NEUROMODULATION

SPINAL CORD STIMULATION AND DORSAL ROOT GANGLION STIMULATION:

Interventional Pain Therapies

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Pain affects more Americans than diabetes, heart disease, and cancer combined¹

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Sufferers</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Pain</td>
<td><strong>100 million Americans</strong></td>
<td>Institute of Medicine of The National Academies (²)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25.8 million Americans</td>
<td>American Diabetes Association (³)</td>
</tr>
<tr>
<td>Coronary Heart Disease</td>
<td>16.3 million Americans</td>
<td>American Heart Association (⁴)</td>
</tr>
<tr>
<td>Stroke</td>
<td>7.0 million Americans</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>11.9 million Americans</td>
<td>American Cancer Society (⁵)</td>
</tr>
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The Opioid Epidemic

**STATE OF EMERGENCY**

- In 2017 HHS declared a public health emergency and announced a 5-point strategy to combat the opioid crisis
  1. Improving access to treatment and recovery services
  2. Promoting use of overdose-reversing drugs
  3. Better public health surveillance
  4. Providing support for research on pain and addiction
  5. **Advancing better practices for pain management**

- Opioid overdoses accounted for more than 42,000 deaths in 2016
- 40% of opioid overdose deaths involved a prescription opioid
Spinal Cord Stimulation
Spinal Cord Stimulation Overview

Spinal Cord Stimulation (SCS) is a non-pharmacologic means of managing chronic pain through the modulation of pain signal transmission in the spinal cord.

Tiny electrical pulses delivered to dorsal column of spinal cord that interferes with the transmission of pain signals to the brain.

![Spinal Cord Diagram](image)

**Descending Tracts (Motor)**
- lateral corticospinal tract
  - main voluntary motor
  - upper extremity moto pathways are more medial (central)
- ventral corticospinal tract
  - voluntary motor

**Ascending Tracts (Sensory)**
- Dorsal columns (DC)
  - Deep touch
  - Vibratory
  - Proprioception
- Lateral spinothalamic tract (LST)
  - Pain
  - Temperature
- Ventral spinothalamic tract (VST)
  - Light touch
Who is the Right Patient?

**INDICATIONS**

SCS can be used to manage chronic pain of the limbs that arises from diseases* such as

- Complex Regional Pain Syndrome I and II (CRPS)
- Peripheral neuropathy
- Peripheral ischemia
- Post-laminectomy syndrome
- Failed back surgery syndrome (FBSS)
- Radicular pain following lumbar or cervical spine surgery

**COMMON ICD10 CODES:**

- M54.16 Lumbar Radiculopathy
- M96.1 Post-Laminectomy Syndrome

**TYPES OF PAIN**

- **Acute Pain**
  - Short term
  - Associated with actual or potential tissue damage

- **Chronic Pain**
  - Frequent or constant pain
  - Responds poorly to usual treatments
  - Persists more than 12 weeks
  - Nociceptive: results from activity in neural pathways secondary to actual tissue damage or potentially tissue-damaging stimuli
  - Neuropathic: initiated by nervous system (CNS or PNS) lesions or dysfunction (Diabetic neuropathy, cancer, degenerative spine conditions)
When do I recommend spinal cord stimulation?

The objective is to move SCS therapy earlier in the continuum of care.
Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome

- 100 FBSS patients with predominant LE pain of neuropathic radicular origin to receive SCS + conventional medical management or CMM alone for at least 6 months
- Primary outcome = proportion of patients achieving 50% or more pain relief in the legs
- Secondary outcomes = improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects
- 6 months: 24 SCS patients (48%) and 4 CMM patients (9%) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction
- 6 – 12 months = 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications

**Conclusion:** Compared with CMM alone, **SCS improves pain relief, quality of life, functional capacity and patient satisfaction in selected patients with neuropathic pain related to FBSS**
BurstDR: A Novel Waveform

- Burst firing is a naturally occurring signaling modality in human physiology and is interpreted differently by the nervous system\(^4,5,6\)
- Thalamic cells can fire in tonic and burst modes\(^4\)
- Thalamic burst firing considered a more potent activator of the cortex\(^5,6\)

**Traditional Tonic**
- Relatively low energy
- Recharge every 1-2 months

**Burst Stimulation**
- Parameters within traditional ranges
- Low-moderate energy
- Average recharge similar to tonic
- Device provides both tonic & burst\(^1\)
- Same projected device life as traditional tonic\(^1\)

**High Frequency Stimulation**
- Parameters outside the traditional ranges
- Highest energy, daily recharge
- Device only provides tonic stimulation at programmable frequencies (up to 10,000hz)\(^2\)
- Reduced projected device life compared to traditional tonic\(^2\)

THE SUNBURST STUDY
A Prospective, Randomized, Controlled Trial Assessing BurstDR Stimulation for Chronic Pain

- Demonstrate the safety and effectiveness of a neurostimulation system that delivers both Burst and tonic stimulation
- Demonstrate non-inferiority of overall pain with Burst versus tonic stimulation

52 Did not meet Inclusion/Exclusion

Enrolled (N=173) → Completed Tonic Trial Evaluation (N = 121) → Randomized (N = 100)

- 9 Failed Tonic Trial
- 12 Exited for Other Reasons

Arm 1: Tonic/Burst (N = 45)
Arm 2: Burst/Tonic (N = 55)
Completed 24 Week Visit (N = 96)

4 Excluded Because they participated in a confounding medical treatment.

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SUNBURST IDE: REASONS FOR PREFERENCE 24 WEEKS\textsuperscript{1,2}

Of the 96 participants in the study,

- **70.8%** prefer **Burst** stimulation
  - 68 participants

- **18.8%** prefer **Tonic** stimulation
  - 18 participants

- **Lack of paresthesia**
  - (N=32, 47%)

- **Better pain relief**
  - (N=31, 43%)

- **Other**
  - (N=5, 7%)

- **Prefer paresthesia**
  - (N=8, 44%)

- **Better pain relief**
  - (N=8, 44%)

- **Other**
  - (N=2, 13%)

10.4% (10 participants) didn’t express a preference

\textsuperscript{1} St. Jude Medical\textsuperscript{TM} Proclaim\textsuperscript{TM} Neurostimulation System Clinician’s Manual. Plano, TX. 2016.

\textsuperscript{2} St. Jude Medical\textsuperscript{TM} Prodigy\textsuperscript{TM} Neurostimulation System Programming and Reference Manual. Plano, TX. 2016.
SUNBURST: Summary

- Burst stimulation provided superior pain relief vs. tonic for overall, trunk, and limb pain
- Burst stimulation was preferred by the majority of patients (69%)
- Burst stimulation was preferred by 70.8% of patients despite only moderately lower VAS scores, suggesting other factors are involved
- Burst stimulation eliminated or reduced paresthesia in 91% of subjects
- There are patients who prefer paresthesia
- Each patient experienced both stimulation modes (tonic and Burst) and chose their preferred mode
BURST STIMULATION MAY RECAPTURE PAIN RELIEF IN CHRONIC NON-RESPONDERS TO TONIC STIMULATION

The following studies show the ability of Burst stimulation to recapture pain relief in patients who have become unresponsive to tonic stimulation. A few of these studies also add to the clinical evidence supporting the safety and effectiveness of Burst stimulation. Table 2 summarizes key findings.

Table 2: Studies supporting the ability of Burst stimulation to recapture pain relief in non-responders to tonic stimulation.

<table>
<thead>
<tr>
<th>Study</th>
<th># of patients</th>
<th>% of Pain Relief in Tonic Non-Responders After Burst SCS</th>
<th>% of Patients Converted to Responder (50% Pain Relief) With Burst SCS</th>
<th>Incidence of Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>de Vos et al. 2014</td>
<td>48</td>
<td>22.0%</td>
<td>0%</td>
<td>10.4%</td>
</tr>
<tr>
<td>Bara et al. 2013</td>
<td>29</td>
<td>66.7%</td>
<td>Not Reported</td>
<td>0%</td>
</tr>
<tr>
<td>Vanneste et al. 2013</td>
<td>102</td>
<td>Not Reported</td>
<td>62.5%</td>
<td>Not Reported</td>
</tr>
<tr>
<td>De Ridder et al. 2014</td>
<td>102</td>
<td>59.0%</td>
<td>Not Reported</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Papjelu A et al. 2015</td>
<td>10</td>
<td>56%</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Sheikh U et al. 2015</td>
<td>15</td>
<td>Back pain scores dropped by 27.7%, while limb pain scores dropped 44.4%</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

BURST STIMULATION MAY ALTER PAIN PERCEPTION THROUGH ACTIVATION OF DIFFERENTIATED PAIN PATHWAYS

The mechanism of action underlying Burst stimulation is not entirely understood. However, findings from several recent studies have begun to elucidate mechanistic differences between Burst stimulation and tonic stimulation. In De Ridder et al.’s double-blinded placebo-controlled study, the authors propose that Burst stimulation activates the medial affective pathway involved in the emotional component of pain whereas tonic stimulation activates the lateral discriminatory pathway. This study and others collectively suggest differential neuronal activation between Burst and tonic stimulation. Summaries of the key findings from these studies are provided below.

BURST STIMULATION PROVIDES GREATER PAIN RELIEF WITHOUT PARESTHESIA IN MOST PATIENTS

St. Jude Medical neurostimulation systems have the ability to deliver either tonic (typical frequency range 40 to 60 Hz) or Burst stimulation (i.e. 40 Hz Burst frequency containing five spikes at 500 Hz per spike) to the spinal cord. Studies have shown that, when compared to tonic stimulation, Burst stimulation results in greater pain relief and improvement in other secondary measures, including cognition, sleep, disability, function, often in the absence of paresthesia, and that patients prefer Burst stimulation over tonic stimulation. The following studies support the clinical safety and effectiveness of Burst stimulation. Table 1 summarizes key findings.
# Clinical Compendium Supporting BurstDR

<table>
<thead>
<tr>
<th>Study</th>
<th># of patients</th>
<th>% Pain Relief</th>
<th>% Patients who Preferred Burst SCS</th>
<th>% Patients Experiencing Paresthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>De Ridder, et al. 2010^</td>
<td>12</td>
<td>Tonic: 30.2%</td>
<td>100%</td>
<td>Tonic: 92.0% Burst: 17.0%</td>
</tr>
<tr>
<td>De Ridder, et al. 2013^</td>
<td>15</td>
<td>Tonic: 31.0% Burst: 54.2%</td>
<td>100%</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Wahlstedt, et al. 2014^</td>
<td>15</td>
<td>Tonic: 29.7% Burst: 40.7%</td>
<td>Not Reported</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Courtney, et al. 2015^</td>
<td>22</td>
<td>46.7% over Tonic Baseline</td>
<td>90.9%</td>
<td>Tonic: Not Reported Burst: 25%</td>
</tr>
<tr>
<td>Schu, et al. 2014^</td>
<td>20</td>
<td>16.1% over Tonic Baseline</td>
<td>80%</td>
<td>Not Reported</td>
</tr>
<tr>
<td>Baledeschi, et al. 2015^</td>
<td>37</td>
<td>73% over Baseline</td>
<td>100%</td>
<td>0%</td>
</tr>
<tr>
<td>Tjepkema-Cloostermans, et al. 2015^</td>
<td>39</td>
<td>30% additional pain relief with low or high amplitude burst</td>
<td>74%</td>
<td>0%</td>
</tr>
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</table>
SCS Trial and Implant

SCS INVISIBLE TRIAL
Creates an opportunity to improve the number of patients open to SCS trials with improved patient comfort and convenience

Key Features:
• First Bluetooth®-enabled system
• First Apple™ iPod touch™ and iPad mini™ programming system
• First direct-connect trial system
• First Burst* and tonic capable IPG
• First “on-body” trial system

CPT Codes:
63650 x 2

SCS IMPLANT
• BurstDR and Tonic enabled
• Paresthesia Free
• Full Body MRI
• Non-rechargeable and rechargeable options
• Upgradeability

CPT Codes:
63650 x 2 and 63685
63655 and 63685
*95972
Dorsal Root Ganglion Stimulation
WHY TARGET THE DRG?

Well mapped & organized to corresponding anatomies – allowing for highly focused treatment of pain

Area of Pain

Traditional Stimulation

DRG Stimulation

Spinal Column

DRGs

Abdomen/Groin/Back
Hip/Groin/Waist/Back
Upper Leg & Low Back
Lower & Upper Leg/Low Back
Leg & Low Back
Foot/Lower Leg/Low Back
ACCURATE STUDY: OBJECTIVE AND STUDY DESIGN

Objective: To assess the safety and efficacy of DRG stimulation compared to a commercially available SCS device

- 152 subjects enrolled
- Randomized 1:1 ratio
  - DRG vs.
  - Control (commercially available SCS device)
- 22 Investigational sites
- 3 month Primary Endpoint
- Subject population
  - Chronic, intractable pain of the lower limbs
  - Complex Regional Pain Syndrome (CRPS) or Peripheral Causalgia

N = 152 Subjects Randomized (1:1)

DRG (n = 76)
  Trial
  > 50% VAS reduction
  Implant
  1 Month Visit
  3 Month Visit (Primary Endpoints)
  6 Month Visit
  9 Month Visit
  12 Month Visit

Control (n = 76)
  Trial
  Implant

Levy R and Deer T. NANS 2015
Accurate: Summary

DRG stimulation provides long-term, sustained and superior pain relief over traditional SCS

Key Takeaways:
• DRG achieved primary endpoint in 93.3% of patients at 3 months
• DRG achieved > 80% pain relief in 70% of patients at 3 months
• DRG stimulation confined paresthesia to area of pain 94.5% vs 61.2% in control
• DRG offered sustained and superior pain relief over 12 month period

Study also found:
• DRG improved psychological disposition and physical/activity levels
• DRG generated > 80% pain relief with no paresthesia for some patients
• Patients with paresthesia had virtually no positional changes in intensity
DRG STIMULATION DEMONSTRATES SUPERIORITY OVER TRADITIONAL SCS

ACCURATE IDE CONCLUSIONS

The 12-month outcome data have confirmed DRG stimulation provides long-term, sustained and superior pain relief over traditional SCS for patients with chronic lower limb pain due to Complex Regional Pain Syndrome (CRPS) and peripheral causalgia.
SCS VS DRG
What does it look like under Fluoro?

Percutaneous Lead SCS

Penta/Paddle SCS

Percutaneous DRG
References:

1. Institute of Medicine Report from the Committee on Advancing Pain Research, Care, and Education: *Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education and Research*. The National Academies Press, 2011.


