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Using Peripheral Nerve Stimulation (PNS) to Treat Neuropathic Pain: A Clinical Series

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Objective: We examined the efficacy of peripheral nerve stimulation (PNS) in treating neuropathic and causalgic pain, with a stimulation system specifically designated for PNS itself.

Materials and Methods: A total of 15 patients were treated between January 2011 and March 2012. The percutaneous lead was implanted on the nerves, exposing it on the electrical nerve stimulation (ENS) guide. The average numeric rating scale (NRS) preimplant was 8.46, and the oxycodone intake was 90 mg/day.

Results: Of the 15 patients, 3 failed the trial phase and 12 were implanted with a permanent pulse generator (Lightpulse 100, Neurimpulse, Rubano, PD, Italy). At an average of 9.3 months of follow-up, the average NRS score was 3.46 ($p < 0.001$), and the average Likert scale score at 7 points was 5.91. Nine patients were working prior to their injuries, seven of whom returned to work after receiving an implant. The average oxycodone consumption decreased to 30 mg/day, and the pregabalin dosage decreased to 75 mg/day.

Conclusion: Our study results confirm that PNS is an effective modality in managing severe neuropathic and intractable pain following multiple joint surgeries that are complicated by causalgic pain.

Keywords: Case series, ischemic pain, neuropathic pain, peripheral nerve stimulation, peripheral neuropathy

Conflicts of Interest: The authors have declared no conflicts of interest.

INTRODUCTION

Neuropathic pain is a complex, chronic pain state that usually develops as a result of lesions or disease affecting the somatosensory nervous system either peripherally or centrally. With neuropathic pain, the nerve fibers themselves might be damaged, dysfunctional, or injured. These damaged nerve fibers lead to pathological electrical activity in other pain centers. The impact of a nerve fiber injury includes a change in nerve function both at the injury and in the areas around the injury (1). Examples of neuropathic pain include painful polyneuropathy, postherpetic neuralgia, trigeminal neuralgia, and poststroke pain. Clinically, neuropathic pain is characterized by spontaneous ongoing or shooting pain and an evoked amplified pain response after noxious or non-noxious stimuli.

Complex regional pain syndrome (CRPS), type I, is a subset of neuropathic pain that affects mostly young, active individuals. The upper and lower extremities are most often affected.

When the pain is focally in the hand or foot, it may be difficult to achieve therapeutic benefit with spinal cord stimulation (SCS).

Peripheral nerve stimulation (PNS) is an appropriate therapeutic management option for these conditions when other less invasive modalities have failed. In fact, the placement of an electrode on the affected nerve or plexus could deliver stimulation that is exactly targeted to the painful area(s). The methodology has been relatively slow to develop compared with SCS, primarily because of the lack of clinical interest in the community of implanting physicians, the lack of devices specifically designed for this task, and the lack of rigorous scientific studies that could reach the Food and Drug Administration approval threshold.

The recent development of devices specifically designed for PNS and the excellent clinical results that have been reported in contemporary publications have renewed interest in this field. The goal of our study was to present our series of 15 patients who were affected by neuropathic pain and treated with a stimulation system designed specifically for PNS.

MATERIALS, METHODS, AND SURGICAL TECHNIQUES

All patients in this series were implanted with products with the CE mark of approval. The implantation was part of the patients' treatment plans, not part of a prospective study requiring Institutional Review Board approval. This study exclusively examined the data collected during the patients' initial visits and during subsequent follow-up visits.

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Table 1. Patient Database: Etiology of the Pain and Involved Nerves.

Case no.	Pathology	Implant site	Status
1	Frozen shoulder	Suprascapular nerve	Permanent implant
2	Trigeminal neuralgia	Foramen ovale, III branch	Permanent implant
3	Occipital neuralgia	Greater occipital nerve	Permanent implant
4	Occipital neuralgia	Greater occipital nerve	Failed trial
5	Causalgia of the upper extremity	Brachial plexus	Permanent implant
6	Causalgia of the upper extremity	Brachial plexus	Permanent implant
7	Causalgia of the upper extremity	Ulnar nerve	Permanent implant
8	Causalgia of the upper extremity	Ulnar nerve	Permanent implant
9	Causalgia of the upper extremity	Median nerve	Permanent implant
10	Causalgia of the upper extremity	Radial nerve	Permanent implant
11	Intercostal neuralgia	VIII Intercostal nerve	Permanent implant
12	Causalgia of the foot	Posterior tibial nerve	Permanent implant
13	Causalgia of the foot	Posterior tibial nerve	Permanent implant
14	Intractable lumbar radiculopathy	Common peroneal nerve	Failed trial
15	Intractable lumbar radiculopathy	Common peroneal nerve	Failed trial

In all patients, all previous therapies failed.
All patients had this complaint for >6 months.

Between January 2011 and March 2012, we treated 15 patients (median age, 46.8 years, 7 males, 8 females).

The etiology of the pain and the implanted areas are shown in Table 1.

The patients completed questionnaires prior to their implants and at 3-, 6-, 9-, and 12-month follow-ups.

The data collected in the questionnaire included the topography and duration of the pain, the numeric rating scale (NRS), and the patient's work status. The primary goal of the data collection was to quantify the reduction of the pain score; we also tracked the subjective improvement of the pain (Likert scale) (2) and the occurrence of postimplant complications.

The patient's medication intake was recorded prior to the implant and at the follow-up visits.

The average preimplant NRS was 8.46; nine patients were employed prior to the injury, and they had to suspend their work activities because of the pain. The patients averaged 90 mg/day of oxycodone and 250 mg/day of pregabalin prior to their implants.

All implants were performed under general anesthesia (i.v. propofol) with a laryngeal mask. Adequate informed consent for PNS was obtained from each patient prior to the procedure.

The nerve was identified with electrical nerve stimulation (ENS) and partial surgical exposure of the nerve on an ENS guide. Neurosurgical assistance was obtained when indicated.

This approach was chosen for two main reasons. First, it allows deep nerves, such as the posterior tibial nerve, or nerves with a nonlinear trajectory, such as the ulnar and radial nerves at the elbow, to be reached. Second, this approach enhanced the ability to position the lead in close proximity to the nerve.

We utilized a 21 G needle with a length of 100 mm and an insulated tip of 6 mm, connected to an external pulse generator. After the targeted nervous structure was identified (nerve or plexus) via muscle contractions elicited at 0.3–0.5 V and 4 Hz, we then proceeded with open dissection of the fascia and muscle planes, following the needle until the nerve was reached and exposed (1,2).

The brachial plexus was approached percutaneously, via a posterior interscalenic trajectory, according to the technique described by Pippa et al. for a brachial plexus blockade (3).

After the nerve or plexus was reached, a cylindrical quadripolar lead (Lightline, Neurimpulse, Rubano, PD, Italy) was placed on the nervous structure(s). The lead has a 1.2 mm diameter. There are two models, one with a 4 mm intercontact length (for nerve placement) and one with a 6 mm intercontact length (for brachial plexus implantation). The spiral configuration of the conductive filaments provides both stiffness and elasticity to the lead.

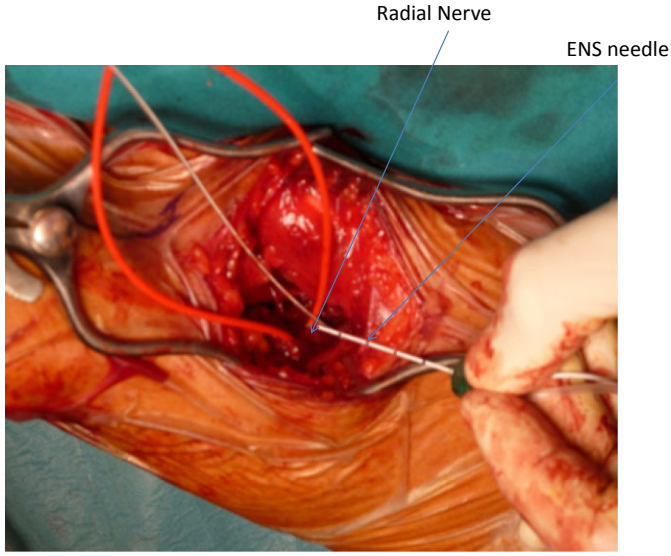

Figure 1. G.C. (November 2, 2011): lesion of the radial nerve at the wrist.

After some centimeters, the lead came in contact with the epinevrium and was fixed with a silicon ring adapter at the perinevrium fascia.

In this manner, the dislocation of the lead is difficult, and the stimulation occurs directly on the nerve and not on the perineurium structure (Fig. 1).

A 4–5 Hz stimulation confirms, in mixed nerves, the correct positioning of the lead. The electrode was then secured to the fascia with a silastic anchor, and we proceeded to close the incision in layers (Fig. 2). The lead was externalized through a separate extension for a trial period (45 days for each patient).

In the postoperative period, radiological confirmation of the position of the lead was obtained (Figs. 3 and 4). In some cases we

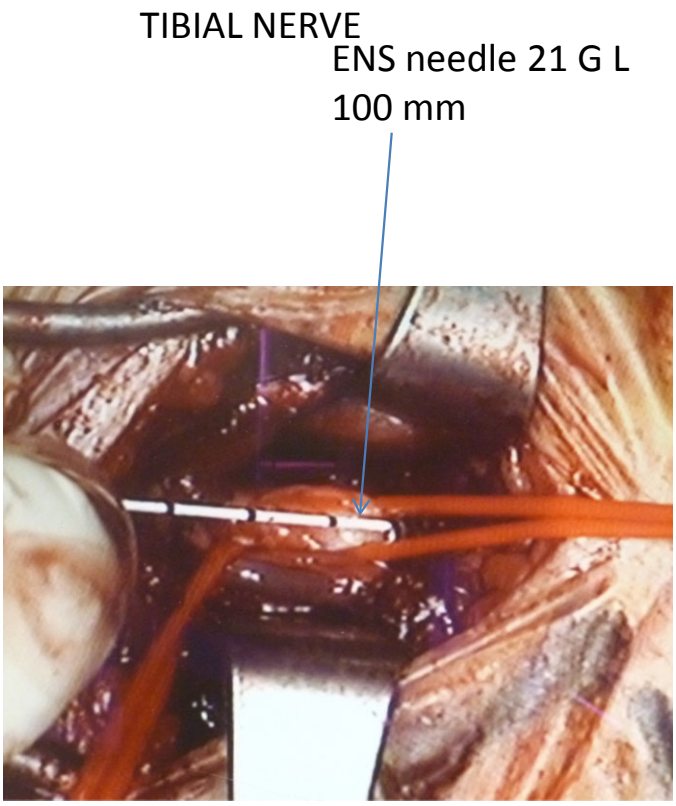

Figure 2. C.M. (September 12, 2011): exeresis schwannoma on the tibila nerve at the ankle.

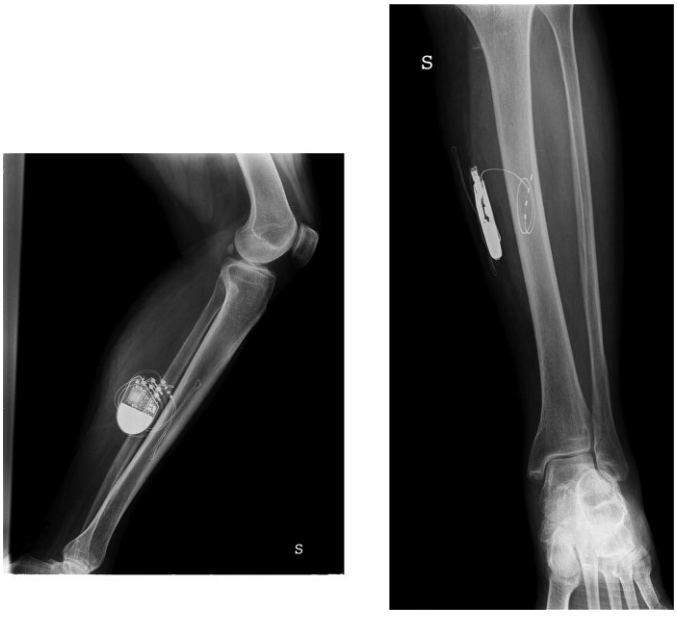

Figure 3. C.M. (September 12, 2011) exeresis Schannoma on tibial nerve at the ankle.

obtained a spiral three-dimensional computerized axial tomography to confirm the position of the lead within the neurovascular bundle (Fig. 5); this process was performed more frequently with deep nerves, such as the posterior tibial nerve in the middle third of the leg. Utilizing three-dimensional imaging has allowed us to evaluate in timing for the persistent positioning of the lead with the neurovascular bundle.

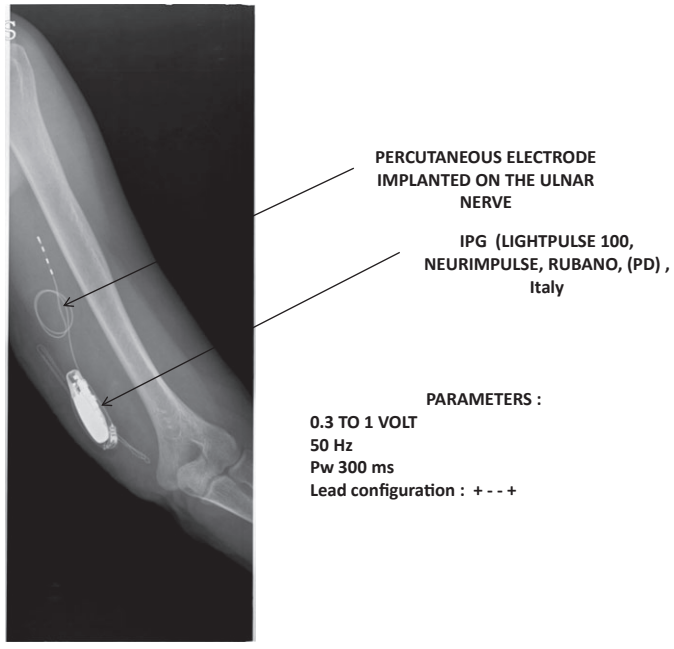

Figure 4. M.S. (October 3, 2011): traumatic lesion of ulnar and radial nerve at the upper arm, with necrotic fascitis.

At the end of the trial, 12 patients obtained over 50% NRS reduction and were deemed to be candidates for implantation of the pulse generator (Lightpulse 100, Neurimpulse). The implanted pulse generator (IPG) dimensions are volume 13 cc, thickness 7 mm, and weight 26 g. This IPG was developed with the goal of being implanted adjacent to the insertion point of the peripheral stimulation lead. The current IPG is quadripolar and only accepts one cylindrical quadripolar lead, which is made by Neurimpulse (30 or 50 cm extensions are available).

The average stimulation voltage was 0.91 (±0.73) V; the average frequency was 21 (±12.12) Hz; and the average pulse width was 247 (±68) μs.

When the voltage was more than 1 V, the IPG was programmed in a cyclic mode (5 sec on and 10 sec off).

The details of the electrical parameters utilized in each patient are listed in Table 2.

The follow-up consisted of office visits and completing specific questionnaire forms. The following data were collected at each follow-up: the NRS value, 7-point Likert scale, and work status.

Data points were collected at 3-, 6-, 9-, and 12-month follow-ups. The medication intake, work status, and subjective efficacy were also measured at these data points.

RESULTS

At an average follow-up of 9.3 months, the average NRS was 3.46 (*vs.* a preoperative average NRS score of 8.46) ($p < 0.001$), while the average Likert Scale was 5.91 (pointing to a significant reduction in the pain intensity compared with the preoperative period) (Fig. 6).

Of the nine patients who were working prior to their injuries, seven returned to work (albeit with some limitations for some) after their implants.

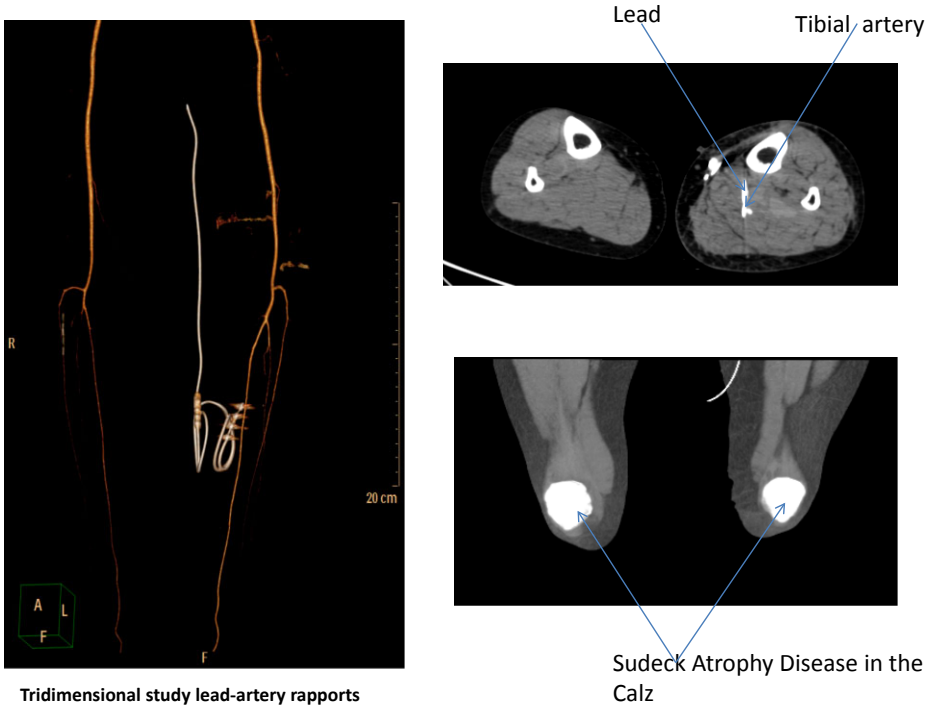

Figure 5. C.M. (September 12, 2011) exeresis Schannoma on tibial nerve at the ankle.

Table 2. Details of the Stimulation Parameters for Every Patient.

Patients	M/F	Age	Site of implant	Date of implant	Tension of stimulation (Volts)	Frequency (Hz)	Pulse width (msec)	Duty cycle (sec on, sec off)	Follow-up trial phase
A.C.	F	74	Great occipital nerve	November 8, 2011	1.98	20	366	5 on, 10 off	Definitive
B.A.	M	41	Great occipital nerve	November 9, 2011	1.35	20	366	5 on, 10 off	Trial failed
B.I.	F	47	Brachial plexus		0.95	20	244	Off	Definitive
C.G.	M	57	Brachial plexus	January 18, 2012	0.24	4	183	5 on, 10 off	Failed
O.S	F	35	Brachial plexus	April 27, 2011	0.40	10	305	Off	Definitive
B.M.	M	71	Sovrascapular nerve	November 30, 2011	1.35	4	214	5 on, 10 off	Definitive
F.L.	M	28	Intercostal nerve	March 30, 2011	0.16	20	244	10 on, 05 off	Definitive
C.R.	M	45	Sciatic nerve (surgical lead)	October 3, 2012	0.64	20	275	Off	Definitive
R.D.	M	65	Sciatic nerve (surgical lead)	August 28, 2012	0.32	40	214	Off	Definitive
C.M.	F	55	Tibial nerve	September 12, 2011	2.46	20	214	On	Definitive
G.C.	M	39	Radial nerve	November 2, 2011	0.24	48	214	Off	Definitive
M.S.	F	32	Radial + ulnar nerve	October 3, 2011	0.24	40	122	Off	Definitive
M.I.	M	80	Peroneal nerve	April 27, 2011	1.11	40	305	5 on, 10 off	Failed
R.S.	F	39	Peroneal nerve	May 18, 2011	1.03	30	397	Off	Failed
V.R.	F	46	Trigeminal nerve	October 19, 2011	1.98	4	183	5 on 10 off	Definitive

The average oxycodone consumption decreased to 30 mg/day, and the average pregabalin consumption decreased to 75 mg/day. Eight patients completely stopped taking medications.

Three patients were explanted at the end of the trial phase because of inefficacy of the modality: one patient had occipital neuralgia, and the other two had pain in the common peroneal nerve distribution in the context of a failed back syndrome. There were no other adverse occurrences.

Battery consumption was minimal, and the most common configuration on the polarities on the nerves was two central anodes and two external cathodes (–++–). On the plexuses, the polarity configurations were tailored to the patient's individual anatomy and to the area of the plexus that was targeted for stimulation.

Table 3 shows the data for each individual patient.

DISCUSSION

Several publications have documented the efficacy of PNS in treating neuropathic pain. PNS is a unique neuromodulation modality that is rapidly gaining popularity for a variety of clinical conditions (3). In 1996, Hassenbusch et al. published the results of a prospective, consecutive series describing PNS in treating severe reflex sympathetic dystrophy (RSD) or CRPS I (4). The patients had symptoms entirely or mainly in the distribution of one major peripheral nerve. Plate-type electrodes were surgically placed on the

affected nerves of 32 patients and tested for 2 to 4 days. The patients were followed for 2 to 4 years, and a disinterested third-party interviewer performed the final patient evaluations. Of the 32 patients tested, 30 (94%) underwent implantation of the IPG, having experienced a ≥50% reduction in pain. Long-term good or pain relief was experienced in 19 (63%) of 30 patients. In successfully treated patients, allodynic and spontaneous pain was reduced on a scale of 10 from 8.3 ± 0.3 preimplantation to 3.5 ± 0.4 at the latest follow-up ($p < 0.001$). Changes in vasomotor tone and patient activity levels all showed marked improvement, but motor weakness and trophic changes showed less improvement. Six (20%) of the 30 patients undergoing PNS placement returned to part-time or full-time work after being unemployed prior to the implantation. The authors concluded that PNS can provide good relief for RSD, but is limited to the distribution of one major nerve.

Novak and Mackinnon reported on 17 patients with a variety of chronic pain conditions who underwent PNS implantation (5). All patients had sustained nerve injuries (10 of the ulnar nerve, 1 of the radial nerve, and 5 of the posterior tibial nerve) and were affected by severe neuropathic pain. In an average 21-month follow-up period, five patients (29%) obtained excellent pain relief, six patients (35%) had good pain relief, four subjects (24%) had fair relief, and in two patients (12%) there was minimal relief.

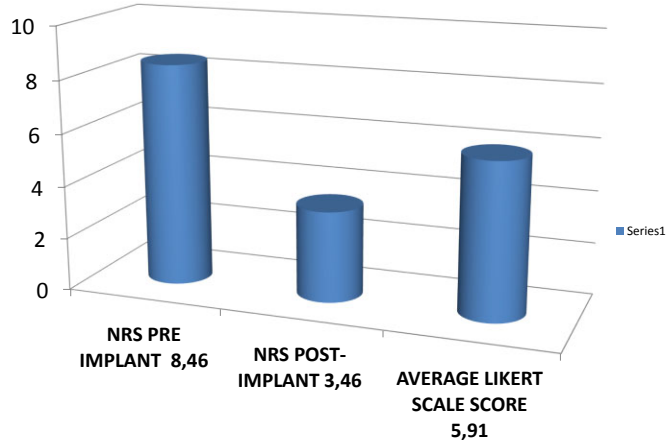

Figure 6. Preimplant and postimplant NRS value.

William and Cooney reported excellent pain relief in their series of patients with causalgic pain treated with PNS (6).

Hammer and Doleys reported good pain relief with peripheral stimulation in a case of traumatic lesion of the greater occipital nerve followed by severe occipitocervical headaches (7).

Slavin et al. reported a case of facial trigeminal nerve stimulation in a patient with trigeminal neuralgia who had failed conventional treatment (8,9).

Rodrigo-Royo et al. and Johnstone and Sundaraj reported on a series of four and eight patients, respectively, with occipital neuralgia treated with PNS of the greater occipital nerve, and showed excellent results with minimal side effects (10,11).

The efficacy of PNS on nociceptive pain in healthy volunteers was studied by Ellrich and Lamp (12). Noxious infrared laser stimulation of the left hand dorsum evoked cortical potentials (LEP) by selective excitation of Aδ-fiber nociceptors in 15 healthy volunteers under controlled and PNS conditions. LEP were recorded before, during, and after electric Aβ-fiber stimulation (i.e., PNS) of the left superficial radial nerve. Under controlled conditions, the LEP and intensity ratings remained unchanged. The electrophysiologic data provide evidence that electric stimulation of peripheral Aβ-fibers reliably suppresses Aδ-fiber nociceptive processing in human volunteers.

Goroszeniuk et al (13). presented a case of partial traumatic avulsion of the brachial plexus treated with brachial plexus stimulation via a posterior approach, according to the technique previously described by Pippa et al. (14).

The authors implanted an octopolar lead directly on the brachial plexus in the interscalenic plane. Stimulation at 4 Hz for approximately 90 min/day was sufficient to produce great pain relief.

The technique of the posterior interscalenic approach to the brachial plexus has been adopted by our group as a possible alternative to cervical SCS. Our first brachial plexus implant through a posterior interscalenic approach was performed in 2008 in a patient with causalgia of the upper extremity following multiple surgical

Table 3. Pain Relief After Peripheral Nerve Stimulation.

Patients	Likert scale score	Status preimplant	Status postimplant	Preimplant NRS	NSAIDS + opioid preimplant	Postimplant NRS	NSAIDS + opioid postimplant	Age
B.A.	Implant removal	No work	No work	8	/		/	40
B.M.	6	No work	No work	8	Yes	2	No	70
B.I.	6	Inactivity	Restart work	7	Yes	2	Yes	46
A.C.	7	No work	No work	8	Yes	0	No	72
G.G.	6	Inactivity	Restart work	6	Yes	0	No	47
C.M.	6	No work	No work	9	Yes	3	Yes	54
C.R.	6	In activity	Restart work	8	Yes	6	No	41
R.S.	Implant removal	Inactivity	Restart work	9	/		/	38
F.L.	6	Inactivity	Restart work	8	Yes	1	No	27
C.R.	6	Inactivity	Restart work	10	Yes	2	No	41
M.I.	Implant removal	No work	No work	8	/	8	/	77
M.S.	6	Inactivity	Restart work	8	Yes	1	No	31
G.C.	6	Inactivity	Restart work	10	Yes	4	No	38
O.S.	5	Inactivity	Not able to work	10	Yes	8	Yes	35
V.R.	5	No work	No work	10	Yes	8	Yes	45
VALORI/MEDIA	5,91666667			8.466666667		3.46153846		46.81

NRS, numeric rating scale.

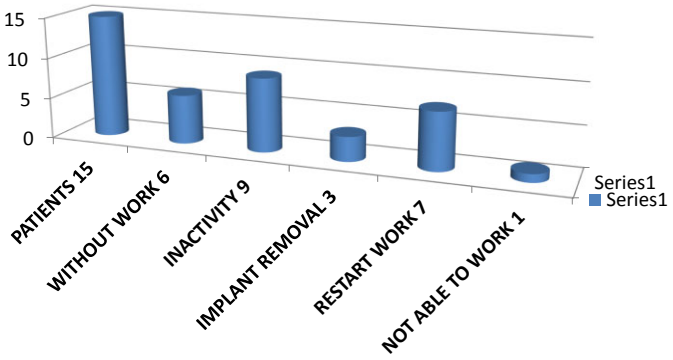

Figure 7. Preimplant and postimplant working ability.

procedures on the elbow. The patient had undergone multiple cervical SCS implants with numerous lead migration and infections. The patient had refused any further attempts at cervical SCS. In her case, an implanted octopolar percutaneous lead (Octad, Medtronic Inc., Minneapolis, MN, USA) on the brachial plexus is still effective in controlling her pain.

Monti (15) reported a case of anterior interscalenic approach to the brachial plexus. Although the clinical results were good, there were several instances of electrode migration and/or fracture.

As stated previously, the NRS in the implanted patients decreased (on average) from 8.46 to 3.46 ($p < 0{,}001$) at a 9.3-month follow-up. This result is a substantial and meaningful pain reduction. Of the nine patients who were active in the workforce but had to quit working because of the pain, seven resumed their working activities. (Fig. 7). Only 3 of the initial 15 implants were removed because of the lack of therapeutic efficacy. Eight patients stopped their narcotic intakes, thereby limiting their pain medication intake to nonsteroidal anti-inflammatory drugs.

Case no. 10 (CM) (Table 3) was a patient who was affected by multiple sclerosis (MS) and severe neuropathic foot pain and who was implanted with one lead on the posterior tibial nerve. In addition to a good pain reduction, the patient observed general improvement in her condition and was able to lessen her corticosteroid intake for her MS.

Case no. 6 (BM) (Table 3) had "frozen shoulder" syndrome following numerous surgical procedures on the shoulder. Stimulation of the suprascapular nerve provided great pain relief with a substantial improvement of the active and passive range of motion of the shoulder joint (Fig. 8). The efficacy of suprascapular nerve stimulation on shoulder pain has been investigated by other authors (16,17). Because the pain in the "frozen shoulder" syndrome is most likely a mixed pain (i.e., nociceptive and neuropathic), we can conclude, as asserted in a previous publication, that PNS could be effective on the nociceptive component of articular pain. A similar result was obtained in case no. 3 (Table 3), a patient who was affected by epicondylitis and necrosis of the articular heads.

CONCLUSIONS

The results of our series indicate, as shown in the literature, that PNS is an effective modality in managing severe neuropathic and intractable pain following multiple joint surgeries complicated by causalgic pain.

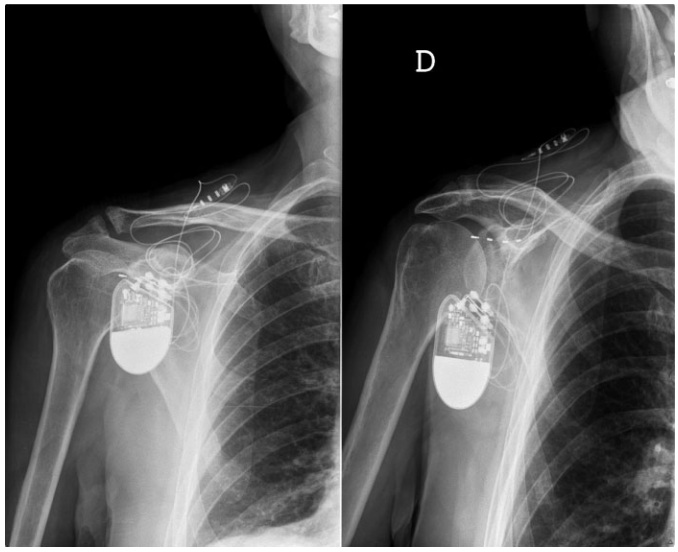

Figure 8. BM, lead placed on suprascapular nerve for frozen shoulder pain.

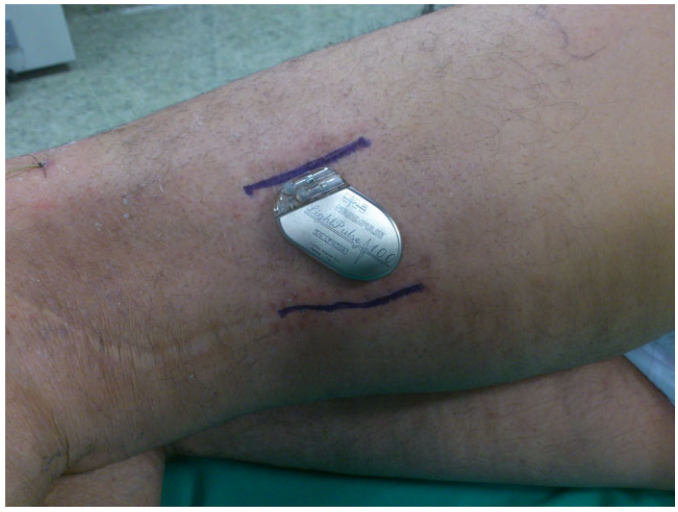

Figure 9. Implanted pulse generator pocket location in permanent implantation.

The modality is effective in reducing both the spontaneous pain and the allodynia, and can lead to a substantial improvement in the functioning of joints and extremities affected by severe neuropathic and mixed pain.

The small dimensions of the Neurimpulse IPG (volume 13 cc, thickness 7 mm, weight 26 g) allow its placement in a small subcutaneous pocket near the electrode insertion site, without having to cross one or more joints (as it is often the case with larger implantable neurostimulators) (Fig. 9). This result greatly reduces the torsional/tractional forces on the electrode, thereby greatly reducing the possibility of break and/or migration.

The authors favor taking a direct, open approach to the nerve, partly because the placement of the lead directly on the nerve reduces greatly power requirements and partly because ultrasound-guided lead positioning is not always feasible.

A larger prospective study will be needed to confirm and solidify the efficacy of PNS in managing chronic pain syndromes.

Authorship Statements

Dr. Reverberi designed and conducted the study; Dr. Dario assisted with the data collection and patient evaluations; Dr. Barolat evaluated the correct references and translated the manuscript from Italian to English; Ms. Zuccon performed the data collection and analysis, and provided technical support.

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