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Research Article

Safety and Effectiveness of Intraoperative Neuromonitoring in Peripheral Nerve Stimulation: A Single-Center Real World Data Analysis, and Review

Ioannis M Skaribas[1*], Peter D Vu[2], Gregory Blazek[2]

[1]Expert Pain Care, Houston, TX, USA

[2]McGovern Medical School at The University of Texas Health Science Center at Houston, Houston, TX, USA

[*]**Corresponding author:** Ioannis M. Skaribas, Expert Pain, 11451 Katy Fwy, Suite 340, Houston, TX 77079, USA

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Abstract

Background: Peripheral Nerve Stimulation (PNS) is an effective treatment for chronic peripheral neuropathic pain. Accurate lead placement traditionally relies on patient feedback, which may be unreliable under sedation. Intraoperative Neuromonitoring (IONM), long used in spinal cord stimulation, offers an alternative for guiding PNS implantation. The objective of this study was to demonstrate that PNS can be implanted accurately and safely under general anesthesia with IONM. **Methods:** This single-center, retrospective case series evaluated consecutive patients with chronic lower back pain who underwent permanent PNS implantation with the micro-implantable pulse generator (Nalu™ Neurostimulation System [Carlsbad, CA]) between April 2024 and February 2025. All procedures were performed under general anesthesia with fluoroscopic guidance and IONM. Pain outcomes were assessed using a numeric rating scale (NRS) at baseline and 3 months post-implant. Safety was evaluated by monitoring for intraoperative and postoperative adverse events through 3 months of follow-up. **Results:** A total of 30 patients (mean age 76.7 years, 66.7% female) were included and underwent successful implantation targeting the cluneal (90%) or lumbar medial branch nerves (10%). Mean NRS pain scores decreased from 8.9 at baseline to 2.6 at 3 months, representing a 70.5% mean reduction. All patients met responder criteria (≥50% pain reduction), and 16.7% were high responders (≥80% reduction). No adverse events were reported. **Conclusions:** PNS implantation guided by IONM under general anesthesia was safe, accurate, and effective in this case series. These findings support IONM as a valuable adjunct in neuromodulation and warrant further prospective study.

Keywords: Chronic pain; Electromyography; General anesthesia; Monitored anesthesia care; Neuromodulation; Micro-IPG

Introduction

Chronic nerve pain, including pain of peripheral nerve origin, is difficult to treat [1], and is a substantial burden for patients, who commonly experience reduced physical activity, compromised daily functioning, decreased productivity, sleep disturbances, depression, anxiety, and diminished health-related quality of life [2-11]. Only 30% to 40% of patients with chronic nerve pain achieve adequate response to conventional stepwise treatment, primarily pharmacotherapy [1]. For patients who fail to receive sufficient relief with conventional medical management, clinical guidelines now recommend interventional strategies, including neuromodulation via Peripheral Nerve Stimulation (PNS) [12,13]. A substantial clinical and real-world evidence base supports the ability of PNS to treat chronic pain of peripheral nerve origin [14-18]. Similar to spinal cord stimulation (SCS) [19], PNS delivers targeted electrical impulses to modulate neural activity and reduce pain, using implanted leads and a pulse generator [20]. Recent technologic advances have enabled PNS to provide the broad, complex programming capabilities and sophisticated stimulation protocols once only available with SCS systems [17,21,22].

PNS systems are inserted using a minimally invasive procedure, with successful implantation requiring precise lead placement proximal to the target peripheral nerve, facilitated by image guidance using ultrasound and/or fluoroscopy [12]. PNS

implantation under local anesthesia alone is uncommon [23], and is generally limited to the temporary placement of small devices [24]. Currently, most PNS procedures are performed with the patient awake (conscious) but sedated under Monitored Anesthesia Care (MAC), or with the patient asleep (unconscious) under general endotracheal anesthesia [23,25,26]. Confirmation of PNS-induced paraesthesia over the area of pain is typically elicited by intraoperative verbal feedback from the sedated patient during awake procedures, or by arousing patients during asleep procedures [12,27]. However, reliance on verbal patient feedback during lead implantation can be unreliable due to factors including patient stress, sedative-related confusion, impaired ability to communicate, and hearing or language difficulties [25,27-29]. Patients woken from general anesthesia may become acutely aware of pain, increasing their risk for agitation, medication-related disorientation, and impaired ability to communicate [27]. There are also safety concerns with MAC, as accidental oversedation can cause central respiratory depression, airway obstruction (due to an unprotected airway), brain damage, and death [28,30,31]. In cases of respiratory distress, the patient's prone position during the PNS procedure can also delay resuscitation [31]. Additional risks include patient movement during the procedure [29,32], and MAC may be contraindicated in individuals with sensitivity to sedatives or local anaesthetics [27].

The use of Intraoperative Neuromonitoring (IONM) with PNS can provide continuous, objective feedback on neural function. IONM involves Electromyography (EMG), Somatosensory Evoked Potentials (SSEP), and motor-evoked potentials (MEP) to ensure accurate lead placement [25,29] while facilitating procedural safety through continuous surveillance [25,29,33]. This added layer of monitoring may support safer and more efficient procedures and improved patient comfort and satisfaction. These advantages are clinically relevant because inaccurate or incomplete patient feedback can contribute to device-related problems; for example, in a 2023 analysis of PNS from the Manufacturer and User Facility Device Experience (MAUDE) database, 8.6% of 1012 device-related Adverse Events (AEs) were related to reports of "unwanted stimulation" [34].

IONM has been used with SCS for over two decades, with increasing frequency [26,35,36] and with studies showing its safety and efficacy to be comparable, if not superior, to awake implantation [26,27,35,37-39]. A 2023 systematic review identified a substantial body of Level II evidence indicating superior pain relief, less extraneous paraesthesia, fewer postoperative neurologic deficits, and a 27% shorter operating time with IONM versus asleep placement for SCS [26]. To mitigate the complications of neurostimulation, the most recent evidence-based guidance from the International Neuromodulation Society (INS) recommends IONM for procedures performed under general anesthesia [25]. However, the use of IONM during PNS procedures remains under-evaluated, with no published reports of IONM in PNS surgery.

In this manuscript, we report the first known case series of standardized use of IONM for permanent PNS therapy using the micro-implantable pulse generator (micro-IPG; Nalu™ Neurostimulation System [Carlsbad, CA]). The micro-IPG has shown high treatment efficacy, effectiveness, and safety across two randomized controlled clinical trials [17,40] and one large-scale real-world registry study in patients with chronic neuropathic pain [18]. The objective of this study was to demonstrate that PNS can be implanted accurately and safely under general anesthesia with IONM.

Materials and Methods

This observational, retrospective real-world study was conducted at a single, outpatient private practice pain clinic (Expert Pain, Houston, TX). All patients who initially presented with chronic peripheral neuropathic pain and numbness over the lower back and superior buttock area, had successful PNS trial procedures (i.e., achieved ≥50% pain reduction during the 7-day trial period), and were permanently implanted with PNS targeting the cluneal or lumbar medial branch nerves between April 2024 and February 2025 were included in this case series. The same surgeon (study author IS) performed all trial and permanent implantation procedures; IS is a double board-certified anaesthesiologist and interventional pain management specialist who has completed more than 2,000 implant procedures over the last 25 years.

To ensure ethical compliance and patient safety, Institutional Review Board (IRB) approval was obtained from WCG IRB, Puyallup, WA (IRB reference: 1331269), and all participants provided informed consent following standards of Good Clinical Practice [41] and Committee of Publication Ethics (COPE) guidelines [42]. The study followed IRB guidelines for data confidentiality and regulatory adherence. Data used herein were collected per usual clinical practice and stored in the patient records at the clinic. The PROCESS guidelines for case series reporting were used to draft this manuscript [43].

Permanent PNS implantation procedures were performed in accordance with the clinic's standard of care, with patients under general endotracheal anesthesia in a prone position, utilizing fluoroscopy to guide anatomic lead placement and IONM (Cadwell Cascade Pro, Cadwell Industries, Kennewick, WA) to ensure accurate electrode placement. Anesthesia consisted of midazolam, fentanyl, and propofol for induction and a volatile agent for maintenance, typically sevoflurane. Trained and experienced technicians operated the IONM device. IONM feedback alone was used to determine if PNS coverage was appropriate; patients were not woken during the surgery. All patients were administered intraoperative antibiotics, and all incisions were closed using Vicryl

and Monocryl sutures. American Society of Regional Anesthesia and Pain Medicine (ASRA) guidelines for anticoagulation were followed for any patients on antithrombotic therapy [44].

Procedures lasted approximately 1.5 hours. Afterward, patients were given detailed postoperative instructions, prescribed a 7-day course of antibiotics, and were instructed to return for evaluation 72 hours after the procedure. After sufficient site healing, all PNS devices were programmed to alternate every 3 minutes between tonic and sub-paraesthesia stimulation.

To evaluate treatment effectiveness, pain scores were obtained from patients using a standard numeric rating scale (NRS, 0 to 10) prior to the PNS trial (i.e., at baseline) and at 3 months after permanent PNS implantation. Response and high response were defined as ≥50% and ≥80% reductions in pain scores from baseline, respectively. To evaluate procedure safety, patients were evaluated immediately post-operation, before discharge, and via phone call within 24 hours. Descriptive statistics were used to calculate and summarize outcomes, including change from baseline in pain scores and response rate.

Results

A total of 30 patients received permanent PNS implantation targeting the cluneal nerve (27/30; 90.0%) or lumbar medial branch nerves (3/30; 10.0%) for chronic intractable lower back pain. Patients were a mean 76.7 years of age (range, 66-89) and 66.7% were female (Table 1). Table 2 provides detailed clinical profiles for each patient, including treatment muscle group targets. The majority (66.7%) had previous back surgery and 83.3% had previously implanted, operating SCS devices. Mean patient baseline pain score was 8.9 (range, 8-10).

Characteristic	N=30
Age, mean (range)	76.7 (66-89) years
Median	77 years
Sex, female	66.7% (20/30)
Mean baseline NRS pain score (range), pre-PNS	8.9 (8-10)
Mean NRS pain score (range), 3 months post-PNS	2.6 (1-4)
Mean pain percent reduction (range), 3 months post-PNS	70.5% (55.6%-88.9%)
Responder rate* 3 months post-PNS	100.0% (30/30)
High responder rate** 3 months post-PNS	16.7% (5/30)
Abbreviation: NRS: numeric rating scale; PNS: peripheral nerve stimulation. *Defined as ≥50% pain reduction. ** Defined as ≥80% pain reduction.	

Table 1: Patient Characteristics (N=30).

Age	Sex	SCS Implant	Previous Spinal Surgery	Patient Diagnosis Summary	IONM Muscle Group Target	NRS		
						Baseline	3 Mo	% Change
74	F	Yes	Lumbar fusion, lumbar decompression, cervical fusion	Bilateral cluneal, low back pain, leg pain, left side worse	Left: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis Right: Iliopsoas, vastus lateralis	8	2	75.0%

78	M	Yes	Cervical fusion, cervical laminectomy, thoracic laminectomy, lumbar laminectomy, L1 and L2 fusion	Bilateral cluneal, low back and buttocks	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	8	1	87.5%
75	F	Yes	Back surgery, back fusion	Bilateral cluneal, low back (entire back), right side worse	Left and right: Iliopsoas, vastus lateralis	8	2	75.0%
74	F	Yes	Right hip replacement	Bilateral cluneal, low back, starts on right side, spreads to left	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	2	77.8%
89	M	Yes	None	Bilateral cluneal, low back, starts on right side, spreads to left	Left and right: Tibialis anterior	9	2	77.8%
78	M	Yes	Lumbar laminectomy and fusion	Bilateral cluneal, low back, equal pain on both sides	Left: Rectus abdominus, tibialis anterior, gastrocnemius Right: Tibialis anterior, gastrocnemius	9	1	88.9%
79	F	Yes	Back surgery, right SI fusion, left SI fusion, total hip replacement	Bilateral cluneal, low back, equal pain on both sides	Left: Iliopsoas vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis Right: Iliopsoas vastus lateralis, tibialis anterior, gastrocnemius	9	1	88.9%
88	M	Yes	None	Bilateral cluneal, low back, equal pain on both sides, leg pain	Left: Rectus abdominis, vastus lateralis/medialis, tibialis anterior, gastrocnemius, abductor hallucis Right: Rectus abdominis, tibialis anterior, gastrocnemius, abductor hallucis	9	4	55.6%
78	F	Yes	Unspecified lumbar surgery	Bi-lateral medial branch, low back, equal pain on both sides, both leg pain	Left and right: Iliopsoas vastus lateralis	9	1	88.9%
76	F	Yes	Lumbar laminectomy, L4-5 SI fusion, right SI fusion	Bilateral cluneal, low back, across back	Left and right: Rectus abdominis, iliopsoas vastus lateralis/medialis	9	3	66.7%

80	F	Yes	None	Bilateral cluneal, low back, radiates to both sides	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
81	M	No	C3 laminectomy, back surgery	Bilateral cluneal, low back	Left: Iliopsoas, vastus lateralis/medialis, tibialis anterior, gastrocnemius, abductor hallucis Right: Iliopsoas, vastus lateralis/medialis, abductor hallucis	9	2	77.8%
76	F	Yes	None	Bi-lateral medial branch, mid/low back pain	Left: Gluteus maximus, iliopsoas, vastus lateralis Right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius	8	1	87.5%
73	F	Yes	Cervical laminectomy, lumbar laminectomy	Bilateral cluneal, low back, both sides, down buttocks and legs	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	2	77.8%
84	F	Yes	Lumbar fusion	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	4	55.6%
69	M	Yes	C5-6 discectomy, lumbar laminectomy	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	8	3	62.5%
81	F	Yes	None	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	10	3	70.0%
68	F	Yes	None	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
77	F	Yes	None	Bilateral cluneal, low back	Left: Rectus abdominis, vastus lateralis/medialis, tibialis anterior, gastrocnemius Right: Rectus abdominis, tibialis anterior, gastrocnemius	9	3	66.7%
77	M	Yes	Right L4-5 discectomy	Bilateral cluneal, low back, mostly left side	Left: Vastus lateralis/ medialis, tibialis anterior Right: Vastus lateralis/ medialis, tibialis anterior, abductor hallucis	9	4	55.6%

82	F	Yes	Laminectomy	Bilateral cluneal, low back and legs	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
79	M	Yes	L5-S1 laminectomy, posterior fusion	Bilateral cluneal, low back, right side only	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	10	3	70.0%
76	F	No	None	Medial branch, bra line/mid back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
78	F	Yes	Back surgery x3	Bilateral cluneal, low back	Left: Rectus abdominis, vastus lateralis/medialis, tibialis anterior, gastrocnemius, abductor hallucis Right: Rectus abdominis, tibialis anterior, gastrocnemius, abductor hallucis	9	2	77.8%
73	M	No	None	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
71	F	No	Neck fusion	Left cluneal/SI, low back/hip	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	4	55.6%
84	M	No	L4-5 disc surgery, facet rhizotomy	Bilateral cluneal, low back, across back	Left and right: Iliopsoas, vastus lateralis	9	4	55.6%
70	F	Yes	Unspecified back surgery	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%
68	F	Yes	Unspecified lumbar surgery	Bilateral cluneal, low back and legs, left side worse	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	4	55.6%

66	F	Yes	None	Bilateral cluneal, low back	Left and right: Iliopsoas, vastus lateralis, tibialis anterior, gastrocnemius, abductor hallucis	9	3	66.7%

F: Female; M: Male; NRS: Numeric Rating Scale; PNS: Peripheral Nerve Stimulation; SCS: Spinal Cord Stimulation; SI, Sacroiliac

Table 2: Detailed Patient Profiles.

All PNS surgeries were performed and completed without incident. All devices were activated within 10 days following surgery, with programming optimized and tailored to patient preferences. All patients' postoperative courses were unremarkable, with no reports of infection, site pain, electrode repositioning, lead migration, loss of stimulation or unpleasant/unwanted stimulation, or serious AEs through 3 months of follow-up.

At 3 months, mean patient pain score was 2.6 (range, 1-4), indicating an average pain reduction of 70.5% (range, 55.6% to 88.9%) (Table 1). All (100%) patients met response criteria (≥50% pain reduction), and 16.7% were high responders (≥80% pain reduction).

Discussion

This case series confirms the effectiveness and safety of using IONM during PNS implantation. All patients achieved meaningful (i.e., ≥50%) pain relief. Notably, 16.7% were high responders with ≥80% pain relief, while the overall reduction in pain intensity was 70.5%. These results align with published data from two large randomized controlled trials (COMFORT and COMFORT 2) evaluating the micro-IPG system for the treatment of peripheral neuropathic pain, without any specified IONM use [40,45]. In these studies, pooled 3-month data (N=103) indicated an 81% responder rate with a 30% high responder rate and an average pain reduction of 66% [40].

IONM used during PNS plays a distinct technical and physiologic role from its use in SCS, but provides similar benefits in terms of optimizing lead placement accuracy and reducing the risk of non-target stimulation. In SCS, IONM is used to confirm appropriate activation of the dorsal column pathways and ensure safe epidural lead placement by avoiding the stimulation of ventral motor roots or other non-target tracts. This process relies on monitoring central conduction pathways, sometimes with the aid of fluoroscopic guidance, to confirm dorsal column engagement [46]. In contrast, PNS targets specific peripheral nerves corresponding to the patient's area of pain, typically involving local peripheral nerve mapping under visualization and low-threshold stimulation to ensure accurate lead placement within the intended nerve distribution [47].

By confirming nerve proximity and adequacy in real time, IONM during PNS enhances the precision of lead positioning and minimizes the likelihood of off-target activation. Evidence from the current study and prior research [25,28,29] shows that IONM offers valuable real-time assessment to guide safe and accurate lead placement without the need for intraoperative patient feedback. With IONM, SSEPs and MEPs monitor the functional integrity of sensory and motor pathways, respectively, during neurointerventional procedures, ensuring that these critical structures are not compromised [29]. The accuracy of electrode placement in anesthetized patients is achieved by eliciting and capturing EMG responses from specific muscle groups innervated by the targeted peripheral nerves [25,28,29]. In addition, intraoperative SSEP collision testing may be used as a physiologic marker of paraesthesia [25,28]. Figures 1 shows examples of the IONM display in the operating room, demonstrating that individual channels can be stimulated independently, and highlighting the extent of therapeutic coverage. Figure 2 shows lead placement along a patient's iliac crest, along with the IONM display during active stimulation.

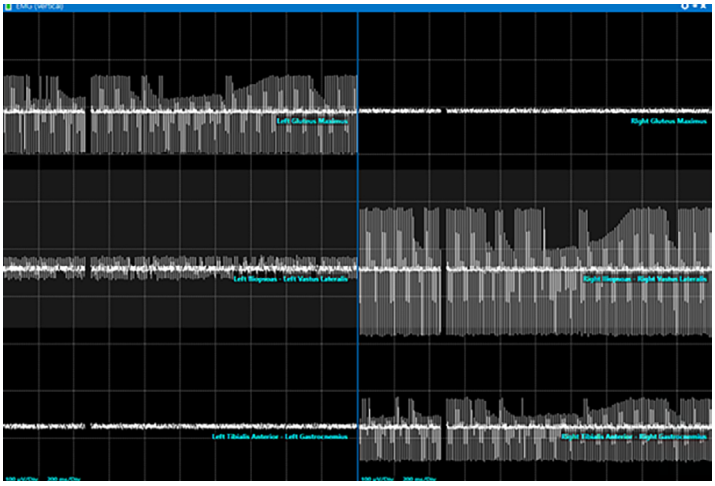

Figure 1: Examples of IONM display, demonstrating that individual channels can be stimulated independently (left and right targets shown), highlighting the extent of therapeutic coverage for the neuromodulation therapy.

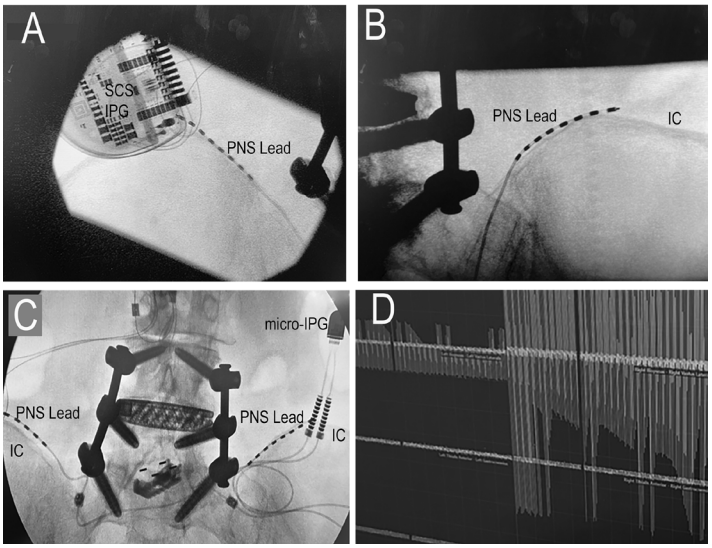

Figure 2: The upper left image shows the placement of the PNS lead along the superior margin of the patient's left Iliac crest (IC) and the upper right image shows placement along the right IC. The lower left image shows the bilateral configuration of the leads along with the pre-existing spinal stabilization hardware. The lower right image shows intraoperative neuromonitoring during stimulation, in which the patient's left side was being actively stimulated showing adequate coverage (left side of image).

As IONM capabilities are increasingly being integrated directly into device platforms [48,49], this is a timely moment for physicians to consider the roles and application of this technology in clinical practice. The potential exists for IONM to decrease healthcare resource utilization related to PNS implantation by increasing lead placement accuracy, leading to fewer revision or repeat procedures [27], and decreasing intraoperative time [26,27]. IONM also eliminates the need for intraoperative wake-up testing, which can otherwise add an average of 35 minutes to procedures [25,27]. Despite these potential advantages, IONM has not been widely adopted for use with PNS. Several factors contribute to this situation, including resource availability, healthcare provider experience, and reimbursement [29,50,51]. While support for IONM is typically available in urban teaching hospitals, this is not always the case in nonteaching hospitals, rural centers, or smaller surgical centers [51]. Likewise, in some settings, IONM has been shown to reduce overall operating room and anesthesia time [27], while in other cases, IONM setup and monitoring requirements can lead to longer procedure durations [52]. Additionally, engaging third-party neuromonitoring companies can present challenges [53].

It is also essential for healthcare providers to be aware that there are applicable reimbursement codes (Current Procedural Terminology [CPT] 95940, 95941) when utilizing IONM services. Many facilities will either directly contract with IONM companies or reimburse them, subsequently billing insurance carriers for these expenses. For facility administrators, effective communication and a thorough understanding of the clinical benefits of IONM during PNS are essential.

Limitations

This study lacked a comparison or control group, limiting the ability to directly assess outcomes against alternative approaches. However, selection bias was minimized by including all patients who received a permanent PNS implant at the clinic during the study period, with none excluded from analysis. This study focused exclusively on patients who received the micro-IPG PNS system; therefore, its findings may not be generalizable to larger PNS devices. Additionally, this research was conducted at a single center with a physician highly experienced in both IONM and PNS permanent implants, which precludes drawing conclusions regarding the learning curve for these procedures. While these early (3-month) outcomes are expected to best reflect the procedural benefits of IONM, all patients will be followed for up to 12 months to assess durability of response.

Finally, only two nerve sites were tested in this study. Additional research is warranted to investigate outcomes when IONM is used during PNS procedures for chronic peripheral nerve pain affecting the upper and more distal lower limbs.

Conclusion

The use of IONM in PNS procedures for chronic lower back pain is safe and effective and can result in outcomes comparable or superior to published PNS research without IONM. These positive results warrant additional research and consideration.

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Ethics Approval

This study involves human participants and was approved by WCG IRB Tracking Number: 20221779. Participants gave informed consent to participate in the study before taking part.

Conflicts of Interest

IS reports consultancy for Abbott Medical and Nalu Medical. DV and GB report no conflicts.

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Data Availability Statement

All data relevant to the study are included in the article.

Contributors

All authors either made a substantial contribution to the study concept, design, and/or analysis. All authors approved the final version of the manuscript. IS is responsible for the overall content as the guarantor and accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled decision to publish.

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