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Peripheral Nerve Field Stimulation (PNFS) in Chronic Low Back Pain: A Prospective Multicenter Study

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Objectives: The goal of this study was to evaluate the long-term efficacy and safety of peripheral nerve field stimulation (PNFS) for chronic low back pain (cLBP).

Materials and Methods: In this prospective, multicenter observational study, 118 patients were admitted to 11 centers throughout Austria and Switzerland. After a screening visit, all patients underwent a trial stimulation period of at least seven days before implantation of the permanent system. Leads were placed in the subcutaneous tissues of the lower back directly in the region of greatest pain. One hundred five patients were implanted with a permanent stimulating system. Patients' evaluation of pain and functional levels were completed before implantation and one, three, and six months after implantation. Adverse events, medication usage, and coverage of the painful area and predictive value of transcutaneous electrical nerve stimulation (TENS) were monitored.

Results: All pain and quality-of-life measures showed statistically significant improvement during the treatment period. These included the average pain visual analog scale, the Oswestry Disability Questionnaire, the Becks Depression Inventory, and the Short Form-12 item Health survey. Additionally, medication usage with opioids, nonsteroidal anti-inflammatory drugs, and anti-convulsants showed a highly significant reduction. Complications requiring surgical intervention were reported in 9.6% of the patients. The degree of coverage of painful areas seems to be an important criterion for efficacy of PNFS, whereas TENS is presumably no predictor.

Conclusions: This prospective, multicenter study confirms that PNFS is an effective therapy for the management of cLBP. Significant improvements in many aspects of the pain condition were measured, and complications were minimal.

Keywords: Chronic pain, low back pain, nonmalignant pain, peripheral nerve stimulation, prospective nonrandomized study

Conflict of Interest: Drs. Kloimstein and Kern are lecturers for Medtronic GmbH. The other authors reported no conflicts of interest.

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Ethical Committee Approval:
The study has been approved by the Ethical Committee Vienna (Magistratsabteilung 15—Gesundheitsdienst der Stadt Wien. Ethikkommission der Stadt Wien).

INTRODUCTION

The main purpose of this study was to demonstrate the efficacy and safety of peripheral nerve field stimulation (PNFS) for chronic low back pain (cLBP), both in combination with spinal cord stimulation (SCS) and as a stand-alone treatment. Efficacy should be demonstrated in terms of pain reduction measured with the visual analog scale (VAS). The study was designed as a prospective, multicenter study. A variety of clinical and functional parameters have been evaluated (1). The reduction of medication was also investigated, as well as the influence on quality of life (QoL) by means of the Short Form-12 item Health survey (SF-12), Oswestry Disability Index (ODI), and Beck Depression Inventory (BDI).

cLBP and failed back surgery syndrome (FBSS) (2) are important causes of physical and emotional suffering, familial and social disruptions, and disability, and represent a leading cause for work absenteeism and visits to healthcare professionals. CLBP is one of the most common, disabling, diagnostically complex, and therapeutically challenging of all chronic pain disorders in adults. FBSS refers to a condition in patients who continue to have back pain and/or leg pain despite successful spinal surgery (3,4). Chronic pain refractory to systemic medical therapies has a significant impact on QoL.

Since 1967, the use of electrical neuromodulation as a reversible and nondestructive method in pain therapy has been expanded to include a number of central and peripheral targets (5–17). Its neurophysiological mechanism of action is partly understood and described (18–23).

SCS has been successfully used for the treatment of chronic intractable neuropathic pain conditions (24–28) and offers the benefits that it is reversible, nonpharmacologic, safe, and cost-effective (29). While SCS is successful for radicular pain, it does not appear to be as effective for axial low back pain. The main reason may be the difficulty of covering the painful lower lumbar area with epidural stimulation. One may argue that the principal reason is the nociceptive nature of cLBP. However, due to several pathophysiological reasons for cLBP (inflammatory agents in herniated discs, sprouting of nociceptive fibers into degenerated discs), the underlying mechanism of cLBP especially in FBSS patients (nerve damage) may be mixed (nociceptive and neuropathic) pain (30–32).

In literature, there are several case series describing the use of a percutaneously placed subcutaneous leads to provide significant relief from well-localized chronic pain in the low back (7–9,14,33) and one randomized controlled study (34). The stimulating electrode was introduced directly at the site of maximum pain. This peripheral neurostimulation technique which stimulates primary afferent neurons offers a new approach for the control of localized chronic neuropathic pain. Various terms are used for this technique: subcutaneous target stimulation (13), peripheral nerve stimulation, and PNFS (37). These subcutaneously placed leads stimulate the region of the affected nerves, cutaneous afferents, or the dermatomal distribution of these nerves, which then converge back on the spinal cord. It is now well established that afferent stimulation may facilitate or inhibit transmission of nociceptive information in the spinal dorsal horn. Electrophysiological studies have shown that cutaneous A-fiber stimulation selectively inhibits C-fiber and noxious stimulus-evoked excitation of dorsal horn neurons (18).

MATERIALS AND METHODS

Patient Selection and Inclusion

Patient enrollment was started in March 2008 and was completed in March 2011. Data have been collected before implantation and at regular follow-up intervals of one, three, and six months. After this, follow-up visits have been performed every six months.

Table 1. Inclusion and Exclusion Criteria.

Inclusion Criteria:	Exclusion Criteria:
• Chronic low back pain for more than six months • Transcutaneous electrical nerve stimulation had to be applied prior to study inclusion • Patient-informed consent signed by the patient	• Age under 18 years • Planned or current gravidity • Drug abuse • Life expectancy less than one year • Patient unable to understand or handle devices • Pension application process ongoing

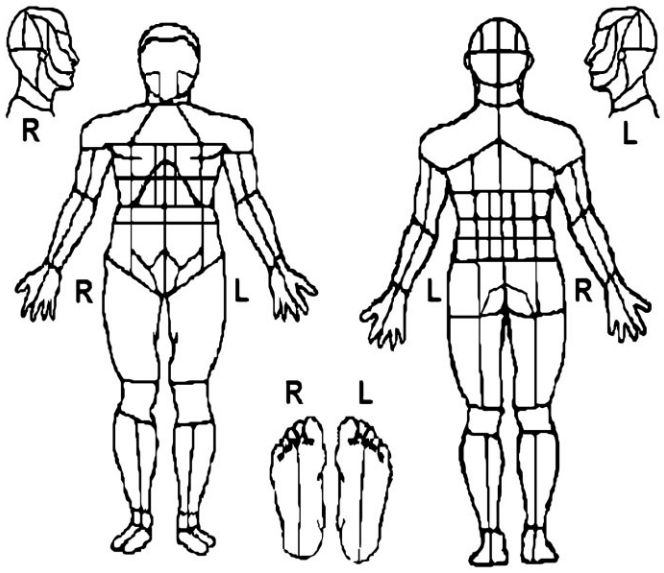

Figure 1. Body map.

Patients who had suffered from cLBP for more than six months with or without radiating pain were screened. They had to fulfill the inclusion and exclusion criteria (Table 1) and had to sign the patient informed consent before being included in the study.

At baseline visit one week before the date of lead implantation, medical history, current medical treatment, as well as previous treatments were monitored. Furthermore, the actual pain intensity was measured using the 11-point VAS. On an anatomical body map drawing (Fig. 1), patients indicated the distribution of their pain by exactly marking the entire painful area in their lower back (pain map). After lead implantation, they had to mark the area of stimulation on a different body map allowing an exact identification of the paresthesia coverage of the painful area (paresthesia map). In addition, they marked the region of pain reduction itself in a separate body map (pain reduction map).

Prior to PNFS, all patients had to obtain transcutaneous electrical nerve stimulation (TENS) for at least one week. The reason was whether TENS could be a predictor of PNFS (Table 1).

Moreover, all patients completed three questionnaires at screening visit: the ODI monitoring the pain-related disability, the BDI screening for the degree of depression, and the SF-12 monitoring the health-related QoL.

Inclusion criteria are as follows:

- cLBP for more than six months
- TENS had to be applied prior to study inclusion
- Patient-informed consent signed by the patient

Exclusion criteria are the following:

- Age under 18 years
- Planned or current gravidity
- Drug abuse
- Life expectancy less than one year
- Patient unable to understand or handle devices
- Pension application process ongoing

Procedure

At least one week after the baseline visit, the stimulation leads were implanted.

A 14-gauge Tuohy-type needle was positioned percutaneously directly into the area of maximum pain in the subcutaneous tissue. After the needle stylet of the Tuohy needle had been removed, the electrode was advanced until the tip of the Tuohy needle. Then the needle was carefully removed observing that the lead position was not changed hereby and then the electrode was connected to the external screening device.

If a patient suffered also from radiating pain due to a radiculopathy of the lower extremities, epidural leads could be implanted as well. Crosstalk of the epidural and the subcutaneous leads should not be performed.

Further particulars concerning the implantation technique itself, the electrodes used, the use of local anesthetics or implantation in general anesthesia, the way of anchoring the leads in the tissue, the perioperative antibiotics regime, and stimulation parameters were not defined in the protocol, but were monitored and reported, respectively.

All patients underwent a trial period of stimulation. There was no maximum time limit set for this test phase; however, a minimum screening duration of at least seven days was set as a condition. In addition, no specific percentage of pain reduction was specified as a condition for an impulse generator (IPG) implantation. The judgment whether a patient was a responder or not was left to the implanting physician. All implanted devices were manufactured by Medtronic® (Minneapolis, MN, USA).

Outcome Measures

One, three, and six months after lead implantation, three visits were carried out. All the patients were contacted by phone to visit the clinic for the assessment of their outcome using the same test instruments employed at baseline.

Again, the area of stimulation (paresthesia map) and the area of pain reduction (pain reduction map) were monitored and compared with the painful area from baseline (pain map). As such, the percentage of coverage of the painful area could be calculated.

The patients' functional status and affective responses to pain were evaluated using the ODI, the BDI, and the SF-12. The ODI, which was designed specifically for patients with low back pain, consists of 10 multiple-choice items that assess patients' ability to function in nine common areas of daily life and their use of pain medication. The BDI contains 21 multiple-choice items designed to measure depressive symptoms. Pain intensity was measured using a modified VAS with a numerical scale of descriptors ranging from 0 to 10–0, representing no pain and 10 the worst possible pain.

Furthermore, all programming parameters as contact setting, frequency, impulse width, and current were monitored as well.

Statistical Methods

Statistical evaluations were performed in R (Version 2.7.0, 2008; The R Foundation for Statistical Computing, ISBN 3-900051-07-0, http://www.cran.r-project.org) respectively (elementary statistics and figures) in HP-RPL (Ver. 2.08, 2006; Hewlett-Packard Company, San Diego, CA, USA).

Tables were analyzed by the chi-square test and the Fisher–Yates test (exact Fisher test). Comparison of groups was performed by the Wilcoxon–Mann–Whitney *U*-test. Normality of data was investigated by the Kolmogorov–Smirnov test (35,36).

RESULTS

General

One hundred eighteen patients were screened to enter the study group (Fig. 2). One patient withdrew his consent resulting in a total number of 117 patients who met the inclusion and exclusion criteria, signed the informed consent, and could therefore be included in the study group. In these 117 patients, test electrodes were implanted. Out of these 117 patients, 105 patients showed a sufficient test stimulation period which means that they had a satisfying pain reduction and/or reduction in pain medication. As a consequence, an IPG was permanently implanted. These 105 patients met the center specific criteria for responders.

One hundred patients completed the one-month follow-up (M01FU), 84 patients the three-month follow-up (M03FU), and 74 the six-month follow-up (M06FU). Over the period of six months, 18 patients could not be followed by the implantation center and as such were defined as "lost for follow-up." Three devices had to be explanted between the M01FU and M03FU due to infection of the leads and two devices because of loss of efficacy or painful stimulation. In the subsequent three months until the M06FU, one explantation was performed because of infection of the leads, three

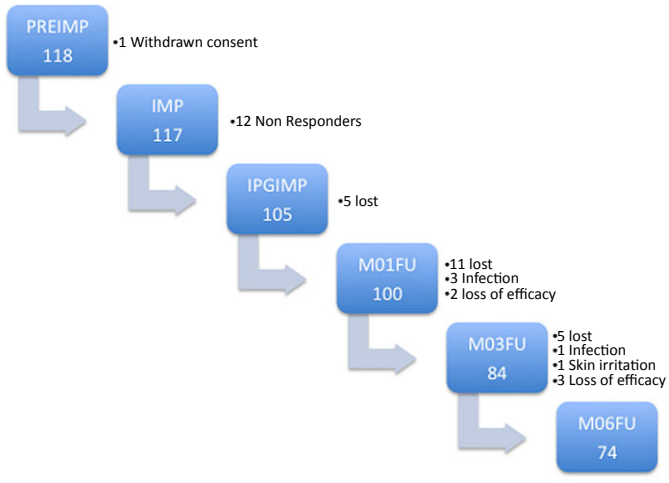

Figure 2. Patients' flow chart: PREIMP, screening visit; IMP, test electrodes implanted; IPGIMP, implantation of permanent stimulation device; M01FU, one month follow-up; M03FU, three months follow-up; M06FU, six months follow-up.

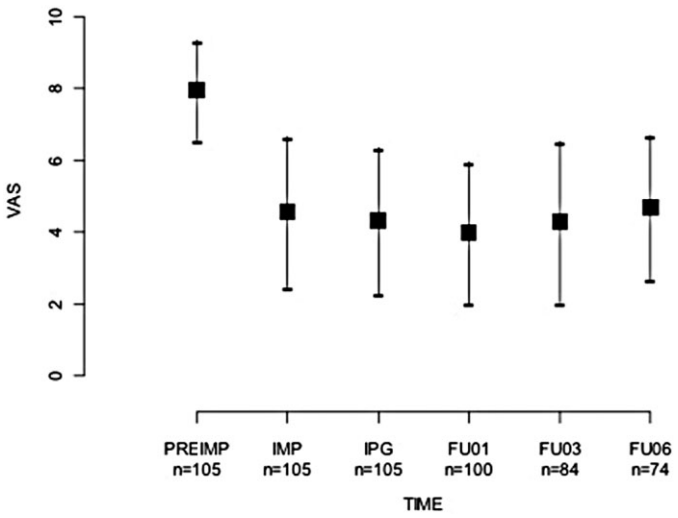

Figure 3. VAS score over the six-month period (per-protocol analysis). M01FU, (Follow-up 1 month); M03FU, (Follow-up 3 months); M06FU, (Follow-up 6 months); IMP, test electrodes implanted; IPG, impulse generator; PREIMP, screening visit; VAS, visual analog scale.

because of loss of stimulation efficacy, and one due to skin irritation (no infection) at the IPG-pocket site. Finally, 74 out of 105 patients completed the observation period of six months.

Pain Reduction and Medication

Conducting a per-protocol analysis (all patients), we found a stable pain reduction over the entire observation period of six months from baseline (Fig. 3 and Table 2). The mean VAS score at baseline was VAS 7.9 (SD 1.38), VAS 4.58 (SD 2.1) right after lead implantation, VAS 4.33 (SD 2.03) after IPG implantation, VAS 4.0 (SD 1.96) after one month, VAS 4.3 (SD 2.24) after three months, and VAS 4.7 (SD 1.99) at the end of the follow-up period of six months. This constitutes an average pain reduction of 44% ($p < 0.01$).

Looking at patients with PNFS alone on one hand and a hybrid stimulation system (PNFS and SCS) on the other hand, we found a slightly lower VAS scores in PNFS alone; however, it was not statistically significant (Table 2).

Looking at the data by means of an intention-to-treat analysis, we formed two subgroups. In the worst-case scenario analysis (Table 4), we assumed that patients who were lost in follow-up or were explanted due to infection or had loss of efficacy returned to baseline VAS score. In the continuation scenario subgroup (cont.), lost and explanted patients stayed in analysis with their last monitored VAS score. Patients' VAS scores with lost of efficacy were assumed to return to baseline VAS score. Mean pain reduction in the worst-case scenario analysis was from 7.97 to 5.45 during the six-month period (Fig. 4), whereas in the optimistic continuation analysis it was down to 4.61 (Fig. 5). In both subgroups, pain reduction was statistically significant ($p < 0.001$).

A subgroup of the implanted patients (Fig. 6) with no TENS effect, meaning that TENS in the preimplant period had no effect on pain reduction, was separately evaluated. In this subgroup, the decrease in pain was from VAS 7.97 (SD 1.3) at baseline to VAS 5.37 (SD 2.26) after six months ($p < 0.01$).

Out of the 105 implanted patients, at baseline 76.2% had opioid medication either with transdermal or oral opioids. Patients took oral or transdermal opioids at M01FU (57.1%), at M03FU (49.6%), and at M06FU (43.9%) (Table 3).

The percentage of patients with intake of anticonvulsive drugs at baseline was 57.2%, at M01FU 41.9%, at M03FU 31.4%, and at M06FU 26.7% ($p < 0.05$; Fisher–Yates test).

Furthermore, the number of patients with medication of NSAIDs at baseline was 38.1%, at M01FU 27.6%, at M03FU 20%, and at M06FU 16.2% ($p < 0.05$; Fisher-Yates-test).

All the patients that took opioids (oral and/or transdermal) from the beginning and had to further on take these throughout the study observation period of six months showed a mean opioid reduction from baseline of 31.1% at M01FU, 48.8% at M03FU, and finally 69.4% at M06FU, all calculated in the morphine equivalent dosage. Table 4 shows the mean opioid reduction over all the patients.

Both the number of patients with no opioid intake anymore at all after six months as well as the percentage of opioid reduction was statistically highly significant (*t*-test, $p < 0.01$).

Functional Status and Quality of Life

The functional status of the included patients determined with the ODI (Fig. 7) showed a highly significant improvement ($p < 0.01$; *t*-test) from mean 38.2 (SD 7.05) at baseline to 34.6 (SD 7.77) after six months. The SF-12 (Fig. 8) monitoring the health-related QoL also showed a highly significant improvement ($p < 0.01$; *t*-test) from mean 4.29 (SD 0.74) at baseline to 3.67 (SD 0.92) measured at M06FU.

Measuring the degree of depression using the BDI, an improvement could be achieved as well (Fig. 9). The mean baseline value was 17.8 points (SD 9.41) and the mean value at the M06FU was 15.1 points (SD 8.41). This reduction was statistically not significant.

Coverage of Painful Area

The mean coverage of the painful area (Table 5) specified on the anatomical body map drawing was 80.58% (SD 27.1). Comparing the covered painful area in the group of the permanently implanted patients (responders $N = 105$) with those who achieved no satisfying pain reduction of the test electrodes (nonresponders $N = 12$), there was a statistically highly significant difference. The coverage of the painful area was 83.46% (SD 23.5) in the responder group vs. 55.3% (SD 41.1) in the nonresponder group.

DISCUSSION

Referring to our large retrospective study (27), the aim of this prospective multicenter Austrian Registry with a standardized study protocol was to evaluate the long-term efficacy of PNFS for the treatment of cLBP. At the time of the composition of this paperwork, 70.5% of the initial responders ($N = 105$) completed the six month observation period. The results for these patients showed a stable reduction in pain score, incremental reduction in medication, and an improvement in QoL, pain-related disability, and psychological impairment. Important to mention is the fact of the ongoing effect over half a year.

Discriminating between PNFS alone and hybrid system stimulation, the efficacy in both groups is equal, with a marginal advantage in the PNFS subgroup.

Moreover showed the intention-to treat analysis, presuming that all dropout patients (31 patients, 29% of initial responders) returned with their VAS score to baseline after six months (this is the worst-case scenario) a statistical significant improvement from mean 7.97 to 5.45 ($p < 0.001$).

Table 2. VAS Scores (Baseline—One Month—Six Months).

Number of Patients		PNFS alone *N* = 40	PNFS+ SCS *N* = 65	All PNFS *N* = 105	PNFS worst *N* = 105	PNFS cont. *N* = 105
Baseline	*N*	40	105	105	105	105
	Mean	7.6	7.97	7.97	7.97	7.97
	SD	1.52	1.38	1.38	1.38	1.38
One month	*N*	40	100	100	105	105
	Mean	3.85	4.0	4.0	4.16	3.94
	SD	2.24	1.96	1.96	2.09	1.97
Evolution from baseline	*N*	40	100	100	105	105
	Mean	3.75	4.0	4.0	3.81	4.03
	SD	2.25	2.06	2.06	2.19	2.04
	p Value	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$
Six months	*N*	28	74	74	105	105
	Mean	4.36	4.7	4.7	5.45	4.61
	SD	2.31	1.99	1.99	2.22	2.05
Evolution from baseline	*N*	28	74	74	105	105
	Mean	3.5	3.58	3.58	2.52	3.36
	SD	2.55	2.13	2.13	2.42	2.13
	p Value	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$	$p < 0.001$

Showing the VAS scores at baseline, M01FU, M06FU, and its evolution from baseline.
Per-protocol analysis first three rows: PNFS alone, hybrid stimulation (SCS and PNFS), all PNFS with data available.
Intention-to-treat analysis last two rows: Worst-case scenario (worst), continuation scenario (cont.).
PNFS, peripheral nerve field stimulation; SCS, spinal cord stimulation; VAS, visual analog scale.

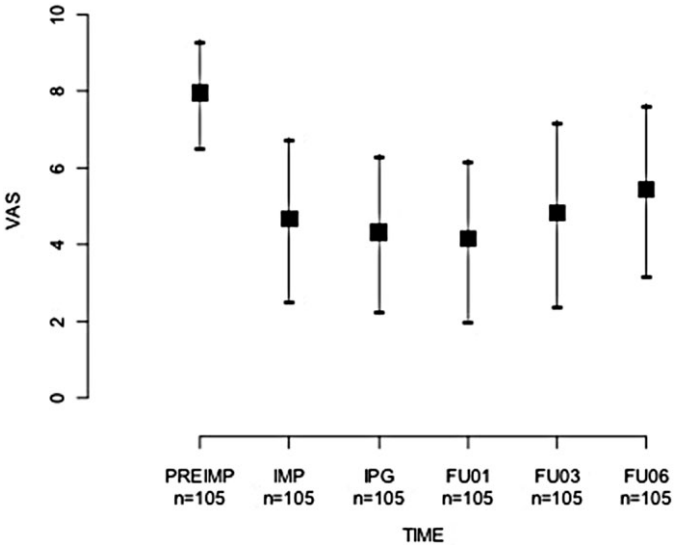

Figure 4. VAS score over the six-month period; worst-case scenario (intention-to-treat analysis). M01FU, (Follow-up 1 month); M03FU, (Follow-up 3 months); M06FU, (Follow-up 6 months); IMP, test electrodes implanted; IPG, impulse generator; PREIMP, screening visit; VAS, visual analog scale.

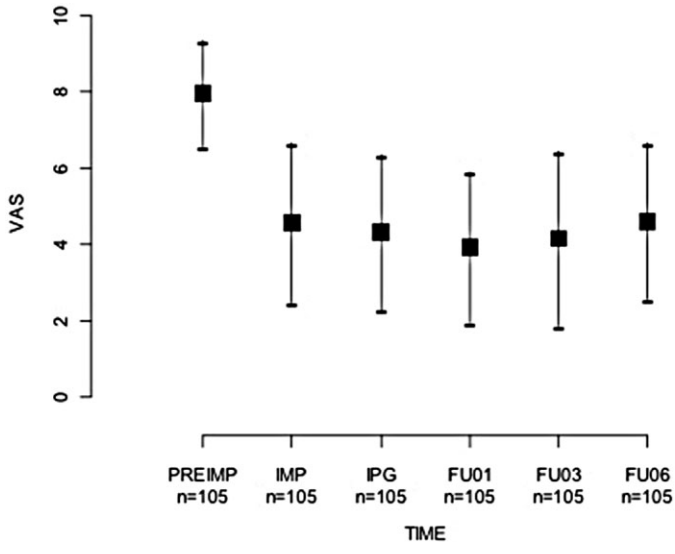

Figure 5. VAS score over the six-month period; continuation scenario (intention-to-treat analysis). M01FU, (Follow-up 1 month); M03FU, (Follow-up 3 months); M06FU, (Follow-up 6 months); IMP, test electrodes implanted; IPG, impulse generator; PREIMP, screening visit; VAS, visual analog scale.

Meanwhile, all patients enrolled into this study have completed the 12 month follow-up already. These results entirely confirm the results presented here, both in terms of pain reduction, QoL measurements, and reduction in medication. These further data will be a matter of future publication. Some of the patients already have completed longer follow-up times up to 48 months that again support the findings presented here.

There have been several concerns that the effect of PNFS could decrease over time due to scar tissue covering the leads and resulting in loss of stimulation and subsequent loss of efficacy of PNFS. However, this effect should occur after some weeks or at latest two to three months after implantation. In the presented study, we could not observe such an effect even after six months postimplantation. The pain-reducing effect was stable and ongoing and over the observation period. Even a further reduction in pain medication could be observed. In five patients where we observed loss of efficacy over time, this was due to dislocation and lead migration.

Not only was reduction in pain intensity statistically highly significant. Moreover, the digression in opioid medication and anticonvulsants was remarkable. Seventy-six percent of the responders had opioid medication at baseline. Not more than 49% needed opioids after three months and 43% after six months. There was the same declining development of anticonvulsants: 56% at baseline, 31% after three months, and 27% at six-month follow-up. The number of patients with nonsteroidal anti-inflammatory drug use was considerably reduced as well: 38% at baseline, 20% after three months, and finally 16% after six months. Side effects in these three drug groups (number needed to harm) on the long run led to frequent hospitalization, additional prescription of adjuvant medication, and reduction in QoL (32).

Looking for a predictor for PNFS efficacy, the pain-reducing effect of TENS and PNFS was compared. All of the included patients had to be treated with TENS prior to lead implantation. Thirty-six patients (one third of the implanted patients) reported no effect of TENS prior to implantation. After lead implantation and screening phase, they could be identified as responders to PNFS and an IPG was implanted. The reduction in pain score in those 36 patients was stable and statistically significant over the study period. This means that the mechanism of action of PNFS is most likely different from the one of TENS.

Another important finding is the fact that the degree of stimulation coverage of the painful low back area is an important predictor for the efficacy of PNFS. An average of 55% of coverage of the painful area was found in the nonresponder group, whereas 83.5% of coverage appeared in the responder group.

In 4.7% of the permanently implanted patients ($N = 5$), an infection (in one patient skin irritation at the IPG-pocket site) occurred. The same number, 4.7% ($N = 5$), had loss of efficacy during the six-month period. This loss of efficacy was not reported consistently but it seems to be due to lead migration or dislocation (unpleasant stimulation or no stimulation as reasons for explantation). All together, this means a complication rate of 9.6%.

One major limitation of this present study is the missing of a control group and the open-label trial design. But the goal of the study was to show the efficacy of PNFS for a long period of time.

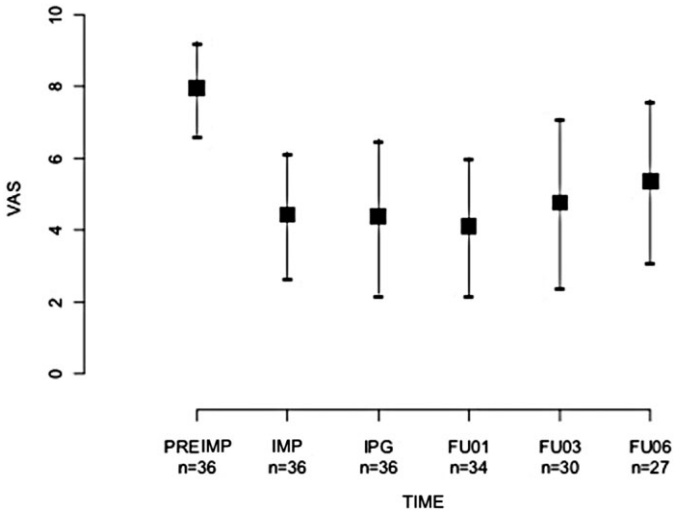

Figure 6. VAS reduction in patients with No-TENS effect. FU01, (Follow-up 1 month); FU03, (Follow-up 3 months); FU06, (Follow-up 6 months); IMP, test electrodes implanted; IPG, impulse generator; PREIMP, screening visit; TENS, transcutaneous electrical nerve stimulation; VAS, visual analog scale.

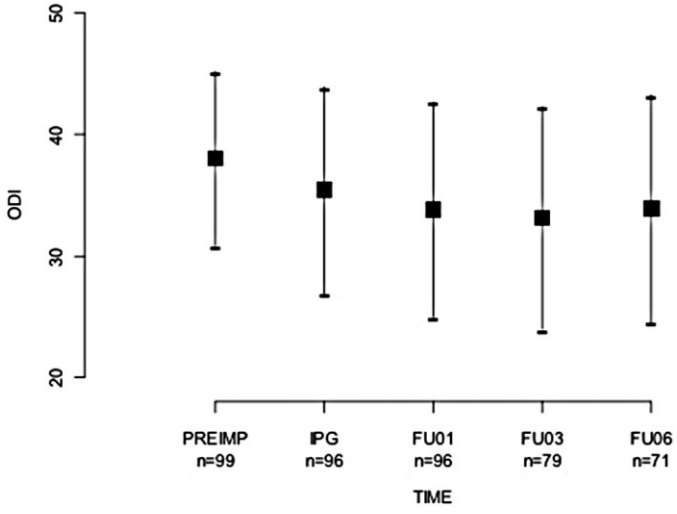

Figure 7. Oswestry Disability Index (ODI) over the six-month period.

Table 3. Number and Percentage of Patients Who Required Opioids, Anticonvulsants, and NSAIDs during the Study Period.

	Baseline	M01FU	M03FU	M06FU
Opioids *N* (%)	80 (76.2)	60 (57.1)	51 (48.6)	45 (42.9)
NSAIDs *N* (%)	40 (38.1)	29 (27.6)	21 (20)	17 (16.2)
Anticonvulsants *N* (%)	59 (56.2)	44 (41.9)	33 (31.4)	28 (26.7)

M01FU, one-month follow-up; M03FU, three-month follow-up; M06FU, six-month follow-up; NSAIDS, nonsteroidal anti-inflammatory drugs.

Table 4. Mean Opioid Consumption (Morphine Equivalent) in mg and its Relative Reduction from Baseline in %.

	Baseline	M01FU	M03FU	M06FU
Opioid intake in mg (mean all patients)	111.9	77.0	63.1	42.5
Reduction from baseline (%)		31.2	43.4	62.0

M01FU, one-month follow-up; M03FU, three-month follow-up; M06FU, six-month follow-up.

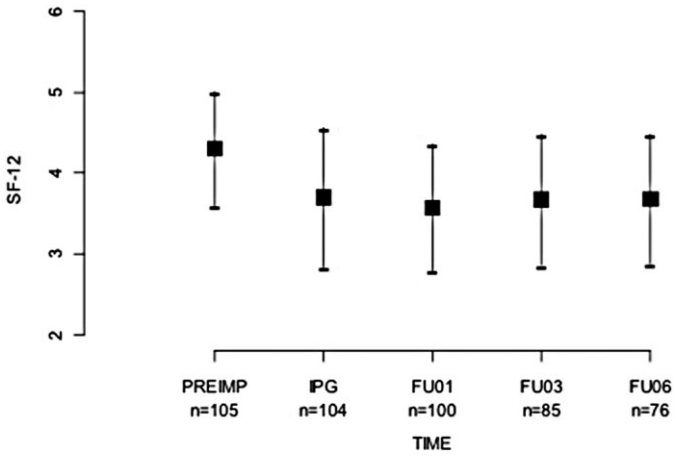

Figure 8. SF-12 over the six-month period. SF-12, Short Form-12 item Health survey.

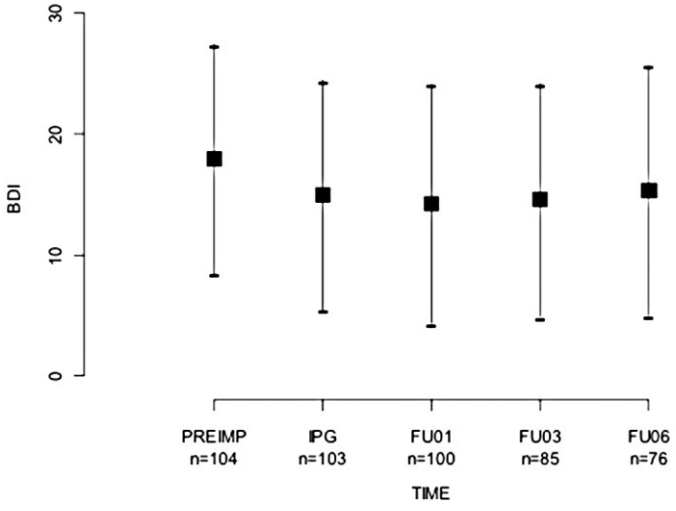

Figure 9. BDI over the six-month period. BDI, Becks Depression Inventory.

Table 5. Coverage of Painful Area (1: All Patients, 2: Responders, 3: Nonresponders).

	Minimum	Median	Maximum	Mean	SD	SEM	*N*
1	0	100	100	80.58	27.01	2.5	117
2	28.57	100	100	83.46	23.52	2.3	105
3	0	62.5	100	55.31	41.07	11.85	12

CONCLUSION

PNFS can be considered as a promising effective therapy option for patients suffering from cLBP. The technique of PNFS shows much less side effects than common medical therapy and in many cases even more effective. In our presented data, PNFS seems to be a safe and reversible treatment option of cLBP with no loss of efficacy in the long run.

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Authorship Statements

Drs. Likar and Kloimstein designed and conducted the study. Prof. Dr. Haro Stettner performed data collection and statistical analysis. Dr. Kloimstein drafted the manuscript. All authors had complete access to the study data. All authors have approved the submitted version.

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COMMENTS

PNFS is an interesting and promising area of neuromodulation, the technique is simple and appears to be reasonably effective from the limited reports that have been published to date. This article is an important piece of work in this field as this is a multi-centre report of 6 months follow up in a cohort of 105 patients. Being a prospective open label report, the results may have been affected by a number of factors including bias towards the technique in the absence of a control. The limited follow up time also does not allow a clear picture of the long term effectiveness of the technique and we are left wondering if a long term decrement of effect will occur as has been demonstrated with SCS. It should also be noted that a number of patients in this report had a mixture of SCS and PNFS; this will further confound the results. However it is heartening to see that the rate of complications reported in this publication is lower than those reported generally for SCS and that no major irreversible complications have been reported with this tecnique.

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This is a fine work with a reasonably large substrate of subjects. The work provides further scientific support for the use of peripheral nerve field stimulation for chronic axial pain and adds to a growing body of support. Multiple proposed randomized trials will be starting in the US and Europe this year with the hope of more robust effect analysis.

Supported in smaller studies, but also interesting to see here, is the lack of significant negative predictive value of TENS in supporting PNFS efficacy. This is important for several reasons: insurers and the public erroneously lump the two treatments together and the difference between the two may shed further light on the still yet-to-be-understood mechanism of efficacy. Lastly, since the concept of judicious use is a nefariously difficult one to agree upon, we must work on setting reasonable expectations for the number of leads to treat particular pain montages. One lead will surely under-serve the patient in most instances; gross misuse sadly characterizes the other extreme. Hopefully this promising, and still new approach will not provide egress for the coming assault on Neuromodulation.

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Comments not included in the Early View version of this paper.

