Spinal Cord Stimulation: 2016 Update

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Seattle, WA
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Plan

- Review SCS History, mechanisms
- Details of trials and implantation
- Evidence review
SCS Case #1:

- 35 year old man with low back pain radiating in right L5 distribution following L4-L5 discectomy 4 years before.
- 6 months of multidisciplinary pain treatment. Taking ~60 MEQ morphine, light duty, part time work, financially stressed. Pain levels 7-8/10.
- SCS trial: leads at T7-T8, pain 2-3/10, walking tolerance increased.
- 1 year after implant: prn oxycodone 5 mg 1-2/week, working full time, coaching soccer, uses SCS “24/7.”
Case #2

- 60 yr old woman with persistent pain following spinal surgery
- Multiple treatment efforts. Dysthymia diagnosis
- SCS trial: “I like it” reports ~60% pain relief, good coverage.
- 1 year later: minimal follow up, “I want it out” “I feel like I psyched myself into this.”
Traditional Spinal Cord Stimulation

- Lead(s) placed in the epidural space
- Leads positioned to provide paresthesia in area of pain
- Leads have multiple contacts
- Patient has control over stimulation
- Typically, permanent system implanted only if temporary stimulation relieves pain
- Programmable, adjustable
SCS History

- Gate-control theory of Melzack and Wall set the background for stimulation of large fibers
  - Stimulation of large fibers inhibit pain
- “Dorsal Column Stimulation” reported by Shealy in 1967
  - Intrathecal, laminotomy, large
- 1970s: Epidural leads, Implanted Pulse Generators
- 1980s: Percutaneous leads (quadripolar)
  - Beyond neurosurgery

SCS History

- Clinical use refined patient populations:
  - Neuropathic, CRPS, vascular disease, failed back surgery patients, angina
- Name evolution to Spinal Cord Stimulation
- Improvements in technology
  - Number of contacts: from 4 to 8 to 16 to 32
  - Rechargeable systems
  - Anchoring
  - Programming, software
  - Smaller, more reliable
  - Competition: several viable companies
  - New stimulation patterns/parameters
SCS has changed

Older systems: 1 program, 1 lead, nonrechargeable battery. Most studies from the 1990s and early this decade used this technology
Then there were 8

More than one program, battery nonrechargeable: newer studies feature this technology (Kumar K Pain 2007)
Now: 16-32 contacts, multiple configurations

Many programs, rechargeable units, variable spacing, multiple columns, new stimulation modes, several companies competing, new targets (DRG, peripheral nerves, subcutaneous)
What happens when SCS is on?

- Multiple actions
- Complex combination of proximal, distal, local effects
- Some “electrical”
- Some change in transmitters
- Some change in protein synthesis
- Hard to study in intact humans!!

Stimulation

- Large, myelinated fibers depolarized, propagating signals
  - Projecting rostrally to periaqueductal gray/thalamus, changes subcortical and cortical activation
  - Antidromically to dorsal horn and dorsal root
  - Likely both contribute to pain relief
  - The antidromic stimulation leads to segmental, localized analgesia, important for analgesia with traditional stimulation
- 20-200 Hz most common
- Traditional stimulation results in discernable paresthesias

Mechanism

- Several possible contributory mechanisms
  - Stimulation of inhibitory fibers
  - Reduced sympathetic activity
  - Retrograde stimulation along large fibers
  - Alterations in GABA, serotonin, substance P
  - Changes in cortical and subcortical activity as a result of SCS
  - Altered glial cell activation
  - Newer stimulation patterns (kHz, Burst) have different mechanisms than conventional stimulation

Ischemia (Raynaud’s)


The stimulation is “steered” – left, right, up, down, and depth

CSF = not our friend

**Figure 4.** The thickness of the dorsal cerebrospinal fluid (CSF) layer varies by vertebral level. The mean thickness of this layer is smaller in the cervical region and larger in the midthoracic level.

**Figure 6.** A T2-weighted axial turbo-spin echo image demonstrates a 2.2-mm difference (dmax–dmin) in the thickness of the cerebrospinal fluid at vertebral level T11 when the patient is in the supine (left) vs. in the prone (right) position. Reprinted with the permission of Medtronic, Inc. © 2013.
Delivering stimulation, 2016

- Medtronic: voltage constant: Voltage = current x Resistance (V = I・R)
- Boston Scientific & most St Jude: current constant (I =V/R)
- Suggestive evidence that current driven is “smoother”
- Better anchoring has reduced lead migration
- Other differences: “Epiducer”, accelerometer, “High Density,” 16 contact leads/ 32 contact paddle (total of 32 with one IPG), MRI compatibility, anchoring
- Nevro: high frequency 10 kHz, leads placed based on anatomy, no perceived paresthesias
- In Europe and nearly here: Burst, DRG stimulation
Trial– much variation

- Temporary leads placed (1-3)
  - Traditional SCS: to provide stimulation of the painful area
  - HF SCS: at T9-T10
  - Limit twisting/bending, keep site dry during the trial
- The patient tries several programs
- Trial duration 3-7 days
- SCS adjusted as needed to optimize “coverage” and pain relief
- Judgment:
  - Pain relief: >50%, I like >75%
  - Function: increased walking or other activity

Recent study: success defined as >50% pain relief at 6 months. Multiple factors analyzed retrospectively, major predictor of poor outcome was <50% relief during the trial period.¹

WHO?
- Neurosurgeon, pain physician, spine oriented orthopaedic surgeon

WHAT?
- Leads:
  - Percutaneous (one, two, three)
  - Paddle or laminotomy: what configuration, contact spacing?
- Battery/computer: Implanted Pulse Generator = IPG

RECOVERY:
- 2 weeks
- 2 months

RISKS:
- Surgical: Infection, bleeding, etc
- Lead migration
- Device malfunction
Indications for Spinal Cord Stimulation
Best evidence in support of SCS:

**Intractable Angina**
- Many studies
- Improvements in pain, quality of life (QOL) and function
- Pacemakers, heart failure not a contraindication
- Compares favorably to other options
- Uncommon indication in the US

**Lower extremity Peripheral Vascular Disease**
- Several studies
- Improvements in pain, oxygen delivery
- Possible limb salvage
- Overlaps with diabetic neuropathy
- Uncommon indication in the US

Best evidence in support of SCS: Neuropathic pain

Persistent pain after spinal surgery = “failed back surgery syndrome”
- Most common indication in the US
- Two controlled, prospective trials
- Assuming less invasive treatment options have not resulted in a satisfactory result: “weak recommendation”

Complex Regional Pain Syndrome
- Controlled, prospective trial, funded by independent third party
- Assuming less invasive treatment options have not resulted in a satisfactory result: “weak recommendation”

Less convincing evidence

- There are less robust data for other neuropathic pain conditions (peripheral neuropathy, post herpetic neuralgia, CRPS type 2, spinal cord injury) resulting in an inconclusive recommendation.
- Some evidence for visceral pain
- Central post-stroke pain: SCS is not recommended
SCS for Spinal Pain

- Long history
- Most common US indication
- Separate outcome data for leg pain and back pain
- Newer technologies specifically for back pain
Spinal Pain

- Most studies of patients who have had at least 1 prior spinal surgical procedure and have persistent pain “FBSS”
- Usually focused on “neuropathic” pain = usually leg pain
- Compared to additional spinal surgery or medical management
Pain of Spinal Origin: North et al.

50 subjects randomized to re-operation or SCS, followed for 3 years:
- Met criteria for re-operation
- Radicular > axial back pain
- Psychological evaluation, functional capacity eval
- Percutaneous SCS trial, if pain not reduced by 50%, crossed to reoperation
  - “Success” 9/19 SCS pts vs 3/26 re-operation pts (50% pain reduction and satisfied with treatment)
  - SCS – less opioid
  - SCS – less likely to cross over to other tx (21% vs 54%)

Spinal Pain, subgroup analysis

- 42 subjects cost effectiveness/utility
  - 3.1 years
  - 13/21 re-operation patients crossed to SCS
  - 5/19 SCS patients crossed to re-operation

Conclusions: “SCS was less expensive and more effective than reoperation in selected failed back-surgery syndrome patients, and should be the initial therapy of choice. SCS is most cost-effective when patients forego repeat operation. Should SCS fail, reoperation is unlikely to succeed.”

- NB: these studies funded by Medtronic

SCS vs Medical Management FBSS

- Prospective Randomised Controlled Multicentre Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS)
- 100 subjects, 12 centers, conventional medical management (CMM) vs SCS
- Leg>back pain, >50 mm VAS, “neuropathic nature” checked per routine practice
- Random assignment, no blinding
- Trial: 80% overlap of their pain with stimulation-induced paresthesia and at least 50% leg pain relief
- 48% vs 9% achieved 50% pain reduction, along with improved QOL, function, reduction of leg and back pain.
- 32% device complication rate

Subsequent PROCESS data

- **6 months**¹
  - Costs greater in SCS group than CMM group (12,653 vs 2,594 Euros)
  - Quality of Life: improvement in EQ-5D, “markedly improved with P<0.001

- **24 months**²
  - 42/52 randomized to SCS still using SCS
  - Improved pain, QOL, function
  - Revision in 13 (31%)
  - Primary outcome (>50% leg pain relief) 37% SCS vs 2% CMM, with crossovers: 47% vs 7%

Modern SCS and Data

- No significant studies for nearly a decade
  - Old technology
  - Out of synch with current practice
- Now: many new prospective, randomized trials for spinal pain with current technology
  - Better outcomes
  - Resemble patients we see in practice
  - Some comparative data
New Technology: 1-10 kHz “High Frequency,” “High Density,” Burst, DRG

- HF = “kHz stim”: Typically above sensory threshold = no paresthesia. More energy requirement. Available in Europe, now approved in US, new company = Nevro
- Burst: spikes of stimulation (500 “spikes” of 5 per second), no paresthesia, less energy than HF, available in Europe
- High Density: 1200 Hz, sub-perception
- DRG: Not the spinal cord. Lateral space, Lumbar, up to 4 quadripolar leads, low energy, available in Europe
High-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back Pain Patients: Results of a Prospective Multicenter European Clinical Study

Jean-Pierre Van Buyten, MD\textsuperscript{1*}, Adnan Al-Kaisy, MD\textsuperscript{1†}, Iris Smet, MD\textsuperscript{*}, Stefano Palmisani, MD\textsuperscript{†}, Thomas Smith, MD\textsuperscript{†}

- 83 subjects: HF trial, 72 implanted
- 6 month data:
  - Back VAS: 8.4 $\rightarrow$ 2.7; Leg: 5.4 $\rightarrow$ 1.4
  - 74% had > 50% back pain reduction
  - Improved Oswestry, sleep, medication use
  - No control/comparison group
- Follow up data: 24 months: sustained pain relief, decrease in opioid use, improved sleep and function


198 subjects with back and leg pain
SCS trial, 1:1 randomized to 10 kHz vs traditional stim (Boston Scientific Precision)
171 implanted
Primary outcome – back pain reduction by ≥ 50% for back and leg pain

“At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain (P < 0.001 for both back and leg pain comparisons). The relative ratio was 1.9 (95% CI, 1.4 to 2.5) for back pain and 1.5 (95% CI, 1.2 to 1.9) for leg pain. The superiority of HF10 therapy over traditional SCS for leg and back pain was sustained through 12 months (P < 0.001)”
Table 2. Back and Leg Pain Responder and Remitter Rates for the Permanent Implant Population

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 12</th>
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<tbody>
<tr>
<td>Traditional SCS</td>
<td>0.0</td>
<td>1.2</td>
<td>76.5</td>
<td>22.2</td>
</tr>
<tr>
<td>HF10 therapy</td>
<td>1.2</td>
<td>45.7</td>
<td>45.7</td>
<td>2.5</td>
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<tr>
<td>Relative ratio (95% CI)</td>
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<td>1.2</td>
<td>76.5</td>
<td>22.2</td>
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<tr>
<td></td>
<td>1.2</td>
<td>45.7</td>
<td>45.7</td>
<td>2.5</td>
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</tbody>
</table>

Responder: ≥50% reduction in pain from baseline for 10 therapy. Rates for traditional SCS with 95% CIs. Rates in group with P value <0.001 at all endpoints. HF10 = 10-kHz high-frequency; SCS = spinal cord stimulation.
DRG Stimulation

- Prospective, multicenter, 32 subjects. Off/on pattern
- Initial trial with paresthesias
- Average of 2 leads/pt
- 6 months: average pain reduction 58%, most successful for foot
- Low energy requirements

Burst Stimulation

- 15 subjects, randomized, double blind placebo
- Burst effective, decreased attention to pain.
- Changes in the impact of pain
- Subset analysis of EEG: burst activates dorsal anterior cingulate and dorsolateral prefrontal cortex

SCS Reviews

It all depends on who does the review..................

“Limited evidence in favour of SCS for Failed Back Surgery Syndrome and Complex Regional Pain Syndrome Type I..”

- Only reviewed initial North study (1995, 27 subjects) and Kemler 2000 “RSD” study (54 subjects)

Mailis-Gagnon et al The Cochrane Library 2007, Issue 3
SCS for pain after spinal surgery

“SCS not only reduces pain, improves quality of life, reduces analgesic consumption, and allows some patients to return to work, with minimal significant adverse events, but may also result in significant cost savings over time.”

Taylor RS Journal of Pain Symptom Manage 2006
2014 Reviews

- “Spinal cord stimulation constitutes a therapy alternative that, to date, remains underused”
- “SCS using a surgically implanted paddle electrode provides significant pain relief for chronic axial LPB, and is a safe treatment modality.”
- “…a new ability to stimulate the axial low back and increase the effectiveness of these therapies to reduce pain.”

SCS in Workers’ Comp, Washington

- Prospective cohort study compared patients with failed back surgery syndrome who received at least a trial of SCS (n = 51), Pain Clinic evaluation (n = 39), or Usual Care only (n = 68) on measures of pain, physical functioning, and opioid medication use at baseline and 6, 12, and 24 months.
- SCS was associated with no benefits beyond 6 months and entailed risks, including one life-threatening event.
- Associated with higher costs.
- After reviewing the results, the workers' compensation program decided to maintain its SCS noncoverage policy.

National Institute for Health and Care Excellence (NICE)

Technology appraisals, TA159 - Issued: October 2008

- Spinal cord stimulation is recommended as a possible treatment for adults with chronic pain of neuropathic origin if they:
  - continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least 6 months despite standard treatments, and
  - have had a successful trial of spinal cord stimulation as part of an assessment by a specialist team
- Treatment with spinal cord stimulation should only be given after the person has been assessed by a specialist team experienced in assessing and managing people receiving treatment with spinal cord stimulation.

http://www.nice.org.uk/Guidance/TA159
SCS is expensive

- I tell patients: you can buy a very nice car with the dollars that will be invested in obtaining/maintaining an SCS system

- Data:
  - The cost of implanting a SCS system in Canada is $21,595 (CAD), in US Medicare $32,882 (USD), and in US Blue Cross Blue Shield (BCBS) $57,896 (USD).
  - The annual maintenance cost of an uncomplicated case in Canada is $3539 (CAD), in US Medicare $5071 (USD), and in BCBS $7277 (USD).
  - The mean cost of a complication was $5191 in Canada, US the figures were $9649 for Medicare and $21,390 for BCBS (both USD).

- Rechargeable systems likely less expensive over the life of the patient

- For “failed back” patients: SCS likely more cost effective than alternatives.

Cost-Effectiveness and Cost-Utility Analysis of Spinal Cord Stimulation in Patients With Failed Back Surgery Syndrome: Results From the PRECISE Study

**Objective:** To assess the cost-effectiveness and cost-utility of Spinal Cord Stimulation (SCS) in patients with failed back surgery syndrome (FBSS) refractory to conventional medical management (CMM).

**Materials and Methods:** We conducted an observational, multicenter, longitudinal ambispective study, where patients with predominant leg pain refractory to CMM expecting to receive SCS+CMM were recruited in 9 Italian centers and followed up to 24 months after SCS. We collected data on clinical status (pain intensity, disability), Health-Related Quality-of-Life (HRQoL) and on direct and indirect costs before (pre-SCS) and after (post-SCS) the SCS intervention. Costs were quantified in € 2009, adopting the National Health Service’s (NHS), patient and societal perspectives. Benefits and costs pre-SCS versus post-SCS were compared to estimate the incremental cost-effectiveness and cost utility ratios.

**Results:** 80 patients (40% male, mean age 58 years) were recruited. Between baseline and 24 months post-SCS, clinical outcomes and HRQoL significantly improved. The EQ-5D utility index increased from 0.421 to 0.630 ($p < 0.0001$). Statistically significant improvement was first observed six months post-SCS. Societal costs increased from €6600 (pre-SCS) to €13,200 (post-SCS) per patient per year. Accordingly, the cost-utility acceptability curve suggested that if decision makers’ willingness to pay per Quality-Adjusted-Life-Years (QALYs) was €60,000, SCS implantation would be cost-effective in 80% and 85% of cases, according to the NHS’s and societal point of views, respectively.

**Conclusions:** Our results suggest that in clinical practice, SCS+CMM treatment of FBSS patients refractory to CMM provides good value for money. Further research is encouraged in the form of larger, long-term studies.

**Keywords:** Cost-effectiveness, cost-utility, failed back surgery syndrome, Spinal Cord Stimulation, quality adjusted life years
Bad things happen

- Lead migration, infection, equipment failure, loss of effectiveness.
- Rare things: Fibrosis/foreign body reaction: reports of myelopathy
- 8 year study of 345 trial patients, 234 implanted:
  - Overall complication rate 34.6%, explant rate = 23.9%, revision rate = 23.9%

<table>
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<tr>
<th></th>
<th>No. of complications</th>
<th>% of total implants</th>
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<tr>
<td></td>
<td>Revisions</td>
<td>Explants</td>
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<td>IPG discomfort/migration</td>
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<tr>
<td>Lead fracture/malfunction</td>
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<td>2</td>
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<tr>
<td>IPG malfunction</td>
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<tr>
<td>Infection</td>
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<tr>
<td>Paresthesia/Dysesthesia</td>
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<tr>
<td>Required for surgery</td>
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</tr>
<tr>
<td>Loss of therapeutic effect</td>
<td>9</td>
<td>23</td>
</tr>
</tbody>
</table>

SCS Questions to think about

- If you refer for SCS: how do you choose where to send your patient?
- If you do trials: how do you select a company/system?
- If you do implants: how many leads/contacts? Which configuration? Laminotomy vs percutaneous?
- How big of a deal is MRI compatibility?
- How early to use SCS?
- Do you need thoracic MRI before implanting percutaneous leads, how about a trial?
- Why is Angina not treated with SCS in the US?
Summary

Who is a SCS candidate?
- Persistent pain following spinal surgery-- “neuropathic” characteristics
- Neuropathic pain
- Patients who have failed coordinated conservative care
- Realistic expectations, goals
- Patients willing to actively manage their SCS system

NOT a candidate:
- Diffuse pain
- Poorly managed anxiety, depression
- Mechanical, musculoskeletal pain
- Unrealistic expectations
- Unwilling to be active in their care

Implantation details
- Good trial before hand: pain relief + increased function
- Clearly delineated targets
- Ideally– redundancy in coverage
- Ideally– assure good coverage in the OR
- Anchor well
- Mind the pocket site
- Limit activity for a few weeks, then
- Consider referral to PT after recovery to maximize function
- Reprogram, work with the reps
Thank YOU!