CASE REPORT

Peripheral nerve stimulation in intractable neuropathic pain

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Abstract

Peripheral nerve stimulation (PNS) is a neurostimulation analgesic technique. PNS is utilized to treat peripheral neuropathic pain. It is highly sophisticated and a specialized technique used where other forms of treatment have failed. This paper describes the PNS procedure, its therapeutic principles, indications, and the comprehensive care for patients after the PNS implant. First, we summarize our experience using this type of invasive treatment. In the second part, a case of intractable neuropathic pain following repeated surgery to the ulnar nerve is reported. Prior to PNS, the patient underwent multiple types of antineuralgic treatment with no significant result. Only after the PNS application, was a significant analgesic effect achieved.

Abbreviations:

CNS	- central nervous system
CRPS	- complex regional pain syndrome
CT	- computed tomography
EMG	- electromyography
MRI	- magnetic resonance imaging
NRS	- numeric rating scale
PMC	- pain management center
PNS	- peripheral nerve stimulation
PNFS	- peripheral nerve field stimulation
SCS	- spinal cord stimulation
SSEP	- somatosensory evoked potentials
TENS	- transcutaneous electrical nerve stimulation
UE	- upper extremity

BACKGROUND

Based on the gait control theory by Melzack, Wall and Sweet (1967), for the first time ever, used an electrode to stimulate a peripheral nerve in order to reduce the intensity of post-traumatic neuralgic pain in eight patients. They used a cuff-shaped electrode, itself comprising TENS (transcutaneous electric nerve stimulation) electrodes. The first results were encouraging, although frequent complications occurred. Later, button electrodes of a bipolar or cuff shape were applied. Subsequently, Long and Hagfors (1975) recognized an analgesic effect from applying rectangular voltage pulses to sites of neuropathic pain.

Initially, White and Sweet (1969) suggested functional mapping using a peripheral electric stimulation in order to correctly localize sensory and motor nerve fibers for proper placement of the peripheral nerve stimulator (PNS) electrodes. The orientation of the sensory and motor fibers within the peripheral nerve, however, is subject to continual change with time, thus making it impossible to create a definitive map of the individual peripheral nerves (Stanton-Hicks 2003). In the 80's, new knowledge in physiology and experiments with the flat and circumferential electrodes widened the interest in PNS and TENS utilization in clinical practice. The last decade has seen PNS utilized most frequently in clinical applications.

The application of a flat electrode with four active contacts on its surface in combination with programmable low-voltage generators dramatically increased the efficiency of PNS in the treatment of particular pain syndromes (Hassenbusch 1996). Recently, PNS has been used successfully in a variety of painful conditions, especially in mononeuropathic lesions (Leak & Ansel 1996; Weiner 2003).

PNS OPERATION MECHANISM

Both the peripheral and the central analgesic effect of PNS are accounted for (Ristić *et al.* 2008). However, the exact mechanism remains unclear. The theories suggest a positive effect on many mediators apparently arising from the neurostimulation (serotonin, alanin, epinefrin, substance P, gama-aminobutyric acid – GABA, calcitonin gene-related peptid – CGRP and others) (Stanton-Hicks & Salamon 1997).

SELECTION CRITERIA FOR THE PNS APPLICATION

The criteria, for the application of PNS are not different from those valid for neuromodulation therapy. Clinically, it is first necessary to verify and objectivize the painful syndrome using routine neurophysiological methods (electromyography –EMG, somatosensory evoked potentials –SSEP) and other imaging methods (MRI, CT). Psychological and psychiatric assessment is of great importance as well, similar to that seen in other neuromodulation technique applications. Prior to processing with PNS implantation, detailed evaluation of the patient is critical to establish the analgesic effect of the procedure. It is our experience that interdisciplinary dialog, analysis of the pre-implant examinations and discussion of all the results is especially beneficial in cases where the PNS indication is not absolutely clear. Furthermore, in PNS, positive outcome of preprocedural nerve block by a local anesthetic or analgesic effect of the TENS is of good prognostic value, although it is not an absolute predictor (Buschmann & Oppel 1999).

PNS PROCEDURE AND THE ELECTRODE PLACEMENT

The surgical electrode should be located in a manner that covers at least 80% of the area where the patient perceives the paresthesia. Since it usually is not possible to confirm ideal placement of the electrode preoperative, it is advisable to place the electrode in a predetermined nerve site, proximal to the lesion in the nerve. Optimal electrode positioning for the individual nerves is described in internationally accepted guidelines (Lewis & Racz 1992). For the ulnar nerve it is the brachial sulcus halfway down the shaft of the humerus. Recently ultrasound-guided percutaneous placement of the electrodes is suggested for its accuracy and minimally invasive approach (Chan *et al.* 2010; Huntoon & Burger 2009; Huntoon *et al.* 2008). If implanting the electrode via surgical incision, especially in major peripheral nerves, it is essential to preserve a nutrition blood vessel (vasa nervorum) and prevent potential morbidity associated with dissection of the nerve from surrounding tissues (scar damage) (Stanton-Hicks 2003). Still, in most cases, the PNS electrode is implanted over an open surgical dissection, approaching the nerve proximally from the lesion under general anesthesia, unlike in spinal cord stimulation (SCS) for which a minimally invasive percutaneous technique is frequently used and where general anesthesia is not required (Hassenbusch 1996). The PNS is usually performed in two phases. During the first phase, the electrode is firmly fixed to the nerve ensuring a proper stimulation and the end of the electrode is tunneled subcutaneously and connected with the stimulator for a trial period lasting about a week. After the trial period we validate the PNS effect by evaluating the following variables: pain relief (should be at least 50%), improvement in function and quality of life, reduction of analgesic medication, patient's satisfaction with the PNS and paresthesia perception. After a successful trial period the second phase of PNS starts. A current generator is implanted in a subcutaneous pocket in the subclavicular area and via a subcutaneous tunnel its extension is connected with the electrode on the nerve (Lewis & Racz 1992).

CASE REPORT

A female patient, born in 1975 was referred to our Pain Management Centre (PMC) by a general practitioner in May 2010, because of intractable neuropathic pain in the right ulnar nerve area. No other health issues were present in the personal history. The patient is married, lives happily with her family, worked as a laborer, now on full disability pension because of the neuropathic pain. On the initial visit to the PMC she was already on full antineuralgic medication (Daily: pregabalin 2×150 mg, oxycodon 2×20 mg, amitriptyline 2×25 mg, and clonazepam 0.5 mg nightly).

The onset of the neuropathic pain was in January 2007 following a trivial right elbow injury, and subsequently a slight edema. One week post-injury, a plaster cast was applied to treat persisting pain. After 3 weeks, the plaster was removed but the right arm edema had not receded. The patient then underwent complex rehabilitation and was treated at the neurological and orthopedic department for continuous and persisting pain. In July 2007 the patient was operated for the first time, where deliberation of the ulnar nerve was performed. This surgery, however, did not bring any pain relief and the patient was operated again at the same neurosurgery department in April 2008 where ulnar nerve anteposition was carried out. After this surgery the neuropathic pain in the right ulnar nerve region amplified though the edema decreased slightly.

Based on the clinical picture a diagnosis of complex regional pain syndrome (CRPS), type II – causalgia, was established. Due to the progressing intractable pain another operation; scar excision, ulnar nerve neurolysis and re-transposition of the nerve into the ulnar sulcus, was performed at the 'Institute of Hand and Plastic Surgery' in October 2008. Subsequently, the pain intensity as well as CRPS symptoms continued to progress and in October 2009, at the same specialized Institute, surgery was again performed; re-neurolysis, deliberation and re-transposition of the nerve out of the elbow ulnar sulcus once more. Since the initial surgery, continuous rehabilitation consisting of individual physiotherapy and various types of electro, hydro and thermotherapy was applied with very little effect. Targeted injections into the area of the compromised nerve made the patient's symptoms worse.

Clinical picture at first visit at the PMC (May 2010)

Subjective symptoms: pain in the right ulnar epicondylar region projecting distally, glove pain distribution at the hand with maximum intensity in the 4th and 5th finger. Pain character: burning, shooting, constricting, and a feeling of constant pressure in the arm. After applied load the pain was mostly sharp. The pain was constant, 24 hours a day and disturbed sleep. The patient had difficulty falling asleep, and would wake several times during the night. On the numeric rating scale (NRS) the pain was reported as 8–9/10 during the morning after taking the medication. For the remainder of the day the pain was mostly perceived as 10/10. Loading the extremity made the pain worse, it decreased slightly after taking analgesic medication and sometimes when elevating the arm.

Objective symptoms: slight shoulder asymmetry with the right shoulder elevated, antalgic posture with the affected arm kept in semi-flexion at the elbow and fingers, right tendon reflexes C5/8 were more brusque, and extreme allodynia in the whole ulnar nerve dermatome on the right. When compared to left arm, the right arm was colder, discolored and slightly edematous. Motor dexterity markedly compromised on the right, with handgrip weaker on the right, despite the patient being right handed.

Clinical conclusion: CRPS type II – dystrophic stage of causalgia

Therapeutic procedures

8% capsaicin patch (Qutenza) was applied on the whole painful area, i.e. at the scar in elbow region, ulnar aspect of the forearm, and 4th and 5th fingers as an "ultimum refugium" trial of the conservative antineuralgic therapy. The effect was only partial and temporary. At this time the effect of all possible conservative treatments, including small doses of opioids, had been exhausted.

The patient was then hospitalized and continual infraclavicular block of the brachial plexus with tunneled catheter was applied (see Figure 1), not only to decrease the pain but also as the diagnostic test prior to considering PNS. The patient reported slight pain reduction from the initial 9–10/10 to 7–8/10. As a result of i.v. neuroleptic application, sleep had improved. Peroral antineuralgic medication (antidepressant and anticonvulsive medication), was still being given, the doses constantly adjusted according to its effect. Opioid rotation was also a part of the treatment strategy, however the patient's responsiveness was rather poor. Partial analgesic effect was achieved only after the catheter was applied, i.e. as a result of constant application of the local anesthetics via the catheter and simultaneous peroral medication consisting in combination of antidepressant, anticonvulsive medication and opioids.

As the effect of the combined therapy during the hospitalization was insufficient, PNS was proposed as the next step in treatment. The patient successfully passed all necessary pre-implantation examination, confirmed full indication for this type of treatment, and no contra-indication for the PNS was identified. It was debated whether cervical spinal stimulation was a possible treatment option but as the pain distribution was strictly in the ulnar nerve dermatome the final decision was to proceed with the PNS.

Conclusions of the pre-implantation examinations

Psychiatric assessment: The patient is depressive even anxious, presenting with hints of auto-accusation of self-incompetence in life but also hetero-accusation

due to multiple unsuccessful surgeries. No suicidal cogitations or signs. The psychiatrist encourages the PNS.

Neurological assessment: CRPS as a result of injury and subsequent multiple surgeries of the right elbow, evident neuropathic signs.

Neurosurgery assessment: Agrees with the PNS treatment option, no other type of effective treatment can be recommended

Psychological assessment: Psychosomatic diathesis to develop algodystrophy. Patient's personality is basal, sensitive, accentuated by chronic pain and significant depression.

Immunological assessment: Basic immunological screening does not show any contra-indication to PNS procedure

Before the PNS, continual analgesia, via an axillary accessed "L" shaped tunneled catheter, was applied for a 3 weeks period (Figure 1). This continual brachial plexus block served not only for a pain relief, but as a diagnostic test before the PNS.

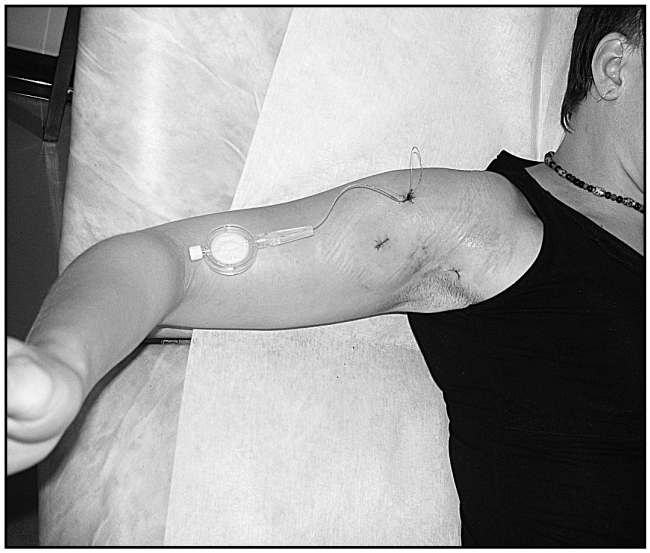


Fig. 1. Axillary applied and L-tunneled catheter.

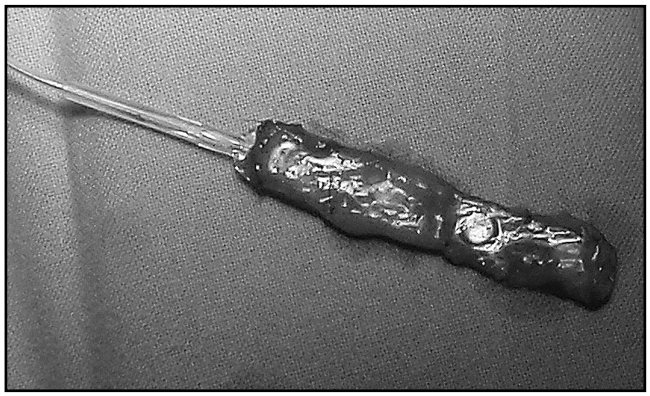


Fig. 2. Electrode encapsulated by fascia.

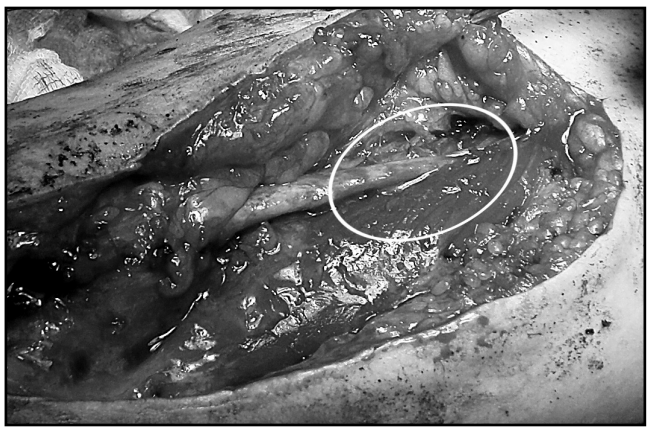
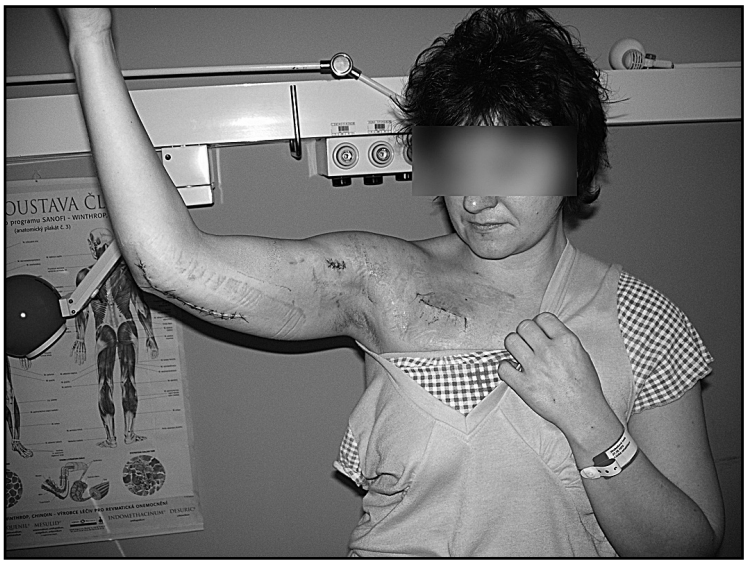
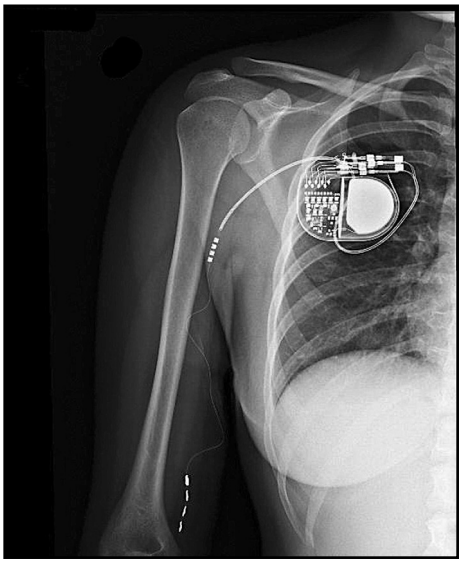


Fig. 3. Electrode placed underneath the ulnar nerve.

PNS Implantation

The initial phase of implantation was done under an antibiotics coverage and general anesthesia at the neurosurgy department. First the ulnar nerve was skeletonized and its position after the previous surgical transpositions revised. A triceps muscle fascia was utilized covering a flat electrode (Figure 2) to prevent a direct contact between the electrode and the nerve. The electrode was fixed underneath the ulnar nerve (Figure 3). The free end of the electrode cable ran in a proximal direction through a 15 cm long subcutaneous tunnel, and was led out externally at the middle radial aspect of the arm. The stimulation efficiency (My Stim electrostimulator) was tested during a one week period. The patient was instructed to switch the stimulator on 3 times a day for a period of 20 minutes. The patient was able to control the amplitude [V] of stimulation (which the patient perceives as stimulation intensity), starting at 0 V and increasing it slowly and gradually as long as the analgesic level was perceived as "comfortable tingling covering the pain". The efficient level was 1.5 V for our patient (usually it is between 1 and 5 V). The post-stimulation effect-interval was between 2 and 4 hours. In the course of the trail period the patient was evaluating the degree and the region of the analgesic effect. The patient's pain decreased to 1–2/10 (from initial 9–10/10) on NRS. The analgesic effect was perceived in both the 4th and 5th finger and in the distal half of the forearm in the entire ulnar dermatome. The patient was unable to analyze the effect of stimulation in the extensive scar area at the elbow, probably also due to recent post-surgical pain. The testing period was considered successful and the optimal stimulation parameters were determined: Amplitude 1.5 V; Pulse Width 300 microsec; Rate 50 pulses/sec. The trial period was followed by the ultimate, second phase of PNS implantation. Via an extension cable the stimulation electrode was connected with the implantable pulse generator (Versitrel Synergy) placed in a subcutaneous pocket in the right subclavicular region (Figures 4 and 5). Post-surgery, the field stimulation parameters were assigned, as determined during the trial period and the patient was instructed on how to handle the system. Three weeks after the PNS implantation the patient reported





Figs. 4 and 5. Final position of the PNS system.

considerable pain relief, 0–1/10 during the stimulation and to 3–4/10 in the course of post-stimulation effect-interval. Pain medications, including opioids, discontinued though pregabalin (3×300 mg) and amitriptyline (25 mg nightly) is still taken. However, this medication is expected to be discontinued gradually, during further check-ups. The patient reports being very satisfied with her pain relief.

DISCUSSION

Aggressive treatment in the early stages improves the prognosis of CRPS (Lee & Nandi 2011). Our patient, however, was subjected to long-lasting and ineffective therapy. Indication for numerous surgeries was not only debatable; it also prolonged the duration of the ineffective therapeutic intervention, and possibly even added to the development of the neuropathic pain by the formation of scar tissues. Entrapment of nerve fibers by collagen has been considered the most probable cause for neuropathic pain associated with scar tissue (Kotani *et al.* 2001)

For maximum restoration of function and pain relief in CRPS, early diagnosis and aggressive treatment is imperative (Hyatt, 2010). A multidisciplinary approach and the inclusion of medical and psychological intervention, physiotherapy, physical and occupational therapy should be applied (Yung Chung & Bruehl 2003). As proposed in our case report, a neurologist, pain specialist, psychologist, psychiatrist, immunologist and neurosurgery and rehabilitation specialists should be involved both in the process of diagnosis as well as treatment. In cases where acceptable conservative treatment fails and the indication criteria are fulfilled, the PNS procedure should be considered early in the continuum of care (Mekhail *et al.* 2010). PNS is a suitable therapeutic approach in CRPS, especially type II, if the pain is perceived in the dermatome of a major peripheral nerve (Hassenbusch 1996). Based on a literature review (Stanton-Hicks 2003; Henderson 2008; Mekhail *et al.* 2010; Hassenbusch 1996) and our own experience we propose the following criteria in patient selection for the use of PNS:

1. Electrophysiological studies (EMG, SSEP) indicate peripheral neuropathy in the appropriate peripheral nerve distribution.
2. Pain is of typical neuropathic nature and perceived in the appropriate peripheral nerve distribution
3. Demonstration of pain relief by 1 to 3 targeted nerve blocks
4. Positive response (at least 50% pain relief) to TENS applied proximal to the nerve lesion
5. Exclusion of psychological overlay
6. The patient must meet all general inclusion criteria for neuro-stimulation procedures. (see the text above: Selection criteria for the PNS application)
7. Not only pain relief but also functional outcome and increased blood supply in the affected area can be expected.

Spinal Cord Stimulation (SCS) is also well established treatment in CRPS and meta-analysis of the CRPS literature suggests that early intervention and the combination of the SCS with physical therapy and rehabilitation are associated with better outcome (Taylor 2006). Stanton-Hicks suggests SCS application in CRPS-I cases, no later than 4 months after failure of conservative treatment (Stanton-Hicks 2006). On the other hand it has been reported that the pain

alleviating effect of SCS in chronic CRPS diminishes with time (Kemler *et al.* 2008). SCS was considered as a possible treatment option, though to minimize the risk of complications related to SCS, we chose the less invasive, more peripheral, and targeted approach of PNS. The advantage of PNS is better electrode fixation unlike rather unstable electrode position in SCS (Stanton-Hicks 2003; Stanton-Hicks *et al.* 2011). To ensure proper electrode fixation in the UE peripheral nerve region Mirone *et al.* (2008) propose the use of a paddle style electrode with a larger profile. This can be secured more effectively by a suture via the subcutaneous tissue to underlying fascia, thus reducing the risk of migration from muscle tension and anchor dislodgment. In case of any uncertainty about electrode position, Klase *et al.* (2009) suggest computer tomography as a reliable method to recognize the position of the implanted peripheral nerve electrodes. According to Ishiszuka *et al.* (2007) migration of the electrode is the most frequent complication in the PNS, occurring in up to 33% of cases and requiring reoperation.

After the PNS has been implanted, all clinical features of CRPS, i.e. pain, impairment of motor function, swelling and autonomic abnormalities (changes in sweating and blood flow) should be evaluated as well as quality of life. Here, the mechanism of peripheral and central sensitization must be taken into account. Peripheral tissue and nerve injury may induce central sensitization, increasing sensitivity of spinal neurons. Pain becomes chronic and non-noxious stimuli painful (Woolf & Mannion 1999) as a result. According to van Hilten (2010), this central sensitization may contribute to the development of movement disorders in CRPS. It is estimated that about 25% of CRPS patients suffer from movement disorders, including loss of voluntary control, bradykinesia, dystonia, myoclonus, and tremor (Hilten 2010). Significant reorganization of central motor circuits (Maihöfner *et al.* 2007), pathological sensorimotor integration in the parietal cortex and inhibition of the primary motor cortex (Baron 2004; Schwenkreis *et al.* 2010) have been identified in CRPS patients supporting the hypothesis that supraspinal involvement may contribute to the development of CRPS and associated movement disorders (van Hilten, 2010). The prevalence of movement disorders increases the longer the duration of CRPS (Veldman *et al.* 1993). The younger the age at onset of CRPS the more likely the patient is to develop dystonia (van Rijn *et al.* 2007). Mechanical hypersensitivity as a result of central and peripheral sensitization (decrease in pressure pain threshold) has been demonstrated in patients with epicondylalgia, more predominantly affecting females (Fernández-Carnero *et al.* 2009). All of the above might be of importance in our patient. Our patient was female, her pain started at rather young age (32 years) at the elbow area, she presented with exceedingly impaired execution of voluntary movements including finger dexterity and a preference of antalgic posture with the affected arm kept in semi-flexion at the elbow and fingers. The unsuccessful treatment of her CRPS took almost 3 years. The signs initially attributed to pain – limited range of motion, motor disturbances, and the semi-flexed position of the arm – might actually have been symptoms of a movement disorder (e.g. bradykinesia and dystonia). Splints or plaster casts, used on our patient after the trauma and following repeated surgeries, are often ineffective in the treatment and may even aggravate dystonic postures and symptoms (van Hilten 2010). As noted by van Hilten (2010), no randomized controlled studies on the treatment of movement disorders in CRPS are available, however we would strongly advocate that an early multidisciplinary approach targeting all the given aspects may benefit these patients. The initial diagnostic and treatment strategy used for our patient lacked the interdisciplinary approach and it can only be speculated that such an approach, as opposed to the more traditional surgical pathway, might have avoided the exacerbation and prolonged duration of the patient's symptoms.

Even though some authors still consider interventional therapies such as PNS and SCS in CRPS to be controversial with unpredictable outcome (Hsu 2009) or its therapeutic effectiveness to be insufficiently demonstrated by randomized controlled trials (van Eijs *et al.* 2011), scientific papers exist reporting improved activity levels and quality of life (Mekhail *et al.* 2010; Van Calenbergh *et al.* 2009; Buschmann & Oppel 1999; Hyatt 2010) and documenting its cost effectiveness (Mekhail *et al.* 2010; Hyatt 2010; Simpson *et al.* 2009). The therapeutic benefit of PNS, such as vasomotor response and improvement in blood flow, and even pain relief may be of a fluctuating nature. The maximum effect may take between 4 and 6 weeks after application to be seen (it was only 3 weeks in our case report). The impact of the stimulation may then attenuate over the next 2–3 months followed by further ongoing improvement. The ultimate effect of the PNS application is best evaluated after 1 year. Better outcomes are reported for the upper extremity compared with the lower extremity (Henderson 2008; Stanton-Hicks 2003).

When considering the SCS or PNS at least partial conductibility of the affected nerve must be preserved. PNS is considered superior if the pain is in the distribution of a peripheral nerve (van Eijs *et al.* 2011). Additionally, PNS is considered to be a safe, effective, nondestructive and less invasive intervention than SCS (Stanton-Hicks *et al.* 2011; Mirone *et al.* 2009; Goyal *et al.* 2010), especially when ultrasound-guided percutaneous placement of the electrodes are used (Huntoon & Burgher 2009; Huntoon *et al.* 2008; Chan *et al.* 2010). Recently Deer *et al.* (2010), introduced an even less invasive approach using a new PNS device which can be implanted via one or two small skin incisions, therefore not requiring conscious sedation or general anesthesia. The electrode is placed subcutaneously at the painful nerve and involves no implanted electronic compo-

nents to which it must be connected. A programmable external pulse transmitter is worn on the skin surface and transmits an electrical current through the skin and tissues to one end of the underlying electrode. Another modern option is utilization of subperineural electrodes applied via micro-dissection or microelectrodes fixed to the subcutaneouse nerves by a simple puncture technique (Alo & Holsheimer 2002). Such technological advances clearly lead a trend to avoid any invasiveness, making the PNS procedure safer, easier and more available.

Additionally, the method of Peripheral Nerve Field Stimulation (PNFS) has now been used more routinely in individual cases where more conventional treatments have failed to control the pain. The PNFS functions in the area of the most intensive pain via percutaneously implanted electrodes (Bittar & Teddy 2009). Subdermal peripheral nerve fibers stimulation prevents transmission of the painful stimuli towards the CNS, positively influences local blood flow, increases endorphin release, regulates neurotransmitters and axonal conductibility and blocks depolarization of the cell membrane (Paicius *et al.* 2006). The PNFS can be used in treatment of various types of neuropathic, as well as chronic nociceptive pain, some types of headache (Yakovlev & Resch 2009), and back pain (Falco *et al.* 2009). It has proved to be effective in relieving post-thoracotomy scar pain (Goyal *et al.* 2010), chronic postoperative pain after total hip replacement (Yakovlev *et al.* 2010) and many other pain syndromes. The advantage is that the PNFS therapy is completely reversible and manual programming permits patients to control the level of stimulation enabling them to take an active role in their pain management (Yakovlev *et al.* 2010). This aspect was also highly appreciated by our patient. In accordance with other studies (Yakovlev *et al.* 2010), our patient reported other positive PNS outcomes like returning to work, as well as social, recreational and sporting activities after a 3 years period of incapacity.

The PNS still is not frequently enough used treatment in neuropathic pain in the Czech Republic for the lack of knowledge and experience among medical professionals and because it is considered to be an expensive treatment method. Evidence based studies, however, prove its cost effectiveness (Mekhail *et al.* 2010; Hyatt 2010; Simpson *et al.* 2009). Since our patient, following the PNS implant, discontinued costly chronic medication and rehabilitation, no longer requires frequent visits with various medical professionals and even returned to work, it can be assumed that the PNS will also prove to be economically the most effective type of treatment, especially considering her young age. PNS should only be considered after careful multidisciplinary evaluation and following discussion of other treatment options. All possible limitations to PNS must be considered prior to its application. Complications like a device breakage or malfunction, migration of the electrode or infection (van Eijs *et al.* 2011) may occur. However, if the PNS procedure is successfully accomplished, in well selected patients with peripheral neuropathic pain, it remains effective even after more than 20 years (Van Calenbergh *et al.* 2009).

CONCLUSION

This case report points out that modern technologies are still not used sufficiently in patients with intractable pain. Debatable repeated surgeries and insufficient medication therapy utilized for far too long could possibly promote the patient's pain, resulting in chronic pain behaviour. Early multidisciplinary approach is emphasized to recognize a candidate suitable for PNS and a successful outcome.

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