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Case Information

Presenting Symptom: Chronic low back pain > lower extremity pain

Case Specific Diagnosis: Failed back surgery syndrome (FBSS) presenting with primarily axial low back pain (LBP)>lower extremity (LE) pain.

Learning Objectives:

- To understand FBSS as a primary indication for SCS in those patients with primarily chronic LBP>LE pain refractory to other methods of conservative treatment.
- To demonstrate the evidence base for various forms of SCS for FBSS as potential options for treatment, and the appropriateness for utilizing one over the other.
- Formulate differential diagnosis for chronic post-surgical LBP pain and identify available treatment options.

History: A 62-year old Male construction worker with a PMH of HTN and DM, presents to the pain clinic with chronic low back pain (LBP) > lower extremity pain (R>L) for over 1 year. He is s/p lumbar laminectomy and fusion from L2-S1 2 years ago after a work related accident that caused acute onset LBP and RLE pain. Over time his pain continued and increased and he was determined to have indications for decompression

and fusion surgery. He reports that he had modest relief of his pain for approximately 6 months after this surgery and returned to work; however, although he has experienced a meaningful decrease in his LE pain, his chronic LBP has progressively increased in severity over the last 1-year and he has been unable to work for the last 6 months due to this condition.

He endorses that his primary site of pain is focal, midline back pain that travels straight across his back and worsens with lumbar flexion>extension. The patient also reports secondary LE pain (R>L) that is associated with intermittent burning, numbness, tingling down his entire RLE down to the dorsum of the right foot. He reports the same symptoms to a lesser degree in his LLE down to the back of his left knee. He reports he can only walk about 5 blocks due to severe low back pain. He denies overt LE weakness other than that which is limited by pain and reports no falls.

The patient denies any recent weight loss, fever/chills, night sweats, bowel/bladder incontinence, or saddle anesthesia.

Pertinent Physical Exam findings

- +lumbar post-surgical scar (L2-S1) with tenderness to deep palpation (no swelling or redness)
- Diffuse and widespread tenderness to palpation across entire lower lumbar spine
- Pain with lumbar flexion>extension causing primarily axial LBP>LE pain
- Equivocal slump test and straight leg raise tests bilaterally limited by axial LBP
- Reflexes 2+ throughout BLE
- Sensation decreased in R>LLE in non-dermatomal distribution
- BLE strength testing indeterminate and limited by pain but at least 3/5 with respect with hip flexion and knee extension; 4/5 dorsiflexion and plantarflexion
- Pt unable to heel/toe walk due to intractable LBP
- Waddell signs negative
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<u>Diagnostic Imaging and results (please keep brief and pertinent to case):</u>

- **Basic labs** (CBC, CMP, Vit D and Rheum panel all WNL)
- **Prior pre-operative MRI of lumbar spine:**
    - Multilevel LDDD with large herniated discs causing severe neuroforaminal and canal stenosis at L3-S1, worse at L4-5 and L5-S1.
    - Grade II and III anterolisthesis at L4-5 and L5-1
    - Moderate facet arthopathy L4-S1
- **New MRI Lumbar spine + Lumbar xray**
    - s/p lumbar laminectomy and fusion with intact instrumentation from L2-S1 without hardware failure or loosening
    - Progressive LDDD worse at L4-5 and L5-S1

    - Progressive and now severe facet arthopathy L4-S1
    - No new dynamic instability or listhesis

Differential Diagnosis (*please list at least 3-5 in order of most➔least likely***)**

- Failed back surgery syndrome/post-laminectomy syndrome/post-surgical pain syndrome
- Adjacent Segment Disease/Facet Joint Syndrome
- Myofascial Pain Syndrome
- Discogenic pain Syndrome
- Pain from Post-surgical epidural adhesions
- Sacroiliac pain dysfunction syndrome

Medications and Interventions: His pain has remained refractory to trials of max doses of multiple neuropathic medications, NSAIDS, and Tylenol. He has received mild benefit from extensive physical therapy (home TENS unit) and cognitive behavioral therapy. Over the course of 2 months under your care, his pain has remained intractable and refractory to multilevel lumbar epidural steroid injections, medial branch blocks, and epidural adhesiolysis procedures, which provided mild/moderate and short-term pain relief. The patient reports that he does not wish to undergo any further surgical revision or intervention at this time. He reports that his CLBP is progressing and is significantly interfering with his daily quality of life and his basic ability to function.

Evidence Based Indications for SCS in FBSS:

- **FBSS Definition:** This patient is suffering from severe, chronic, and intractable LBP>BLE pain likely secondary to FBSS. The International Association for the Study of Pain defines failed back surgery syndrome as: “Lumbar spinal pain of unknown origin either persisting despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same topographical location” (1).

- **Efficacy:** The nature of his pain state related to FBSS is primarily nociceptive, but there are elements of neuropathic pain. After the failure of therapy, assisted by injections and medications to treat his mechanical pain, he is an appropriate candidate for a trial of spinal cord stimulation. The predicted success rate long term success with SCS is lower than radicular leg pain, but given the persistence of his pain, waiting will further decrease efficacy. Persistent axial and radicular complaints currently has **USPSTF Level IA evidence supporting its efficacy (2)**.

- **Cost-effectiveness:**
    - The utility of tonic SCS for pain associated with FBSS has been well studied in the literature, and recent studies show that SCS implantation is cost-effective in 80%–85% of patients with FBSS when adjusting for quality-adjusted life years. This includes the cost of untreated FBSS on society as a whole, loss of productivity, costs associated with disability,

emergency room visits, imaging costs, and costs of medications and hospitalizations (**PRECISE Trial)** (3).

- The largest study of FBSS patients studied to date (122,827 FBSS patients) along with the longest follow-up interval ever analyzed (2000 to 2012), demonstrated that only 4.34% underwent SCS implantation. Total annual costs decreased over time following implantation of the SCS system, with follow-up analysis at 1, 3, 6, and 9 years. Study demonstrated that placement of an SCS system was associated with an initial increase in total costs at the time of implantation, however there was a significant and sustained 68% decrease in cost in the year following SCSplacement compared to CMM. There was also an aggregate time trend that for each additional year after SCS, cost decreased on average 40% percent annually with follow-up up to 1, 3, 6, and 9 years post-procedure. (4)
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- **Tonic vs. Burst vs. High Frequency (10kHz) SCS in FBSS to treat back and leg pain:**
  - A review of five clinical trials using Burst stimulation for the treatment of chronic back and leg pain reports slightly lower pain scores and a higher frequency of likability when compared to tonic stimulation. Evidence supports that there is possibly greater efficacy with axial back pain relief. It should be noted that many of the studies included are non-randomized and unblinded.(5) Furthermore, the US FDA approved SUNBURST trial was not included in the review and is pending publication of this report.
  - Large-scale review studies from 2017 also suggest that Burst stimulation offers a salvage strategy for failed tonic spinal cord stimulation (tSCS), thus improving both quality of life and cost-effectiveness of SCS by reducing explant rates. The goal of this therapy is to use more than one waveform in the same device so that lost efficacy from tSCS can be salvaged (5-6).
  - An industry sponsored, multicenter, randomized controlled clinical trial showed a clinically and statistically significant reduction in axial back pain scores in the use of 10kHz (“high-frequency”) stimulation that was most often focused on the T9-10 interspace. There was an 84.5% responder rate with 10kHz in back pain compared to 43.8% for tonic stimulation mode. (7)

  - The two most cited, and the only randomized prospective trials on the use of traditional low-frequency SCS for FBSS treating back and neuropathic leg pain, are those from North et al and Kumar et al.Kumar et al showed that at 24 months, 37% of patients in SCS group continued to achieve at least 50% pain relief versus 2% of patients in the CMM group. (8-10)
  - An 2016 industry sponsored-randomized, controlled, multicenter, prospective clinical trial recently completed in the United States, provided Level 1 evidence evaluating the efficacy of 10 kHz SCS compared with

traditional low-frequency SCS for subjects with both chronic back and leg pain. At 24 months, more subjects were responders to 10 kHz SCS than traditional low-frequency SCS (back pain: 76.5% vs. 49.3%; leg pain: 72.9% vs. 49.3. (11)

- **SCS vs. Re-operative surgical management:**
  - Current literature suggests that SCS is still underutilized in FBSS compared to re-operation, and that SCS demonstrates a lower complication rate and improved outcomes compared to re-operative management (12).

  - A 2017 large-scale review found that evidence is weak for medications and re-operation, but strong for active exercise and interventional procedures such as adhesiolysis. The strongest evidence for long-term treatment of FBSS is for spinal cord stimulation (SCS), showing favorable Level I RCT results compared to conventional medical management and re-operation for predominant LBP (12).

Treatment recommendations for this case: This case presents a common clinical scenario- with a patient meeting the criteria of FBSS, but predominant axial back pain complaints. This patient is not a clear cut candidate for SCS as he does not demonstrate the same pain profile with patients selected for clinical trials showing excellent clinical outcomes. Nevertheless, due to the lack of neurologic progression requiring re-operative intervention, and the failure of more conservative measures, the patient is an appropriate candidate for a SCS trial. Counseling should be performed to prepare the patient on proper expectations during the trial. While there does exist industry sponsored evidence to support Burst or HF10 therapy over traditional tonic stimulation for back pain, it should be noted that at the time of this review, there is not sufficient evidence to identify a superior modality and device selection should be based on a provider's skill set, comfortability, and experience.

Take home points

- There is level 1A evidence for SCS as a treatment for FBSS with persistent axial and radicular complaints
- There is Level 1A evidence for SCS vs. re-operative surgical management for FBSS
- Newer studies suggest that Burst SCS may be superior to tonic SCS for treating FBSS with predominantly axial LBP.
- Burst and HF (10 kHz) SCS are both effective treatment options for refractory axial LBP due to FBSS, and that Burst SCS may have greater responsiveness than high frequency stimulation.
- Efficacy of SCS for FBSS increases when implemented earlier in the treatment algorithm (especially when utilized prior to 2 years of chronic low back pain)
- The largest study of FBSS patients studied to date (122,827 FBSS patients) along with the longest follow-up interval ever analyzed (2000 to

2012), demonstrated that improved long-term health economics at 1, 3, 6, and 9 years supports the long-term cost utility of SCS in the treatment of FBSS patients

References (*Please incorporate at least 3-5 references utilizing the most current and quality large-scale data*):

1) Baber Z, Erdek MA. Failed back surgery syndrome: current perspectives. *Journal of Pain Research*. 2016;9:979-987.

2) Deer TR et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. *Neuromodulation*.2014 Aug;17(6):515-50; discussion 550.

3) Zucco F, Ciampichini R, Lavano A, et al. Cost-effectiveness and cost-utility analysis of spinal cord stimulation in patients with failed back surgery syndrome: results from the PRECISE study. *Neuromodulation*. 2015;18(4):266–276

4) Farber SH, Han JL, Elsamadicy AA, Hussaini Q, Yang S, Pagadala P, Parente B, Xie J, Lad SP. Long-term Cost Utility of Spinal Cord Stimulation in Patients with Failed Back Surgery Syndrome**.** *Pain Physician.* 2017 Sep;20(6):E797-E805.

5) Hou S[1], Kemp K[1], Grabois M. A Systematic Evaluation of Burst Spinal Cord Stimulation for Chronic Back and Limb Pain. *Neuromodulation*. 2016;19(4):398-405.

6) Deer TR, Campos LW, Pope JE. Evaluation of Abbott's BurstDR stimulation device for the treatment of chronic pain. *Expert Review of Medical Devices.* 2017 Jun;14(6):417-422.

7) Kapural L[1], Yu C, Doust MW, Gliner BE, et al. Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial. 2015;123(4):851-60.

8) North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomised, controlled trial. Neurosurgery 2005;56: 98–106.

9) Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomied

controlled trial in patients with failed back surgery syndrome. Pain 2007;132:179–88

10) Kapural L, Peterson E, Provenzano DA, Staats P. Clinical Evidence for Spinal Cord Stimulation for Failed Back Surgery Syndrome (FBSS): Systematic Review. *Spine (Phila Pa 1976)*. 2017 Jul 15;42 Suppl 14:S61-S66.

11) Kapural L, Yu C, Doust MW, et al. Comparison of 10-kHz high frequencyand traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results mfrom a multicenter, randomized, controlled pivotal trial. Neurosurgery 2016;79:667–77.

12) Amirdelfan K, Webster L, Poree L, Sukul V, McRoberts P. Treatment Options for Failed Back Surgery Syndrome (FBSS) Patients with Refractory Chronic Pain: An Evidence-Based Approach. *Spine.* 2017 Apr 12. Epub ahead of print]