

The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

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# Disclosures

Richard B. North, MD

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### PAIN and the NEUROSURGEON

A Forty-Year Experience

BASED ON A SERIES OF OVER 1700 PATIENTS AND ON THE AUTHOR'S STUDY OF THE WORLD LITERA-TURE AIDED BY THEIR OWN EX-PERIENCE, THIS VOLUME IS AN EVALUATION OF NEUROSURGICAL PROCEDURES FOR THE RELIEF OF OTHERWISE INTRACTABLE PAIN.

CHARLES C THOMAS • PUBLISHER Springfield • Illinois With Assistance in the Psychiatric Section of Chapter XVII from

#### STANLEY COBB, M.D.

Former Chief of Psychiatric Service Massachusetts General Hospital Bullard Professor of Neuropathology Emeritus, Harvard Medical School

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#### FRANK R. ERVIN, M.D.

Psychiatrist Massachusetts General Hospital Associate Clinical Professor of Psychiatty Harvard Medical School APOLLO How America Won the Race to the Moon

THE ASSOCIATED PRESS

AP

White & Sweet, 1969



# The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

Mechanisms and rationale

(onlinelibrary.wiley.com) DOI: 10.1111/j.1525-1403.2012.00484.x

### FROM THE EDITOR-IN-CHIEF

### The Need for Mechanism-Based Medicine in Neuromodulation



"How are we to know how to alter stimulation parameters, other than by trial and error, to optimize outcomes if we do not know where and how they act on neural tissues?"

Neuromodulation 2012; 15: 273–279

### Merging evidence-based and mechanism-based medicine

The example elucidates several points. First, the questions of an intervention's effectiveness and its mechanism are closely linked: an intervention is always based on an idea or a model of how the symptoms of a disease present, and how an intervention might exert its effect. This model and its empirical basis might, however, become obscured over time. Second, an intervention can be effective, even though it is based on an erroneous assumption about its mechanism of action. Third, the effectiveness of an intervention can be assessed, without inquiring into its mechanism. Although such a study might produce important information, it does not improve knowledge of the underlying pathophysiological processes. Not having such knowledge might hinder development of novel and potentially more efficacious interventions in the long term. Fourth, efficacy and mechanistic issues can be addressed in one study, but the underlying model needs to be made explicit and additional data obtained to test it.

> \*Gert Jan van der Wilt, Gerhard A Zielhuis Department of Epidemiology, Biostatistics and Health Technology Assessment, University Medical Centre St Radboud, 6500 HB Nijmegen, Netherlands (GJV, GAZ)

THE LANCET Volume 372, Issue 9638, 16–22 August 2008, Pages 519-520

# Contradicted and Initially Stronger Effects in Highly Cited Clinical Research

John P. A. Ioannidis, MD

Of 49 highly cited original clinical research studies, 45 claimed that the intervention was effective. Of these,

- 7 (16%) were contradicted by subsequent studies,
- 7 others (16%) had found effects that were stronger than those of subsequent studies,
- 20 (44%) were replicated, and
- 11 (24%) remained largely unchallenged.

JAMA. 2005;294:218-228.

# Mechanisms





### **Results**



Fig. 4. Schematic diagram of the gate control theory of pain mechanisms: L, the large-diameter fibers; S, the small-diameter fibers. The fibers project to the substantia gelatinosa (SG) and first central transmission (T) cells. The inhibitory effect exerted by SG on the afferent fiber terminals is increased by activity in L fibers and decreased by activity in S fibers. The central control trigger is represented by a line running from the large-fiber system to the central control mechanisms; these mechanisms, in turn, project back to the gate control system. The T cells project to the entry cells of the action system. +, Excitation; -, inhibition (see text).

Melzack & Wall, Science 150:971-9,1965

# "Gate theory"

"Gate" in dorsal horn governs central transmission of neural activity signaling pain

Opened by excess of small over large fiber activity in the peripheral nervous system.

Closed by excess of large fiber activity



# Selectivity of Electrical Stimulation

Large fibers have relatively low threshold for recruitment by externally applied electrical stimulation pulses

At the proper stimulation amplitude, they may be activated selectively, closing the "gate."



### **Temporary Abolition of Pain in Man**

Abstract. In eight patients with intense chronic cutaneous pain, sensory nerves or roots supplying the painful area were stimu PATRICK D. WALL millisecond puls Department of Biology and Research Laboratory of Electronics, second were ap Massachusetts Institute of Technology, was raised unti Cambridge tingling in the a WILLIAM H. SWEET lation, pressure Department of Neurosurgery, areas failed to Massachusetts General Hospital, tients, who had Boston, and Department of Surgery, ripheral nerves, Harvard Medical School, Boston their pain for m after stimulation for 2 minutes. Wall & Sweet 1967

# **Peripheral Nerve Stimulation**

Mixed sensory and motor fibers

Similar thresholds for large diameter sensory afferents and motor efferents [Law]

Uncomfortable motor effects at amplitudes near sensory threshold



# **Dorsal Column Stimulation**

Primary afferents, conveniently segregated from motor fibers Antidromic activation Collateral processes to dorsal horn provide access to "gate"







Courtesy of Bengt Linderoth Adapted from Brown 1981; and further from Bradley K. (personal comm Nov 2015)

# 50<sup>th</sup> anniversary!

### 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, Ohiot

 $R_{\rm relevent}$  neurophysiologic studies have raised the possibility of electrical insibilion of pain. Electronarcosis has been widely investigated1 f2 but no previous attempts are known of application of inhibiting currents to the spinal cord. Wall<sup>13</sup> demonstrated that activity in large peripheral ensory nerve fibers carrying nonpainful impulses inhibits in the spinal cord subsequent activity from the smallest fibers considered essential to pain conduction. Melzack and Wall 's suggested using this knowledge to suppress pain. Mechanical surface activation of the non-painful 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.

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 noxious substances. Nonpainful mechanic fibers predominate.

A preliminary report of Dr. Shealy's first successful clinical application of this technic will appear 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, 1,td., Crosse, Wisconsin.



When the whole nerve stimulus responis 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.<sup>11</sup> Ele trical stimulation of skin through two sul cutaneous needles at current intensity su ficient to elicit pain in man (greater that Unfortunately, most "intractable" pain 40 volts) also elicits prolonged small-fibafter-discharge in cats: Similarly, PSA can be evoked by pinching a paw with a he mostat, by heat sufficient to produce tissu damage, and by subcutaneous injection stimuli such as hair movement, deep rubbir





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

Shealy March 24, 1967

#### Mortimer 1968 PhD thesis

Brain (1976), 99, 123-158

### THE GATE-CONTROL THEORY OF PAIN

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#### A CRITICAL REVIEW

by p. w.  $nathan^1$ 

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(From The National Hospital for Nervous Diseases, Queen Square, London WC1N 3BG)

#### IS PAIN A SPECIFIC SENSATION?

#### EDWARD R. PERL\*

Department of Physiology, University of Utah College of Medicine, Salt Lake City, Utah

PAIN became classified as a sensory quality relatively late in the evolution of ideas on sensation and consciousness. Prior to the Nineteenth Century most authorities had followed Aristotle's view in setting pain opposite to pleasure and assigning it to the realm of emotion. Under impetus of the analyses that followed BELL'S (1811)<sup>1</sup> and MAGENDIE'S (1822)<sup>2</sup> separation of peripheral sensory and motor pathways in the spinal roots, concepts of nervous organization and function clarified. In company with the increasing dominance of experimentally dictated views of the nervous system, pain came to be more commonly thought of in terms of a sensory phenomenon; however, the specificity of neural mechanisms leading to it has been continually doubted.

As a first step in deciding whether or not pain has the characteristics associated with a specific sensation, it is necessary to set down attributes that might be accepted for this category. Some possible semantic problems may be avoided by starting from an unambiguous model. Vision begins with the excitation of structures in the eye, a particular and unique sense organ. Under ordinary conditions the receptive tissue of the eye has a responsiveness limited to a clearly definable set of environmental events. The receptive elements of the retina, in turn, excite a chain of nerve cells that transmit signals related to incoming light to regions of the forebrain. Consequently, a neural sequence from the receptive structure to neurons of the thalamus and cortex are dedicated to the relaying and analysis of information contained in the light reaching the eyes of the organism. Generalizing from this example, a specific sensation has a kind of receptive apparatus (receptor) that is particularly responsive to a limited class of events. Activity generated by specialized receptors then engages a series of neurons forming a projecting system (to higher centers) devoted to the signals initiated by the effective stimuli. Current opinion would agree that the 'special senses' (vision, hearing, smell and taste) are associated with mechanisms fitting this generalization. On the other hand, the situation for somatic sensibility, particularly pain, is less clear.

As the Twentieth Century began, the physiologists and their allies in this cause, the clinical neurologists, apparently had won the argument with the philosophically-oriented over the nature of pain, and it was widely accepted as a sensory experience rather than the emotional reaction opposite to pleasure. At that time there were two viewpoints on the

# BJA

### "I would have everie man write what he knowes and no more."—Montaigne BRITISH JOURNAL OF ANAESTHESIA

### Volume 88, Number 6, June 2002

### **Editorial I**

Gate Control Theory of pain stands the test of time



A. H. Dickenson Department of Pharmacology University College London WC1E 6BT UK

# **"Dorsal Column" Stimulation**

Topographically accurate Physiologically confirmed but Physiologically simplistic, as other structures are affected; therefore

"Spinal cord stimulation" preferred



### DORSAL COLUMN STIMULATION

### AND PAIN

Experimental studies of putative neurochemical and neurophysiological mechanisms

**Bengt Linderoth** 

Stockholm 1992

## **Animal models**

Scaling electrodes and stimulation parameters problematic Chronic pain model problematic Neuropathic pain (sciatic n. ligature) Hyperactive flexion withdrawal reflex attenuated by SCS [Meyerson][Simpson]







# EFFECTS OF SCS



If the GABA-B receptor is blocked, the reduction of GLU is abolished

Courtesy of Bengt Linderoth

From Cui et al 1996;1997; Stiller et al 1996



Available online at www.sciencedirect.com



European Journal of Pain 12 (2008) 132-136



www.EuropeanJournalPain.com

Clinical Note

### Baclofen-enhanced spinal cord stimulation and intrathecal baclofen alone for neuropathic pain: Long-term outcome of a pilot study

Göran Lind \*, Gastón Schechtmann, Jaleh Winter, Björn A. Meyerson, Bengt Linderoth

Department of Neurosurgery, Karolinska University Hospital, SE-171 76 Stockholm, Sweden

Received 31 August 2006; received in revised form 8 March 2007; accepted 10 March 2007 Available online 1 May 2007

"A deficient SCS effect in neuropathic pain may be considerably improved by intrathecal baclofen" Average followup 67 months

n = 7





# Spinal cord stimulation paresthesia and activity of primary afferents

Case report

#### RICHARD B. NORTH, M.D.,<sup>1,2</sup> KAREN STREELMAN, M.S.H.S., P.A.-C.,<sup>1</sup> LANCE ROWLAND, B.S., C.N.I.M.,<sup>1</sup> AND P. JAY FOREMAN, M.D., PH.D.<sup>1</sup>

<sup>1</sup>Sandra and Malcolm Berman Brain & Spine Institute, and <sup>2</sup>Johns Hopkins University School of Medicine, Baltimore, Maryland

A patient with failed back surgery syndrome reported paresthesia in his hands and arms during a spinal cord stimulation (SCS) screening trial with a low thoracic electrode. The patient's severe thoracic stenosis necessitated general anesthesia for simultaneous decompressive laminectomy and SCS implantation for chronic use. Use of general anesthesia gave the authors the opportunity to characterize the patient's unusual distribution of paresthesia. During SCS implantation, they recorded SCS-evoked antidromic potentials at physiologically relevant amplitudes in the legs to guide electrode placement and in the arms as controls. Stimulation of the dorsal columns at T-8 evoked potentials in the legs (common peroneal nerves) and at similar thresholds, consistent with the sensation of paresthesia in the arms, in the right ulnar nerve. The authors' electrophysiological observations support observations by neuroanatomical specialists that primary afferents can descend several (in this case, at least 8) vertebral segments in the spinal cord before synapsing or ascending. This report thus confirms a physiological basis for unusual paresthesia distribution associated with thoracic SCS.

(http://thejns.org/doi/abs/10.3171/2012.7.SPINE11642)

# Properties of afferent nerve impulses originating from a neuroma

Patrick D. Wall

Department of Anatomy, University College, London WCIE 6BT Department of Zoology, Hebrew University, Jerusalem

#### Michael Gutnick

Department of Zoology, Hebrew University, Jerusalem, Israel

Damaged nerves attempt to regenerate. The nerve membrane changes its properties, becomes spontaneously active and may be the source of pain. These impulse generators have unusual properties. They become silent after high frequency activity. This silence may partially explain the effect of counterstimulation as a pain therapy.

Nature Vol. 248 April 26 1974

# What is "Stimulation"?

Depolarization, action potential propagation Primarily cathodal effect Hyperpolarization Primarily anodal effect

"Anodal break" causing depolarization At high amplitudes and longer pulse widths (over 400 microseconds)

Brain Research, 98 (1975) 417–440 © Elsevier Scientific Publishing Company, Amsterdam – Printed in The Netherlands

417

#### **Review Article**

WHICH ELEMENTS ARE EXCITED IN ELECTRICAL STIMULATION OF MAMMALIAN CENTRAL NERVOUS SYSTEM: A REVIEW

JAMES B. RANCK, Jr.\*

Department of Physiology, University of Michigan, Ann Arbor, Mich. 48104 (U.S.A.) (Accepted May 23rd, 1975)



### Traditional (tonic, paresthesia based) SCS



F: 40-80 Hz PW: 200-450 microsec A: Above perceptual, below motor threshold

From Pope, Falowski & Deer 2015

### Paresthesia-based stimulation: Dosing



Pulse parameters (amplitude, width, rate) scaled to usable or tolerable range eliciting paresthesia

[Law 1982]

### Paresthesia-free stimulation



Paresthesia no longer a surrogate for pain relief; neither necessary nor sufficient

### Paresthesia-free stimulation



New "usage range" or "therapeutic window"



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### Postural Changes in Spinal Cord Stimulation Perceptual Thresholds

John C. Olin, PA • David H. Kidd, MS • Richard B. North, MD

Department of Neurosurgery, The Johns Hopkins University School of Medicine, Baltimore, Maryland, USA



Neuromodulation, Volume 1, Number 4, 1998 171-175

# **Computer Modeling of SCS**

- Distribution of electrical fields and current densities in the spinal cord
- Finite element methods tissue volumes (e.g. CSF, white matter) considered as multiple, small geometric figures [Coburn, Holsheimer, Rustioni, Sin, Strujik]

Variable electrical conductivity of different tissues

- Cerebrospinal fluid has the highest conductivity
- Anisotropy (e.g., white matter has greater conductivity longitudinally than transversely)










Fig. 15 Isopotentials and current density vectors,  $\mu A mm^{-2}$ , within a transverse section of upper-thoracic spinal canal. Mid-line EDS-M cathodic current 1 mA as Fig. 13. Contours, excluding k, spacing 0.1 V, min. (inner) -11.6 V. Contour k -15.2 V. Approx. scale 4.4

# **Modeling Predictions**

Recruitment threshold varies as depth of dorsal cerebrospinal fluid space

Minimizing lateral recruitment (dorsal roots, lateral dorsal columns)

- Optimal longitudinal contact spacing (to maximize selectivity for deep, medial fibers) is approximately 1.4 times CSF depth, or 6-8 mm.
- Longitudinal cathode position is more important than arrangement of anodes in a linear array



# **Modeling Predictions (cont.)**

To minimize lateral recruitment (dorsal roots, lateral dorsal columns):

Dual (side by side) linear arrays are inferior (lacking midline cathode position(s))
Triple (side by side) linear arrays are superior Retain midline cathode position(s).
Add lateral anodes, shielding roots and lateral dorsal columns

"Transverse tripole" [Holsheimer]



SPINE Volume 30, Number 12, pp 1412–1418 ©2005, Lippincott Williams & Wilkins, Inc.

#### Spinal Cord Stimulation for Axial Low Back Pain

A Prospective, Controlled Trial Comparing Dual With Single Percutaneous Electrodes

Richard B. North, MD,\* David H. Kidd, MA,\* John Olin, PA,\* Jeffrey M. Sieracki, MS,\* Farrokh Farrokhi, MD,\* Loredana Petrucci, MS,\* and Protagoras N. Cutchis, MD†

"We observed disadvantages for dual electrodes in treating axial low back pain."

Meet Am Soc Stereotact Funct Neurosurg, Snowbird, Utah, 1999 Stereotact Funct Neurosurg 1999;73:126–130

Stereotactic "Functional Neurosurgery

#### Efficacy of Transverse Tripolar Stimulation for Relief of Chronic Low Back Pain

**Results of a Single Center** 

Konstantin V. Slavin Kim J. Burchiel Valerie C. Anderson Beverly Cooke

Department of Neurological Surgery, Oregon Health Sciences University, Portland, Oreg., USA

"We conclude that chronic low back pain is not particularly responsive to the transverse stimulation provided by the TTS system."

# SCS waveforms 2010 ff A Tonic • Burst MM MM C HF10

From Pope, Falowski & Deer 2015



From Pope, Falowski & Deer 2015

 Bursts (intermittent tonic stimulation) resemble normal neural activity

 "Source localized EEG" has demonstrated that burst SCS activates the dorsal anterior cingulate and the dorsolateral prefrontal cortex (regions involved in emotions) more than does tonic SCS.

• Burst SCS might modulate attention to pain.







Received: June 1, 2015 Revised: September 5, 2015 Accepted: September 24, 2015

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12368

### Burst and Tonic Spinal Cord Stimulation: Different and Common Brain Mechanisms

Dirk De Ridder, MD, PhD\*; Sven Vanneste, PhD<sup>+</sup>



Figure 1. Ascending and descending pain pathways. Two ascending pain-supporting pathways have been described, and one pain-inhibitory descending pathway. The lateral ascending pathway processes the discriminatory components of pain, whereas the medial pathway processes the motivational, affective, attentional components of pain. The pain inhibitory pathway suppresses ongoing pain (figure modified and extended from Squire (12)).

# Burst effect **NOT** dependent on **DC** activation or block



Tang R. et al 2014

#### **ALLODYNIA AND SERUM GABA CONCENTRATIONS DURING BURST AND TONIC SCS** Live animal experiments



Courtesy of Bengt Linderoth

# SCS waveforms 2010 ff A Tonic • Burst MM որդո C **HF10**

From Pope, Falowski & Deer 2015



Courtesy of Bengt Linderoth Adapted from Brown 1981; and further from Bradley K. (personal comm Nov 2015)

# No block or activation of DC neurons by HF10 SCS



Example recording from a group of 6 rats; HF SCS: No total block of sensory input (v Frey)

Courtesy of Bengt Linderoth



Song et al. Neuromodulation 2014.

### Data from J. Hopkins Univ. Group 30 min. SCS (applied to DCs T10-T12

(biphasic; 24 µsec) on 3 consequtive days

PAIN MEDICINE



Conventional and Kilohertz-frequency Spinal Cord Stimulation Produces Intensity- and Frequencydependent Inhibition of Mechanical Hypersensitivity in a Rat Model of Neuropathic Pain



They also used 20% MT: no sign differences at all Stimulation at 80% MT: Larger differences for all freq., best for 1000 Hz - BUT NOT clinically relevant for HF SCS

Courtesy of Bengt Linderoth

Shechter et al 2013

# HF Sensory Threshold Determination:





Chose

Time (min)

Song et al 2014;2015



### Electrophysiological investigation of the effects of 10 kHz spinal cord stimulation on the excitability of superficial dorsal horn neurons in experimental pain models

S. McMahon et al, King's College London (Unpubl 2016-2017 -2018)



Courtesy of Bengt Linderoth

Electrophysiological investigation of the effects of 10 kHz spinal cord stimulation on the excitability of superficial dorsal horn neurons in experimental pain models

S. McMahon et al, King's College London (Unpubl 2016-2017-2018)





From S. McMahon et al.: Poster at NANS, Las Vegas Jan. 2018

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(onlinelibrary.wiley.com) DOI: 10.1111/ner.12614

## Are 10 kHz Stimulation and Burst Stimulation Fundamentally the Same?

Dirk De Ridder, MD, PhD\*; Sanjaya Perera, MD\*; Sven Vanneste, PhD<sup>+</sup>

"By performing EEGs or PET or fMRI studies a conjunction analysis can demonstrate whether both stimulation designs modulate the dACC, that is, the medial pain pathway, and a subtraction analysis can demonstrate where they differ, analogous to what has been done for burst versus classical tonic stimulation."

# SCS waveforms 2010 ff A Tonic • Burst MM MM C HF10

From Pope, Falowski & Deer 2015

# SCS waveforms 2016 ff



Received: July 13, 2015 Revised: August 26, 2015 Accepted: September 1, 2015

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12357

### Paresthesia-Free High-Density Spinal Cord Stimulation for Postlaminectomy Syndrome in a Prescreened Population: A Prospective Case Series

Jennifer Sweet, MD; Anish Badjatiya, BS; Daniel Tan, PhD; Jonathan Miller, MD



"VAS was 2.29 ± 0.41 during subthreshold HD stimulation and 6.31 ± 1.22 during sham stimulation, which was a significant difference (p < 0.05 . . .)

Received: April 15, 2016 Revised: August 1, 2016 Accepted: August 23, 2016

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12529

# Altering Conventional to High Density Spinal Cord Stimulation: An Energy Dose-Response Relationship in Neuropathic Pain Therapy

#### Frank Wille, MD\*<sup>†</sup>; Jennifer S. Breel, MPA\*<sup>†</sup>; Eric W.P. Bakker, PhD<sup>‡</sup>; Markus W. Hollmann, MD, PhD<sup>†</sup>

**Objectives:** To examine whether converting from conventional Spinal Cord Stimulation (SCS) to High Density (HD) SCS reduces neuropathic pain over a period of 12 months in patients with failed SCS therapy.

**Methods:** Retrospective, open label, single center, consecutive case series of 30 neuropathic pain patients (Failed Back Surgery Syndrome [FBSS], Complex Regional Pain Syndrome [CRPS], and polyneuropathy [NP]). Patients with an initial adequate response to conventional SCS, but in whom pain increased over time, were included (Numeric Rating Scales [NRS] >6). These patients were stimulated with HD-SCS parameters and followed-up for 12 months. We report pain intensity, measured with NRS, before SCS implantation, 1 and 3 months after starting SCS with conventional stimulation, and after 1, 6, and 12 months of HD SCS.

**Results:** Pain reduction with conventional stimulation was initially adequate (NRS mean 8.6 to 5.3 at three months postimplant) but increased over time to a mean NRS of 7.7 at the time of reprogramming. NRS scores decreased significantly to 4.3 (p = 0.015) after reprogramming from conventional SCS (30 Hz, 300 µsec, 3.0 V) to HD SCS (409 Hz, range 130–1000 Hz, 409 µsec, 2.4V) in the patients still using HD-SCS at 12 months. In the nonresponders (patients who stopped HD-SCS for any reason), 76% had a diagnosis of FBSS. Almost half of the patients aborting HD-SCS preferred to feel paresthesias despite better pain relief. There was a significant difference between nonresponders and responders regarding the amount of electrical energy delivered to the spinal cord.

**Conclusion:** Neuropathic pain suppression is significantly enhanced after converting from failed conventional SCS to HD SCS in patients with FBSS, CRPS, and NP over a measured period of 12 months. There appears to be a dose-related response between the amount of energy delivered to the spinal cord and clinical effect.

Received: April 15, 2016 Revised: August 1, 2016 Accepted: August 23, 2016

(onlinelibrary.wiley.com) DOI: 10.1111/ner.12529

# Altering Conventional to High Density Spinal Cord Stimulation: An Energy Dose-Response Relationship in Neuropathic Pain Therapy

#### Frank Wille Markus W.

Objectives: To neuropathic pa Methods: Retr Syndrome [FBS to conventiona stimulated with implantation, 1 Results: Pain r but increased of after reprogram patients still usi of FBSS. Almost difference betw Conclusion: N

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is postimplant) 4.3 (p = 0.015) sec, 2.4V) in the had a diagnosis vas a significant I cord.

S to HD SCS in oonse between





The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

Potential overlap with: **Rod Taylor** John Markman Ali Rezai Salim Hayek Simon Thomson **Brian Kopell** Sam Eldabe



# The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

# Johns Hopkins Department of Neurosurgery



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



# Early enthusiasm

"Thus far there appear to be no major pain syndromes which of themselves are not, at least in part, amenable to temporary or perhaps permanent control by electrical stimulation methods."

> Seminar on the Electrical Stimulation of the Human Nervous System for the Control of Pain 1975

Advances in Pain Research and Therapy, Vol. 5, edited by John J. Bonica et al. Raven Press, New York © 1983.

#### Ten-Year Follow-up of Dorsal Column Stimulation

\*D. L. Erickson and \*\*D. M. Long

\*Department of Neurosurgery, University of Minnesota, Minneapolis, Minnesota 55455; and \*\*Department of Neurosurgery, Johns Hopkins Hospital, Baltimore, Maryland 21205

"Followup was carried out by different personnel who were entirely new to the patients . . . only 15% of the original 60 were considered successes."

"We believe that unsophisticated methods of evaluating pain patients led to the early enthusiastic reports."

# Percutaneous trial of stimulation for patient selection for implantable stimulating devices

DONALD L. ERICKSON, M.D.

Department of Neurosurgery, University of Minnesota Hospitals, Minneapolis, Minnesota

The author describes a flexible electrode which can be inserted percutaneously for a period of several days in candidates for an implantable electrical stimulating device for pain relief. This allows the patient a trial of stimulation which closely mimics that of the intended implantable system. If this trial does not give adequate pain relief in a variety of situations, the patient is not considered to be a suitable candidate for an implantable device. The trial of stimulation in no way obviates the need for careful scrutiny of the social and psychological factors accompanying chronic pain problems.

J. Neurosurg. / Volume 43 / October, 1975



APL/JHU CP 052 MARCH 1977

Biomedical Engineering

### A CLINICAL STUDY OF SPINAL EPIDURAL STIMULATION FOR THE TREATMENT OF INTRACTABLE PAIN

R. B. NORTH (Applied Physics Laboratory)
T. A. FISCHELL (Cornell University)
R. E. FISCHELL (Applied Physics Laboratory)
D. M. LONG (Johns Hopkins Hospital)

This work was supported by the National Aeronautics and Space Administration, under Contract IPD 55719A, as part of the Technology Utilization Program, established to apply NASA technology in the public domain.

THE JOHNS HOPKINS UNIVERSITY 
APPLIED PHYSICS LABORATORY Johns Hopkins Road, Laurel, Maryland 20810 Operating under Contract N00017-72-C-4401 with the Department of the Navy

"Third party followup"
### THE JOHNS HOPKINS UNIVERSITY APPLIED PHYSICS LABORATORY LAUREL, MARYLAND

### Table 5

### Efficacy of Epidural Stimulation for Pain Relief: Summary by Diagnosis

P. P. New York		Average	P	Percen ain Rel	t ief	Wo fo	uld Do Ag r Same Re	ain lief	Comparis by Ot	on with her Me	h Relief thods
Diagnosis	Number of Patients	of Use (months)	0-40	40-70	70–100	No	Neutral	Yes	Less Effective	Same	More Effect <b>ive</b>
Chronic Low Back Syndrome	24	6.0	6	6	12	3	1	20	2	4	18
Cervical Syndrome	1	9.5	-	-	1	_	-	1	-	-	1
Terminal Cancer	2	5.7	1	-	1	1	-	1	-	-	2
Phantom Limb	1	7.2	-	-	1	-	-	1	-	-	1
Amputation Neuroma	1	1.0	-	-	1	-	-	1	-	-	1
Thoracic Outlet Syndrome	1	9.0	-	1	-	-	-	1	-	-	
Muscular Dystrophy	1	5.5	-	-	1	-	-	1	-	n/a	
Total	31	6.0	7	7	17	4	1	26	3	4	23

APPLIED PHYSICS LABORATORY



Fig. 6 Effect of Epidural Stimulation on Patients' Pain Experience

### THE JOHNS HOPKINS UNIVERSITY APPLIED PHYSICS LABORATORY LAUREL, MARYLAND

### Table 6

### Time Lags of Analgesic Effect

Time Period	Latency *	Persistence **
0-1 min	8 Patients	3 Patients
1-30 min	18 Patients	11 Patients
30-120 min	4 Patients	7 Patients
2-12 h	0 Patients	8 Patients
Over 12 h	0 Patients	1 Patient
No Impression	1 Patient	1 Patient

\*Time elapsed after stimulation begins
until relief is felt
\*\*Time elapsed after stimulation ends until
relief ceases

### Table 8

Drug Classification	Trade Name	Generic Name	No. of Patients	Dai	ly Dos: (mg)	age	Durat (	ion of years)	t Use
				Min	Med	Max	Min	Med	Max
Narcotic Analgesic	Percodan Demerol Codeine Morphine Dilaudid	Oxycodone + APC Meperidine Codeine Morphine Hydromorphone	15 7 4 1 1	4 50 60 *	12 300 240 *	24 1200 240 *	0.5 1 3 *	2343*	9 12 7 3
Nonnarcotic Analgesic	Darvon Talwin Parafon Forte Empirin Percogesic	Propoxyphene Pentazocine Chloroxazone + Acetaminophen APC Acetaminophen + Phenyltoloxamine	5 4 1 1	65 * * *	195 150 * *	500 150 * *	223*	2 2 3 * 2	4 5 3 8 2
Tranquilizer	Valium Miltown Prolixin	Diazepam Meprobamate Fluphenazine	7 1 1	5 1600 *	20 1600 *	60 1600 *	1 3 *	4 3 *	10 3 *
Sedative	Dalmane Fiorinal Nembutal Doriden Placidyl	Flurazepam Butalbital + APC Pentobarbital Glutethimide Ethchlorvynol	3 1 1 1 1	30 1 100 50 700	30 * 100 50 700	30 * 100 50 700	* 10 * 3	0.3 * 10 * 3	* 10 * 3
Antidepres- sant	Elavil	Amitriptyline	4	75	75	75	*	0.3	2

### Drug Usage Eliminated as a Result of Epidural Stimulation

\*Not known by patient.

- 50 -

### THE JOHNS HOPKINS UNIVERSITY APPLIED PHYSICS LABORATORY LAUREL, MARYLAND

### Table 7

### Grading Scale for Ability to Perform Various Activities

0 -	Able to do easily and normally
1 -	Able to do with slight difficulty because of pain
2 -	Able to do with difficulty because of pain
3 -	Able to do only with extreme difficulty because of pain
4 -	Unable to do at all because of pain
x -	Impossible because of non-pain factors



DIFFERENCE LEVEL = (GRADE WITHOUT STIMULATION)-(GRADE WITH STIMULATION)



1







# **Spinal Cord Stimulation**

# **3-year followup**



# Chronic Stimulation via Percutaneously Inserted Epidural Electrodes

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### SYMPOSIUM: NEUROAUGMENTIVE DEVICES

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### SESSION ON SPINAL CORD STIMULATION 217

Diagnosis	No. of Pa-	Average		% Pain Re	lief	Wo	uld Do Aga Same Relie	in for ef	Comparison with Relief by Other Methods			
	tients	Use (Mo)	0-40	40-70	70-100	No	Neutral	Yes	Less ef- fective	Same	More ef- fective	
Chronic low back syn- drome	24	6.0	6	6	12	3	1	20	2	4	18	
Cervical syndrome	1	9.5	<ul> <li></li> </ul>		1			1			1	
Terminal cancer	2	5.7	1		1	1		1			2	
Phantom limb	1	7.2			1	-		1			1	
Amputation neuroma	1	1.0			1			1			1	
Thoracic outlet syn- drome	1	9.0		1				1	1			
Muscular dystrophy	1	5.5			1			1		N/A		
Total	31	6.0	7	7	17	4	1	26	3	4	23	

TABLE 1 Efficacy of Epidural Stimulation for Pain Relief: Summary by Diagnosis

### TABLE I

A review of the literature on spinal cord stimulation reveals a variety of indications for the procedure, temporary electrode screening protocols, follow-up methods and intervals, and criteria for success; comparisons are difficult.

Author, year	No. screened	No. implanted	No. FBSS	Other diagnoses	Follow-up mean	Follow-up range	Third party follow-up	Exc/good results	Exc/good FBSS results
Broseta 82		. 11		Causalgia, amputations		3-20 mos.			
Burton 75	0	75	55		1 yr.		y (mfr)	58.7%	
Burton 77		198	186				,	43%	
Clark 75		13	6					54%	67%
De La Porte 83	94	36	.36		36 mos.	3-96 mos.		60%	
De Vera 90	124	110	18	PVD, RSD, spasticity, Ca				75%	
Devulder 90		45					, · · ·	78%	
Erickson 83	10	70				up to 10 yrs.	y (60) ໌	15-20%	
Hoppenstein 75		27	12					58%	64%
Hunt 75		13	5			9 mos4 yrs.		15-31%	20-60%
Kälin 90			77					88%	88%
Koeze 87	0	26	5	PVD	28 mos.		v	46-62%	0070
Krainick 85	126	91	5	Amputations			2		
Kumar 86		60	54			6-60 mos.		62%	
Law 83		81						36-80%	
Law 87		46	46		25 mos.			20 00/0	
Leclercq 81		20	20			1 - > 24  mos.		50%	50%
Leclercq 84	50	36						2010	50%
Long 75		69	54			12-35 mos.	v	18%	
Long 81		31	24			4-7 yrs.	v	73% @ 3 vrs	
McCarron 87		22				3-24 mos.	5	68%	
Meglio 89	109	64	19	PVD 40, SCI 15, PHN 10, Ca 11			n	59% PVD: 100% PHN	2396
Mittal 87	31	26	21					46%	2570
Nielson 75	221	130	79	Ca, postcordotomy		1 - > 35  mos.	v	49%	46%
North 77		31	24	Ça 2	6 mos.		v	55-77%	50-75%
North 84		20	20		8 yrs.		v	35%	3595
Pineda 75		76	56		-		2		43%
Racz 89	0	26	18			12-42.7 mos.	n	65%	4570
Richardson 79	36	22	12	Ca		1-3 yrs.		56%	
Robb 90	65	79	22	"Peripheral" 22, "deaff" 21		6 mos5 vrs.		72%	69%
Shatin 86		116		•		0.9-13.3 mos.	v (mfr)	74% @ 6 mos	0710
Shealy 75	0	80				7 mos?	n	25%	15-459
Shelden 75		27	3	Ca 17				20 %	67%
Siegfried 82	191	89	75		- 4 vrs.	1-8 yrs.		37%	07.0
Sweet 74	100	98	33					2 T T T	
Urban 78	20	7	9					86%	
Winkelmüller 81	94	71	56	Amputation, SCI		4 mos7 yrs.			69%

Diagnoses: Ca = cancer; deaff = deafferentation; FBSS = failed back surgery syndrome; PHN = postherpetic neuralgia; RSD = reflex sympathetic dystrophy; SCI = spinal cord injury. Third party follow-up: mfr = device manufacturer.

| ability a<br>in mean<br>The<br>sidematic<br>third-pe   | Acteenia<br>tion is<br>importa<br>Patie<br>criterios<br>reportad<br>autochily  | Neuro<br>The dir<br>endity (<br>in term<br>internal  | CLINIC  | with a cenvical<br>of the el<br>necessite<br>To de<br>for angle<br>become   
   | o cN  | 11. No po<br>12. No<br>12. Plan<br>to annu<br>concurn<br>electron  | 2 Signil<br>2 Signil<br>3 Descr<br>4 Roin<br>6 Non<br>7 Aldh<br>8 Non<br>7 Aldh<br>8 Non<br>9 Non<br>9 Non  | 2172<br>TABLE<br>Selact  
   | TABLE  | 155-4 • Clink   | al Results o   | of Spinal Cor   
  | d Stimulation fo   | e Neuropathic Pa  | ain - A Compreher  | uive Selection from Repo  | rts  
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   | Indication Ind  | Mean Months o<br>Follow-up Ran   | f<br>pr) Results  | Complications   | Nicto  
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| e in pro-<br>nction<br>of this in<br>example<br>cristwo  | when a 40% when a 40% to a 10% to a 10\%   | An of S  | and per   | trat de<br>fields o<br>oral of t<br>mands of<br>with a<br>with a  | ralso an<br>enace de<br>lorence a<br>hovestige  
   | therapy<br>the applied in the second   | Contry at<br>Investit<br>weith to<br>conte my<br>heart di<br>heart di<br>pacente<br>the<br>factors  | Marka Internet   
   | Heideckie<br>et al <sup>m</sup>  | Retrospecti   | ve 42  | 42   | 42   
   | FBSS  | 46 madan<br>(5-74)   |   | E fractures or disrupted<br>insulation, 4 cable   | Time to hardware<br>failure - median   
   |   |  |  |   
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| ductive ac<br>formation<br>to data co<br>can differ  | adjustment<br>adjustment<br>be insplasse<br>effet is the<br>last for "su-<br>definition",<br>set of mu-<br>rome of mu-<br>roment, wh-  | S for neu<br>nd investig<br>re of perm<br>of tempor  | ngina who<br>S  | thefiliance,<br>he SCS ele-<br>sold result :<br>he electros<br>d SCS spec-<br>reccess rational<br>success rational in the second<br>success ratio   | and pattern<br>aring long-<br>martion to<br>more moon<br>spored a su<br>spored a su   
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   | Hord et al   | Retrospect  | və 23  | 16   | 15   
   | CRPS  | 1.9  | 15 had "good" pain relief<br>at 1 month<br>11 at 9 months   | 1010/05   | Assessed<br>predictive value<br>of sympathetic   
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  | Kaup 41 4  | Prospective   | 17/23  | 19   | 19  
  | F0.5.6, 21  | 18.5 (7-38)  | Statistically significant   | 2 migrations.   | block response<br>for SCS success   
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   | a corda  | A DATE OF COMPANY   | den l  
   |  | 0/94-7/9  | 46   | 2  | 6  
   | Spinal pain, 2<br>Other, 6  |  | improvement in pain<br>accres (55% benefited<br>only one patient  | 2 repositioned<br>pulse generators  |  
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   | Kay et al <sup>46</sup>  | Retrospecti   | we construction  | 70   | 70   
   |   |  | obtained pain relef<br>60% "substantial"<br>oats safet  | 72 revisions,<br>Elisteritione  |  
   | TABLE 1<br>Published  | 5 4 • Ginical<br>Eince 1995 •  | icouits of Epi<br>mit'd  | nal Cord B  
  | finalities for N  | europathis Pak  | A Composition  
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   | thing thing the thing   | or need  |   | C Contraction  
   | Kemier et  | ** Fatrospect<br>(1991-19   | 97)<br>VB 195.742<br>67)   | 28  
  | 29   | CRPS  | 32   | 16 (28%) Improved<br>16 still use SCS   | 9 patients   
  |  | Reference   | Study Design<br>Effetel  | Number N<br>Scenario D   
   | regionation  | Number  | induction (d)  
  | Mean Months -<br>Follow-up (Ran   | pel Fesults   | Complications  | Note  
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| 2 5 F 8 7 8  | 123732   | E SE SE ET   |   | a ≓ a 88.   
   | ELES-TP   |  | E RAPPER  | dia be   
   | Kernier et   | *** RCT (0/80-3   | 590 50   | 24  
  | 74   | 160 (019)   | 6  | Compared with physical<br>therapy alone,<br>significant point railed  | 2 dural punctures<br>6 (25%) petients<br>had 31 other  
  | Not clear if<br>4 with long-term   | Sharan et al'   | <ul> <li>Prospective<br/>ladditional<br/>data from</li> </ul>  | ,  
   | •  | Poenop, 16;<br>5-month, 21;<br>12-month, 20;  | F035, 15<br>Anathroidtle, 5<br>Radcultis, 6  
  | 24  | 12 months 54%<br>24 months 75%  |  | complex<br>electrodes and   
   |
| f 10 p   | Anoth<br>rapy is<br>any form<br>well to<br>them.   | S succ   | nd then a   | lary ox<br>S choo<br>S choo<br>S choo   
   | chin in   | prod<br>prod<br>servi (<br>fine p<br>fine p<br>fine p<br>fine p<br>fine p<br>fine p<br>fine p  | advertished   | view<br>ause<br>notre  
   |  |   |  |   
  |  |   |  | and improved NRQOL  | complications<br>(4 had long-term  
  | are included<br>in the 6 with  | Simpson   | Earstant et al<br>Prosportive  | n<br>No 4  
   |  | "Most"  | tow book perce<br>"Damage," 9  
  | 50 median   | 60% pain relief   | Surgical revisions to  | brase deventions  
   |
| n with pha<br>wed the pa<br>effect" with<br>S failed, d<br>stients.**  | ter neuropa<br>postherper toor<br>trive study<br>trive study<br>herper toor<br>SCS that<br>SCS that<br>SCS that<br>school abrid<br>had service<br>retorned ab  | thirds of the<br>newstigator<br>mest in parts<br>S group we  | the destroyable<br>(1 = 36) or to<br>(1 =   | atment ver<br>sing to ulix<br>il Nerve Inj<br>i Inportant<br>i Inportant  | interest to a<br>result only<br>loaned that<br>by to be to<br>a. <sup>13</sup> The f<br>theoremay to  
   | satents, re<br>acc hetter<br>i with nocy<br>R.B.N.'s) e<br>respective,<br>estation in<br>capetition<br>more to<br>more to<br>more to   | since 1995<br>tive, it is en<br>les are prov<br>the absolu-<br>tudomized<br>the case of<br>the case of  | of physicia<br>this differ<br>ad itarevi   
   | Kemler et i  |   |  |  | 21   
   |   | 24   | "Intent-to-treat" hed<br>pain relief<br>As treated also<br>improved HIPCOL  | 1/24 had 22 surgical<br>revisions<br>2/24 serviced<br>22/24 had uncleasant  | Claims first report<br>of "impossible<br>to solve" side<br>effects   
   | et si <sup>m</sup>  |  |  |   
  |   | FBSE, 4<br>CRFS, 15<br>Cothar<br>neuropathic, 1<br>Amputation, 5  | 0-139  
  | decial pain did<br>not respond  | correct & fractures,<br>2 migrations,<br>5 postural problem<br>2 infections,<br>1 unitrown   |   |
| noom linub p<br>in in 6 (3.27<br>h stimulatio<br>kep brain ut  | this pain a<br>to indicate<br>the and post<br>ter and post<br>sense patien<br>mady, the or<br>n comorbid or<br>n core, SCS co  | <ul> <li>SCS groups</li> <li>anity come<br/>in corrections</li> <li>in correction</li> <li>in correction</li> <li>in correction</li> </ul> | ninod a pro-<br>physical the<br>physical the<br>hy subjects h<br>tr pain neuron<br>ner armularis<br>re armularis  | na only 5 o<br>undergo re<br>SCS prop   | rach this p<br>2 of 12 S<br>patients we<br>tailed with<br>had smalts<br>pailecare for   
   | mapority with<br>results with<br>results, 140<br>research groo-<br>modorited<br>FRSS patie<br>as were eling<br>FRSS patie<br>as were eling<br>FRSS patie<br>as were eling<br>FRSS patie<br>as were eling   | Although to<br>mensive. As<br>porties or m<br>males—ad<br>an interven<br>Spademen   | ne office re<br>more likely<br>caver reduce<br>dasique   
   | Kin et a <sup>se</sup>   | Petrospecti<br>(1/90-12/  | 49 122<br>989  | , 24   | 60.7%  
   | Neuropathic pain  | -48 (-16-05)   | 34 i45.9%) still used SCS<br>7 excellent, 17<br>good, and 10 fair<br>pain relief  | 50.5% surgically revise<br>10.0% infection,<br>59.2% migration,<br>16.3% fracture,  | t: Third-party<br>follow-up  
   | Sindou et al <sup>ra</sup>  | Prospective<br>(1984-2006  | No 9   | 5   
  | ю   | Partonal N. 3<br>Othir, 4<br>Partonal, 10<br>Rodoular, 27<br>Root, 8  | 18.8   
  | At least \$275, pain relief<br>in 54.7% d3,559<br>No success in patients  |  | rations selection   |
| b), are<br>b), are<br>b), are  | In this<br>flue of<br>the of the of<br>the of the of<br>the of   | g must   | no ditta<br>moyak<br>ad faile<br>an Out   | f24 participantic   | Solution of the second  
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  | r# Netrospecti  | + 12   | 12   | 12   | ONES  
   | 41   | Pain relief   | 24 removed<br>1 fracture,   | Third-perty  
   |   |  |  | | |
  |   | cost species, 32  |  
  | abvornal" SSEPs<br>70.416 krpts with<br>norma SSEPs   |  | and see a   |
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   | P Antospectiv   | a 235  | 189  |  | FBSS, 114  
  | 66   | >75% in 8<br>111 (59%) setisfactory   | 2 replaced<br>35 repositioned   | nonow up   | Slavin et al <sup>ne</sup>   
  | Prospective  | 11 1   | ۰.   
   | I month in 10:<br>"konger" in 7   | FBSS, 6<br>Other<br>Insufficial St  |   | Insign fisant decrease<br>in pain and disability; a<br>last follow-on anly 377  
   | t I delayed healing  | fransvorse<br>Tripolar  |
| in and   | we have<br>be inter-   | S treat  | A REAL PROPERTY AND   | andom name  
   | 10.5 more   | out that<br>(0)4, the<br>sector of the rest<br>of t | cases, a<br>alay a cases, a<br>alay a c<br>alay a c<br>alay a c<br>alay a<br>cases, a<br>alay a<br>cases, a<br>alay a<br>c<br>alay a<br>a<br>alay a<br>a<br>alay a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>a<br>a<br>a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>alay a<br>a<br>a<br>a<br>a<br>a<br>a<br>ala<br>a<br>a<br>alay a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a<br>a  | ure of the second  |  
   | ("past"<br>15 years)  |  |  |  | PVD, 39<br>Perpheral<br>neuropethy, 3  
  | 30   | pain relief<br>25 rejoined workforce  | 11 infections,<br>8 maillunctions,<br>8 fractures,  |  |  
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   |   | ull significant<br>Shark (480)  |   | continued use   
   | 1 mailunction<br>4 problems with   |   |
| 27862  | . Norder   |  |   |   
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   | Kumar 41.4 <sup>10</sup>   | Prospective   | 104  | 10 (44  
  |  | 1855  | 60   | Q of L improved in 27%  | Avenge per peliert   
  | Cost study   | Tong <sup>an</sup>  | Retopective  | 3 4  
   |  |   | Cord injury, 2<br>Pret, 1<br>Fablis, 1   
  | 21 (18-18)  | "Setisfacory"<br>pain relef   | 1 migration  |   
   |
| TABLE 155<br>Published 5   | -1 • Clinical Results<br>Since 1995  | of Spinal Cord   | d Stimulation for   | Neuropathis Pai   
   | - A Comprehens  | ive Selection from Repor   | 5   |  
   | Kumér et eff   | Properties  | 104  | f0 (44<br>others<br>considere<br>controlal  
  | d  | F855  | 80   | G of L improved in 27%,<br>verse 12% in controls<br>89% pr set<br>15%, neurored to work<br>Drug intake reduced  | Average per patient<br>electrode change =<br>ty5 years<br>Pulse generator replaced<br>a UK years<br>a Meteorora  
  | Cost study   | Torang <sup>an</sup><br>Nga Bunan<br><sub>ga B</sub> aw   | Retropective<br>Retropective<br>B(56-257)  | 3 4<br>198.8+7 29  
   |  | 1<br>17   | Cord injury, 2<br>PH4, 1<br>FBIS, 1<br>FBIS at INV<br>Mack and ING<br>paint  
  | 21 (18-18)<br>28 (20-38)  | "Satisfactory"<br>pain relief<br>Ling and back pain<br>significantly doceased<br>obover, and betteral<br>bow back and betteral  | 1 migration<br>No serious complication<br>byt *sectomal hard-<br>arobiens cocumed  | 005<br>99   
   |
| TABLE 155<br>Published S<br>Reference  | -1 + Cilinical Results<br>Lince 1995<br>Smoty Design Numb<br>(Dete) Sorea  | of Spinal Cord<br>er Namber<br>ed Implanted  | f Stimulation for<br>Nonlast<br>Followed  | Neuropathic Pail  
   | A Comprehens<br>Mees Months of<br>Follow up (Range  | Per Solection from Report  | ts<br>Complications   | Note   
   | Kumar et alf   | Prospective<br>Retraspective  | 104  | ft0 (44<br>others<br>considere<br>controlal<br>75   
  | d<br>67 suniasiwa<br>livre peny  | FB55<br>FB55, 56<br>Lipper limb<br>care, 10   | 60<br>24 (most 132)  | O ef L improved in 27%,<br>wareas 12% in controls<br>89% pd est<br>15% network to work<br>Drug status reduced<br>90% pain table in 85%<br>91% pdf and in 85% at<br>9 months, 45% at   | Average per passent<br>electrode change =<br>1/5 years<br>Pulse generativ<br>replaced<br>distances<br>2/6 pulse replaced<br>distances<br>2/7 investors 2.7%<br>infector; 13.7%   
  | Cost study   | Tang **<br>van buran<br>at alle   | Retropective<br>Retropactive<br>B(56-2)97)   | 3 4<br>188.8+7 29  
   |  | k<br>17   | Cod injuns, 2<br>Pret, 1<br>FBISS, 1<br>FBISS call the<br>back and ling<br>paint   
  | 21 (18-19)<br>28 (20-28)  | "Satisfacory"<br>pain rated<br>Lag and sizer pain<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adoption<br>adop | 1 migration<br>No serious complication<br>but "external hardwardblams occurred"  | ions<br>me  
   |
| TABLE 155<br>Published I<br>Reference<br>Alogs on a <sup>th</sup>  | - 4 • Citinical Results<br>Since 1965<br>South County Design<br>South Screen<br>Proposition 172<br>14/36-2011  | of Spinal Cord<br>er Namber<br>inglanted<br>102  | 1 Stimulation for<br>Nomber<br>Followed   | Neuropathic Pail<br>Indication (n)<br>Meyoy 117<br>F855, 29<br>View 28  
   | - A Comprehense<br>Mass Months of<br>Follow-up (Range<br>12   | Per Solaction from Report<br>Results<br>Effective 00.4%;<br>Phase 71%  | 5<br>Complexitiess<br>Not read to encode<br>for "realfican"   | Note<br>Constraint rag<br>materials<br>of the constraint<br>personalities  
   | Fumer et all<br>Kumar et all<br>Lavaque et a   | <ul> <li>Prospective</li> <li>Retrospective</li> <li>(12/62-149)</li> </ul>   | 104  | tto jaa<br>others<br>controlst<br>75<br>10  
  | d<br>67 Sunfacend<br>Termis paint<br>76  | F855<br>F955, 98<br>Upper imb<br>par, 10<br>Odec, 7<br>F855   | 80<br>24 (most 122)<br>Minimum 6   | Q of L improved in 27%,<br>wareau 12% in control<br>19% of etc.<br>19% of e  | Average per patient<br>electrode sharape –<br>15 years<br>A to 4 years<br>d Machine a to 4 years<br>avgest demplosteres<br>or falsers in 12 periors<br>1 selection  | Cost study<br>Third-party follow-op<br>More pain decrease<br>with laminectury   
  | Theng <sup>th</sup><br>san Boran<br>et al <sup>the</sup><br>san   | Recorpective<br>Recorpective<br>B/56-2(97)<br>Recorpective<br>(10 year)  | 3 4<br>185.8+7 29<br>254 297<br>6<br>8   | covering<br>ectrose<br>and far   
   | 23 totas<br>22 declared<br>22 hed and<br>22 hed<br>explantational   | Cord Injury, 2<br>PH4, 1<br>PB33, 1<br>PB33, 1<br>PB33, 2<br>Not and Ing<br>Sent<br>Set S<br>Set S<br>Oder 16%  | 21 (1)-19<br>28 20-38<br>-48  
   | "Jasisfacory"<br>gain relef<br>signification<br>signification<br>of the second second<br>line & with comparative<br>low topic and bisterial<br>loo book, wolco<br>dots, wolco   | 1 migration<br>16 technis templosis<br>arobians exclused<br>10 september<br>10 regention<br>21 regention<br>20 regention<br>20 regention<br>20 regention<br>20 regention   | ions<br>area<br>Third petry<br>Tuliperup  |
| TABLE 155<br>Published 1<br>Reference<br>Alogs or a <sup>p</sup><br>Alo et a <sup>p</sup><br>Berlin en a <sup>p</sup>  | - L + Cilinical Results<br>Bines 1995<br>Soudy Design Reveal<br>Based Street<br>Properties<br>1426-3011<br>Properties<br>0309-1930<br>Dissection   | of Spinal Cord<br>are Number<br>Inglated<br>102<br>80<br>54  | 62  | Neuropathia Pail<br>Indication (n)<br>Neuro, 117<br>P855, 27<br>Visc. 28<br>P3552, 27<br>Taskolak, 11<br>Otim, 2<br>P355, 640%  
   | - A Compretense<br>Mean Munchs of Poliser up (Range<br>12<br>49<br>5, 12, 24  | Ave Salection from Report<br>Results<br>Discover of Arts,<br>Prace 71%<br>"Sprogder"<br>Chr. y 20 Hose<br>"More" had portfacet   | 5<br>Compliantions<br>his receit 10 minutes<br>for "refrant"<br>DESut to depending<br>from balas<br>Zrendons,   | Note<br>Contactual ray<br>messaary to<br>contactual
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   | F855, 56<br>Upper Ima<br>- pen, 10<br>Ohm, 7<br>F855<br>-   | 60<br>24 (most 132)<br>Minimum 6<br>Soon efter<br>implemation  | O of Lingeneral in 27%<br>waters 12% in controls<br>(19% pt est<br>10% interret of lower<br>Cody pain selected on over<br>10% pt est<br>10% | Average or patient<br>electrode charge –<br>May generative trapped<br>a tablectoria<br>20% PC registerments<br>20% PC registerments<br>21% revealed a 22<br>surgest complianterial<br>24 electrode impations<br>or falsers in 2 activities<br>1 infection   | Cert Huly<br>The-Serty follow-th<br>More part decrease<br>Comparison of<br>technical results   | Tong <sup>17</sup><br>Vari Boren<br>et a <sup>10</sup><br>Vari Boson<br>et a <sup>10</sup>  
   | Retropective<br>Retropective<br>(1076-2027)<br>Retropective<br>(10 year)<br>Rompwolue  | 3 4<br>195,5+7 20<br>254 207<br>10<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0<br>0  |
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| TABLE 155<br>Published<br>Alags of a <sup>th</sup><br>Add of a <sup>th</sup><br>Bartlet et a <sup>th</sup>   | - E + Cilinical Results<br>Bines 1995<br>Soudy Design Remot<br>Batta Source<br>14265-3011<br>Possecitive<br>(3190-1302)<br>Possecitive<br>(3190-1302)  | of Spinal Cord<br>and Nambur<br>102<br>80<br>54  | 6 Stimulation for<br>Number<br>Followed<br>62<br>41   | Neuropathia Pala<br>Indication (n)<br>Nego, 117<br>7855, 29<br>Vec. 39<br>7975, 19<br>Radioude, 11<br>Other, 2<br>Radioude, 11<br>Other, 2<br>Radioude, 11<br>Other, 2  
   | <ul> <li>A Compretense</li> <li>Mass Number of Hange</li> <li>12</li> <li>49</li> <li>41, 2, 24</li> </ul>  | Are Salection from Report<br>Results<br>Effects of Salection<br>Print 27%<br>"Promption"<br>Charles of Salection<br>The Salection Salection<br>Salection Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salection<br>Salec   | 5<br>Compliantions<br>his next, 10 networks<br>for "reflam,"<br>DRILOU to determine<br>from balas<br>the sectors,<br>2 interesting  | Nete<br>Consistent out<br>methods of the
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   | d<br>97 turistand<br>19mb party<br>18<br>9<br>34<br>9<br>40  | F855<br>F955, 56<br>Upper Imb<br>Jain, 10<br>Obs<br>F855<br>F855<br>F855<br>All F855 end  | 60<br>24 (most 132)<br>Minimum 6<br>Soon gitar<br>implemation<br>12, 24                              | G of Linearound in 27%;<br>restance of<br>10% interved to work<br>10% interved to an interved<br>10% interved<br>10% interved, 10% interved<br>10%  | Average or patient<br>intervals charge –<br>May generative trapped<br>a tablectoria<br>20 Million (Constantia)<br>20   | Cest study<br>Thirdyparty Molecular<br>Mona and Johnson<br>Mona an   | Toang TT<br>tam Baran<br>et al <sup>the</sup><br>uan Banan<br>et al <sup>the</sup><br>Without   | Retrospective<br>Retrospective<br>(0.05-2027)<br>Retrospective<br>Retrospective<br>Retrospective<br>Retrospective   
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  | "Satisfacury"<br>gan relation<br>of the second<br>of   | 1 nightion<br>1 nigh | 005 gang<br>gang<br>Sabor Kg<br>Sabor Kg<br>Jasawa Ind S<br>System<br>Na<br>Biblygeny m   | | | | | | | | | | | | | | | | | | | | | | | | | | |
| TABLE 155<br>Published<br>Alagsi or a <sup>17</sup><br>Al5 et a <sup>17</sup><br>Bendet et a <sup>14</sup><br>Bendet et a <sup>14</sup>  | Le Citologi Results<br>Exce 1965<br>South Seeing North<br>South Sectors<br>Notes 1967<br>Sectors 1970<br>Sectors 1   | of Spinal Cord<br>m Number<br>Inplanted<br>107<br>80<br>54<br>134  | 4 Stimulation for<br>Norman<br>Followed<br>41<br>30 ignorp 1 a<br>Pisco Quad<br>with Xibit C  | Neuropathie Pair<br>Indiastic Pair<br>Press, 29<br>Viet, 29<br>F955, 22<br>Reduke 11<br>Reduke   | A Comprehense     Manne Marchae of Mathema primary     12     49     412,24     10.7 (51-326)   | Ave Extraction from Report<br>I Instants<br>Ellipspace (a Ars),<br>Prace 27 15<br>""arounds"<br>Chr. y 20 ans ac<br>"Mare" had spinisteret<br>17 anothe<br>Had Still-All propio<br>Prace (a propio<br>Destingtion on the<br>Prace of the Still<br>Prace of   | B<br>Compliantion<br>for "anticar"<br>Difficult Compliant<br>Ser "anticar"<br>Difficult Comprising<br>term tables<br>2 renderson,<br>2 renderson,<br>2 renderson,<br>3 statectore,<br>3 statectore   | Note<br>Constantial one,<br>messeary to<br>colone constantial<br>bitmer up<br>bitmer up<br>participation<br>bitmer up<br>participation<br>bitmer<br>particip   | Fumer 40 eff<br>Kumar 40 eff<br>Leveque 41 a<br>North ar a <sup>100</sup><br>Observation 17  | <ul> <li>Prospective</li> <li>Reseased/vector</li> <li>Reseased/vector</li> <li>Prospective</li> <li></li></ul>  | 70<br>70<br>77 54<br>87<br>70<br>789   | AD (44<br>others<br>controls)<br>75<br>16<br>24 (12 series<br>12 lenges<br>tomys<br>40   | d<br>67 Suntaent<br>19<br>= 34<br>9<br>-   | PBSS, 54<br>Light mo<br>Jam, 10<br>Obs. 7<br>PSS<br>All FBSS and<br>"some" Carls  | 00<br>24 (mont 122)<br>Misimum 6<br>Soon after<br>implemention<br>12, 24                             | G of L неропла 2015,<br>чисть 275 по полтай<br>втор рг не<br>1016 востати 50 коло<br>1016 востати 50 кол<br>1016 востати 50   | Average bot potent<br>alexande home -<br>Vo yaan<br>ya at Vorgene<br>pa - t Vorgene<br>da betove<br>da betove  | Cett Huly<br>Third-party follow-in<br>Mars and adverter<br>for and adverter<br>for adverter<br>following testing<br>following<br>following   | Tong Tr<br>van Donan<br>et all<br>van Donan<br>et all<br>et all<br>tall<br>tall<br>tall   | Retropocive<br>Retropocive<br>BISS-2007<br>Retroposition<br>(10) (we)<br>Retroposition<br>(10) (we)  | 3 4<br>195.5+7 27<br>254 27<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10  | connecting<br>society<br>programs<br>and for<br>programs<br>and society<br>of the<br>society<br>of the<br>society<br>of<br>society<br>of the<br>society<br>of the<br>societ  | 12) botas<br>22 daul and<br>22 daul and<br>22 had exclusional<br>23 merits<br>6, 12 merits,<br>14 services 20 atta<br>5 sears 20 atta<br>13 lavoiaestarryd  | Cord Injury, 2<br>Providence, 3<br>Providence, 2<br>Providence, 2<br>P  | 21 (1)-15<br>28 (2)-28<br>-40<br>37 4 (1-44)<br>37 4 (1-44)<br>37 matin   | "Selektrony"<br>genneter<br>Spräczych Scosses<br>Bydiatry Scosses<br>Bill and Scosses<br>Scosses<br>Bill and Scosses<br>Bill and Bill and Scosses<br>Bill and Scosses<br>Bill and Bill and Bill and Bill and Bill and<br>Bill and Bill and<br>Bill and Bill and<br>Bill and Bill and<br>Bill  | 1 migration<br>1 migration<br>10 activus consciously<br>10 migrations accurate<br>10 migrations<br>10 migr   | Inse geny<br>Sporte<br>Sporten<br>Assess and 3<br>Sotten<br>Balaury<br>Balaury  |
| TABLE 155<br>Published f<br>Reserve<br>Adopted d <sup>21</sup><br>Bordet et d <sup>42</sup><br>Bordet et d <sup>42</sup><br>Bordet et d <sup>42</sup>  | Clinical Results      Ence 199      Ence 199      Ence 199      Ence 199      Ence 199      Figure 199       Figure 199  | of Spinal Cord<br>ref Nepland<br>103<br>80<br>54<br>134<br>20  | 4 Stimulation for<br>Reference<br>42<br>41<br>20 typop 1 an<br>Pistove 2 an<br>21 typop 2 an<br>22 typop 2 and<br>23 typop 2 and<br>24 typop 2 and<br>25 typop 2 and<br>26 typop 2 and<br>27 typop 2 and<br>20 typop 2 a  | Neuropathis Pais<br>Indication (H<br>Party 113)<br>P655, 29<br>Viet, 28<br>P765, 20<br>CPRS, 10<br>C2015  | - A Comprehension<br>Mean Marchard Marchard<br>Alaber sep Marcy<br>48<br>6, 12, 24<br>18, 701-328<br>23, 8,-44<br>60  | Are Selection from Report<br>A Description<br>State (Selection from Report<br>Part 2014)<br>The 2014<br>The 2014<br>Th   | S<br>Complexities<br>Song rungst, dramouted<br>Song rungst,   | Nets<br>Constant only<br>message with the second<br>message wit   | Fumar et all<br>Fumar et all<br>Laveout et al<br>Generata II<br>Oborneta II<br>Bashbarn  | <ul> <li>Prospective</li> <li>Resospective</li> <li>Resospective</li> <li>Comparison</li> <li>Resospective</li> <li>Resospective</li> <li>Resospective</li> <li>Resolution</li> </ul>   | 104<br>20<br>17 24<br>18<br>7<br>100   | no sea<br>others<br>considere<br>considere<br>considere<br>considere<br>75<br>10<br>10<br>12 entres<br>12   | d<br>C7 funitored<br>Trime party<br>TS<br>- 34<br>- 40<br>- 28   | 7855<br>F855, 58<br>Joan Into<br>Joan, 10<br>Oder, 7<br>F955<br>-255<br>All F855 and<br>-some Corrison<br>-some Corrison  | 00<br>24 (mont 122)<br>Molemum 6<br>500, gtar<br>implemention<br>12, 24<br>105, (c.5-c.9)            | O of Linectowic in 27%<br>watch and a control<br>of the standard control<br>10% standard to work<br>10% standard to wo  | Average bot potent<br>advector known -<br>Vo yana<br>2 - 6 Voyana<br>2 - 7 Voyana | Cett muty<br>Third garty follow-p<br>Man and another<br>Man and another<br>Comparison of<br>Selfonger muture<br>Third garty<br>following   | Dang <sup>17</sup><br>van Banan<br>et gint<br>van Banan<br>et gint<br>Westerde<br>Westerde<br>Cited some  | Retrospective<br>SISS-2027<br>Retrospective<br>(13 year)<br>Prospective<br>(13 25-1,000<br>x regional gain may<br>a calculate standard   | 3 4<br>195.8+7 27<br>254 27<br>9<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1   | onwaring<br>botoste<br>sed 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Science<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Construction<br>Constr 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 |
| TABLE 155<br>Pablished 1<br>Adapt of al <sup>2</sup><br>Adapt of al <sup>2</sup><br>Burdet et al <sup>4</sup><br>Burdet et al <sup>4</sup><br>Burdet et al <sup>4</sup>  | 4 Clinical Results<br>Base 190<br>Study Dedge Song<br>Suby Children Song   | of Spinal Core<br>me Number<br>Inglands<br>102<br>90<br>54<br>134<br>20  | 4 Sciences for<br>Non-New<br>Factories<br>41<br>50 sproop 1 =<br>Place Quart<br>71<br>71 sproop 2 =<br>20<br>20   | Neuropathis Pais<br>Indication (H<br>Prop. 113)<br>7655, 29<br>7465, 29<br>7455, 20<br>7455,  | - A Coorgenetations<br>Mean Manufacture of Manage<br>12<br>49<br>4, 12, 24<br>18, 7 (11-32)<br>23, (6-42)<br>60   | Ar Extension from Report<br>Ar Extension<br>Chapter per 4%,<br>Theory of the<br>Theory of theory of theo   | B<br>Complexitient<br>for and standards<br>for and standards<br>for 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<li>Prospective<br/>Participation</li> <li>Retringentive<br/>(1980-2000</li> </ul>  | 20<br>20<br>21<br>24<br>35<br>7<br>7<br>89<br>41   | AD LAME<br>Consider<br>consider<br>constrolation<br>75<br>75<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76<br>76   | d<br>47 Junitawid<br>19<br>36<br>-<br>34<br>-<br>36<br>-<br>36<br>-<br>36<br>-<br>36<br>-<br>36<br>-<br>36<br>-<br>31<br>-<br>31<br>-<br>31<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-<br>-   | PBSS 86<br>PBSS 86<br>Upper line 10<br>Orex 7<br>PBS 7<br>PB | 80<br>24 (nost 122)<br>Mainum 6<br>500, spin<br>spin<br>spin<br>spin<br>spin<br>spin<br>spin<br>spin | O of Lineound in 27%<br>of the second second second<br>control of the second second second<br>control of the second second second second<br>control of the second second second second<br>second second   | Annya or select<br>to see the selection of the selection<br>of see the selection of the selection<br>of the selection of the selection of 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| TABLE 155<br>Pablished 1<br>Adapt st. of<br>Adapt st. of P<br>Bernard et al <sup>44</sup><br>Bernard et al <sup>44</sup><br>Durin et al <sup>44</sup><br>Durin et al <sup>44</sup>   | L Citical Results     Kar 199     Citical Results     Kar 199     Results     Toperating     Soft Paring     Results     Toperating     Results  | ef Spinel Cert<br>rei Negland<br>107<br>80<br>84<br>138<br>20<br>182<br>20<br>182<br>23<br>23  | Estimutation for<br>Realized<br>41<br>50 Sprop 1 =<br>Pace Que<br>30 Sprop 1 =<br>70<br>70  | Neuropatile Pai<br>Industrie V<br>Neuropatile<br>Viet. 28<br>Pais<br>Come: 2<br>Pais Come: 2<br>Pais Com  | A Cooperference<br>Material March March March<br>12<br>49<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40<br>40   | Are Education Strem Report<br>The Transformer Control of the Stremmer Control of   | Completence     Second Se   | Net Constant org message you personal of the org personal of the o   | Eventre et d'<br>Eventre et d'<br>Lonettan 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| TABLE 155<br>Published<br>Alagran at<br>Alagran at<br>Bendar et at <sup>4</sup><br>Bendar et at <sup>4</sup><br>Bendar et at <sup>4</sup><br>Bendar et at <sup>4</sup>   | -1         Chickal Results           Lan 1990         Total Science           Exact Folge         Exact Folge  | of Spinal Core<br>we Number<br>Suplace<br>103<br>103<br>103<br>103<br>103<br>103<br>103<br>103   | 4 Stimulation for<br>Networks<br>42<br>41<br>50 Sprop 1 to<br>Package 2<br>71 Sprop 2 to<br>72 Sprop 2 to<br>73 Sprop 2 to<br>74 Sprop 2 to<br>75 Sprop 2 to<br>75 Sprop 2 to<br>76 Sprop 2 to<br>76 Sprop 2 to<br>77 Sprop 2 to<br>78 Sprop 2 to<br>78 Sprop 2 to<br>79 Sprop 2 to<br>70   | Neuropathis Pail<br>Indicates of the<br>Indicates of  | - A Comprehense<br>Mass March March<br>12<br>- 49<br>- 6, 12, 24<br>- 13, 24<br>- 14, 7 (1-22)<br>- 12<br>- 12<br>- 13, 14<br>- 12<br>- 12<br>- 12<br>- 12<br>- 12<br>- 12<br>- 12<br>- 12  | Are Education Strem Report<br>24 Results<br>Ellipsycal cards,<br>35 Results<br>36 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# The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation

# Chronic Stimulation via Percutaneously Inserted Epidural Electrodes

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SYMPOSIUM: NEUROAUGMENTIVE DEVICES

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FIG. 3. Reliability: time to failure by mode.

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# The Appropriate Use of Neurostimulation: Avoidance and Treatment of Complications of Neurostimulation Therapies for the Treatment of Chronic Pain

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# Incidence and Avoidance of Neurologic Complications with Paddle Type Spinal Cord Stimulation Leads

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**Introduction:** While reference is frequently made to the risk of spinal cord or nerve root injury with the surgical implantation of paddle type spinal cord stimulation (SCS) electrodes, data are lacking on the frequency, causes, and prevention of these complications.

**Methods:** To determine the incidence and frequency of neurologic complications, we performed 1) a comprehensive analysis of the literature to determine the incidence of complications that have caused or could lead to neurologic injury; 2) an analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) data base; and 3) an investigation of manufacturers' data on surgically implanted paddle electrodes. We then convened an expert panel of neurosurgeons experienced in the surgical implantation of paddle electrodes to provide recommendations to minimize the risk of neurologic injury.

**Results:** The scientific literature describes the breadth of neurologic complications that can result from SCS electrode implantation but does not provide interpretable data with respect to the incidence and frequency of these complications. The MAUDE data base is not constructed to be sensitive or specific enough to provide these critical data. Primary data show a risk of neurologic injury from implantation of paddle electrodes below 0.6%.

Discussion: Preoperative, intraoperative, and postoperative measures to further minimize this risk are described.

**Conclusions:** This investigation, the first comprehensive evaluation of the incidence and frequency of neurologic injury as a result of SCS paddle electrode implantation, suggests that neurologic injury is a rare, but serious, complication of SCS. The incidence of these complications should be decreased by the adoption of approaches that improve procedural safety and by careful patient follow-up and complication management. Physicians should be aware of these approaches and take every precaution to reduce the risk of neurologic injury. Physicians also should report any adverse event leading to injury or death and work together to improve access to these data.



For what a man had rather were true he more readily believes.

> -Sir Francis Bacon 1561-1626



# A Numbers Needed to Treat (NNT) Analysis of the Pivotal SUNBURST Study

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### INTRODUCTION

New spinal cord stimulation (SCS) devices have expanded options, including multiple stimulation modes (burst and tonic). With initiatives to reduce opioid use for chronic pain patients, the context of SCS efficacy compared to pharmacological therapies is important. Number Needed to Treat/Harm (NNT/H) analyses provide relative prevalence of benefit and harms for comparison to pharmaceutical therapies.

Number Needed to Treat (NNT) - a marker for the rate of benefit - is defined as the number of subjects that need to be treated with a given therapy for one subject to achieve benefit. An NNT of 1 is a perfect score whereby all subjects achieved benefit: lower values are more favorable for a therapy. Conversely, Number Needed to Harm (NNH) is defined as the number of subjects that need to be treated with a given therapy for one subject to have a specified adverse outcome; higher values are more favorable

#### METHODS SUNBURST Study

SUNBURST, a randomized, crossover study, implanted subjects with a spinal cord stimulation (SCS) device (Prodigv™, Abbott) capable of delivering both burst (BurstDR™, Abbott) and tonic stimulation. Subjects completed a 7-day visual analog scale (VAS) diary for overall daily pain (Overall VAS) prior to each visit. Percentage change in mean overall VAS was calculated for the ITT population (N = 100) at 24 weeks, after subjects used tonic for 12 weeks and burst for 12 weeks. Percentage change in VAS was computed for available data at 1 year (N=80). After 24 weeks, subjects were free to select programs at-will. Subjects completed the Oswestry Disability Index (ODI) at baseline and 24 weeks and completed a Patient Global Impression of Change (PGIC) scale at 24 weeks. The majority of subjects (93% or 74/80) were using burst or a combination of burst and tonic programs at the 1-year visit

Primary results of the study were previously published. [1]

Table 1 shows the baseline demographics of the SUNRURST subjects

	,
Age [Mean (SD)]	59.1 (13.5)
Male [N(%)]	43 (43%)
Time Since Onset of Pain [Mean(SD)]	12.9 (10.1)
Using or had Used Oral Medications [N(%)]	97 (97%)
Primary Diagnosis [N(%)]	
Arachnoiditis	1 (1%)
CRPS I/CRPS II	2 (2%)
Degenerative spine disease	3 (3%)
Failed back surgery syndrome (FBSS)	42 (42%)
Neuritis/neuropathy/neuralgia	2 (2%)
Postoperative chronic pain	3 (3%)
Radiculopathies	38 (38%)
Chronic pain (non-postoperative)	9 (9%)

### METHODS

### Comparative Data from Pharmaceutical Pain Treatments

To provide context to the NNT and NNH values calculated for SUNBURST, comparative values were extracted from published meta-analyses of pharmaceutical therapies.[2,3] In both reviews, NNTs were based upon 50% reduction in pain and NNHs were based upon number of subjects who exited a study due to an adverse event. Comparative NNT values extracted from published meta-analyses were calculated from studies with the following:

- Treatment duration of 3 to 24 weeks
- Placebo-controlled BCTs
- Subjects with neuropathic pain: radiculopathy is noted as underrepresented

#### Statistical Methods (SUNBURST)

For SUNBURST, NNT was calculated for the device overall. irrespective of the specific therapy mode delivered to the patient. As such. NNTs were calculated, using within-subject methods [4] as the inverse of the proportion of subjects meeting pre-specified benchmarks. Per IMMPACT guidelines [5], the following benchmarks were used in calculating NNT values:

- Clinically meaningful reduction in mean overall VAS (30%) reduction)
- Clinically substantial reduction in mean overall VAS (50%) reduction)
- Clinically perceptible improvement in function (10 pt improvement in ODI)
- · Patient reported moderately better, much better, or great deal better on the PGIC (5 or better rating)

To be consistent with the NNH benchmarks in the comparative systematic reviews. SUNBURST NNH was calculated using the number of subjects who exited the study due to an adverse event or intolerable side effect through 24 weeks.

For all NNT and NNH values calculated using SUNBURST data, 95% Confidence Intervals for each were calculated using the Bender method [4]. Statistical comparisons of SUNBURST data to pharmacological meta-data were not appropriate due to potential differences in patient populations and none were performed. The Likelihood of being harmed or helped (LHH), a marker of the relative risk/benefit, was calculated as NNH/NNT [7].

### RESULTS

Clinical Benchmark	NNT (95% CI)			
24 Weeks				
30% Reduction in VAS	1.4 (1.3, 1.7)			
50% Reduction in VAS	2.0 (1.7, 2.5)			
ODI (10 pt improvement)	1.4 (1.3, 1.7)			
PGIC (5 or better rating)	1.2 (1.1, 1.3)			
1 Year				
30% Reduction in VAS	1.7 (1.4, 2.0)			
50% Reduction in VAS	2.7 (2.1, 3.5)			

### RESULTS

### NNT Values for the SCS device and Pharmaceutical Pain Management Therapies



FIGURE 1. Numbers Needed to Treat for Benefit (NNT) was defined as the number of subjects needed to treat for one subject to obtain 50% reduction in pain intensity. Multi-mode SCS device (SUNBURST) NNT value was calculated using pain relief at 24 weeks. All pharmacological NNT values were published in systematic reviews and included studies with a treatment duration een 3 and 24 weeks. Bars represent 95% confidence intervals. ^ Error bar truncated fo

scale (upper bound = 50) \*Cochrane Review of 5 RCTs for the treatment of neuropathic pain including morphine, methadone, oxycodone, levorphanol and dihydrocodeine.[2] \*\*S review and metanalysis of 229 RCTs examining treatments for neuropathic pain.[3] TCA: tricyclic antidepressants; strong opioids: morphine or oxycodone or similar; SNRI: norepinephrine reuptake inhibito

#### NNH Values for the SCS device and Pharmaceutical Pain Management Therapies



for one subject to exit the study due to an adverse event or intolerable side effect. Multi-mode SCS device (SUNBURST) NNH was calculated using subjects withdrawn through 24 weeks of the levorphanol and dihydrocodeine [2] \*\*Systematic review and metanalysis of 229 RCTs study. All pharmacological NNH values in published systematic reviews were based upon treatment duration between 3 and 24 weeks. Bars represent 95% confidence intervals. ^ Error

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### RESULTS

- For the SCS device, NNTs ranged from 1.2 to 2.0 at 24 weeks (Table 2).
- At 1 year post-implant. NNT values were similar. NNH values indicated 1 of every 100 subjects would exit the study due to
- an adverse event. The multi-modal SCS device had lower NNT and higher NNH values than a
- variety of common pain management medications (Figures 1 & 2). The overall risk/benefit profile (LHH) of the SCS device was more favorable
- than those calculated for the pharmacological therapies (Figure 3).

### DISCUSSION

At 24 weeks, NNT values were similar across a variety of benchmarks (pain reduction, functioning, patient global impression), Moreover, NNT was lowe than reported for a variety of pain management medications, indicating that the SCS device resulted in a 50% pain reduction more often than occurred with pharmacological therapies. Furthermore, NNH values were higher than those reported for oral medications. The LHH value is one indicator for the risk/benefit profile for the SCS device and results were favorable as compared to the other therapies included in this analysis

The favorable profile of the SCS device is especially notable in this population of subjects with an average of 12 years of pain history for which almost all subjects had used or were using pharmacological pain management therapies upon entry in the study

Interpretation of the comparisons to the pharmacological literature is limited by the fact that all the reviewed studies used a placebo comparator and had variable follow-up periods. Additionally, surgically implanted SCS devices require a bigger financial and emotional investment in the therapy, and the patient populations were unlikely to be directly comparable. In addition, differences in patient populations may limit the ability to make strong conclusions from this analysis; additional work with meta-analytic methods will provide a more accurate comparison of the device to other pain mana therapies.

### CONCLUSIONS

- Examination of NNT and NNH values, developed and used primarily for pharmaceuticals, confirms that the multi-modal SCS device provides an effective and safe therapy, which may have a better treatment profile than pain medications
- The more favorable benefit/risk profile (high LHH value) is especially notable in this population of subjects who failed to achieve adequate pain control with pharmacological therapies.

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### NNH Values for the SCS device and Pharmaceutical Pain Management Therapies

FIGURE 2. Numbers Needed to Harm (NNH) was defined as the number of subjects to be treated for one subject to exit the study due to an adverse event or intolerable side effect. Multi-mode SCS device (SUNBURST) NNH was calculated using subjects withdrawn through 24 weeks of the study. All pharmacological NNH values in published systematic reviews were based upon treatment duration between 3 and 24 weeks. Bars represent 95% confidence intervals. ^ Error

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North et al., NANS poster 2018



# Conclusions

# The history of research on the mechanisms, efficacy, and **safety** of spinal cord stimulation

# Mechanisms-based Medicine

"An efficiently working reflex [gives] a correct answer, so to say, to an improper or wrong question."

> Sir Charles Sherrington 1932 Nobel laureate

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# PAIN AND THE NEUROSURGEON

A Forty-Year Experience

BASED ON A SERIES OF OVER 1700 PATIENTS AND ON THE AUTHOR'S STUDY OF THE WORLD LITERA-TURE AIDED BY THEIR OWN EX-PERIENCE, THIS VOLUME IS AN EVALUATION OF NEUROSURGICAL PROCEDURES FOR THE RELIEF OF OTHERWISE INTRACTABLE PAIN.

CHARLES C THOMAS • PUBLISHER Springfield • Illinois and in Chapter XVIII on Stereotactic Surgery of the Thalamus from

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White & Sweet, 1969

Anatomic	Augmentative	Ablative
Decompression Stabilization Reconstruction	Electrical stimulation Transcutaneous Implanted devices Peripheral nerve Spinal cord Intracerebral Chemical infusion systems Spinal epidural Spinal subarachnoid Intraventricular	Open Neurotomy Sympathectomy Ganglionectomy Rhizotomy DREZotomy Cordotomy Myelotomy Tractotomy Percutaneous radiofrequency Neurotomy ( <i>e.g.</i> facet) Rhizotomy ( <i>e.g.</i> facet) Rhizotomy ( <i>e.g.</i> trigeminal) Cordotomy Cingulumotomy Percutaneous chemical Lytic subarachnoid block Celiac alcohol block Stereotaxic hypophysectomy

TABLE 9.1 Neurosurgical Procedures for Pain Management<sup>e</sup>

<sup>a</sup> Neurosurgical procedures for the relief of pain may be divided into three categories: 1) anatomic procedures are directed at the structural cause, 2) augmentative procedures modulate pain transmission by electrical or chemical means, and 3) ablative procedures block pain transmission by destroying pain pathways.

North RB: Neurosurgical procedures for chronic pain: General neurosurgical practice. *Clinical Neurosurgery 40:182-196, 1992.* 

# LIFEBRIDGE

## Functional Neurosurgery Versus Reconstructive Spine Surgery for Failed Back Surgery Syndrome: An Evidence-Based Approach

Richard B. North, MD, Baltimore, Maryland

### The Sandra and Malcolm Berman Brain & Spine Institute

### Introduction

Repeated lumbosacral spine surgery for persistent or recurrent pain (FBSS) yields diminishing returns, as is well known (e.g., Fritsch 1996). Spinal cord stimulation (SCS), a reversible pain-relieving procedure performed by functional neurosurgeons and interventional pain specialists, compares favorably with repeated surgery by virtue of higher yield with lower morbidity and greater cost-effectiveness.

### Methods

This review of the evidence comparing SCS with surgical and medical alternatives clarified future study design issues and objectives.

### Results

A single-center RCT of SCS vs. reoperation for FBSS demonstrated significantly better clinical outcomes (North 2005) and greater cost effectiveness (North 2007a) for SCS in patients with prominent radicular pain. A multi-center RCT comparing SCS with conservative medical management reached similar conclusions (Kumar 2007). This is consistent with the nonrandomized studies that comprise the rest of the evidence base (North 2007b). A multi-center RCT of SCS vs. reoperation, which will incorporate the latest techniques and equipment for each, is underway (North 2010).

### Discussion

SCS is a minimally invasive treatment for otherwise intractable neuropathic pain. SCS treatment success depends upon proper patient selection, equipment choice, and physician training. Studies of SCS must include protocols to protect patient safety, including careful patient selection criteria. SCS studies must also rely on appropriate outcome measures to determine treatment success. Additional outcomes can and should be collected,



**Figure 1.** This RCT protocol allows crossover to occur once. Randomized treatment success is indicated by solid lines. Randomized treatment failure is indicated by dashed lines. but pain relief should be the primary outcome. SCS studies must follow accepted standards regarding patient selection, sample size calculation, group comparability, standardized group treatment during data collection, reduction of bias, data analytical methods, and appropriate follow-up methods, including basing intervals on intervention dates (instead of study entry). Data reporting should include raw figures as well as percentages and information on all sub-group outcome.

### Conclusion

The evidence indicates that SCS, a functional procedure, is superior to reconstructive spine surgery in selected cases. A new multi-center RCT will provide additional up-to-date evidence.

### Disclosure

Neither I nor a member of my immediate family has received anything of value\* from or own stock (or stock options) in a commercial entity related directly or indirectly to the subject of this presentation. The FDA has cleared SCS for the use described in this presentation.

\*In the past five years. Usual disclosure follows: Dr. North has no personal income from or equity interest in the medical device industry. His former employer (Johns Hopkins University) received funding from industry as does the nonprofit Neuromodulation Foundation, of which he is an unpaid officer.

### References

Fritsch EW et al. Spine 21:626-33, 1996. North RB et al. Neurosurgery 61:361-69, 2007a North RB et al. Neurosurgery 56:98-106, 2005. Kumar K et al. Pain 132:179-188, 2007. North RB et al. 2007b www.neuromodfound.org North RB et al. 2010, submitted.

# A Numbers Needed to Treat (NNT) Analysis of the Pivotal SUNBURST Study

Richard North<sup>A</sup>; Tim Deer<sup>B</sup>; Konstantin Slavin<sup>c</sup>; Peter Staats<sup>D</sup>; Chananit Hutson<sup>E</sup>; Kristina Davis<sup>E</sup>

<sup>A</sup> Johns Hopkins University School of Medicine, Baltimore, MD; Center for Pain Relief, Charleston, WV; Oliversity of Illinois, Chicago, IL; Premier Pain Centers, Shrewsbury, NJ; Abbott

### INTRODUCTION

New spinal cord stimulation (SCS) devices have expanded options, including multiple stimulation modes (burst and tonic). With initiatives to reduce opioid use for chronic pain patients, the context of SCS efficacy compared to pharmacological therapies is important. Number Needed to Treat/Harm (NNT/H) analyses provide relative prevalence of benefit and harms for comparison to pharmaceutical therapies.

Number Needed to Treat (NNT) - a marker for the rate of benefit - is defined as the number of subjects that need to be treated with a given therapy for one subject to achieve benefit. An NNT of 1 is a perfect score whereby all subjects achieved benefit: lower values are more favorable for a therapy. Conversely, Number Needed to Harm (NNH) is defined as the number of subjects that need to be treated with a given therapy for one subject to have a specified adverse outcome; higher values are more favorable

#### METHODS SUNBURST Study

SUNBURST, a randomized, crossover study, implanted subjects with a spinal cord stimulation (SCS) device (Prodigv™, Abbott) capable of delivering both burst (BurstDR™, Abbott) and tonic stimulation. Subjects completed a 7-day visual analog scale (VAS) diary for overall daily pain (Overall VAS) prior to each visit. Percentage change in mean overall VAS was calculated for the ITT population (N = 100) at 24 weeks, after subjects used tonic for 12 weeks and burst for 12 weeks. Percentage change in VAS was computed for available data at 1 year (N=80). After 24 weeks, subjects were free to select programs at-will. Subjects completed the Oswestry Disability Index (ODI) at baseline and 24 weeks and completed a Patient Global Impression of Change (PGIC) scale at 24 weeks. The majority of subjects (93% or 74/80) were using burst or a combination of burst and tonic programs at the 1-year visit

Primary results of the study were previously published. [1]

Table 1 shows the baseline demographics of the SUNRURST subjects

	,
Age [Mean (SD)]	59.1 (13.5)
Male [N(%)]	43 (43%)
Time Since Onset of Pain [Mean(SD)]	12.9 (10.1)
Using or had Used Oral Medications [N(%)]	97 (97%)
Primary Diagnosis [N(%)]	
Arachnoiditis	1 (1%)
CRPS I/CRPS II	2 (2%)
Degenerative spine disease	3 (3%)
Failed back surgery syndrome (FBSS)	42 (42%)
Neuritis/neuropathy/neuralgia	2 (2%)
Postoperative chronic pain	3 (3%)
Radiculopathies	38 (38%)
Chronic pain (non-postoperative)	9 (9%)

### METHODS

### Comparative Data from Pharmaceutical Pain Treatments

To provide context to the NNT and NNH values calculated for SUNBURST, comparative values were extracted from published meta-analyses of pharmaceutical therapies.[2,3] In both reviews, NNTs were based upon 50% reduction in pain and NNHs were based upon number of subjects who exited a study due to an adverse event. Comparative NNT values extracted from published meta-analyses were calculated from studies with the following:

- Treatment duration of 3 to 24 weeks
- Placebo-controlled BCTs
- Subjects with neuropathic pain: radiculopathy is noted as underrepresented

#### Statistical Methods (SUNBURST)

For SUNBURST, NNT was calculated for the device overall. irrespective of the specific therapy mode delivered to the patient. As such. NNTs were calculated, using within-subject methods [4] as the inverse of the proportion of subjects meeting pre-specified benchmarks. Per IMMPACT guidelines [5], the following benchmarks were used in calculating NNT values:

- Clinically meaningful reduction in mean overall VAS (30%) reduction)
- Clinically substantial reduction in mean overall VAS (50%) reduction)
- Clinically perceptible improvement in function (10 pt improvement in ODI)
- · Patient reported moderately better, much better, or great deal better on the PGIC (5 or better rating)

To be consistent with the NNH benchmarks in the comparative systematic reviews. SUNBURST NNH was calculated using the number of subjects who exited the study due to an adverse event or intolerable side effect through 24 weeks.

For all NNT and NNH values calculated using SUNBURST data, 95% Confidence Intervals for each were calculated using the Bender method [4]. Statistical comparisons of SUNBURST data to pharmacological meta-data were not appropriate due to potential differences in patient populations and none were performed. The Likelihood of being harmed or helped (LHH), a marker of the relative risk/benefit, was calculated as NNH/NNT [7].

### RESULTS

Clinical Benchmark	NNT (95% CI)			
24 Weeks				
30% Reduction in VAS	1.4 (1.3, 1.7)			
50% Reduction in VAS	2.0 (1.7, 2.5)			
ODI (10 pt improvement)	1.4 (1.3, 1.7)			
PGIC (5 or better rating)	1.2 (1.1, 1.3)			
1 Year				
30% Reduction in VAS	1.7 (1.4, 2.0)			
50% Reduction in VAS	2.7 (2.1, 3.5)			

### RESULTS

### NNT Values for the SCS device and Pharmaceutical Pain Management Therapies



FIGURE 1. Numbers Needed to Treat for Benefit (NNT) was defined as the number of subjects needed to treat for one subject to obtain 50% reduction in pain intensity. Multi-mode SCS device (SUNBURST) NNT value was calculated using pain relief at 24 weeks. All pharmacological NNT values were published in systematic reviews and included studies with a treatment duration een 3 and 24 weeks. Bars represent 95% confidence intervals. ^ Error bar truncated fo

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Interpretation of the comparisons to the pharmacological literature is limited by the fact that all the reviewed studies used a placebo comparator and had variable follow-up periods. Additionally, surgically implanted SCS devices require a bigger financial and emotional investment in the therapy, and the patient populations were unlikely to be directly comparable. In addition, differences in patient populations may limit the ability to make strong conclusions from this analysis; additional work with meta-analytic methods will provide a more accurate comparison of the device to other pain mana therapies.

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