PainWeek

Interventional Pain Management: Opioid-Sparing Technologies

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Disclosure

- Consulting Fee (eg, Advisory Board):
  Abbott, Avanos, Biotronik, Boston Scientific, Gruenthal, Nalu, Nevro, PainTeq, Saluda, SI Bone, SPR Therapeutics, Vertos
- Contracted Research (Principal Investigators must provide information, even if received by the institution):
  Avanos, Biotronik, Boston Scientific, Nalu, Nevro, PainTeq, Saluda, SPR Therapeutics
- Stock Shareholder (individual stocks/stock options; diversified mutual funds do not need to be disclosed):
  Nalu, National Spine and Pain Centers

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Learning Objectives

- Review pain and analgesia
- Discuss the impact of chronic pain
- Describe the evolution of opioid therapy
- Review current and future application of technology in treating chronic pain
- Review supporting evidence

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Outline

- Chronic pain
- History of analgesia
- Evolution of pain opioid therapy
- Technologies in treating chronic pain
  - Neuromodulation
  - Minimally invasive spinal interventions
- Evidence review in opioid reduction
- Explore the latest clinical trials

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Pain

- "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage..."

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Raja, S. et al. IASP Task Force on Taxonomy; Pain, 2020

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"Like a rope ringing a bell"

FIG. 1-1. Descartes' (1664) concept of the pain pathway. He writes: "If for example fire (A) comes near the foot (B), the minute particles of this fire, which as you know move with great velocity, have the power to set in motion the spot of the skin of the foot which they touch, and by this means pulling upon the delicate thread (cc) which is attached to the spot of the skin, they open up at the same instant the pore (d.e.) against which the delicate thread ends, just as by pulling at one end of a rope makes to strike at the same instant a bell which hangs at the other end." From Melzack, R., and Wall, P.D.: Pain mechanisms: A new theory. Science, *150*:971, 1965.

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Origin of Analgesia

- Sumerians, 3000 BC who first cultivated the poppy plant for its opium
- Homer in 300 BC Helen of Troy to treat her grief over the absence of Odysseus
- Morphine, codeine, heroin, oxycodone

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Ancient Pain Management

Auricular acupuncture depicted during Han dynasty, 200 BC

Cauterizing the external ear to treat migraine, 12th century Persian surgery text

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Morphine

- Discovered by Friedrich Serturner in 1803
- Named after Morphius, the god of dreams
- Commercially made available by Merck in 1827

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Opioid Problem is Not New

- 1849, Mrs. Charlotte Winslow, Bangor, Maine
- 65 mg morphine per ounce
- "sooth any human or animal…effectively quieted restless infants and small children, especially for teething"

PainWeek https://en.wikipedia.org/wiki/Mrs._Winslow%27s_Soothing_Syrup

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Diacetylmorphine

- Alder Wright, 1874 by adding 2 additional acetyl groups
- 4x more potent than morphine
- Manufactured by Bayer
- Prescribed in the UK for withdrawal and analgesic
- Schedule I substance in US

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Chronic Pain in America

- 1 in 5 Americans suffer from chronic pain
- Large economic impact: ~$600 billion/year
- Loss of productivity: ~$300 billion/year
- Opioid epidemic: #1 health crisis in America
- National health survey by NIH 2012
  - 50 million adults experience pain every day
  - Pain→ worse overall health status
  - Female, elderly, non-Hispanics (Asians less likely)

PainWeek *A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients.* http://jama.ama-assn.org/cgi/content/abstract/274/20/1591

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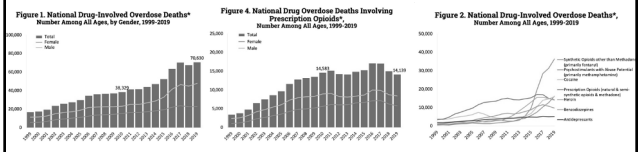
Opioid Crisis in America



- Over 70,000 Americans died in 2019 from drug overdose
- Deaths involving prescription opioids have decreased
- Synthetic opioid deaths have surged
- Increasing trend for 2020 due to COVID-19 pandemic

PainWeek https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates

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Paradigm Shift in Opioid Therapy

- Lack of long-term efficacy for treating chronic pain
- Risk for tolerance, dependency, and abuse
- National opioid crisis
- CDC opioid prescribing guidelines

PainWeek https://www.cdc.gov/drugoverdose/prescribing/guideline.html

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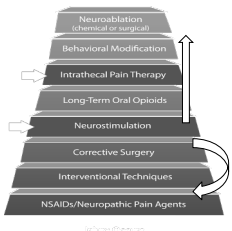
Evolution of Pain Medicine

In contrast to earlier thinking on the order of treatments in the pain treatment continuum,[1] it has been proposed that device therapies be considered at an earlier stage.[2]



[1] Krames ES. Intraspinal Opioid Therapy for Nonmalignant Pain: Current Practices and Clinical Guidelines. *J Pain Symptom Manage* 1998;11:333-352.
[2] Stanton JM, et al. *Live Your Life Pain Free*, October 2005. Based on the interventional pain management experience of Dr. John Stanaton.z

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Emergence of Electroceuticals

- Bioelectronics
- Therapeutic devices
- External or implanted
- Delivering electricity
- Neuromodulation
- Alter disease states
- Market prediction of $35.5 billion global market by 2025

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1. Kristoffer Framm, Nature, 2013
2. https://www.grandviewresearch.com/press-release/global-electroceuticals-bioelectric-medicine-market

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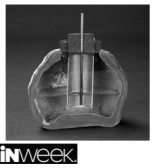
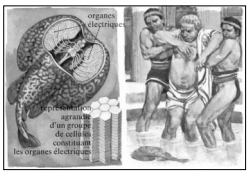
Ancient Opioid-Sparing Technologies

- Baghdad Battery
- 250 BC, outside Baghdad
- Clay jar with asphalt stopper
- Iron rod surrounded by copper
- If filled with vinegar: 1.1 volts



- Torpedo fish
- 46 AD: Scribonius Largus used torpedo fish to treat chronic pain



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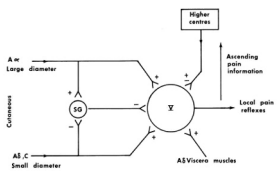
Gate Theory of Pain



- Wall and Melzack, 1965
- Aβ (sensory) and Aδ, C pain fibers compete for passage through physiologic "gate"
- Stimulation of larger Aβ fibers: closes the gate

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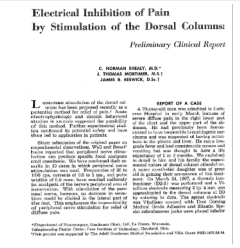
50+ Years of Spinal Cord Stimulation



Electrical Inhibition of Pain
by Stimulation of the Dorsal Columns:

Preliminary Clinical Report

C. NORMAN SHEALY, M.D.*
J. THOMAS MORTIMER, M.S.†
JAMES B. RESWICK, D.Sc.†

Dr. Shealy

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Contemporary Landmark Studies

- Kemler, et al. NEJM. 2000
  - SCS vs. PT alone in treatment of CRPS (n=54)
  - at 6 mo. 58% of SCS compared to 6% of PT improved
- North, et al. Neurosurgery. 2005
  - Re-operation vs. SCS with crossover (n=50)
  - 47% SCS vs. 12% re-op improved
  - 37% crossover, and 43% achieved pain relief
- Manca, et al. PROCESS Trial, Eur. J. Pain. 2008
  - SCS vs. CMM for FBSS
  - SCS with improved health and function, but higher $
- Kumar, et al. Neurosurgery. 2008
  - SCS vs. CMM alone for 6 month with crossover (n=100)
  - at 24 mo. 37% of SCS compared to 2% CMM

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Spinal Cord Stimulation

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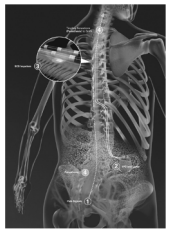
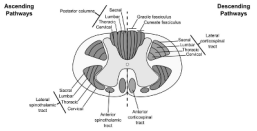
Traditional SCS Therapy





- Electrical stimulation of dorsal column
- Activation of Aβ sensory fibers
- Generate paresthesia in areas of pain

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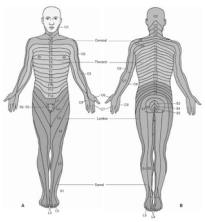
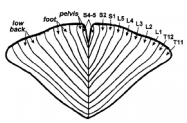
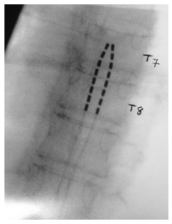
Paresthesia Dependent SCS Therapy







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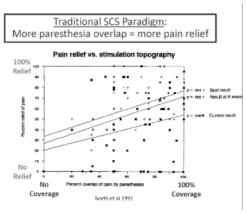
Paresthesia Dependent SCS Therapy



- Paresthesia coverage of pain is considered necessary for efficacy
- Paresthesia mapping
- Advanced lead placement

painweek *North et al 1991*

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Renaissance of Neuromodulation

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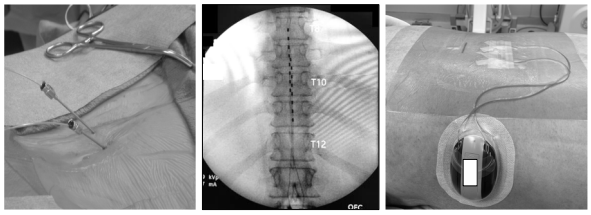
SCS Trial



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Innovations in Neuromodulation

- Adaptive stimulation
- MRI compatibility
- Novel wave forms
- Novel targets of stimulation
- Closed loop technology
- Remote access, distance healthcare

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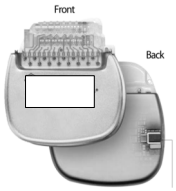
Adaptive Stimulation

- To address intensity variations due to postural changes
- Distance to spinal cord changes with posture
- Accelerometer controlled programming options
- 41% reported reduction of daily adjustments[1]
- First use of feed back in SCS



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1. Schultz, et al. Pain Physician, 2012

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Novel Targets of Stimulation

- Dorsal root ganglion
- Vagal nerve stimulation
- Peripheral nerve stimulation
- Multifidus stimulation

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Paresthesia Free Stimulation

- "High Density": ~ 1kHz, top of the traditional "low frequency" range, adjusted below perceptual threshold
- "High Frequency": 10 kHz, beyond perceptual threshold
- "Burst": 500 Hz x 5 pulses x 40/sec, totaling 200/sec, adjusted below perceptual threshold
- Differential targeted multiplexed (DTM) wave forms to target multiple cell types

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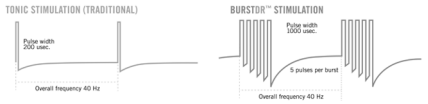
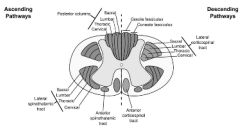
Burst Waveform in SCS Therapy





- Target medial descending pathway
- Both pain intensity and quality
- Via C-fiber activation in lamina I
  - Medial thalamic nuclei
  - Anterior cingulate cortex

Expert Review of Medical Devices, 2018

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High Frequency SCS

RESEARCH—HUMAN—CLINICAL TRIALS

Comparison of 10-kHz High Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24 Month Results From a Multicenter, Randomized, Controlled Pivotal Trial

- Prospective, multicenter RCT
- N=198
- t-SCS vs HF-SCS
- 12 and 24 month follow up
- Low back and leg pain
- Level 1 evidence for LF-SCS and HF-SCS

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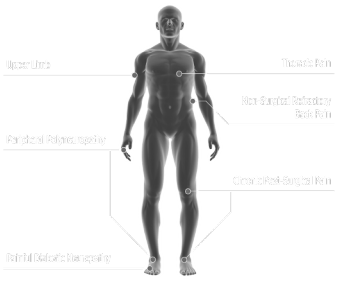
Potential Targets of HF10 Therapy



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Expanding Indication of SCS

- SENZA-ULN: 12-month, 89.2% (NP), 95% (UL)[1]
- SENZA-DPN: 3-month, 86% vs 5% (6-month data at NANS 2021)[2]
- SENZA-NSBP[3]: NANS 2021 US data
- SENZA-Abdominal pain: 12-month, 78.3%[4]
- SENZA-Pelvic pain: N=21, 14 implanted, 77% responders[5]
- SENZA-Post surgical pain: 6-month, 78% responders[6]
- Opioid reduction: ad-hoc (SENZA-EU, SENZA-RCT), N=137, 46% reduction[7]

1. Amirdelfan et al. Neurosurgery, 2019
2. Petersen et al. NANS, 2020
3. Al-Kaisy et al. Neuromodulation, 2017
4. Kapural et al. Clinical and Translational Gastroenterology, 2020
5. Tate et al. Pain Practice, 2020
6. Gupta et al. ASRA, 2018
7. Al-Kaisy et al. Scientific Reports, 2019

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HF10 SCS: Non-Surgical Back Pain "Al-Kaisy Study"

Pain Medicine 2017; 0: 1–8
doi: 10.1093/pm/pnx237

Medicine
OXFORD

Original Research Article

Long-Term Improvements in Chronic Axial Low Back Pain Patients Without Previous Spinal Surgery: A Cohort Analysis of 10-kHz High-Frequency Spinal Cord Stimulation over 36 Months

Adnan Al-Kaisy, MB, ChB, FRCA, FPMRCA, FIPP,* Stefano Palmisani, MD,* Thomas E. Smith, MBBS, MD, FRCA, FPMRCA,* Roy Carganillo, RN, MSc,* Russell Houghton, MB, ChB, MRCP, FRCR,* David Pang, MB, ChB, FRCA, FPMRCA,* William Burgoyne, MB, BS,† Khai Lam, FRCS (Orth),* and Jonathan Lucas, MBBS, FRCS (Eng), FRCS (Tr&Orth)*

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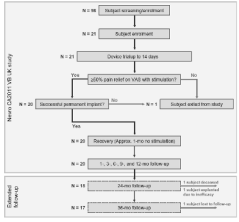
Al-Kaisy NSRBP Pilot Study Design



Single Arm, Prospective Study

- 20 successful implants
- 3 year observation
- Predominant back pain
  - Baseline 7.9cm VAS
- Multiple outcomes assessed:
  - Opioid usage
  - Function (ODI)

Published results at 12 and 36 months

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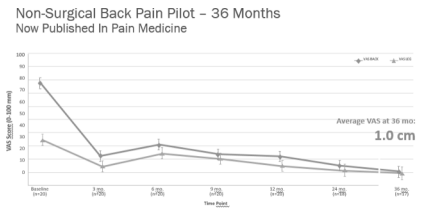
Non-Surgical Back Pain Pilot Study: 36 Months



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1. Al-Kaisy, Adnan, Palmisani, Stefano, Smith, Thomas E. Carganillo, Roy, Houghton, Russell, Pang, David, Burgoyne, William, Law, Rhei, Lucas, Jonathon. Long-Term Improvement in Chronic Axial Low Back Pain Patients Without Previous Spinal Surgery: A Cohort Analysis of 10-14H; High-Frequency Spinal Cord Stimulation over 36 Months. Pain Medicine 2017; 0: 1–8
2. Boyo, Richard A. Fusion surgery for lumbar degenerative disc disease: still more questions than answers. The Spine Journal 15 (2015) 272-274.

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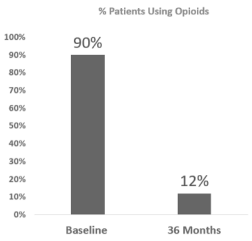
NSBP Study: Significant Reduction in Opioids

- 90% of patients on opioids at baseline
- 12% of all subjects were using opioids at 36 months



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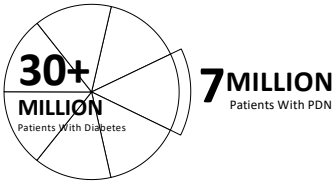
Diabetic Peripheral Neuralgia: Prevalence and Cost

Diabetes is a national epidemic

- 30.2 million people with diabetes = 9.3% of the population
- Another 86 million people are pre-diabetic (more than 1 in 3 people)
- Costs: $245 billion
  - Direct medical costs = $176 billion
  - Indirect costs = $69 billion

Painful diabetic neuropathy is common

- 20% to 26% of those with diabetes have PDN



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CDC National Diabetes Statistics Report, 2014; Davies M et al. Diabetes Care 2006; Schmader KE. Clin J Pain 2002

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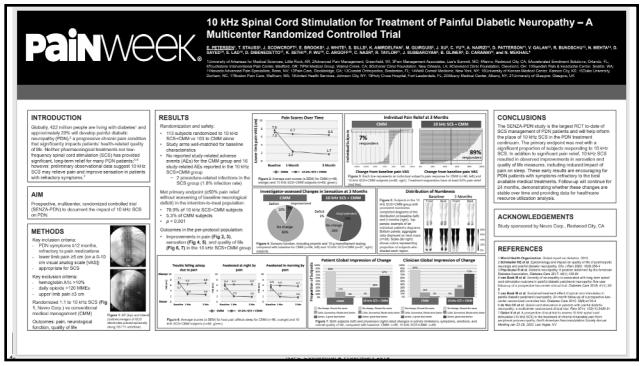

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SCS for Painful Diabetic Neuropathy

- Prospective, multicenter RCT
- N=216
- 6-month data, HF-SCS vs CMM
- VAS: 7.6→1.7 SCS, 7.0→6.9 CMM
- 50% pain reduction: 73.6% SCS, 5% CMM

Petersen et al. JAMA Neurology, 2021

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Real World Results

High-Volume Centers Study Shows Real World Outcomes Comparable to SENZA-RCT

Design
- 1660 consecutive patients enrolled (2014-2018)
- Eight global, high-volume HF10 centers

Long term efficacy (n=1100*)
- 78% responder rates
  - 74% responder rates in prior SCS patients
- 90% satisfaction
- 32% of patients reduced medication intake
- 3.7% reported explant rate
  - 1.2% due to loss off efficacy

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*Staats, Thomas et al. A Multicenter Real-World Review of 10kHz SCS Outcomes for Treatment of Chronic Trunk & /or Limb Pain. Annals of Clinical and Translational Neurology. January 2019. Among the 1,298 patients with safety data available, 48 had their devices explanted (3.7%). Of these, 22 were removed sequela to infection (1.7%), 15 due to lack of efficacy (1.2%), and 11 for other reasons (0.8%). *The mean time between implantation and the last visit was 8.9 months (range 0.1–33.2).*

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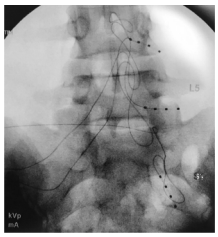
Dorsal Root Ganglion SCS Therapy



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PAIN

OPEN

Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial

Timothy R. Deer[a,*], Robert M. Levy[b], Jeffery Kramer[c], Lawrence Poree[d], Kasra Amirdelfan[e], Eric Grigsby[f], Peter Staats[g], Allen W. Burton[h], Abram H. Burgher[i], Jon Obray[j], James Scowcroft[k], Stan Golovac[l], Leonardo Kapural[m], Richard Paicius[n], Christopher Kim[o], Jason Pope[p], Thomas Yearwood[q], Sam Samuel[r], W. Porter McRoberts[s], Hazmer Cassim[t], Mark Netherton[u], Nathan Miller[v], Michael Schaufele[w], Edward Tavel[x], Timothy Davis[w], Kristina Davis[y], Linda Johnson[z], Nagy Mekhail[aa]

- US pivotal trial, comparing DRG and traditional stimulation
- Multicenter, randomized controlled trial
- 152 subjects with CRPS, causalgia of the lower extremity
- 76 DRG, 76 SCS
- At 3 months DRG group 81.2% and SCS group 55.7% efficacy

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Deer T. et al. Pain, 2017

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Recent Landmark Studies

- Accurate Trial: pivotal US study DRG stimulation
- Sunburst Trial: pivotal US study for Burst
- SENZA RCT: pivotal US study for HF10
- Accelerate Trial: HF-SCS vs conventional SCS
- Avalon Trial: closed loop SCS study in Australia
- Evoke Trial: pivotal US study for closed loop SCS
- Acute Trial: pivotal US study for DTM

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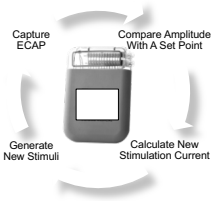
Closed-Loop Stimulation

- Not FDA approved
- Measure the response of Aβ fibres to stimulation
- Capture ECAP and make real time adjustments to stimulation
- 1,000,000 times per day
- Maintain stim within individual therapeutic window



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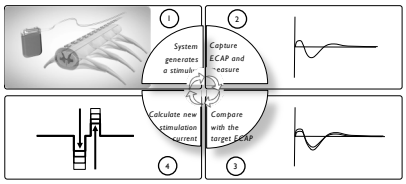
Variable Output Feedback Controlled Stimulation



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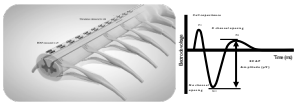
What is an ECAP?

- **E**voked **C**ompound **A**ction **P**otentials (ECAPs) are the sum of the electrophysiological response from multiple nerve fibers
- ECAPs provide insight into the type of fibers stimulated and are a measure of spinal cord (SC) activation



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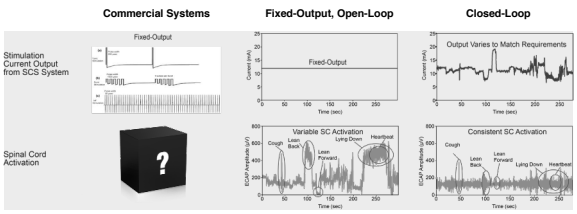
Fixed-Output vs Closed-Loop SCS



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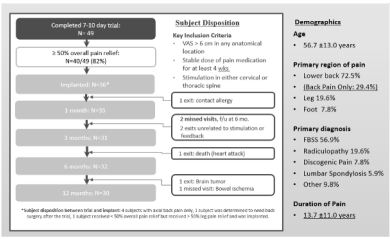
Closed-Loop SCS: Avalon Study (Australia)



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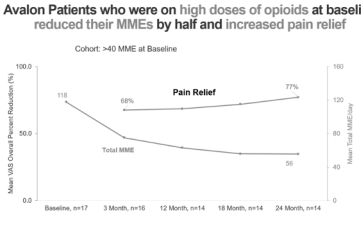
Avalon Study Results



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Brooker et al. Pain Practice, 2021

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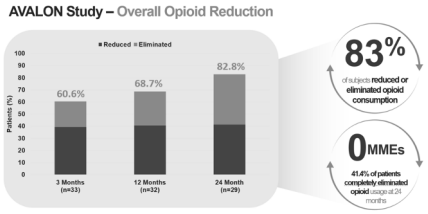
Avalon Study Results



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Brooker et al. Pain Practice, 2021

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Closed-Loop SCS: EVOKE Study Results: 12 month

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

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

Summary

Background Spinal cord stimulation has been an established treatment for chronic back and leg pain for more than 50 years; however, outcomes are variable and unpredictable, and objective evidence of the mechanism of action is needed. A novel spinal cord stimulation system provides the first in vivo, real-time, continuous objective measure of spinal cord activation in response to therapy via recorded evoked compound action potentials (ECAPs) in patients during daily use. These ECAPs are also used to optimise programming and deliver closed-loop spinal cord stimulation by adjusting the stimulation current to maintain activation within patients' therapeutic window. We aimed to examine pain relief and the extent of spinal cord activation with ECAP-controlled closed-loop versus fixed-output, open-loop spinal cord stimulation for the treatment of chronic back and leg pain.

Lancet Neurol 2019
Published Online
December 20, 2019
https://doi.org/10.1016/S1474-4477(19)30414-4
See Online/Comment
https://doi.org/10.1016/S1474-4477(19)30458-3

*Members of the Evoke Study Group are listed at the end of the

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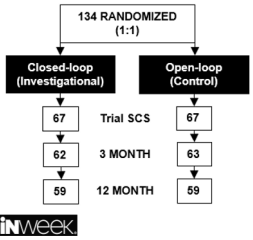
US EVOKE Study Results: 12 month



Baseline = not significantly different	Closed-loop	Open-loop
Duration of pain	14 years	11 years
Subjects on Opioids	61%	60%
Previous back surgery	58%	61%

Double-blind study maintained out to 3 years. This presentation will not affect ongoing data collection (only group statistics will be presented).

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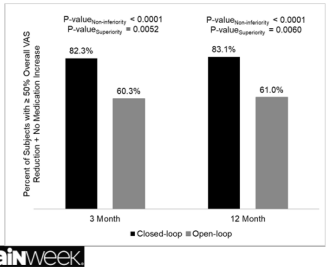
EVOKE: Primary Outcomes



- 83% responder rate for back and leg pain
- 56% high responder rate (≥80% pain relief)
- Time spent within therapeutic window was nearly doubled

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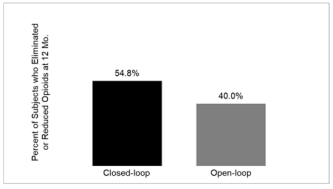
EVOKE: Reduction/Elimination of Opioids



MME	Closed-Loop	Open-Loop
Baseline	80	66
12 Months	45	45

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PNS for Chronic and Acute Pain

- FDA approved
- 0.2mm coiled lead via 20g introducer needle
- Coiled lead design for tissue ingrowth
- Temporary and revisable
- External wearable power source
- Forgiving lead placement
- Low infection risk

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PNS for Chronic and Acute Pain

- FDA approved
- 0.2mm coiled lead via 20g introducer needle
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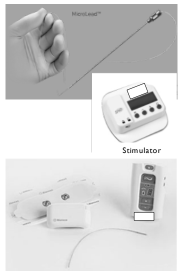

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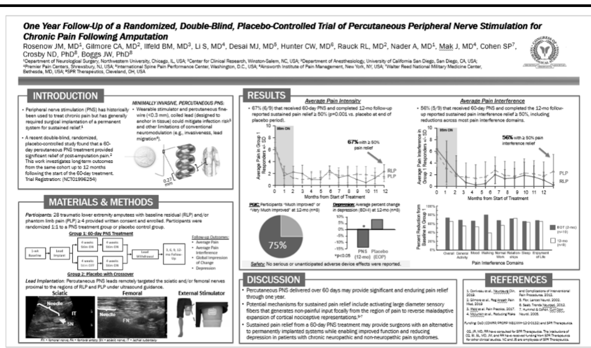

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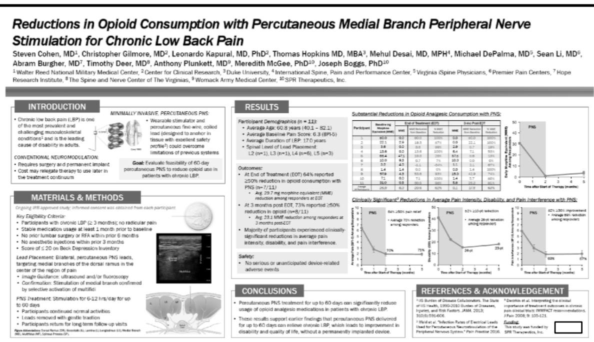

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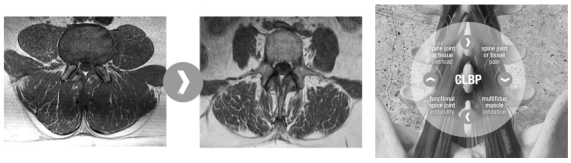
Restorative Multifidus Stimulation for LPB



- Multifidus stimulation via L2 lumbar medial branch nerve
- ReActiv8 A&B clinical trials
- Available 2-year data, presented at NANS 2021

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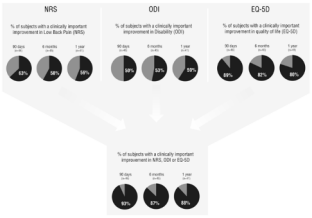
Multifidus Stimulation

- Multifidus stimulation
- ReActiv8 clinical trial
- N=53, multicentered RCT
- Improvement of chronic LBP
- 56% responder rate at 12 months



PainWeek *Neuromodulation, 2018*

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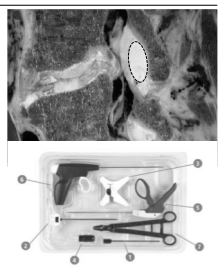
LSS Treatment: Percutaneous Image-Guided Decompression (PILD)

- Debulk the hypertrophied dorsal ligamentum flavum
- Image-guided percutaneous approach
- Key safety factor is the epidurogram
- Ligament greater than 2.5mm
- Outpatient procedure
- Under mild sedation
- 24 month data, MiDAS ENCORE trial
- Re-Approved by Medicare, 2018



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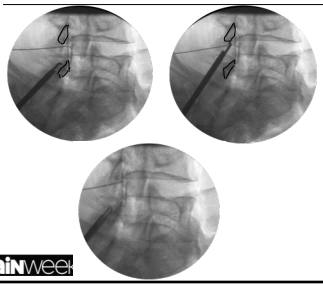
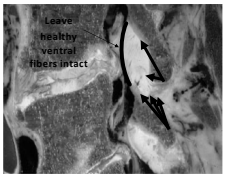
LSS Treatment: PILD Procedure





Decompression of inferior and superior lamina

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ENCORE Study 2-year Outcomes
Confirmed Long-term Safety and Efficacy[3]

Study Protocol
- Coverage with evidence development (CED)
- Prospective, multicenter, randomized controlled
- Randomization:
  - *mild* versus ESI
- Study visits:
  - Baseline, 6 month, 1 year, 2 years
- Comparative data through 1 year
  - *mild*-only at 2 years
- Outcome measures:
  - Oswestry Disability Index (ODI)
  - Numeric Pain Rating Scale (NPRS)

Study Population
- Patients experiencing neurogenic claudication symptoms
- Hypertrophic ligamentum flavum
  - >2.5 mm
- 65 years or older
- ODI >31
- NPRS >5
- No surgery at any treatment level
- Spondylolisthesis
  - < Grade III

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Staats PS, Chafin TB, Golovac S, et al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43:789-794.

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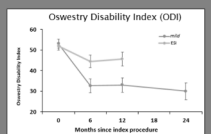
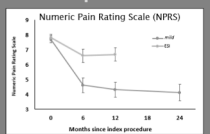
ENCORE Study 2-year Outcomes
Functional and Pain Improvement Compared to ESIs[3]



- Significant and sustained functional improvement through 2-year follow-up
- Mean ODI improvement of 22.7 points at 2 years
  (10-point improvement is clinically significant.)



- Significant and durable reduction of pain through 2-year follow-up
- Mean NPRS improvement of 3.6 points at 2 years
  (2-point improvement is clinically significant.)

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Staats PS, Chafin TB, Golovac S, et al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43:789-794.

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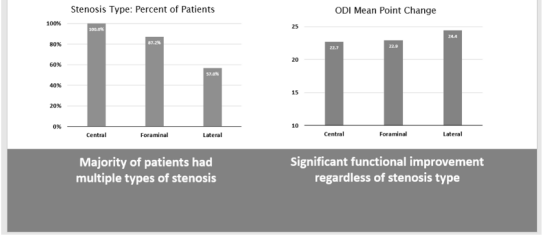
ENCORE Study 2-year Outcomes
Significant Improvement by Stenosis Type[3]



Majority of patients had multiple types of stenosis

Significant functional improvement regardless of stenosis type

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Staats PS, Chaffin TB, Golovac S, et al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43:789–794.

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LSS Treatment: Interspinous Process Decompression (IPD)

- Various spacers have been introduced
- Superion is the only percutaneous device
- Serves as a back stop preventing compression of the spinal canal and lateral recess during extension

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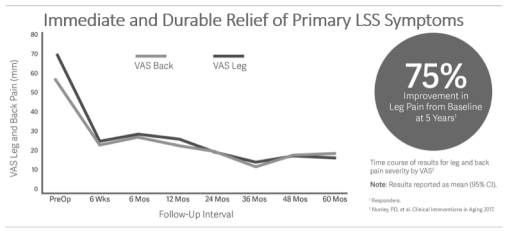
LSS Treatment: IPD 5 Year IDE Study Results



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Journal of Pain Research
Dovepress
open access to scientific and medical research
Open Access Full Text Article
CLINICAL TRIAL REPORT

Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis

- **85%** reduction in the proportion of subjects using opioids at 5 years
- Interspinous process decompression is associated with decrease in the need for opioid medications

PainWeek. *Nunely. PD et al. J Pain Research, 2018*

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Interspinous Process Decompression following Spinal Cord Stimulation Inefficacy in Lumbar Spinal Stenosis: Short Report

Timothy Deer M.D.,[1] Pankaj Mehta, M.D.,[2] Roy Brownlow, M.D.,[3] Christopher Bovinet, D.O.,[4] Sean Li, M.D.[5]
[1]West Virginia University School of Medicine, Charleston WV, 2Pain Specialists of Austin-Killeen, Killeen TX,[3]Georgia Pain & Spine Care, Newnan GA,[4] The Spine Center of SE Georgia, Brunswick GA,[5] Jasper Spine Institute and Jasper Ambulatory Surgical Center, Shrewsbury NJ

INTRODUCTION

Spinal cord stimulation (SCS) offers a promising nondestructive treatment option in the management of recalcitrant symptoms of neurogenic claudication associated with lumbar spinal stenosis (LSS). The goal of SCS treatment in LSS is to ameliorate both neuropathic and ischemic pain components associated with intermittent neurogenic claudication. However, the degenerative anatomical changes with LSS render neurovascular structures vulnerable to repetitive mechanical compression during lumbar extension. In this setting, spinal degeneration continues unabated and SCS can lose therapeutic efficacy over time.

Interspinous process decompression (IPD) using stand-alone interspinous spacers builds on the concept that back extension is a seminal factor in the causative chain that instigates neurogenic claudication in LSS. By preventing spinal extension, spacers effectively alleviate the compression of neurovascular elements during back extension that is the primary source of neurogenic claudication and radicular symptoms. Long-term clinical results with IPD have been excellent.

We explored whether IPD could be used to reestablish sufficient pain relief in cases of LSS where SCS had eventually failed to provide adequate symptom amelioration.[23]

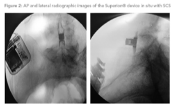
Figure 1: Superion® Indirect Decompression System

METHODS

This was a retrospective study involving 11 physicians at 10 geographically - dispersed medical centers in the US. In this case series, 32 patients with confirmed LSS and a primary complaint of neurogenic claudication were treated with IPD following SCS inefficacy due to reemergence of claudication symptoms or new onset LSS.

Stand-alone IPD used the Superion® Indirect Decompression System (Vertiflex, Carlsbad, CA USA). Employing retrospective chart review, opioid medication usage, and back and leg pain severity using a numeric pain rating scale (0 to 10) were captured prior to IPD and at the latest follow-up interval available. All data were de-identified and anonymous, and thus did not require institutional review board approval or patient informed consent.

Figure 2: AP and lateral radiographic images of the Superion® device in situ with SCS



RESULTS

Thirty-two patients were identified via chart review that underwent IPD following SCS inefficacy. The average age was 69.5 ± 9.8 years with 39% females. The average duration of SCS usage prior to IPD was 30.0 ± 29.9 months. Eighteen patients (58%) had a spacer implanted at one-level and 13 patients (42%) had a two-level procedure. The median length of follow-up following IPD was 42 days (range: 21 to 240 days).

Prior to IPD, 25 patients (81%) reported using opioids to manage LSS symptoms. At final follow-up, only 4 patients (13%) were using opioids, with the remainder of patients tapering off medication (42%, 13 of 31) or reporting no opioid therapy (45%, 14 of 31). Average back pain severity decreased from 6.7 ± 3.6 at baseline to 2.1 ± 2.3 at final follow-up (mean difference: -4.3, p<0.0001), representing a 69% improvement. Average leg pain severity decreased from 8.2 ± 2.0 at baseline to 2.6 ± 2.5 at final follow-up (mean difference: -5.5, p<0.0001), representing a 68% improvement.

DISCUSSION

While the use of SCS in patients with chronic LSS symptoms has shown encouraging results, a substantial proportion of patients may experience eventual lack of therapeutic efficacy. In contrast to open surgical decompression, IPD offers a minimally-invasive treatment option for this patient group that does not require anatomical disruption of ligamentous or osseous tissue.

Improvements in condition-specific clinical outcomes with IPD are similar to those realized after decompressive laminectomy. We noted a similar robust therapeutic response in the current case series, suggesting that IPD may provide a rescue intervention after SCS inefficacy that obviates the immediate requirement for surgical laminectomy. Our enthusiasm, of course, is tempered by the retrospective nature of this study and the short-term follow-up of patients. We encourage the continued observation of these cases, and support the use of IPD in subsequent patients undergoing a similar treatment course.

CONCLUSION

Short-term evidence suggests that IPD may provide a rescue treatment option when SCS no longer provides effective symptom amelioration in LSS. Opioid medications were less frequently used after IPD, and back and leg pain severity decreased, on average, by 69% and 68%, respectively.

The Science Behind Successful Outcomes

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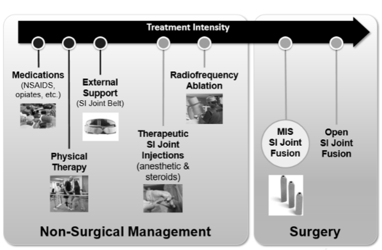
SI Joint Treatment Continuum



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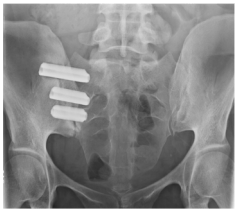
SI Joint Fusion

- **Open**
  - –Invasive
  - –Lengthy recovery
  - –Rarely performed
- **Minimally Invasive**
  - –Small incision
  - –Low blood loss
  - –Short procedure (~ 1 hour)
  - –No need for bone grafting



Minimally invasive surgical SI joint fusion

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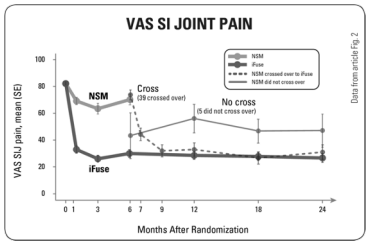
INSITE 2 Year Results: VAS SI Joint Pain

Improves more after SI joint fusion than NSM



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Polly – Int J Spine Surg 2016 (INSITE 2yr)

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INSITE 2 Year Results

		iFuse % subjects	NSM % subjects
Primary Endpoint *	Success @ 6 mo	82%	26%
Patient Satisfaction	Very or somewhat satisfied	90% (6 mo) 88% (2 yr)	61% (6 mo)
Clinical Improvement (Minimum Clinically Important Difference)	VAS improvement ≥ 20pt	83% (2 yr)	10% (2 yr)
	ODI improvement ≥ 15pt	68% (2 yr)	7.5% (2 yr)
Opioid Use	% change in number of subjects taking opioids	30% ↓ (baseline to 2 yr)	7.5% ↑ (baseline to 6 mo)

* Binary success/failure composite measure. Success if all criteria met: VAS SI joint pain reduction ≥ 20 points, no device-related SAEs, no neurological worsening, and no surgical re-intervention for SI joint pain.

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Polly – Int J Spine Surg 2016 (INSITE 2yr)

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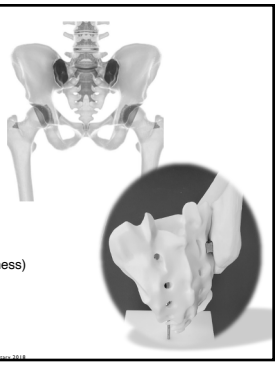
Sacroiliac Joint Dysfunction

- Common cause of low back pain
  - Degenerative change
  - Pregnancy
  - Lumbar spine surgery
  - Trauma
- Symptoms may include:
  - Lower back pain
  - Pain in the SI joint area
  - Lower extremity pain (numbness, tingling, weakness)
  - Sciatic like pain in the buttock area
  - Hip/groin pain



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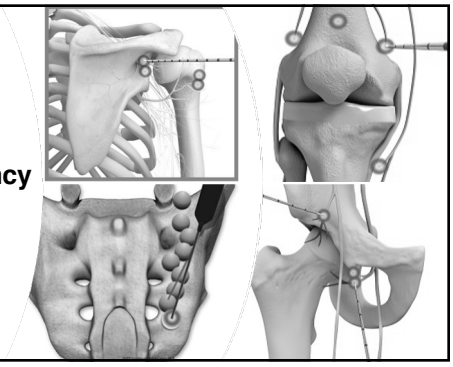
Radiofrequency Ablation



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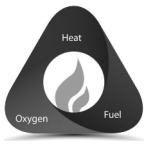
Summary

- Opioid epidemic
- Unmet treatment needs
- Health economics

- Chronic pain
- #1 cause of disability
- Aging population



- Innovation
- Technology
- Level I evidence

Future of interventional pain management is bright

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Questions

In addition to greater than 50% relief in pain and reduction of VAS score, several interventional pain procedures have show level I evidence for opioid reduction. They include:

a. Percutaneous sacroiliac joint fusion
b. High frequency spinal cord stimulation
c. Interspinous process decompression
d. Closed loop spinal cord stimulation
e. All of the above (correct answer)

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Questions

Various clinical trials in interventional pain management are now incorporating metrics other than pain scores such as the VAS. Additional clinical study end points include:

a. Functional status in the form of disability index (ODI)
b. Sleep (PSQI)
c. Opioid reduction
d. Severity of neurogenic claudication (ZCQ)
e. All of the above (correct answer)

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Questions

A 75 year old female presents with chronic back and leg pain due to multilevel degenerative disc disease. She has tried various conservative treatment options such as physical therapy, acupuncture, anti-inflammatories, and anticonvulsants. Patient has consulted with a spine surgeon who did not think she was an ideal surgical candidate. In addition to long-term opioid therapy, what other interventional pain therapy should she be considered for?

a. Interspinous process decompression
b. Sacroiliac joint fusion
c. High frequency spinal cord stimulation (correct answer)
d. Peripheral nerve stimulation
e. Percutaneous image-guided decompression

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Thank You

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