and consumers.



UnitedHealth Group Incorporated is a for-profit[4] American multinational managed healthcare and insurance company . . . the world's seventh-largest company by revenue and the largest healthcare company by revenue, and the largest insurance company by net premiums.

- Wikipedia

INSURANCE

STAT+

The health insurer will see you now: How UnitedHealth is keeping more profits, as your doctor

By Bob Herman Dec. 5, 2022

Reprints

JAMA and Conflict of Interest

2008

Industry-Sponsored Clinical Research
A Broken System

Marcia Angell, MD

OVER THE PAST 2 DECADES, THE PHARMACEUTICAL industry has gained unprecedented control over the evaluation of its own products. Drug companies now finance most clinical research on prescription drugs, and there is mounting evidence that they often skew the research they sponsor to make their drugs look better and safer. Two recent articles underscore the problem: one showed that many publications concerning Merck's rofecoxib that were attributed primarily or solely to academic investigators were actually written by Merck employees or medical publishing companies hired by Merck[1]; the other showed that the company manipulated the data analysis in 2 clinical trials to minimize the increased mortality associated with rofecoxib.[2] Bias in the way industry-sponsored research is conducted and reported is not unusual and by no means limited to Merck.[3]

The problem is not so much the sponsorship itself but

In recent years, however, sponsoring companies have become intimately involved in all aspects of research on their products. They often design the studies; perform the analysis; write the papers; and decide whether, when, and in what form to publish the results. In some multicenter trials, authors may not even have access to all their own data. The Pharmaceutical Research and Manufacturers of America, the trade association of the industry, justified withholding data in this way: "As owners of the study database, sponsors have discretion to determine who will have access to the database."[4] At its extreme, investigators have become little more than hired hands, supplying patients and collecting data according to the company protocol.

Adding to the willingness of medical centers to tolerate these encroachments on their traditional responsibilities is the competition from a huge new for-profit research industry that vies with medical centers for pharmaceutical contracts. Called contract research organizations (CROs), these businesses organize networks of physicians to supply patients. Contract research organizations are only too ready to accede to drug company terms because their only clients

JAMA and SCS and CoI

Unacknowledged CoI - Industry funding by UHC/Optum

Proxy SCS outcomes do not include pain, QOL

Failure to mention contrary evidence and publications

Selective reporting of data

“Policy based evidence?”

See ABOUT WIKISTIM

NEWSLETTER #111 JANUARY 2023

No Conflict, No Interest

In our November newsletter, we noted that the *Journal of the American Medical Association* (JAMA), an early leader in the promotion of evidence-based medicine, had just published the results of a spinal cord stimulation (SCS) outcomes study with important methodological shortcomings that peer reviewers should have caught (Hara et al. 2022). Similarly, JAMA editors have led efforts to define conflict of interest (CoI) and potential bias arising from industry sponsorship of research (Angell 2008, DeAngelis et al. 2008). In December, however, *JAMA Neurology* published an analysis of "big data" proxy SCS outcomes (Dhruva et al. 2023) that has raised concerns not only about the methodology used in this analysis but also about CoI on the part of the authors.

Cochrane Library

Cochrane Database of Systematic Reviews

Spinal cord stimulation for low back pain (Review)

Adrian C Traeger[1,2], Stephen E Gilbert[1,2], Ian A Harris[1,3], Christopher G Maher[1,4]

[1]Institute for Musculoskeletal Health, The University of Sydney and Sydney Local Health District, Sydney, Australia. [2]School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia. [3]South West Sydney Clinical School, University of New South Wales, Liverpool, Australia. [4]School of Public Health, Faculty of Medicine and Health, The University of Sydney, Sydney, Australia

RESULTS

Description of studies

Results of the search

Our search, conducted up to 10 June 2022, yielded 6492 records across five databases and two clinical trials registers (CENTRAL = 921; MEDLINE = 1014; Embase = 2719; CINAHL = 54; Bielefield = 940; trials registers (WHO ICTRP, clinicaltrials.gov) = 844). After duplicates were removed, 4776 unique records remained. Of these, we retrieved 113 articles for full-text screening on the basis of their titles and abstracts. We deemed 13 trials eligible for inclusion (Al-Kaisy 2018; De Ridder 2013; Eisenberg 2015; Eldabe 2020; Hara 2022; Kumar 2007; Kapural 2022; Perruchoud 2013; Rigoard 2019; Schu 2014; Sokal 2020; Sweet 2016; Wolter 2012). Three trials are awaiting classification (see Characteristics of studies awaiting classification). We initially identified 14 relevant ongoing trials in clinical trials registries, one of which was published on 18 October 2022 and subsequently included in this review (Hara 2022). Thus, we have classified 13 studies as ongoing (see Characteristics of ongoing studies). We excluded 29 studies (see details in Excluded studies and Characteristics of excluded studies). We present a flow diagram of the study selection process in Figure 1.

Comparison 1: SCS versus placebo

No trials assessed SCS versus placebo at long-term follow-up. Only the Hara 2022 study assessed the benefits of SCS versus placebo using a treatment period of longer than three weeks. We judged

Cochrane Library

Cochrane Database of Systematic Reviews

Implanted spinal neuromodulation interventions for chronic pain in adults (Review)

O'Connell NE, Ferraro MC, Gibson W, Rice ASC, Vase L, Coyle D, Eccleston C.

Implanted spinal neuromodulation interventions for chronic pain in adults.
Cochrane Database of Systematic Reviews 2021, Issue 12. Art. No.: CD013756.
DOI: 10.1002/14651858.CD013756.pub2.

www.cochranelibrary.com

WILEY

See ABOUT WIKISTIM

NEWSLETTER #113 MARCH 2023

Et Tu, Cochrane?

A Cochrane review on spinal cord stimulation (SCS) for low back pain was published on March 7, 2023 (Traeger et al.). Based on an analysis of 13 studies described as "randomised controlled trials (RCTs) and cross-over trials comparing SCS with placebo or no treatment for low back pain" and limited further to subsets of each of these categories, the authors drew the broad conclusion that “SCS probably does not have sustained clinical benefits that would outweigh the costs and risks.”

Cochrane Review

Author	Posts

April 21, 2023 at 5:01 pm REPLY #71356

sdurbha3
Participant

Society is primed to revere Cochrane publications as the peak of academic #excellence. Yet, this review by Traeger et al is methodologically #flawed and intentionally curated to fit a specific agenda and narrative.

Check out our Pain Medicine Journal commentary (free to download) at: https://academic.oup.com/painmedicine/advance-article/doi/10.1093/pm/pnad047/7126436

#Science, #medicine, and #publichealth are not meant to be politicized. When they are, the #implications are vast for #patients. Interestingly, there are #parallels to another recent Cochrane review on #masks for #Covid-19. That review also grouped apples and oranges, used flawed methodology and made sweeping #generalizations not supported by the data. Just because an article comes from what we consider a "reputable" source, it doesn't mean the science is solid.

Pain Medicine, 2023, **00**, 1–3
https://doi.org/10.1093/pm/pnad047
Advance access publication 17 April 2023
Commentary

OXFORD

Striking errors in the methodology, execution, and conclusions of the Cochrane Library review of spinal cord stimulation for low back pain by Traeger *et al.*

Shravani Durbhakula, MD, MPH, MBA[1,*], Mustafa Y. Broachwala, DO[2], Nathaniel M. Schuster, MD[3], Zachary L. McCormick, MD[4]

"Multiple responses in JAMA and other medical journals outline the lack of validity of the Hara et al. study based on:

1) trialing with tonic stimulation rather than the experimental burst SCS waveform . . .

2) allowing placebo-level responders to pass into the implant phase,

3) using a single, ineffective waveform which is not used as monotherapy in clinical practice . . . amplitude corresponding to 50%–70% of the paresthesia perception threshold, effectively rendering it a placebo versus placebo trial, and

4) trialing followed by randomization after the trial, which is inconsistent with other SCS studies and masks the true high attrition rate . . . "

https://www.cochrane.org/news/spinal-cord-stimulation-doe

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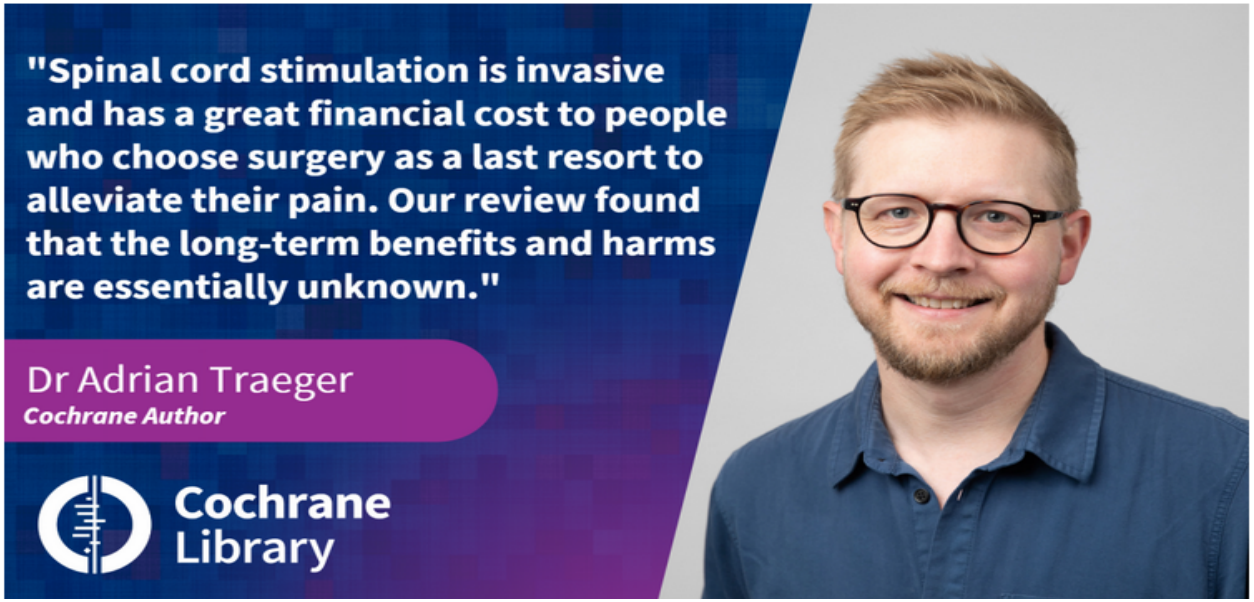
Cochrane Evidence Synthesis and Methods

Spinal cord stimulation doesn't help with back pain, says new review



The Sydney Morning Herald SUBSCRIBE

Exclusive National Medicare

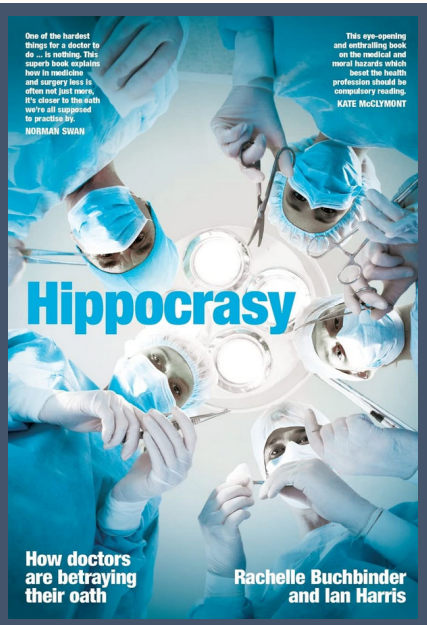
This was published 5 months ago

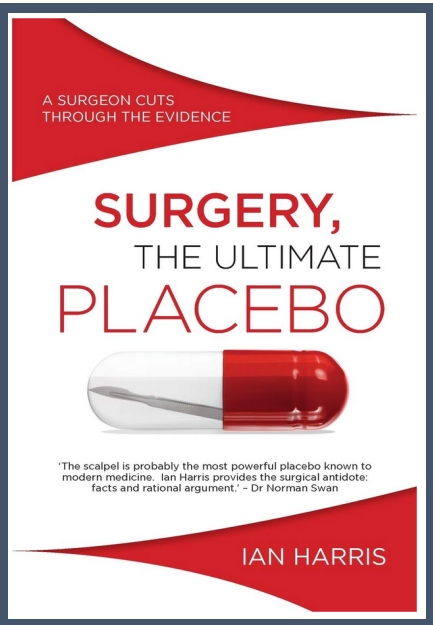
Insurers call for ban on spinal cord stimulator subsidies after new trial

Liam Mannix

October 27, 2022 — 12.30pm

"This is a strong signal this treatment may not work," said the Institute for Musculoskeletal Health's Dr Adrian Traeger, who has been writing a review of the evidence for spinal cord stimulators to treat back pain. He called on Medicare to stop subsidising the surgery until more evidence was collected."





Traeger AC, Gilbert SE, Harris IA, Maher CG.

Spinal cord stimulation for low back pain (Review)

The New York Times

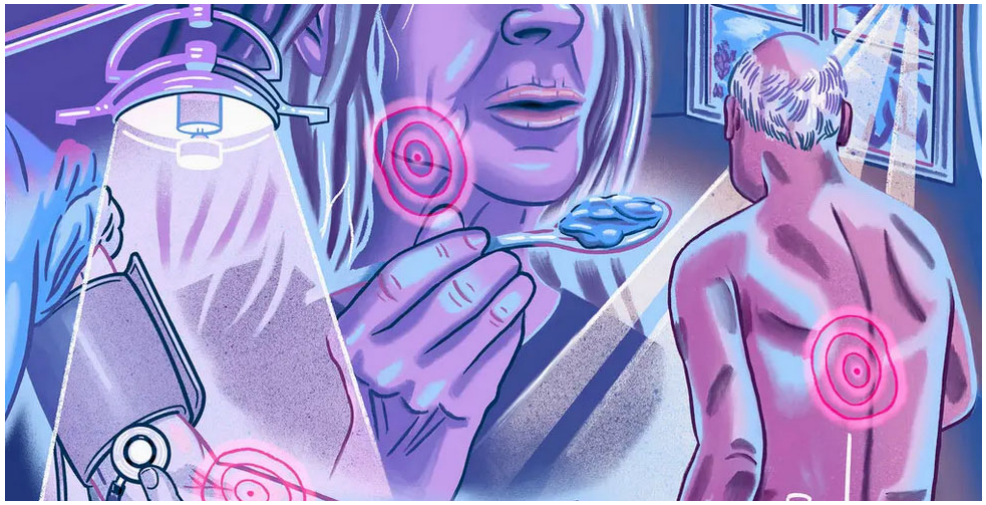
By Paula Span

Sept. 14, 2024

THE NEW OLD AGE

Three Medical Practices That Older Patients Should Question

Some treatments and procedures become routine despite lacking strong evidence to show that they're beneficial. Recent studies have called a few into question.



The New York Times

By Paula Span

Sept. 14, 2024

THE NEW OLD AGE

Three Medical Practices That Older Patients Should Question

Two Cochrane reviews, meta-analyses by an independent network of researchers, have found "low to very low certainty evidence" that stimulation reduces pain intensity and "little to no sustained benefit" for low back pain.

Pain specialists and professional organizations were quick to criticize the new study's methodology, however.

"That's a very imprecise criteria to judge someone's pain relief by — the amount of medication they take," said Dr. Konstantin Slavin, a neurosurgeon at the University of Illinois, Chicago, and president of the International Neuromodulation Society.

"That doesn't correlate with patients' self-reported experiences."

NEWSLETTER #129 July 2024 See ABOUT WIKISTIM

Using WIKISTIM to Support Meta-analysis Researchers, Peer Reviewers, Readers, and Policymakers

Meta-analyses (MAs) of clinical trials continue to proliferate in health care, sometimes with resulting controversy. This has been the case recently for spinal cord stimulation (SCS), and it continues: the lead author of a Cochrane review of SCS last year [Traeger-23], Adrian Traeger, published critical editorial comments last month [Traeger-24] on a new MA [Eldabe-24]. The new critique focused attention on two SCS trials, along with Traeger's MA, all of which raised concerns reported in our newslettters [Nov-22, Jan-23, March-23, May-23, June-23]. In brief, the new critique says that the conclusion of Eldabe and Duarte [Eldabe-24] "is entirely misleading" and "yet another attempt to control the narrative." This comes on the heels of a disappointing Traeger polemic published by JAMA Int Med [Traeger, Bero-24], which we discussed in our January newsletter [Jan-24].

Comparison of clinical outcomes associated with spinal cord stimulation (SCS) or conventional medical management (CMM) for chronic pain: a systematic review and meta-analysis.

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Publication Information

Author(s): Zhou M, Zhong H, Xing C, Li H, Liu S, Wang L, Ma H, Ning G.
Title: Comparison of clinical outcomes associated with spinal cord stimulation (SCS) or conventional medical management (CMM) for chronic pain: a systematic review and meta-analysis.
Journal: Eur Spine J
Volume, issue, pages: 32(6):2029-2041
Year: 2023
PubMed Link: https://pubmed.ncbi.nlm.nih.gov/37067600/

Description of Meta Analysis

Location: China
Sponsor/source of support of meta-analysis (AMSTAR 16): None
Competing interests stated? (AMSTAR 16): Yes
Journal impact factor: 2.721

Eligibility Criteria

Intervention: SCS
Primary outcomes of interest: Pain intensity, physical functioning
Duration of follow-up of reports: 6-60 months
Required participant characteristics: CRPS, FBSS, PDN, critical limb ischemia, refractory angina

Search Strategy

Method of Data Extraction

Statistical Methods

Sample size needed for sufficient power: Yes

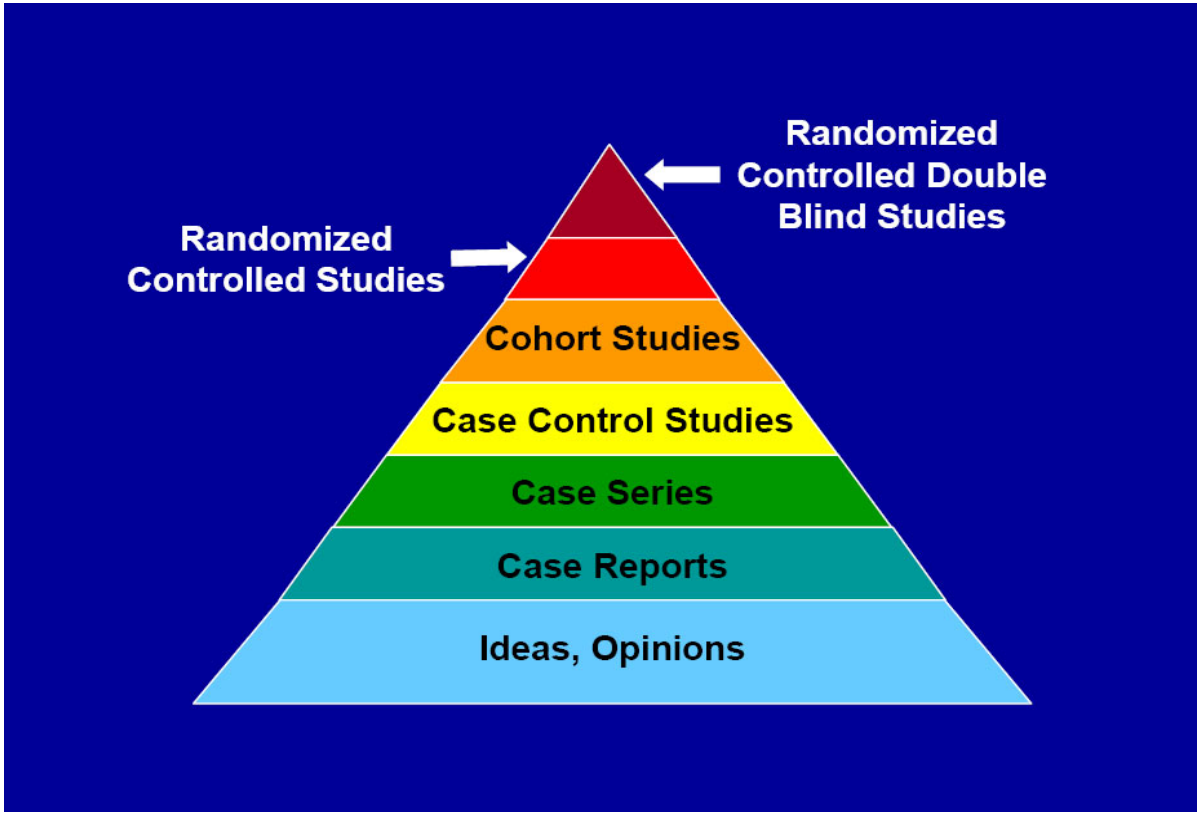
Results

Exclusions enumerated & justified? (AMSTAR 7): ✓
Number of reports included: 8
Number of participants: 893
Assessment of publication bias (AMSTAR 15): ✓

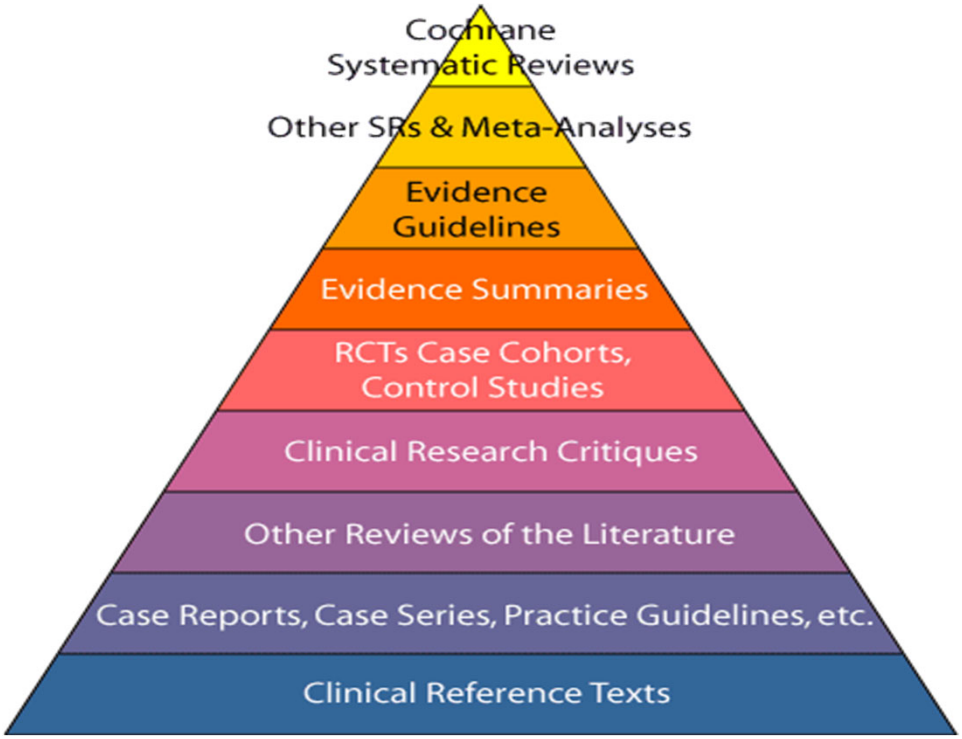
Wikistim Data Abstraction

Name of abstracter(s): Kleppel et el. https://rapm.bmj.com/content/rapm/early/2024/02/21/rapm-2023-105249.full.pdf (transcribed for WIKISTIM by Sujeivan Mahendram and Mahtab Darvish)
Date: 2023-24

Evidence pyramid, v 1.0

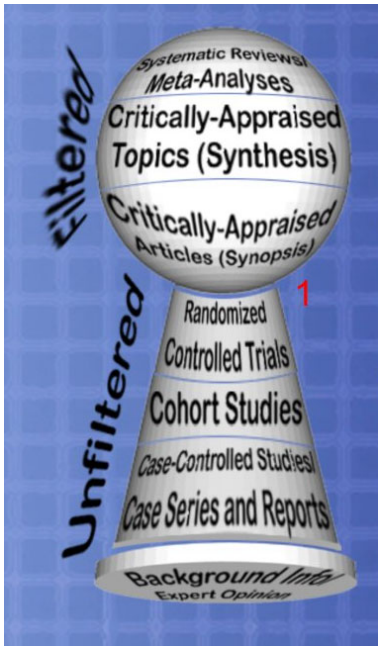


Evidence pyramid, v 2.0



http://healthlinks.washington.edu - modified from: Navigating the Maze, University of Virginia, Health Sciences Library

Evidence pyramid, v 3



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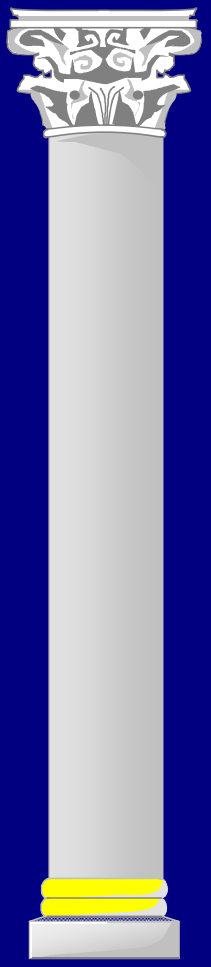
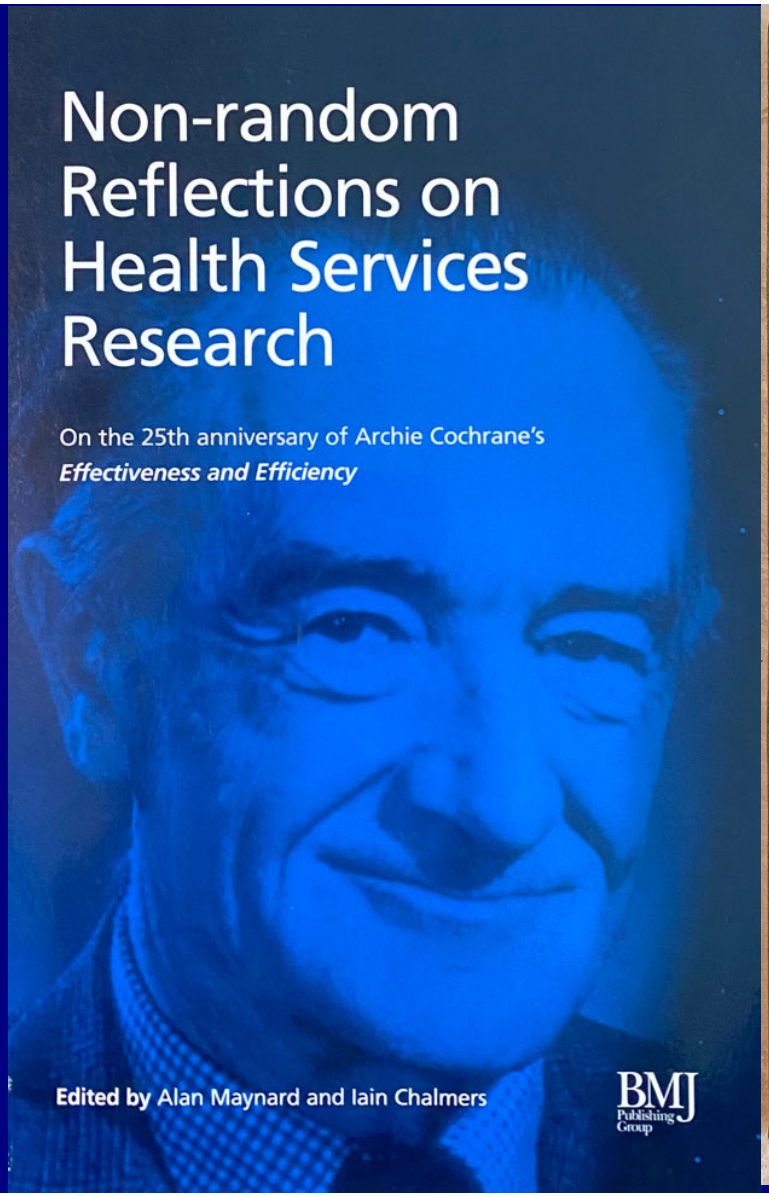
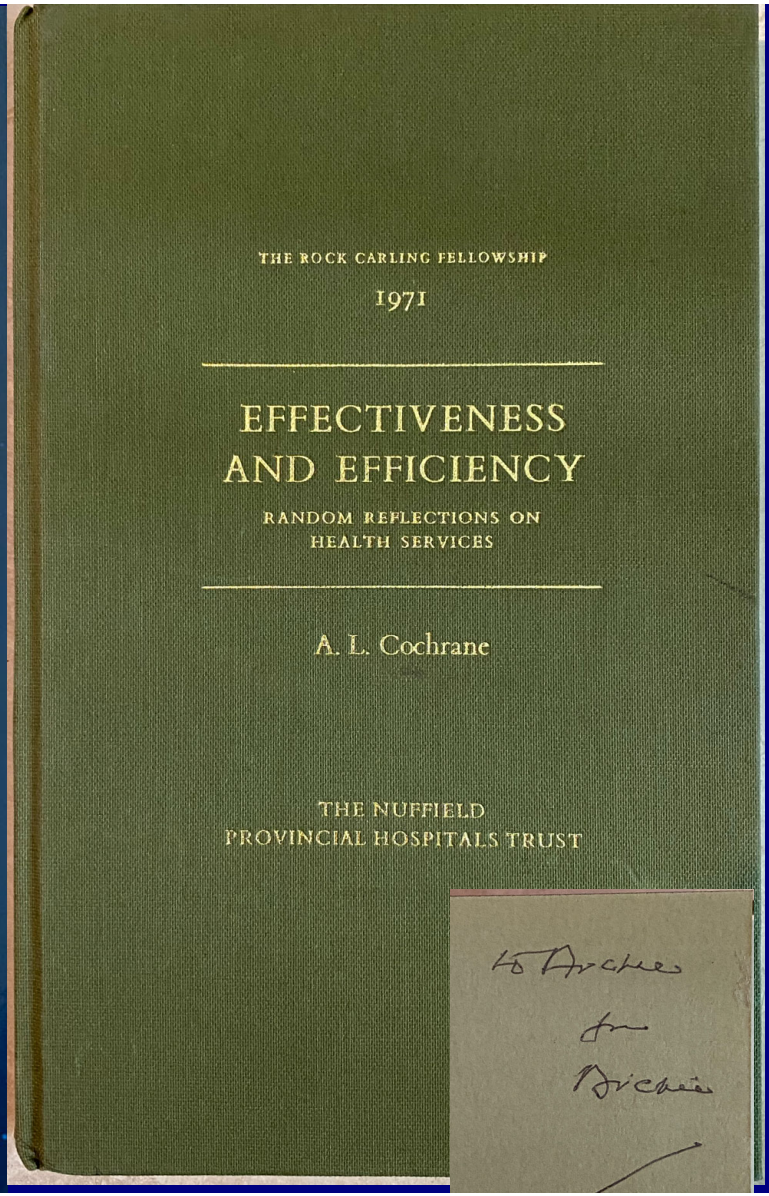


Never ask a question unless you already know the answer.

- Harvey Specter, *Suits*


Non-random Reflections on Health Services Research
On the 25th anniversary of Archie Cochrane's
Effectiveness and Efficiency
Edited by Alan Maynard and Iain Chalmers
BMJ Publishing Group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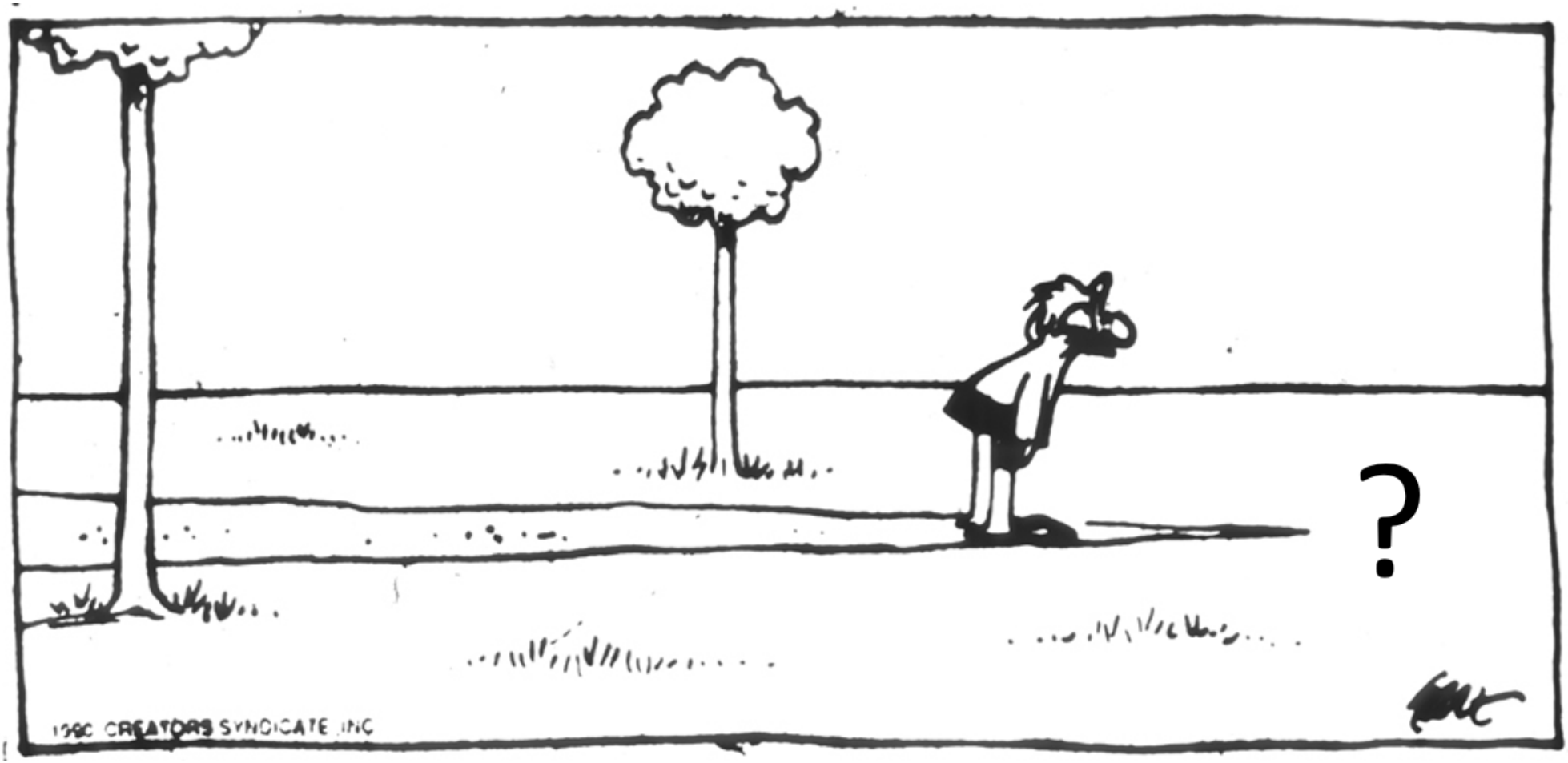
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