Advancements in non-opioid alternatives for chronic pain management

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• J. Rafe Sales, MD

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  – Specializes in minimally invasive solutions for complex spinal problems, and offers the latest in spinal technology
  – Founded Summit Spine Institute in 2007, Based out of St Vincent Hospital
  – Completed residency in orthopedic surgery and rehabilitation at Oregon Health & Science University and Spine surgery fellowship at San Francisco Spine Institute
Have you ever heard of a spine transplant?
Neither have we.
Take care of the one you have.
Burden of Chronic Pain in the United States

**Affects 100 million Americans**
(more than heart disease, cancer, and diabetes combined)

Costs society up to $635 billion annually

Associated with 40 million doctor visits annually

Results in 515 million lost work days annually

40% of all work absences are related to low back pain

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## Complications and Comorbidities Associated with Chronic Pain

In addition to the significant economic burden and negative impact on quality of life, untreated chronic pain is associated with physical and psychological complications.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Reference(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>35% of chronic pain patients vs 4.6% of the general study population</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
</tr>
<tr>
<td>Suicide</td>
<td>Suicide ideation: lifetime prevalence in chronic pain patients, ~20% vs 13.5% in the general population</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
</tr>
<tr>
<td>Hypertension</td>
<td>39% of chronic pain patients vs 21% of the general population</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
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<tr>
<td>Insomnia</td>
<td>53% of chronic pain patients vs 3% of pain-free controls</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
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<tr>
<td>Overweight/obese</td>
<td>62.7% of patients with low back/neck pain vs 56.5% of the general population</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
</tr>
<tr>
<td>Opioid misuse/abuse</td>
<td>20-24% of chronic pain patients vs 3.8% of the general population</td>
<td>2, 3, 4, 5, 6, 7, 8, 9</td>
</tr>
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### Indications for Use:
Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and limbs.

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Opioid epidemic in Oregon

- Oregon Medical Board coming out with guidelines to reduce opioid dependence
- How do we decrease opioids in chronic pain?
  - Many of the chronic pain patients have tried and failed to receive relief from: Physical therapy, massage, acupuncture, diet, and exercise
  - Only other option is high dose narcotics which come with high risk
Reasons for ongoing pain

- American Academy of Pain Medicine along with the National Institute of Health Statistics reports that the top four common types of pain:
  - 27% low back pain
  - 15% severe migraines
  - 15% neck pain
  - 4% facial ache

- Incidence:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Sufferers</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>100 million Americans</td>
<td>Institute of Medicine of the National Academics</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25.8 million Americans</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>Coronary Heart Disease/Stroke</td>
<td>16.3 million Americans/ 7.0 million Americans</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>Cancer</td>
<td>11.9 million Americans</td>
<td>American Cancer Society</td>
</tr>
</tbody>
</table>
The Dimensions of Back Pain

• According to the 2012 National Health Interview Study, 11.2% of adults report daily pain and 20% of non-cancer pain patients receive opiates.

• More than 65 million Americans annually suffer from lower back pain (LBP)
  – 2nd most common reason for a PCP visit accounting for over 354 million visits a year
  – 3rd most-frequent reason for surgery overall.
  – 5% of LBP patients account for more than 75% of total costs.
  – LBP now accounts for up to 1/3 of total health care costs
    • Institute for Clinical Systems Improvement

• 15% of all LBP have an identifiable, anatomic explanation. The other 85% are identified as “non-specific”. Only 1/3 of all LBP patients describe a specific event related to onset. (Rubin, 2007)

• Majority of acute LBP patients return to work within 2 weeks and 30-60% will suffer recurrent symptoms. 1/3 of these cases will last over 1 year. (Hayden 2010)

• Approximately 250,000 lumbar spinal fusions performed
• Approximately 400,000 lumbar spinal decompression procedures performed

The Nervous System and Pain

- Somatosensory System
  - Brain
    - Somatosensory Cortex
    - Thalamus
  - Spinal Cord
    - Dorsal Horn
    - Ventral Root
  - PNS
    - Afferent Neuron
    - Efferent Neuron
    - A-delta Fibers
    - C-Fibers
Some common causes of back pain.
Facet Disease (hypertrophy)

- Severe hypertrophy may lead to atypical osteophyte formation that protrudes ventrally from the medial aspect of the facet joint.
- This may lead to narrowing of the intervertebral foramina or even the central canal.
Degenerative scoliosis

- Think “Arthritic pain”
  - Gradual onset
  - Worse in early AM and Eve
  - Sitting improves symptoms
  - Pain is from arthritis of the facet joints. When hypertrophy is severe, stenosis and leg pain may develop. This usually occurs on the ipsilateral side.
Lumbar Spondylosis
Spondylolisthesis

• An anterior listhesis of a vertebrae relative to the one below.
  – If it is a posterior listheis it is called a retrolisthesis.
  – Typically degenerative but can be congenital, pars defect (isthmic), degenerative, traumatic, pathologic or iatrogenic (prior laminectomy)
  – Depending on the severity it can lead to stenosis due to the collapse neuro foramina, Ligamentous and Facet Hypertrophy
  – Meyerding gradient is most common tool by rating the slip 1-4
Surgical Conditions

- Spine surgery is a good option for three primary problems / conditions (presuming they have failed extensive therapy)
  - Nerve compression/ extremity pain or symptoms
    - Disc herniation, bone spur, spinal stenosis
  - Instability/ Deformity
    - Spondylolithesis, fracture, lateral lithesis/ scoliosis
  - Neurologic deficit
    - Weakness, foot drop, bowel or bladder dysfunction, cauda equina
Lots of surgeries we love to do...

Current MIS surgical options

- Cervical and Lumbar Microdiscectomy
- ACDF (cervical fusion) +/- using zero profile technology
- TDR-cervical disc arthroplasty
- MIS TLIF- Minimally invasive translateral/foraminal interbody fusion
- XLIF- Extreme lateral interbody fusion Lumbar spine
- ALIF- Anterior lateral interbody fusion
- PSF- Percutaneous screw fixation
- Motion Preservation Lumbar spine (Coflex-non fusion device)
- Spinal cord stimulator-neuromodulation
- Sacroiliac fusion
But what if surgery isn’t a good option?

• Pain that has no clear cause OR
• Patient is not a great candidate for a surgery to correct the issue
  – Age, comorbid risk factors, body habitus
• Previous well-done surgery that has failed and there is no good solution AKA
  – FAILED BACK SURGERY SYNDROME
  – ICD 9:722.83, ICD 10: M96.1
MISTAKES

It could be that the purpose of your life is only to serve as a warning to others.

www.despair.com
Failed Back Surgery Syndrome

• Non-specific term
• Lumps together many “problems”
  – Structural pathology
  – Neuropathic changes
  – Psychological issues
  – Surgeon’s judgment
FBSS Etiology

- Causes of FBSS
  - Foraminal Stenosis – 25-29%
  - Discogenic Pain – 20-22%
  - Pseudoarthrosis – 14%
  - Neuropathic Pain – 10%
  - Recurrent Disc Herniation – 7-12%
  - Facet Arthropathy – 3%
  - SI Joint Pain – 2%
Well what is spinal cord stimulation? Newer “hot topic”, but what does it do?
SCS-Spinal Cord Simulation

- Developed in the Mesopotamian times when electric eels were used to treat painful extremities (early TENS)
- “Neuroaugmentation” born in the late 1960’s when electrodes were implanted in the sub arachnoid space!
  - Unfortunately lead to CSF leak, Meningitis, Arachnoiditis
- Rapid advances in cardiac pacemakers in the 1970’s lead to the more traditional epidural placement found today
- Rapid advances in battery and chip technology have dramatically improved analgesia specifically in the last 5 years.
- Opioid epidemic has lead to an increased demand for alternative treatment options
Spinal Nerves

- Thirty-one pairs of spinal nerves branch off the spinal cord.
- Carry messages back and forth between peripheral nerve and spinal cord to control sensation and movement.
- Each spinal nerve has two roots
  - Ventral (motor)
  - Dorsal (sensory)
Dorsal Column Fibers – Key to SCS

- Dorsal column carries sensory information to the brain
- Composed primarily of large-diameter afferent nerve fibers
Nerve fiber types, sizes, and locations

- IA: Largest diameter sensory afferents (muscles)
- $\text{A}_\beta$: Slightly smaller diameter fibers (touch)
- $\text{A}_\delta$, C: Smaller diameter fibers (pain and temperature)

<table>
<thead>
<tr>
<th>Sensory function</th>
<th>Receptor type</th>
<th>Afferent axon type</th>
<th>Axon diameter</th>
<th>Conduction velocity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprioception</td>
<td>Muscle spindle</td>
<td>A(x, II)</td>
<td>13–20 μm</td>
<td>80–120 m/s</td>
</tr>
<tr>
<td>Touch</td>
<td>Merkel, Meissner, Pacinian, and Ruffini cells</td>
<td>$\text{A}_\beta$</td>
<td>6–12 μm</td>
<td>35–75 m/s</td>
</tr>
<tr>
<td>Pain, temperature</td>
<td>Free nerve endings</td>
<td>$\text{A}_\delta$</td>
<td>1–5 μm</td>
<td>5–30 m/s</td>
</tr>
<tr>
<td>Pain, temperature, itch</td>
<td>Free nerve endings</td>
<td>C</td>
<td>0.2–1.5 μm</td>
<td>0.5–2 m/s</td>
</tr>
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</table>

Fiber diameter, nerve mylenation and CSF layer surrounding the cord
Key principles of nerve stimulation

- Larger fibers require less energy to stimulate that smaller fibers

- The closer a fiber is to the stimulating electrode, the less energy is required to stimulate

Positive ions outside the cell hyperpolarize it, preventing stimulation. Thus, anodes go over areas you don’t want to stimulate.

When activated, each electrode attracts ions of the opposite charge. Positive ions attract negative ions, and cathodes attract positive ions. Negative ions outside the cell depolarize it, causing stimulation. Thus, cathodes go over areas you do want to stimulate.

MOA of SCS: Creating Stimulation
Stimulation Targets: Dorsal Columns

- Contain primary sensory (afferent) fibers
- Stimulation produces paresthesia over large areas of selected regions corresponding to level of cathode and below
Evolving understanding of Patient Anatomy
Based on studies from the 1930s

- T8-T10 are common lead placement targets
- Between T8 and T10 the low back fibers are lateral and near the dorsal roots
- Stimulation/recruitment of dorsal roots may create unwanted abdominal stimulation
Patient Selection for SCS: Chronic Pain

Etiology

• SCS treats symptoms not the specific etiology
• SCS has been studied in the following neuropathic pain conditions:
  – Post laminectomy or Failed back surgery syndrome (FBSS)\(^1,2\)
  – Peripheral neuropathy\(^1,3\)
  – Peripheral ischemia\(^1\)
  – Post-herpetic neuralgia\(^1\)
  – Phantom limb pain/residual limb pain\(^1\)
  – Complex Regional Pain Syndrome (CRPS) I and II\(^1,4\)
• Scientific advances suggest it may be possible to specifically target certain types of neuropathic pain by modifying various factors of neurostimulation\(^5\)

Indications for use: SCS as an aid in the management of chronic, intractable pain of the trunk and limbs.

Spinal Cord Stimulators

• Neuropathic Pain – difficult to treat
  – Not the "normal" pain we associate with stubbing a toe or getting a paper cut – this is nociceptive pain.
• Neuropathic pain is caused by abnormal nerve signalling in the nervous system
  – does not respond to most pain relief strategies.
• SCS is a very exciting area of development and is becoming widely accepted for use in many areas of neuropathic pain management.
  – SCS does not eliminate pain but creates a numbness / paresthesia in the area. This results in a masking of the pain.
As part of the continuum of care for patients who suffer from chronic pain, proper diagnosis is the first phase, followed by first- and second-tier therapies. SCS, among other advanced pain therapies, is considered a late resort.
Expanding the treatable patient population?

- General Surgeons/ Endoscopic
  - Post Hernia Surgery
- Orthopedic Surgeons
  - Joint Replacement (Knee/Hip)
- Foot/Ankle/Sports Medicine
  - CRPS Lower Extremity
- Podiatrist
  - CRPS of the Foot/Ankle
- PM&R
  - CRPS/Post Surgical Pain Lower Extremity
- Family Practice
  - All of the above
  - CRPS/Post Surgical Pain Syndromes
- Neurologists
  - CRPS Lower Extremity
- OB/GYN
  - Post Surgical Pain Syndromes, Abdominal Wall/Groin
- Urologist
  - Scrotal/Inguinal Pain
- Local Patient Advocacy Groups
  - RSDSA
  - CRPS
  - Post Total Joint Programs
The Process

Trial

Psych evaluation

Paddle vs percutaneous lead placement

(If Paddle, patient needs Thoracic MRI first)
Patient Selection

Contraindications:

- Pregnancy - May turn system off for duration of pregnancy
- Unable to operate system
- Failed stimulator trial
- Poor surgical candidate
  - Systemic infection
- Psychological condition/ Chemical dependency
- MRI *
Patient Selection-SCS versus Surgery

Relative Indication
- Age
- Duration of pain
- Severity of pain
- Comorbidities- May limit other surgical options
- Effectiveness of conservative care
- Prior infection or Surgical complication
- Psycho-Social issues/support
- Surgery too large Cost>Gain

Relative Contraindication
- Fixable problem with no prior attempt to correct
- Short duration or limited severity of symptoms
- Weakness
- Risk of rapid deterioration of underlying condition i.e Stenosis ->Cauda Equina
- Arthritis
- Severely altered mentation*
Evidence-based Therapy With Sustained Results

Stimulators are clinically proven to manage hard-to-treat pain

At 2 years, 67% of patients reported ≥50% relief of back pain

After 2 years, 72% of patients reported ≥50% relief of overall pain

81% of patients with cervical implants reported excellent or good pain relief at 1 year


Criteria: Chronic back pain with or without leg pain. 7 out of 10 patients reported at least 50% pain relief; N = 130, multicenter, prospective
Interim Results From the Partnership for Advancement in Neuromodulation Pain Registry 2013 - Timothy Deer, MD et. al.  
- Interim data collected from 579 patients in 40 prospective, observation and non-interventional studies sites  
- Data points were collected at 3mo, 6mo and 12mo post implant of SCS  
- Pt reported pain relief was 58%, 58.1%, and 57% at those data points  
- PDI reduce from baseline 47.7 to 33.3, 32.4 and 31.9  
- 78% of patients were “satisfied” or “very satisfied” with SCS therapy

Longer Delay From Chronic Pain to Spinal Cord Stimulation Results in Higher Healthcare Resource Utilization 2015 Shivan and P. Lad  
- Retrospective observational study of 762 patients, Median pain-to-scs 1.35 yrs  
- 1 year increase in pain-to-SCS lead to  
  - 33% increase risk of being in the high medical cost group (> $4153 over avg.)  
  - 39% increased risk of being in the high opioid Rx group  
  - 44% high office visit group, 55% high hospitalization group
Study with 2 year back pain

**INTRODUCTION**

Spinal cord stimulation (SCS) is a proven treatment for chronic pain, but there is still a need for additional high-quality prospective clinical study data to verify efficacy of treatment of chronic lower back pain with or without leg pain. An interim analysis of a prospective, multicenter, 2-year follow-up study in which a dual or bipolar array of percutaneous leads or surgical leads was used in conjunction with the rechargeable Eon™ implantable pulse generator (St. Jude Medical Neuronutlomulation Division, Plano, TX) is presented.

**METHODS**

- The study was designed as a prospective, multicenter study. 130 patients were enrolled from 29 medical centers.
- Institutional Review Board (IRB) approval was obtained for all sites prior to patient enrollment.
- The study criteria included a diagnosis of chronic lower back pain with or without leg pain.
- Each patient who complied with the study criteria underwent the informed consent process prior to any study activities.
- Patients returned to the clinic for evaluations at 1 month, 3 months, 6 months, 1 year, 18 months, and 2 years post-implant.
- At each visit, patients reported:
  - Percentage of pain relief
  - Current pain score [1-10, Numeric Rating Scale, NRS]
  - Satisfication
  - Quality of Life

**RESULTS**

- Most patients (75%) reported their overall pain relief as 50% or greater (scale ≤ 0.001), which remained consistent throughout the 2 years post-implant, while 69% reported 50% or greater relief of back pain and 75% are a 50% or greater reduction in leg pain.

**SUMMARY & CONCLUSION**

- At the 2-year visit, 75% of patients reported that their overall pain relief was 50% or greater. 69% and 75% reported 50% or greater reduction in their lower back and leg pain, respectively.
- Patients consistently reported a reduction in current pain scores throughout the 2 years following implantation (Numeric Rating Scale 1–10, 10 worst pain).
Summary & Conclusion

• At the 2-year visit, 70% of patients reported that their overall pain relief was 50% or greater; 68% and 73% reported 50% or greater reduction in their lower back and leg pain, respectively.

• Patients consistently reported a reduction in current pain scores throughout the 2 years following implantation (1-10 Numeric Rating Scale).

• 89% of patients were satisfied or very satisfied with SCS treatment and 88% reported quality of life as being improved or greatly improved.

• Chronic lower back pain patients completing 2 years of treatment with spinal cord stimulation therapy maintained consistent and successful results in pain relief, satisfaction, and quality of life.
Currently 5 Companies… with more on the way

- St Jude/ Abbott Medical (Market Share Leader)
- Boston Scientific
- Medtronic
- Nevro
- NuVectra
For more information…

- Patient / Provider video for better understanding spinal cord stimulator paddle lead placement
Thank you!!!
References


