

A NOVEL CASE REPORT OF CLOSED-LOOP SPINAL CORD STIMULATION FOR NEUROPATHIC PAIN IN CERVICAL SPINAL CORD INJURY

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Background: Neuropathic pain after spinal cord injury (SCI) is common and often refractory. Closed-loop spinal cord stimulation (CL-SCS) is a novel intervention that adjusts stimulation based on evoked compound action potentials in real time, but its use for pain in complete SCI is not well described.

Case Report: A 45-year-old man with complete C6-C7 SCI developed severe, diffuse neuropathic pain below the injury level refractory to multiple medications, an intrathecal fentanyl pump trial, and ketamine infusions. With extensive epidural scarring, a staged buried CL-SCS trial with a combined open/percutaneous approach implanted bilateral C2-C5 leads. Trial stimulation produced complete analgesia. After internalization, pain improved to 4/10 on the Numeric Rating Scale at 3 months, with sustained 50-60% subjective improvement through 12 months. A wound complication at 11 months prompted surgical washout. Persistent concern for device colonization ultimately led to explantation at 18 months.

Conclusions: CL-SCS may provide meaningful, sustained analgesia and functional benefit in select patients with complete cervical SCI. Systematic studies are needed to quantify benefit, durability, and risk.

Key words: Spinal cord stimulation, closed-loop, open-loop, neuropathic pain, evoked compound action potential, refractory pain, cervical spinal cord injury

BACKGROUND

Spinal cord injury (SCI) is a life-altering condition, with approximately 18,400 new traumatic cases occurring annually in the United States, and an estimated 900,000 new cases globally in 2019 (1,2). SCI often results in motor, sensory, and autonomic deficits, and notably, neuropathic pain in approximately half of these patients (3).

Current treatment options include gabapentinoids, antidepressants, opioids, and muscle relaxants, as well as interdisciplinary modalities including physical and cognitive-behavioral therapy. These interventions are often limited by partial relief, medication side effects, and risk of dependency (4).

There is a strong need for alternative therapies in SCI patients with chronic neuropathic pain who do not improve with conservative management and pharmacotherapy. Spinal cord stimulation (SCS) is an established neuromodulation therapy for chronic neuropathic pain in several instances, having demonstrated efficacy in conditions such as failed back surgery syndrome and complex regional pain syndrome. SCS establishes pain control via electrical impulses generated by epidural electrodes, activating dorsal column fibers and modulating pain (5). Early reports and small series suggest that SCS can reduce pain in select SCI patients, though evidence remains limited. Recent advances in SCS technology include closed-loop SCS (CL-SCS) systems, capable of

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adjusting stimulation in real time to achieve an optimal “dose” that consistently activates analgesic mechanisms, avoiding overstimulation and discomfort (6).

This case is, to our knowledge, the first in the literature to demonstrate the implantation of CL-SCS in a patient with post-SCI refractory neuropathic pain, and with meaningful sustained analgesia at 12 months after implant.

CASE PRESENTATION:

A 45-year-old healthy man sustained unstable C6 and C7 vertebral body burst fractures with complete American Spinal Injury Association Impairment Scale (AIS) Grade A SCI after a 20-foot mechanical fall (Fig. 1). He underwent surgical stabilization (C6-T1 corpectomy, discectomy and fusion, C3-T1 decompression and fixation), and decompression (C6-7 posterior laminectomy and foraminotomy). Following the surgery, he developed chronic, refractory neuropathic pain below the injury level.

The pain was characterized as “radiating everywhere” below the neck including the bilateral lower extremities, with severe burning dysesthesia and hyperalgesia of the left hand. Allodynia forced him to wear a glove to minimize any contact. His baseline pain 8 years following initial injury was 10/10 on the Numeric Rating Scale (NRS) without relief. He was unable to concentrate on daily tasks, tolerate lying flat, ride in a car, or sleep more than 1-2 hours per night due to pain.

Over years, he received various neuropathic pain medications, including gabapentin, pregabalin, duloxetine, methadone, and baclofen, as well as cannabinoids. All therapies were either ineffective or caused adverse effects. He did not improve with an intrathecal fentanyl pump trial or intravenous ketamine infusions. At the time of evaluation in the clinic, he was using baclofen and cannabinoids for analgesia with minimal effect, and he was seeking alternative treatments for his uncontrolled pain.

Given the pain severity and failure of conservative measures, SCS was discussed as a next step. A trial of a closed-loop SCS system (Evoke® SCS System, Saluda Medical) was proposed. After consideration with the medical team, patient, and family, discussion of the risks and benefits, as well as the investigational nature of SCS in SCI, the patient opted to proceed with planned cervical CL-SCS.

Imaging for operative planning revealed extensive cervical epidural scarring from prior multilevel laminect-

omies, and loss of the dorsal epidural fat layer, precluding percutaneous lead access below C4. A staged, buried trial approach was recommended, where combined open surgical and percutaneous approach was used to safely place bilateral electrode leads spanning C2-C5 via C4 laminotomy and fluoroscopic guidance (Figs. 2 and 3). Despite technical challenges from adhesions, both leads were positioned successfully and connected to the implantable pulse generator.

During the 1-week trial, the patient experienced complete pain relief in his hands, feet, and lower back whenever the device was on, despite manually powering it off at night due to his apprehension. Family observed marked improvements in mood, sleep, and function. His pain returned immediately whenever stimulation was paused.

One week later, the system was internalized, placing the implantable pulse generator in a right lower abdominal pocket and tunneling leads subcutaneously. The procedure and postoperative period proceeded without complication.

At his 3-month follow-up, the patient reported peak analgesic effect, with an NRS score of 4/10 and 60% subjective improvement. Device utilization was high (>50%) and satisfaction was marked, though he noted pain was not always fully eliminated. Device programming adjustments were made to further optimize therapy. At his 6- and 12-month follow-up appointments, pain relief was sustained (NRS 5-7). He reported that his subjective improvement was consistent at 50-60% overall improvement. Functional gains were made and persisted, with sleep improving from 1.5 hours prior to the implant, to 4 hours per night after the implant. He was able to achieve previously impossible goals including car rides, family visits, and prolonged reading for pleasure.

Device reports demonstrated that 98% of stimulation stayed within the therapeutic window. The average dose ratio was 1.01 and evoked compound action potential (ECAP) amplitude fluctuations were minimal, at $< \pm 5 \mu V$ from target. Minor reprogramming was completed at 6 months and resolved brief output interruptions due to positional changes. No neurologic deterioration or lead migration was observed at 10-month follow-up. The patient reported consistent high satisfaction, and that the device “took away the pain that was ruining [his] life.”

At 11 months after implantation, the patient developed a wound complication with concern for infection and underwent surgical washout. He maintained



Fig. 1. Sagittal T2-weighted magnetic resonance image of the cervical spine following C6-C7 burst fractures.

meaningful analgesia thereafter, but due to persistent concern for device colonization, the system was explanted at 18 months after implantation. At the time of explant, he continued to report substantial pain relief and expressed interest in reimplantation following full clearance of the infection.

This case report is devoid of identifiable patient information and is therefore exempt from written informed consent and institutional review board review in accordance with both University of Arkansas for Medical Sciences and NYU Langone Health policy.

DISCUSSION

This case illustrates the successful use of closed-loop SCS in a patient with chronic C6 SCI suffering from intractable neuropathic pain, with profound and sustained improvement in pain, function, sleep, and quality of life. Such significant pain relief in complete AIS-A SCI is rare, underscoring this case's novelty. Neuromodulatory interventions may provide meaningful benefit for SCI patients, even for many years post-injury.

An emerging treatment for pain in SCI patients, SCS operates on the proposed gate control theory of pain, whereby selective stimulation of A β fibers in the dorsal column inhibits nociceptive C fiber response, impairing the central transmission of pain before it can reach the brain (5). In SCI patients, SCS may restore inhibi-

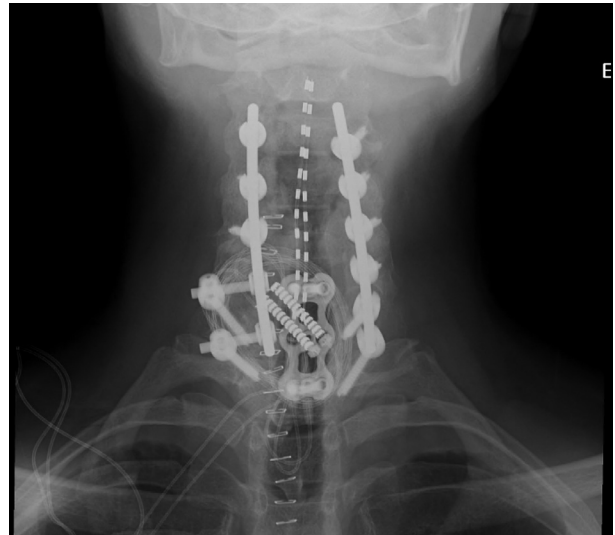


Fig. 2. Anteroposterior cervical radiograph demonstrating bilateral spinal cord stimulation leads spanning C2-C5 and prior posterior instrumentation.



Fig. 3. Lateral cervical radiograph demonstrating bilateral spinal cord stimulation leads spanning C2-C5 and prior posterior instrumentation.

tory control of pain by modulating long-term synaptic changes and reducing central sensitization, and promote gamma-aminobutyric acid and serotonin release in the spinal cord, further contributing to analgesia (7).

CL-SCS is an emerging technology in neuromodulation, which adjusts stimulation output to maintain an evoked response at a set target between the minimum inhibitory

effect and the threshold of discomfort, effectively monitoring and adjusting the “dose” of current applied in real time based on ECAPs from the dorsal columns. Output is passively monitored and controlled by the implanted device, and is able to maintain the therapeutic window (8). This technology theoretically eliminates the need for manual adjustment of dose due to positional changes, habituation, and/or overstimulation causing discomfort, all challenges of the more traditional open-loop spinal cord stimulation (OL-SCS) system.

Though studies and cases have shown meaningful analgesia through SCS in SCI patients with refractory neuropathic pain, the literature encompasses mostly incomplete injuries, raising concerns about the applicability of SCS in complete SCI (5,9). Sabourin et al (10) prospectively studied 114 patients with chronic neuropathic back and limb pain undergoing SCS, and found that even modest NRS reductions were associated with clinically meaningful benefit. One-year follow-up minimal clinically important difference in NRS scores was established at 0.9-2.7 points, and receiver operating characteristic analysis confirmed that a one-point reduction on the NRS could reliably differentiate satisfied patients. This disproportionate link between pain reduction and function may explain the satisfaction and subjective percent-improvement in our patient as well, whose NRS reduction post-procedure (10/10 to 4-5/10) far surpassed Sabourin et al’s established minimal clinically important difference.

Levy et al (11), in a post hoc analysis of the EVOKE randomized controlled trial, identified a mean optimal dose ratio of approximately 1.4 in CL-SCS for lower back pain, though notably our patient’s dose was at 1.01. As evidenced by Goree et al (12), the cervical region has significantly lower ECAP thresholds and an approximately 48% narrower therapeutic window as compared to the thoracic region. The cervical spinal cord may be more sensitive to stimulation due to a narrower cross-sectional area yet higher neuron density. Combined with the smaller epidural space in the cervical spine, and shorter distance between nerve and electrode, it is more sensitive to overstimulation, and may require lower amplitudes for analgesia than the lumbar spine (13). This case report demonstrates this key finding, demonstrating excellent and consistent pain relief at a lower dose ratio. Further research may seek to define optimal dose ratios for cervical SCS, and establish whether they are truly lower than the reported range for lumbar or thoracic SCS.

To our knowledge, this is the first reported case of ECAP-controlled CL-SCS used for pain in a complete spinal cord injury at any level. Though the body of literature exploring neuromodulation for SCI-related pain is growing, most published reports involve small samples or anecdotal results. While numerous clinical trials are currently under way to evaluate SCS in SCI, only 2 investigate closed-loop systems: one in China (ClinicalTrials.gov Identifier: NCT04969042) recruiting participants with any-grade SCI T10 or higher to assess gait outcomes, and one in the US (ClinicalTrials.gov Identifier: NCT05267951), recruiting patients with C8-or-higher injuries with AIS C or D to compare CL-SCS vs OL-SCS for upper extremity function and spasticity (14,15). Neither trial targets pain relief or focuses on complete cervical injuries. A recent systematic review of SCS in SCI (16) demonstrated a lack of high-quality evidence, and limited selection criteria. Present literature favors incomplete SCIs, short time frames between injury and SCS implantation, and variable pain relief. Our report demonstrates that even long-standing complete SCI patients may glean meaningful relief with SCS from SCI-related pain.

Despite sustained analgesia through explantation, this case was complicated by a late wound complication requiring washout and explant for infection concern. This limits the generalizability of longer-term outcomes and underscores the need for risk stratification and careful postoperative surveillance. This report is limited by the fact that placebo effects or spontaneous improvement cannot be excluded, though the on-off effects during the trial and sustained benefit increase confidence in SCS’ causality for pain relief. As with any case report, this case cannot convey generalizability to SCI patients, yet it provides a compelling case for future research. Robust, controlled, prospective studies may seek to clarify efficacy, compared to OL-SCS in SCI patients, and further determine optimal parameters for CL-SCS, including frequency, intensity, dose ratio, and placement within the SCI population.

CONCLUSION

SCI patients frequently suffer with chronic neuropathic pain following initial injury, and struggle with limited treatment options. SCS is a growing treatment modality in many chronic pain conditions, with CL-SCS an emerging technology meant to optimize its efficacy and tolerability even further. This case demonstrates that CL-SCS may present both a substantial and durable

option for this patient population, despite the many challenges of high-level cervical SCI cases. We posit that SCS should be discussed on a case-by-case basis with such patients, and that there is a need for further research to confirm efficacy as well as optimize treatment parameters and potentially establish guidelines for integrating SCS into the algorithm of SCI care.

Author Contributions

Ruben Dovlatyan: Conception and design of the case report; literature review; drafting of all sections; figure preparation; coordination of revisions; final approval of the submitted manuscript.

David Jevotovsky: Project initiation and mentorship; provided outline/strategic guidance; critical revision of the manuscript for important intellectual content; final approval of the submitted manuscript.

Jarna Shah: Clinical evaluation and management of the patient; contributed clinical details and context; critical revision of the manuscript; final approval of the submitted manuscript.

Erika Petersen: Surgical evaluation and operative management including CL-SCS implantation; contributed procedural/operative details; critical revision of the manuscript; final approval of the submitted manuscript.

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