NEUROPATHIC PAIN SECTION

Original Research Article
Peripheral Nerve Field Stimulation for Chronic Pain: 100 Cases and Review of the Literature

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Abstract

Objective. To evaluate the clinical outcomes of 100 consecutive patients receiving peripheral nerve field stimulation (PNFS) for the treatment of chronic intractable pain.

Design. Prospective, observational study.

Setting. A private interventional pain specialty referral practice.

Patients. One hundred consecutive private practice patients receiving PNFS for the treatment of chronic craniofacial, thorax, lumbosacral, abdominal, pelvic, and groin pain conditions.

Outcome Measures. Pain (11-point numerical rating scale), complications, changes to analgesic use and employment status, disability (Oswestry or Neck Disability Indexes), depression (Zung Depression Index), and patient satisfaction.

Results. We demonstrate an average pain reduction of 4.2 ± 2.5 pain scale points on an 11-point scale following PNFS (preimplant pain score of 7.4 ± 1.7 to a follow-up average of 3.2 ± 2.3 pain scale points) (P ≤ 0.00). At a follow-up period of 8.1 ± 4.7 months (range 1–23 months), an overall 72% of patients reduced their analgesic use following PNFS. Patients receiving a lumbosacral PNFS for chronic low back pain reported a significant reduction in disability following treatment, as determined by the Oswestry Disability Index. Of the 100 cases, no long-term complications were reported.

Conclusions. This prospective 100 consecutive PNFS patient outcome study demonstrates that PNFS can be a safe and effective treatment option for, otherwise, intractable chronic pain conditions. PNFS has the potential to fundamentally change the way we think about pain management.

Key Words. Peripheral Nerve Field Stimulation; Chronic Pain; Neuromodulation; Subcutaneous Lead Stimulation; Craniofacial Pain; Low Back Pain

Introduction

Neuromodulation generally involves the selective application of a programmable pulse waveform through a series of electrodes within a lead to stimulate afferent nerve fibers and, subsequently, reduce the perception of pain [1]. This treatment is most indicated in cases of severe localized pain, intractable to analgesics, and other conventional therapies. The use of electrical stimulation for the treatment of pain dates back to the late 1800s when Julius Althaus applied alternating current electrotherapy to peripheral nerves for pain relief [1]. However, it was not until the publications by Melzack and Wall [2] and Shealy and colleagues [3] did neuromodulation in the form of spinal cord stimulation (SCS) become a noted alternative to traditional pain management.

Historically, SCS has primarily been used for widespread leg, buttock, and to some extent back pain, particularly, following failed back surgery [4–14]. In some cases, SCS becomes ineffective over time with some contributing factors postulated to stem from original lead placement, lead migration, and changes in pain patterns [15,16]. Traditionally, SCS stimulation has not adequately covered and diminished axial back pain. In addition, it has failed to address pain in key regions such as the face and trunk [17]. This led to individuals experimenting with the placement of subcutaneous leads within these areas of significant pain.

In peripheral nerve field stimulation (PNFS), leads are subcutaneously placed to stimulate the region of affected nerves, cutaneous afferents, or the dermatomal distribution of the nerves, which converge back to the spinal cord [15]. Original insight into treating craniofacial pain with neurostimulation was first observed by Wall and Sweet in the 1960s, through the implantation of an electrode into their own infraorbital foramina, resulting in a decrease in pain perception during the period of stimulation [18]. Years later, Weiner and Reed [19] were the first to report the stimulation...
of the greater occipital nerve for the treatment of occipital neuralgia in 1999. Further occipital nerve stimulation (ONS) studies have supported these initial findings [20–39] (Table 1).

PNFS is emerging as a promising treatment option for neuropathic pain in a growing list of clinical pain settings [17,40–46] (Table 2). Here, we report our first 100 consecutive cases of PNFS carried out over a 3.5-year period with indications of chronic pain in craniofacial, thoracic, low back, abdominal, and pelvic regions. We demonstrate significant pain relief and reductions in analgesic use following PNFS, with minimal to no long-term complications, suggesting that PNFS is a safe, reversible, and effective treatment alternative to traditional pain management strategies.

### Table 1  Selected cases of occipital nerve stimulation

<table>
<thead>
<tr>
<th>Indication</th>
<th>No. of Patients</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache/migraines</td>
<td>11</td>
<td>All patients reported an average of 67% reduction in pain scores [28]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Five patients reported a 40–95% reduction in their pain at an average follow-up of 20 months [20]</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Reduction in pain and analgesic use [35]</td>
</tr>
<tr>
<td></td>
<td>25</td>
<td>90% improvement in migraines at an average follow-up of 18 months [31]</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>All patients received excellent pain relief [27]</td>
</tr>
<tr>
<td>Craniofacial pain</td>
<td>30</td>
<td>50% of patients reported complete pain relief [36]</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Patient experienced 5 months of complete pain relief [17]</td>
</tr>
<tr>
<td>Occipital neuralgia</td>
<td>10</td>
<td>70% of patients experienced pain relief at an average follow-up of 22 months [37]</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Five of the seven patients reported reductions in their pain [26]</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>Patient experienced a 90% improvement in pain [24]</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>All patients achieved &gt;75% pain relief at the 1- and 6-month follow-up [30]</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>A reduction of pain from 8 to 3 VAS points, with marked improvements in quality of life [17]</td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td>12</td>
<td>All patients received significant pain reduction at 6 months following implantation [38]</td>
</tr>
<tr>
<td>Postherpetic neuralgia</td>
<td>2</td>
<td>Both patients maintained excellent pain relief for 3 years [21]</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Two of the patients maintained more than 50% pain relief after 2 years of follow-up [25]</td>
</tr>
</tbody>
</table>

### Table 2  Applications of peripheral nerve field stimulation

<table>
<thead>
<tr>
<th>Peripheral Nerve Field Stimulation Approaches</th>
</tr>
</thead>
<tbody>
<tr>
<td>Region</td>
</tr>
<tr>
<td>Low back pain</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Neck and shoulder pain</td>
</tr>
<tr>
<td>Inguinal and pelvic pain</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Thoracic pain</td>
</tr>
<tr>
<td>Abdominal pain</td>
</tr>
</tbody>
</table>

VAS = visual analog scale.
Methods and Materials

Patient Population

We assessed 100 consecutive patients from the Metro Spinal Clinic in Melbourne, Australia who received PNFS octrode percutaneous lead implants for the treatment of chronic craniofacial, thoracic, lumbosacral, or abdominal/pelvic pain. All patients had undergone a successful PNFS trial, defined by a reduction of at least 50% of the original pain, with the stimulation covering most of the painful region, a reduction of reliance on analgesics and improvements in valued activities of daily living. Most of the patients selected for the PNFS trial either suffered from failed back surgery syndrome or had failed other minimally invasive and conservative treatments.

Selection criteria for PNFS trial are the following:

- A clearly defined, discrete focal area of pain with a neuropathic or combined somatic neuropathic pain component with characteristics of burning and increased sensitivity.
- Failure to respond to other conservative treatments including medications, psychological therapies, physical therapies, surgery, and pain management programs.
- Psychological clearance (including a psychologist ruling out major drug addictions or significant psychiatric disorders that might impact on successful treatment.)
- Informed consent.

PNFS Trial Procedure

Based on clinical assessment, the area of pain is clearly outlined. Procedures are performed within a sterile operating room. Patients are minimally sedated and routinely given intravenous antibiotics (1 g cefazolin, ACS Dobfar SpA, Tribiano, Italy). Under live c-arm fluoroscopy, octrode leads (St. Jude Medical Neuromodulation, St. Paul, MN, USA and Boston Scientific, Natick, MA, USA) are placed subcutaneously within the area of maximal pain using a 14-G angiocath (Becton Dickinson, Mexico DF, Mexico) and a small amount of lidocaine 1% (AstraZeneca, Sydney, Australia) at the insertion site. Between one and four leads may be used in the trial. On table stimulation is performed to determine that paresthesia is felt in the area of pain and that it is comfortable. The leads are then stitched to the skin and dressings are applied. Patients are monitored in the recovery suite, while initial stimulation parameters are programmed. The patient wears an external power source for 5–7 days attached to the leads (two leads can be tested at a time), and careful monitoring occurs over the following days to determine whether adequate pain relief ensues. Approximately 72% of all patients undergoing a PNFS trial at the Metro Spinal Clinic achieved successful results and progressed to a permanent implant.

PNFS Implantation Procedure

Similar to the trial procedure, the patient’s skin is marked for area of pain, position of successful trial leads, and placement of the implantable pulse generator (IPG). A small incision is made outside the area of pain, and the leads are inserted via a 14-g angiocath. On table stimulation is performed.

The leads are sutured to the deep fascia (Figure 1) and tunneled to the site of the IPG where a blunt dissection is used to create a tight pocket approximately half an inch deep. The common sites for IPG placement include the upper buttock (below the belt line without impeding sitting positions), upper chest, posterior axillary fold, and the abdominal wall. The leads are connected to the IPG; impedance is verified and leads are secured. Refinement of the stimulation parameters are performed over the following weeks.

Outcome Measures

Outcome measures were assessed via a combination of patient answered questionnaires and patient medical histories. Ethical approval to carry out the data collection was obtained via The Avenue Human Research Ethics Committee. One hundred ten patients were invited to participate in the study before we obtained our sample size of 100 patients. A 100% follow-up rate was obtained for the pain scores as measured on the 11-point pain scale.

Further outcomes assessed were changes to analgesic use, capacity for paid employment, disability (Oswestry and Neck Disability Index), depression (Zung Depression Index), and patient satisfaction. Not all patients completed or were given the opportunity to complete these remaining outcome measures due to us introducing the Neck Disability Index, Oswestry Disability Index (ODI), and Zung Depression Index into the study at a later date. Complications and adverse events (AEs) were collected for all patients in the study. Patients were followed up on average 8.1 ± 4.7 months (range 1–23 months) after treatment (Table 3).

Statistical analysis was performed using the nonparametric, unpaired Mann–Whitney U-test and paired samples t-test with a P value of <0.05 considered statistically significant. These tests were performed using IBM SPSS Statistics 18 (IBM, Armonk, NY, USA).

Results

The total number of permanent implants assessed in this study was 100, whereby 40, 44, 8, 5, and 3 patients received PNFS implants in their occipital/craniofacial, lumbosacral, thoracic, groin/pelvis or abdominal region, respectively (Table 3).

For the total cohort of 100 patients, with an average follow-up of 8.1 ± 4.7 months (range 1–23 months), a statistically significant reduction of 4.2 ± 2.5 pain scale points was observed (preimplant pain score of 7.4 ± 1.7 to a follow-up average of 3.2 ± 2.3 pain scale points) (P ≤ 0.00). Patients receiving PNFS implants in their occipital/craniofacial, thoracic, or groin area achieved a
Figure 1  Peripheral nerve field stimulation procedure and lead placement. **Top row, left to right:** Marking out region of pain and placement of leads within this area; insertion of leads; live c-arm fluoroscopy aids in visualizing lead position; fluoroscopic image of four octrode leads placed bilaterally across the area of pain in the lower back. **Middle row, left to right:** left supraorbital and right occipital leads positioned in a migraine sufferer; with the implantable pulse generator placed in the upper right chest cavity; octrode leads placed bilaterally over lower back; octrode leads placed in right lower back. **Bottom row, left to right:** Two octrode leads placed bilaterally over T12; and two octrode leads placed in the right chest cavity for thoracic region pain; two right octrode leads placed in the lower pelvic region; and two octrode leads placed in the left upper to mid abdominal cavity to treat chronic abdominal pain.

Table 3  Patient demographics

<table>
<thead>
<tr>
<th>Region</th>
<th>Females</th>
<th></th>
<th>Males</th>
<th></th>
<th>Average Follow-Up (Months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total No. of Patients</td>
<td>No. of Patients</td>
<td>Average Age (Years)</td>
<td>No. of Patients</td>
<td>Average Age (Years)</td>
</tr>
<tr>
<td>Occipital/craniofacial</td>
<td>40</td>
<td>25</td>
<td>48.6 (24–72)</td>
<td>15</td>
<td>57.0 (43–76)</td>
</tr>
<tr>
<td>Thoracic</td>
<td>8</td>
<td>6</td>
<td>52.7 (40–62)</td>
<td>2</td>
<td>65.0 (62–68)</td>
</tr>
<tr>
<td>Lumbosacral</td>
<td>44</td>
<td>25</td>
<td>59.2 (27–87)</td>
<td>19</td>
<td>60.6 (33–88)</td>
</tr>
<tr>
<td>Abdominal</td>
<td>3</td>
<td>2</td>
<td>61.0 (51–71)</td>
<td>1</td>
<td>78</td>
</tr>
<tr>
<td>Groin/pelvis</td>
<td>5</td>
<td>4</td>
<td>47.3 (26–75)</td>
<td>1</td>
<td>32</td>
</tr>
<tr>
<td>Combined regions</td>
<td>100</td>
<td>62</td>
<td>53.6 (24–87)</td>
<td>38</td>
<td>59.1 (32–88)</td>
</tr>
</tbody>
</table>
significant reduction in pain of an average 4.7–4.9 points (Figure 2). The greatest reduction was observed in the abdominal PNFS group with these patients reporting an average drop of 7.0 ± 1.0 pain scale points ($P = 0.007$). A statistically significant reduction in pain was observed in the lumbosacral group with a reduction of 3.3 ± 2.3 pain scale points ($P = 0.000$).

We assessed for possible effects of age and gender on the results following PNFS. Comparative analyses were performed for follow-up times, pre- and postpain scale points and pain relief. Patient age and gender was not a predictor of outcome following PNFS with no significant difference noted between the groups (Table 4).

Pain relief was calculated as a proportion of the difference in pain scale points following PNFS. Patients receiving ≤24% pain relief or between 25% and 49% pain relief were classified as attaining a poor or fair response to PNFS, respectively, while a 50–74% result reflected a good response and 75–100% improvement in pain denoted an excellent response to PNFS. Approximately 34% of all patients reported an excellent response to PNFS with 69% of all patients experiencing pain relief of greater than 50% following PNFS (Figure 3).

Fourteen percent of all patients receiving PNFS described a poor response with four patients reporting no change in pain at all and, furthermore, two patients reporting an

Table 4  Gender and age comparisons of combined region peripheral nerve field stimulation

<table>
<thead>
<tr>
<th></th>
<th>No. of Patients</th>
<th>Follow-up (Months)</th>
<th>Pre-PNFS VAS</th>
<th>Post-PNFS VAS</th>
<th>% Pain Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>38</td>
<td>7.9 ± 4.7(2–20)</td>
<td>7.0 ± 1.7 VAS</td>
<td>2.9 ± 2.1 VAS</td>
<td>57.9 ± 26.3%</td>
</tr>
<tr>
<td>Female</td>
<td>62</td>
<td>8.3 ± 4.8(1–23)</td>
<td>7.6 ± 1.7 VAS</td>
<td>3.4 ± 2.4 VAS</td>
<td>55.7 ± 30.1%</td>
</tr>
<tr>
<td>Gender difference</td>
<td>NS ($P = 0.687$)</td>
<td>NS ($P = 0.087$)</td>
<td>NS ($P = 0.444$)</td>
<td>NS ($P = 0.787$)</td>
<td></td>
</tr>
<tr>
<td>&lt;60 years of age</td>
<td>58</td>
<td>7.9 ± 4.7(1–23)</td>
<td>7.4 ± 1.6 VAS</td>
<td>3.6 ± 2.5 VAS</td>
<td>60.3 ± 27.1%</td>
</tr>
<tr>
<td>≥60 years of age</td>
<td>42</td>
<td>8.4 ± 4.9(2–20)</td>
<td>7.5 ± 1.9 VAS</td>
<td>3.2 ± 2.3 VAS</td>
<td>51.3 ± 30.0%</td>
</tr>
<tr>
<td>Age difference</td>
<td>NS ($P = 0.656$)</td>
<td>NS ($P = 0.768$)</td>
<td>NS ($P = 0.115$)</td>
<td>NS ($P = 0.121$)</td>
<td></td>
</tr>
</tbody>
</table>

PNFS = peripheral nerve field stimulation; VAS = visual analog scale; NS = not significant.
increase in their pain following PNFS. Both patients who reported an increase in their pain persisting at the 6-month follow-up also responded poorly to the analgesic, employment, and satisfaction parameters described below.

Given the smaller participation rate in the remaining outcome measures, results from the different implant regions were combined to increase power in the analysis. Participation rates for these assessments were as follows: 1) changes to analgesic use—68/100; 2) changes to capacity for paid employment—40/100; 3) Neck Disability Index—9/100; 4) ODI—10/100; 5) Zung Depression Scale—15/100; and 6) patient satisfaction—61/100.

The principle of PNFS treatment is to provide alternatives to traditional analgesic and surgical options. Given this, we asked patients to report on any changes to their analgesic use by selecting one of the following options: not applicable, unsure, no change, increased, slight decrease, moderate decrease, or extreme decrease. Over 40% of patients declared an extreme decrease in their analgesic intake with an overall 72% of patients reducing their analgesic use following PNFS. Approximately 20% of patients stated that their analgesic regimen had not been altered following PNFS, while only three patients reported an increase (Figure 3).

Patient satisfaction was determined by the following scale: completely satisfied, very satisfied, satisfied, not completely satisfied, or unsatisfied. Thirty percent of all patients were completely satisfied with their outcome. A combined 86% of patients were satisfied, very satisfied, or completely satisfied with their results (Figure 3).

Patients aged below 60 years were asked to assess their capacity for paid employment following PNFS. Overall, 43% of patients reported an increase in their capacity for paid employment with half of this group assessing their improvement as extreme. No surveyed patients reported a decrease in their capacity for paid employment following PNFS, and only 14% of the cohort stated that capacity for paid employment was not applicable to their situation. The remaining cohort of patients stated that their employment capabilities had not changed (Figure 4).

Patients receiving an occipital/craniofacial PNFS implant were asked to complete the Neck Disability Index, prior to the implantation and at follow-up. A trend towards a
decrease in disability from baseline values following PNFS was evident; however, the difference was not statistically significant (Figure 5). Likewise, chronic low back pain patients receiving a PNFS implant in their lumbosacral region were assessed for degree of disability using the ODI. These patients demonstrated a statistically significant reduction in their degree of disability as measured by the ODI (Figure 5).

Patients’ self-assessed depression was measured prior and following treatment using the self-assessed Zung Depression Index. Similarly to the results obtained from the Neck Disability Index, a trend depicting a reduction in patient depression following PNFS was evident, but no statistical difference was present.

Given the positive results obtained with pain relief and improvements in quality of life, we assessed whether results obtained shortly after PNFS implantation was sustained over a longer period. Patients were divided into two groups: those that were followed up less than 8 months after treatment (average of 4.6 ± 1.4; range of 1–7 months) and those followed for at least 8 months (average of 14.8 ± 1.3; range of 8–24 months). These groups were compared with respect to changes in disability, self-rated disability, and quality of life. PNFS: 100 Consecutive Cases

Figure 4 Peripheral nerve field stimulation (PNFS) positively impacts on capacity for paid employment. Patients were asked to assess any changes to their capacity for paid employment following PNFS at an average follow-up time of 8.1 ± 4.7 months. Results were combined from the five different regions and expressed as proportions of the entire patient population. Of the patients who were under the age of 60 years, 43% of them reported an increase in the capacity for paid employment, with 24% of the <60 years age group describing an extreme improvement.

Figure 5 Peripheral nerve field stimulation (PNFS) significantly reduces self-rated disability. Based on their region of pain, patients were asked to complete either a Neck or Oswestry Disability Index, along with the self-assessed depression Zung Questionnaire prior to PNFS and post-PNFS at an average follow-up time of 8.1 ± 4.7 months. Each dot on the plots represents one individual patient PNFS significantly reduces Oswestry’s assessed disability. No significant difference following PNFS was observed with the Neck Disability or the Zung Depression Score (P ≤ 0.086 and P ≤ 0.226, respectively). Statistical differences were tested using the t-test comparison of paired-means, with the P value set at 0.05. NDI = Neck Disability Index; ODI = Oswestry Disability Index.
months) and those that were followed up at 8 months or longer (average of 12.3 ± 3.8; range of 8–23 months).

Pre-PNFS pain scores were equivalent for each group negating any potential impact on the follow-up results. Both groups demonstrated the same reduction in pain scores, confirming that in our study, there was no deterioration in therapeutic response over time (Figure 6).

Complication and AEs were monitored and collected for all 100 patients included in this study (Table 5). Fourteen percent of patients reported an AE with three people complaining of unpleasant stimulation where the leads had been placed too superficially and another with a tight excessive scar around the lead. There were five lead erosions, two hardware failures, one lead migration, and one battery migration. One case of infection was noted, which ironically occurred 1-year postimplant following minor trauma over the occipital lead area. Twelve of the patients had their conditions resolved, and two patients had their systems explanted. Furthermore, three patients had their systems explanted due to the lack of efficacy and ability to achieve adequate pain relief.

Discussion

Based on the general principles of SCS, a number of peripheral neurostimulation techniques have evolved and have been proven useful over the past several years. These include ONS for headache and migraine syndromes, trigeminal branch stimulation for neuropathic craniofacial pain, and PNFS (subcutaneous nerve stimulation) for areas not optimally treated with SCS. This study assessed all three types of techniques measuring outcome parameters such as pain, impact on daily life, analgesic use, and psychological factors such as depression.

An overall reduction of pain and increase in pain relief were observed in most patients receiving PNFS treatment for chronic occipital/craniofacial, thoracic, lumbosacral abdominal, and groin/pelvic pain. Most significant were the results obtained from the three patients receiving PNFS for chronic abdominal pain, who reported an average reduction of 7.0 ± 1.0 visual analog scale.

Pharmacological pain management has yielded varied results over the years. Many drugs are no more, or only slightly more, effective than placebo, while others have side effects that outweigh their usefulness [47]. Opioids have been shown to reduce pain by an average of 10 points on a 100-point pain scale while having very little impact on improving the function or psychological condition of patients with chronic low back pain [47]. While other drugs, such as tramadol, have been shown to provide moderate relief in 35% of patients, the observed time frame was only 4 weeks [48]. In contrast to these observations, PNFS was able to provide pain relief with a mean decrease of 4.2 (95% CI: 3.8, 4.8) pain scale points (42 points on 100 scale) and sustain that pain relief in the 8- to 23-month follow-up cohort. Moreover, an overall 72% of patients were able to reduce their analgesic use following PNFS.

Being effective at relieving pain, the evidence of pharmacological therapies to impact on other factors, such as quality of life and daily activity function, is poorly reported in the literature. This study demonstrated that following PNFS treatment, 43% of patients below the age of 60 acknowledged an increase in their capacity for paid employment. This reflects the findings of Taylor and colleagues in their systemic review of 74 studies, where they report that approximately 40% of previously employed chronic leg/ back pain and FBSS patients return to work following SCS therapy [49]. Furthermore, patients receiving a lumbosacral PNFS for chronic low back pain reported a significant reduction in disability following treatment as determined by the Oswestry Disability Index.

Table 5  Tabulated adverse events for PNFS patients

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead infection</td>
<td>1</td>
</tr>
<tr>
<td>Hardware erosion</td>
<td>7</td>
</tr>
<tr>
<td>Hardware migration</td>
<td>2</td>
</tr>
<tr>
<td>Leads too superficial</td>
<td>3</td>
</tr>
<tr>
<td>Leads too tight</td>
<td>1</td>
</tr>
<tr>
<td>Hardware failure</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>16</strong></td>
</tr>
</tbody>
</table>

PNFS = peripheral nerve field stimulation.
PNFS has a number of advantages over traditional SCS including that it does not carry the same neurological risks such as epidural hemorrhage, paralysis, and meningitis. Given the low invasiveness of PNFS, its reversibility, testability, and adjustability, PNFS is also a preferable option in comparison with the more intrusive surgical alternatives available. The main issue, as with any implantable device, is the risk of infection. A previous study of 41 patients receiving PNFS reported 15% of their patients requiring their leads be removed due to either infection or lack of pain relief after an initially good response [50]. Here, we report an infection rate of only 1% with the patient having their leads reimplanted after a 3-month period; whereby, we were able to replicate their previously successful outcome. Five patients were explanted, three were due to the lack of efficacy with the remaining two explanted due to recurrent lead erosions in the scalp. Other complications such as lead migration and hardware failure occurred in 4% of the patients studied, with no patients reporting a serious or severe AE, suggesting that PNFS is a safe and a well-tolerated pain control option for intractable pain conditions. Moreover, the efficacy in achieving pain relief relies on correct patient selection and the correct placement of the leads, including lead depth.

Randomized placebo-controlled clinical trials are the “holy grail” in truly validating any drug or device. However, given the nature of PNFS, a true double-blinded placebo-controlled trial is nearly impossible without deliberately deceiving the patient. This creates a serious dilemma for surgeons and interventional pain specialists designing scientifically valid studies. Furthermore, interpretation and comparisons between many currently published studies can be difficult due to the lack of consistency among the patient selection criteria, varied follow-up intervals, and differing outcome measurements. Nevertheless, the general consensus on PNFS is still positive with most published studies demonstrating a significant benefit form PNFS in large proportion of their cohorts. Overall, the recent innovations in PNFS technology combined with comprehensive patient outcome studies have the potential to fundamentally change the way we think about pain management.

Acknowledgments

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References


Verrills et al.


