

LONG-TERM EFFICACY OF A NOVEL EXTRAFORAMINAL APPROACH FOR NERVE ROOT STIMULATION IN COMPLEX REGIONAL PAIN SYNDROME: A CASE REPORT

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Background: Neuromodulation techniques can be employed as part of the treatment approach for refractory complex regional pain syndrome (CRPS).

Case Report: We present a case report of a 62-year-old male patient with CRPS of the lower limb who underwent spinal nerve root stimulation using a novel extraforaminal lead placement as a treatment modality after the failed replacement of a defective dorsal root ganglion lead. This case report highlights the successful long-term application of dorsal nerve root stimulation with an alternative extraforaminal lead placement technique, resulting in significant pain relief and improved functional outcomes in a patient with refractory CRPS.

Conclusions: The novel anatomical approach and neurostimulation technique described in this case provide a promising alternative for patients who have not responded to other treatment modalities.

Key words: CRPS, dorsal root ganglion stimulation, peripheral nerve root, extraforaminal approach, case report

BACKGROUND

Complex regional pain syndrome (CRPS) is a debilitating chronic pain condition characterized by severe and often refractory pain (1). Despite the various treatment options available, managing CRPS can be challenging (1). Neuromodulation, including various techniques, such as spinal cord stimulation (SCS) (2), dorsal root ganglion (DRG) (3), and peripheral nerve stimulation (PNS) (4), have been explored as a treatment option for refractory CRPS.

While SCS has been found to be effective in some individuals with CRPS, DRG stimulation has been demonstrated as an effective neurostimulation procedure, particularly in cases where pain is localized to specific areas inaccessible to SCS (5). However, there are limita-

tions associated with the implantation technique due to anatomical factors, such as previous surgeries and degenerative changes. Issues related to electrode placement, such as migration or lead fracture (6), further complicate the primary implantation process, making it challenging or sometimes even impossible. Revisions of the implants are often necessary and time consuming (7,8). These revision procedures carry an increased risk of complications or failure (8).

Spinal nerve root stimulation (SNRS) is a neuromodulation technique that has shown promise in the treatment of chronic neuropathic pain (9,10). One of the advantages of SNRS is its ability to target the specific nerve roots that innervate the affected area, and in comparison to PNS, it covers a broader area of stimulation (11). The SNRS

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approach allows for more precise pain management and can be particularly beneficial when the pain is localized to a specific dermatomal distribution (10,11).

Several clinical studies and case reports (9-11) have demonstrated the effectiveness of SNRS in providing pain relief for various conditions, including CRPS. Patients who have undergone SNRS have reported reduced pain intensity, improved function, and enhanced quality of life (9,10). However, one prospective trial (12) reported the failure of long-term SNRS to improve neuropathic pain.

SNRS involves the implantation of electrodes near the proximal SNRs. Various techniques of lead placement have been described (13,14). These techniques typically entail the placement of electrodes intraspinally to stimulate the SN rootlets, either in a transforaminal position targeting the SNR or in a retrograde fashion from the epidural space (13,14), or in an "outside-in" fashion from extraforaminal to intraforaminal (13,15). To the best of our knowledge, this is the first case report documenting the long-term effects of distal extraforaminal SNRS using a unique extraforaminal lead placement technique.

CASE REPORT

A 62-year-old man presented with a 2-year history of intense burning pain, hyperalgesia, allodynia, swelling, and functional impairment in his left lower limb following a traumatic injury and surgery. Despite previous treatments, including medications and physical therapy, the patient experienced limited pain relief and continued functional impairment. The debilitating pain significantly impacted his quality of life and ability to perform daily activities or work, as indicated in the baseline assessment (Table 1).

A comprehensive evaluation was conducted, including a detailed medical history, physical examination, and imaging studies to rule out other potential causes of the patient's symptoms. Based on the clinical presentation and the Budapest criteria, a 2003 proposed research criteria for CRPS, the patient was diagnosed with CRPS, primarily affecting the left lower extremity.

Given the refractory nature of the patient's symptoms, he was considered for DRG stimulation. The leads were percutaneously implanted at the level of L4 and L5 nerve roots, targeting the DRG. Following a successful trial period, during which the patient experienced significant pain relief and improved functionality, the L5 electrode (Quattrode, Abbott, Plano, TX) was permanently im-

planted. A subcutaneously placed pulse generator was connected to the lead (Proclaim DRG System, Abbott, Plano, TX). Stimulation parameters, including intensity, frequency, and pulse width, were adjusted to optimize pain relief while minimizing adverse effects.

However, one month later, the patient returned to the office with new-onset pain. X-rays revealed a broken lead. Due to anatomical constraints, a revision with replacement of the L5 DRG lead was not possible. During the procedure, a transforaminal approach, which involved accessing the DRG from outside the spinal canal through the neural foramen, was also nonresponsive. As a rescue method, a new alternative approach was performed to gain access to the L5 SNR. The needle was percutaneously directed infrapedicularly under fluoroscopy until the extraforaminal space was reached. An octrode lead (Octrode, Abbott, Plano, TX) was then inserted in a craniocaudal manner along the distal SNR in the region near the psoas muscle.

Intraoperative paresthesia testing covered almost the entire pain area in the foot corresponding to the L5 dermatome. Instead of placing an additional DRG lead, the medical team opted for the placement of another octrode lead (Octrode, Abbott, Plano, TX) in the epidural space at the T11 level to ensure pain coverage in the lower extremity. There were no intraoperative complications. Intraoperative electrophysiological testing closely monitored the safety of the whole procedure and demonstrated good coverage of the painful areas. The patient tolerated the procedure very well.

Following 2 years of successful pain relief with the permanently implanted combined system, the patient's pain relief began to decrease due to a dysfunctional system with recharging problems. System assessment revealed a defective SNRS L5 lead. Reprogramming the epidural lead was not able to provide proper pain relief despite moderate pain coverage at the cost of unwanted stimulation in nonpainful areas. Due to the lack of pain relief, the patient resumed using opioids and neglected to recharge the system, as outlined in the preoperative assessment (Table 1). Upon presentation, the implantable pulse generator (Prodigy MRI, Abbott, Plano, TX) was found to be deeply discharged.

This led us to the conclusion that SCS did not yield a favorable outcome, and the previous long-term positive effect might be solely attributed to the effect of the SNRS. Consequently, the patient underwent another revision in which the dysfunctional system was replaced with a new system from another manufacturer. This

Table 1. Pain assessment scores.

	Baseline Aug 2018	Preop Assessment Jun 2022	1st Assessment Oct 2022	2nd Assessment May 2023	3rd Assessment Aug 2023	4th Assessment Sep 2023
Pain Intensity (NRS-11* 0-10)	9	9	1	3	4	2
Current	7	9	1	3	3	2
Average	9	9	1	3	3	2
Maximum	9	10	2	4	7	3
Tolerable	2	2	2	2	2	2
Disability Days (3 mo)	90	0	0	0	4	0
Impairment (NRS-11* 0-10)						
Daily Activities	9	8	0	0	3	0
Leisure Activities/Family/Friends	7	8	0	0	3	0
Workability	8	7	0	0	2	0
DASS**						
Stress	5	3	0	1	4	0
Anxiety	1	0	0	0	0	0
Depression	0	3	0	0	2	0
Von Korff Index (0-4)	4	3	1	1	1	1
FW7***	0	3	35	31	21	30

* Numeric Rating Scale

** Depression, Anxiety, and Stress Scale

*** Functional Well-being Scale With 7 Items

replacement included the placement of two 8-contact leads (Vectris, Medtronic Inc., Minneapolis, MN) directly on the left distal L4 and L5 SNRs using the same extraforaminal approach. A subcutaneously placed rechargeable pulse generator was connected to the leads (Intellis, Medtronic Inc., Minneapolis, MN). Stimulation parameters were carefully adjusted to optimize pain relief. The paresthesia coverage was precise along the specific dermatome using similar stimulation parameters as used for DRG stimulation. Figure 1 illustrates the lead position at the 2-month follow-up (Fig. 1).

Following the permanent implantation of SNRS, the patient reported significant pain reduction and functional improvement in his lower limb. He regained the ability to perform daily activities with minimal discomfort, as indicated in the first assessment. Follow-up visits were conducted to monitor the patient's progress and make necessary adjustments to the stimulation parameters (Table 1). The timeline displays the entire course with revision and monitoring stages (Fig. 2).

Although the patient needed reprogramming during the 12-month follow-up to optimize coverage, the overall result was excellent. At the last follow-up session, the patient reported > 60% reduction in pain,

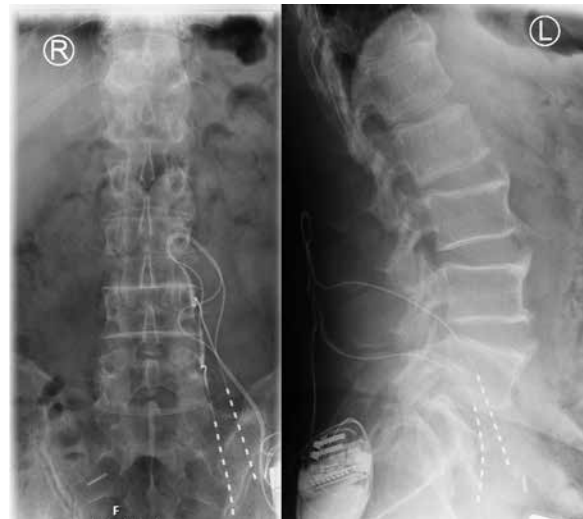


Fig. 1. AP and lateral radiograph showing L4 and L5 extraforaminal nerve root electrodes in position on the left side. AP, anteroposterior.

sustained improvement in function, and a substantial enhancement in his overall quality of life. He no longer required pain medications and reported no adverse effects related to the neuromodulation therapy.

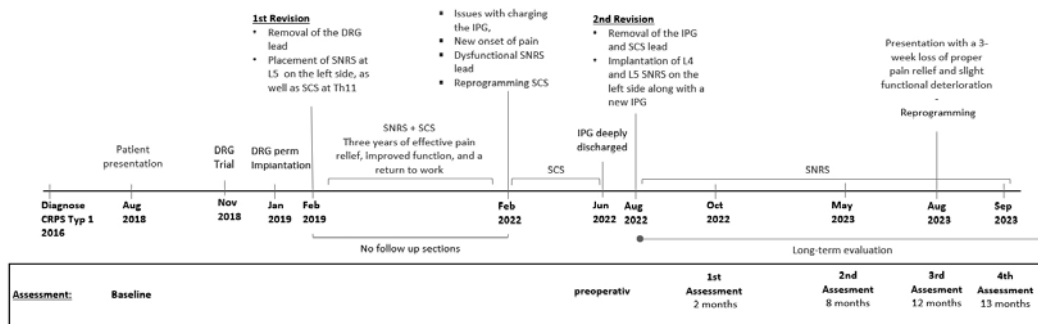


Fig. 2. Timeline from presentation to the last follow-up in September 2023.

DISCUSSION

The positive outcomes observed in this case report suggest that the anatomical approach, targeting the SNR, and the neurostimulation technique could be a potentially viable option for individuals who have exhausted or nonresponsive to traditional neurostimulation treatment options. It opens up new possibilities for improving patient outcomes and enhancing their quality of life.

CRPS is a challenging condition to manage, often necessitating innovative treatment approaches (16). While DRG stimulation is an established effective therapy for CRPS (3), some patients may experience mechanical complications or are excluded due to contraindications (7,8). Several contraindications need consideration when it comes to the placement of DRG stimulation.

Structural abnormalities or previous surgical procedures in the region of the targeted DRG may complicate or prevent the proper placement of the electrodes or interfere with the effectiveness not only of DRG but also of traditional transforaminal SNRS, for instance, foraminal stenosis or fibrosis. With this technique, we avoid passing through the neuroforamina. This approach enables stimulation of the nerve root itself while circumventing the potential challenges and limitations associated with lead placement within the neuroforamina. Moreover, the limited long-term stability of the currently available DRG system, and the difficulty of revising the system, increase the need for an alternative procedure (8).

The incidence of DRG lead breakage is a known complication in the field of neuromodulation (7,8). The leads used for DRG stimulation are thin and flexible. Over time, these leads can experience wear and tear, which may lead to breakage. Additionally, factors, such as patient movement, trauma, or inadequate lead anchoring, can contribute to the risk of lead migration

or breakage (6-8). Revisions can be challenging and time consuming, and carry the risk of severe complications, such as neural damage (8).

In the current case, we used a conventional 8-contact SCS lead for the revision procedure. The potential problem of using an octrode lead (Octrode, Abbott, Plano, TX) with traditional methods of DRG stimulation or SNRS that could contribute to narrowing the foramina is a valid concern. However, by placing the electrodes extraforaminal, not passing through the foramina, bypasses this potential complication.

The novelty of the current SNRS approach lies in its departure from traditional methods of SNRS combined with regional anesthesia techniques. In traditional SNRS, electrodes are commonly placed either 1) intraspinal – in the epidural space far lateral on the nerve rootlet; 2) transforaminal – through the spinal canal toward the distal nerve root; 3) transpinal – from the contralateral side; or 4) a transforaminal outside-in manner (14). The last 3 approaches cover not only the stimulation of the SNR, but also the DRG.

The alternative SNRS approach used in this particular case was a rescue option for the patient and allowed for optimal coverage of the affected area, first in combination with SCS and later alone as SNRS. The SCS lead alone proved to be no option for this patient. Although many adjustments to the stimulation parameters were made, it was not possible to achieve optimal coverage of the painful area without uncomfortable stimulation in nonpainful regions.

The advantage of SNRS over SCS is that it can target specific nerve roots that innervate the affected limb, allowing for more precise pain management (13). This is particularly useful in cases where CRPS pain is localized to a specific dermatome or nerve distribution. After the revision with the removal of the SCS electrode and the

implantation of 2 SNRS electrodes, the patient exhibited exceptional long-lasting pain reduction, indicating that the effect of SNRS alone was sufficient to induce pain relief.

In summary, we present a case demonstrating the long-term effectiveness of SNRS as a viable treatment modality for patients with CRPS who were nonresponsive to conventional SCS or DRG stimulation. We propose that the SNR alone can be a potential target for stimulation. To the best of our knowledge, the case described in this study appears to be the first reported instance of a long-term effect of distal SNRS using a unique lead placement technique, which involves placing the electrodes distally from the extraforaminal space, avoiding both the epidural space and passing through the foramina.

Given the lack of previous reports on similar techniques, the case report's findings can be considered significant in advancing the understanding and poten-

tial applications of SNRS for patients with treatment-resistant conditions. It is important to note that, being a case report, the findings are based on the experience of a single patient. Further research with larger cohorts or controlled studies would be necessary to validate the efficacy, safety, and generalizability of this unique lead placement technique for SNRS.

CONCLUSIONS

This case report illustrates the successful application of SNRS with extraforaminal lead placement for the management of CRPS of the lower limb following nonresponsive DRG stimulation. The innovative technique resulted in significant pain relief and improved functional outcomes for the patient. Further research and larger studies are necessary to establish the long-term efficacy and safety of this approach and determine the optimal patient selection criteria for successful outcomes.

REFERENCES

1. Taylor SS, Noor N, Urits I, et al. Complex regional pain syndrome: A comprehensive review. *Pain Ther* 2021; 10:875-892. Erratum in: *Pain Ther* 2021; 26.
2. Oliveira MJ, Matis GK. Spinal cord stimulation as a treatment option for complex regional pain syndrome: A narrative review. *Br J Neurosurg* 2022; 22:1-5.
3. Chapman KB, Sayed D, Lamer T, et al. Best practices for dorsal root ganglion stimulation for chronic pain: Guidelines from the American Society of Pain and Neuroscience. *J Pain Res* 2023; 16:839-879.
4. Chmiela MA, Hendrickson M, Hale J, et al. Direct peripheral nerve stimulation for the treatment of complex regional pain syndrome: A 30-year review. *Neuromodulation* 2021; 24:971-982.
5. Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: A randomized comparative trial. *Pain* 2017; 158:669-681.
6. Abraham ME, Potdar A, Ward M, Herschman Y, Mammis A. Risk factors associated with lead migration requiring revision in dorsal root ganglion stimulation. *World Neurosurg* 2019; 128:e649-e652.
7. Hines K, Swaminathan V, Thalheimer S, Kogan M, Wu C, Sharan A. Single-Center retrospective analysis of device-related complications related to dorsal root ganglion stimulation for pain relief in 31 patients. *Neuromodulation* 2022; 25:1040-1044.
8. Horan M, Jacobsen AH, Scherer C, et al. Complications and effects of dorsal root ganglion stimulation in the treatment of chronic neuropathic pain: A nationwide cohort study in Denmark. *Neuromodulation* 2021; 24:729-737.
9. Chalil A, Santyr BG, Abbass M, Lau JC, Staudt MD. Spinal nerve root stimulation for chronic pain: A systematic review. *Neuromodulation* 2024; 27:36-46.
10. Levine AB, Steven DA, Parrent AG, MacDougall KW. Successful long-term nerve root stimulation for chronic neuropathic pain: A real world, single center Canadian experience. *Pain Physician* 2017; 20:95-106.
11. Gargya A, Singh H, Lin T, Gulati A. Extraforaminal thoracic and lumbar spinal nerve ultrasound-guided percutaneous peripheral nerve stimulation. *Pain Med* 2020; 21(suppl 1):S38-S40.
12. Weigel R, Capelle HH, Krauss JK. Failure of long-term nerve root stimulation to improve neuropathic pain. *J Neurosurg* 2008; 108:921-925.
13. Haque R, Winfree CJ. Spinal nerve root stimulation. *Neurosurg Focus* 2006; 21:1-7.
14. Kellner CP, Kellner MA, Winfree CJ. Spinal nerve root stimulation. *Prog Neurol Surg* 2011; 24:180-188.
15. Falco FJ, Kim D, Onyewu CO. Cervical nerve root stimulation: Demonstration of an extra-foraminal technique. *Pain Physician* 2004; 7:99-102.
16. Ghaly L, Bargnes V, Rahman S, Tawfik GA, Bergese S, Caldwell W. Interventional treatment of complex regional pain syndrome. *Bio-medicines* 2023; 11:2263.

