

PERIPHERAL NERVE STIMULATOR IMPLANT FOR SUPERIOR CLUNEAL NEURALGIA IN PATIENTS WITH PERIPHERAL NEUROPATHY: A CASE SERIES

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- Background:** Superior cluneal neuralgia is a recognized but often underdiagnosed cause of chronic axial low back and leg pain. Peripheral nerve stimulation (PNS) has shown promise in treating neuropathic pain disorders.
- Case Report:** We report 2 patients—one with diabetic peripheral neuropathy and another with idiopathic neuropathy—who underwent PNS implantation for superior cluneal neuralgia. Both patients were on high doses of neuropathic pain medications (gabapentin or pregabalin), and one was also taking duloxetine. Following implantation, both experienced marked pain relief, allowing reduction and eventual discontinuation of these medications.
- Conclusions:** The Freedom® Peripheral Nerve Stimulator System (Curonix LLC) showed reductions in pain, alongside a favorable safety profile. These results support the clinical utility of high-frequency electromagnetic coupling-based PNS as a minimally invasive and clinically valuable treatment option for chronic neuropathic pain and highlight its potential to reduce the intake of pharmacologic agents.
- Key words:** Peripheral nerve stimulation; chronic low back pain; superior cluneal neuralgia; diabetic peripheral neuropathy; neuropathic pain

BACKGROUND

Chronic low back pain is a common yet complex complaint with many potential causes. These include facet arthropathy, discogenic pain, sacroiliac dysfunction, and others. One frequently overlooked but clinically significant cause is superior cluneal nerve entrapment and neuralgia. The diagnosis is often missed or met with skepticism. It is not as well-known and lacks standardized guidelines (1).

Superior cluneal neuralgia (SCN) typically presents as gluteal or mid-lateral low back pain. This sometimes radiates to the upper leg but potentially all the way down the leg to the foot (1). Diagnostic blocks guided by ultrasound (2) or fluoroscopy can help confirm the condition. Treatments such as nerve injections (3), acupuncture (4), radiofrequency ablation (5), cryoneu-

roablation (6), neuromodulation (7), or decompression (8) have shown promising outcomes. This entity deserves greater attention as part of the differential diagnosis for chronic low back pain (9,10).

Superior cluneal neuralgia arises from entrapment or irritation of the superior cluneal nerves. The superior cluneal nerves provide sensory innervation to the upper buttock and posterior iliac crest regions (2) (Fig. 1). It may mimic axial low back pain or sacroiliac joint dysfunction. Spinal cord stimulation is a well-established but invasive treatment for chronic back pain. In contrast, peripheral nerve stimulation (PNS) is a minimally invasive neuromodulation technique, gaining support as an effective option for managing refractory neuropathic pain (11-15).

Characteristic findings include pain worsened by

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Patient consent for publication: Consent obtained directly from patient(s).

This case report adheres to CARE Guidelines and the CARE Checklist has been provided to the journal editor.

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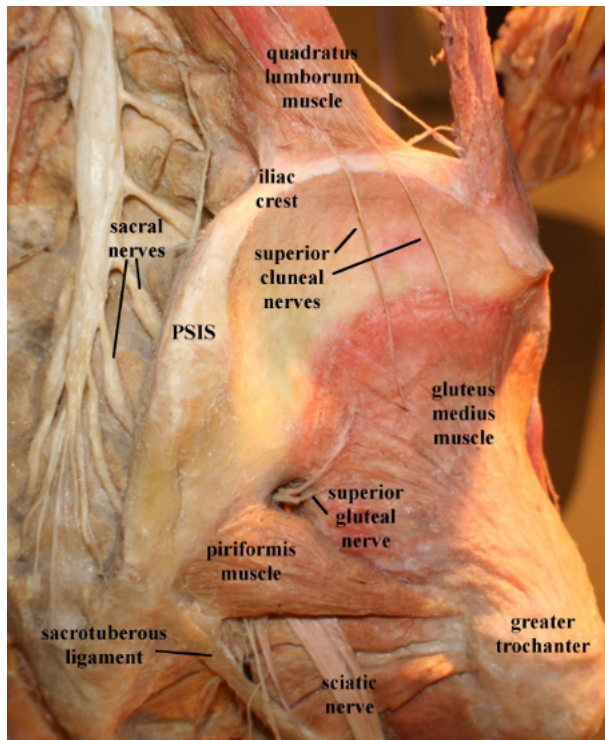


Fig. 1. Medial branches crossing the posterior iliac crest to innervate the upper buttock region (Image courtesy of Andrea Trescot MD)

lumbar extension, lateral flexion, rotation, or prolonged standing, sometimes radiating down the leg. A positive response to targeted local anesthetic injection can help confirm the diagnosis and distinguish it from sacroiliac joint pathology, which may present similarly.

Because superior cluneal neuralgia can mimic radiculopathy or sacroiliac joint pain, it is frequently overlooked in the differential diagnosis of low back pain. Accurate diagnosis requires thorough history-taking and physical examination, especially given the presence of several known risk factors. Early recognition is key, as conservative measures, such as physical therapy, posture correction, and medications, can significantly improve outcomes (12).

This retrospective case series describes the use of the Freedom® PNS System (Curonix LLC) to target the superior cluneal nerve for chronic neuropathic pain. Two patients with treatment-resistant lower extremity pain underwent successful trial stimulation followed by permanent implantation. Both experienced significant pain reduction and were able to taper off neuropathic medications within months. These findings suggest the

potential role of the superior cluneal nerve PNS as a practical option for managing refractory neuropathic pain.

METHODS

This case series was exempt from WCG IRB review for retrospective chart review (minimal risk).

Patient Selection

This retrospective study involved 2 patients who underwent a trial of the Freedom® PNS System targeting the superior cluneal nerve. Following successful diagnostic injections and trial stimulation with 50% pain relief or more, both patients proceeded with permanent implantation of the system. A retrospective chart review was performed to assess baseline characteristics and postimplantation outcomes.

Device Description

The PNS system used in this study (Freedom® Peripheral Nerve Stimulator System; Curonix LLC) consists of an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, and an external transmitter assembly with a wearable accessory (Fig. 2). The external transmitter utilizes high-frequency electromagnetic coupling technology to transmit data and radiofrequency energy to the 2-component implant, which the physician connects during the procedure. The physician also creates a separate, dedicated pocket to anchor the implanted device securely.

Permanent Implant Surgical Technique

Informed consent was obtained from all patients before the procedure. Patients were positioned prone on the operating table, and the implant site was prepared and draped in a sterile manner. Needle entry point and trajectory were determined through palpation and fluoroscopic guidance. Local anesthetic was administered along the planned introducer path, including the skin and deeper tissues.

A first skin incision was made with an 11-blade scalpel, followed by inserting a 13-gauge introducer needle, which was advanced subcutaneously within the fascial plane along the top of the iliac crest under image guidance. Additional local anesthetic was administered as needed. A 4-contact electrode array with tines was introduced through the cannula and positioned at the superior cluneal nerve. This technique was repeated contralaterally.

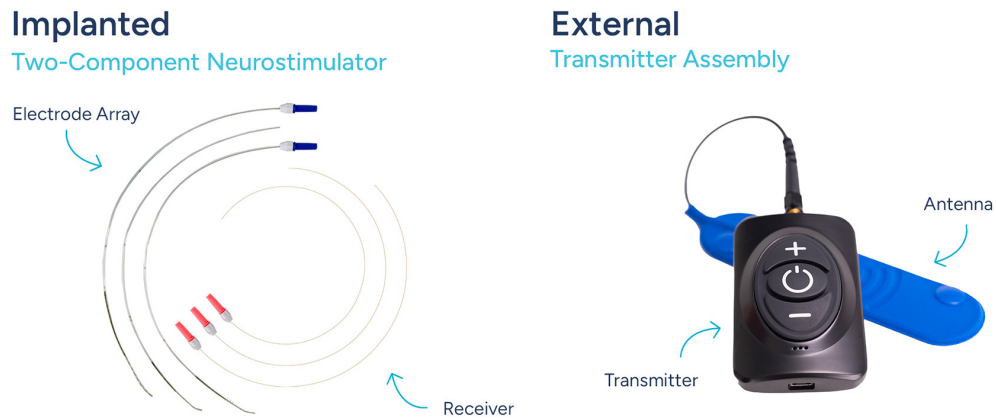


Fig. 2. Freedom PNS System

A separate second incision was made to create a receiver pocket via blunt dissection. Steering stylets were removed, and the receivers were connected to the implanted electrode arrays. The neurostimulators were then tunneled to the receiver pocket. Receiver coils were formed and secured using 2 nonabsorbable sutures, with the coil ends tucked beneath to avoid protrusion. The coils were anchored to the fascia at a minimum of 2 points, ensuring flat placement within the pocket. Layered incision closure was performed using deep and superficial absorbable sutures.

Programming Protocol

Patients were programmed with subthreshold stimulation at a frequency of 1,499 Hz and a pulse width of 30 μ s, using variable current intensities (mA). The transmitter assembly was held in place by a wearable accessory.

CASE PRESENTATIONS

Case 1: A 62-year-old man with type 2 diabetes mellitus and chronic peripheral neuropathy presented with severe leg and foot pain, with a Visual Analog Scale (VAS) score of 8/10, along with axial hip pain. His medical regimen included gabapentin 2,400 mg/day and duloxetine 60 mg/day. Due to persistent, treatment-resistant symptoms, he underwent implantation of a PNS system targeting the superior cluneal nerve. The patient presented with persistent pain reduction up to 6 months post-permanent implant.

Case 2: A 68-year-old woman with a history of idiopathic peripheral neuropathy presented with chronic hip and leg pain, with a VAS score of 7/10. Her symptoms

were persistent despite pharmacologic management, which included pregabalin at a dose of 450 mg/day. Given the limited relief from medical therapy and the ongoing impact on her quality of life, she was evaluated for and subsequently considered a candidate for PNS targeting the superior cluneal nerve. The patient presented with persistent pain reduction up to 6 months post-permanent implant.

RESULTS

Case 1: Following implantation, the patient reported significant pain relief, with his VAS score decreasing to 2-3/10 at 2 months post-permanent implant. Encouraged by the improvement, he began voluntarily phasing out his gabapentin dosage. Within 2 months, he had successfully discontinued gabapentin entirely, while continuing on a reduced dose of duloxetine at 30 mg/day. Notably, his preprocedural HbA1c was elevated at 8.5%, indicating suboptimal glycemic control at the time of implantation (Tables 1 and 2). No surgical complications were reported.

Case 2: Following implantation of the superior cluneal PNS system, the patient reported a marked improvement in her symptoms, with pain levels decreasing to 2/10 on the VAS at 3 months post-permanent implant. As a result of sustained pain relief, she voluntarily began tapering her pregabalin regimen and entirely discontinued the medication within 3 months post-implantation. Her glycemic control remained stable throughout treatment, with a preprocedural HbA1c of 5.6%, within normal limits (Tables 1 and 2). No surgical complications were reported.

Table 1. Pain levels before and after PNS implantation.

Patient	Pre-implant Pain (VAS)	Post-implant Pain (VAS)
Patient 1 (Diabetic)	8/10	2–3/10
Patient 2 (Idiopathic)	7/10	2/10

Table 2. Laboratory data.

Patient	HbA1c (%)	Glycemic Status
Patient 1 (Diabetic)	8.5	Elevated
Patient 2 (Idiopathic)	5.6	Normal

DISCUSSION

Low back pain is one of the most common and costly musculoskeletal conditions worldwide. Most cases are classified as nonspecific. Superior cluneal neuralgia (SCN) is an increasingly recognized cause of lower back, buttock, and referred leg pain. However, it remains underdiagnosed because its symptoms overlap with lumbar radiculopathy, sacroiliac joint dysfunction, and myofascial pain. Understanding the anatomy and pathophysiology of the superior cluneal nerves is essential for accurate diagnosis and treatment (13).

SCN entrapment is an underrecognized source of axial and gluteal pain. The superior cluneal nerve arises from the posterior rami of T11–L5. It passes through the thoracolumbar fascia about 3–4 cm from the midline at the iliac crest, a common site of entrapment (14).

Clinically, SCN presents with burning, stabbing, or electric shock-like pain in the lower back and buttock. Pain may radiate to the posterior thigh. Symptoms often worsen with lumbar extension, lateral bending, or prolonged standing. Because symptoms overlap with other conditions, diagnosis requires careful history and physical examination. Diagnostic nerve blocks help confirm the diagnosis. Relief after local anesthetic injection at the entrapment site supports SCN entrapment over sacroiliac or other lumbar pain syndromes (12,14,16).

Although SCN was traditionally managed surgically, interventional pain medicine now offers nonsurgical options. Conservative treatments such as physical therapy, posture correction, and activity modification may help in mild cases. Nerve blocks are often used as first-line therapy and can provide meaningful relief (15). For refractory or recurrent pain, minimally invasive

techniques such as PNS have shown benefit in case series and observational studies (15).

A case series by Abd-Elseyed (17) described 5 patients with various neuralgias, including superior cluneal involvement, who experienced substantial pain relief after PNS implantation. PNS is one of the oldest neuromodulation techniques, but early technical limitations restricted its use. Advances over the past decade have improved its safety and feasibility (18). PNS modulates pain signals through targeted electrical stimulation and can provide durable analgesia without the risks of open surgery. In 2024, the American Society of Interventional Pain Physicians published evidence-based guidelines supporting implantable PNS for moderate to severe chronic pain unresponsive to conservative therapy. These guidelines review the growing evidence for its clinical effectiveness (19).

Our 2 cases demonstrate meaningful pain reduction and decreased medication use after superior cluneal PNS implantation in patients with peripheral neuropathy. PNS likely works through multiple mechanisms along the nociceptive pathway, from peripheral nerves to the spinal cord and brain. The Gate Control Theory suggests that stimulation of large-diameter afferents inhibits nociceptive transmission in the dorsal horn (20–22).

Clinically, percutaneous PNS has demonstrated lasting benefits after short treatment periods and reduced analgesic use in several conditions. This aligns with our patients' voluntary discontinuation of gabapentin and pregabalin (23).

Limitations

Limitations include small sample size, absence of a formal tapering protocol, and lack of standardized functional outcomes. Findings from individual case studies may not be generalizable to outcomes across different contexts and circumstances. Nevertheless, the reproducible pattern—substantial pain relief with rapid self-directed deprescribing—aligns with the multimodal neuromodulation mechanisms summarized above and supports further controlled study.

CONCLUSIONS

PNS targeting the superior cluneal nerve resulted in substantial analgesia in 2 patients with chronic neuropathic pain, both of whom experienced significant reductions in their use of gabapentinoid medications. These outcomes suggest that an externally powered PNS system may offer a safe, minimally invasive, and

effective treatment option for individuals with refractory chronic pain who have not achieved adequate relief with conservative therapies. These findings further support its potential clinical utility in this patient population. The findings support its clinical utility in optimizing pain management while reducing reliance on systemic pharmacologic agents.

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