# 16
# Peripheral Nerve Stimulation

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The gate control theory of pain proposed by Melzack and Wall in 1965[1] suggested that electrical activation of large diameter afferent fibers would have an inhibitory effect on the central transmission of small diameter afferent fibers, thereby blocking pain perception. Wall and Sweet[2] tested this hypothesis by observing that low threshold electrical stimulation of peripheral nerves via subcutaneous electrodes produced temporary pain relief in a group of five patients with posttraumatic neuralgias. This led Sweet[3] in October 1965 to perform the first permanent implantation of a peripheral nerve electrode in an attempt to obtain long-term pain relief. Peripheral nerve stimulation (PNS) has been employed by numerous other investigators since that time, and it has become established as a valid treatment option in a small group of carefully selected patients.

## Mechanisms of Action

Although the gate control theory was extremely influential in provoking new ways of thinking about chronic pain, many of its central tenets were not supported by subsequent investigations. Nevertheless, there is experimental evidence that PNS may act through a central inhibitory mechanism. Chung et al[4,5] have shown that a 5-minute conditioning stimulus applied to a peripheral nerve produces profound inhibition in primate spinothalamic tract cells in response to both noxious electrical and thermal stimuli. The inhibitory affect often outlasted the conditioning stimulation by 20 to 30 minutes. This was seen in spinalized animals as well as intact anesthetized monkeys indicating that inhibition was, in part, dependent on spinal cord neuronal circuitry. Their work suggested that the most effective way of producing analgesia with PNS would be high-frequency stimulation at an intensity sufficient to activate A-$\delta$ fibers applied to a nerve enervating the area from which the pain originates.

There is also evidence that PNS may produce analgesia through a peripheral mechanism. Ignelzi and Nyquist[6] recorded single fiber activity in the cat superficial radial nerve using glass micropipettes. After repetitive high-frequency electrical stimulation of the nerve through a cuff electrode similar to that used for clinical pain control, there were transient excitability changes in both large and small diameter afferent fibers. These consisted of a slowing in single fiber conduction velocity, an increase in electric threshold, and/or a decrease in response probability. Their data support a hypothesis that clinical electroanalgesia is mediated by a direct change in peripheral nerve fiber excitability.

Campbell and Taub[7] confirmed that human subjects experience sensory loss in the distribution of a peripheral nerve stimulated transcutaneously. The onset of analgesia was associated with the loss of the A-$\delta$ component in the compound action potential recording, suggesting that a peripheral axonal blockade was responsible for the observed effect.

Experimentally produced neuromas in rats, cats, and mice have been shown to generate spontaneous neuronal activity that may be a source of pain. Axonal firing is further increased by mechanical



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stimulation of the neuroma or by exposing the neuroma to catecholamines. Wall and Gutnick[8] have shown that tetanic stimulation of a cut dorsal rootlet markedly reduces the rate of spontaneous firing from a rat sciatic nerve neuroma for periods of minutes to more than an hour. This degree of suppression was never seen for intact sensory endings where excitability and ongoing discharge returned to baseline levels within seconds after antidromic stimulation. Direct stimulation of the neuroma itself had a similar effect in depressing ongoing neuronal activity.

The laboratory investigations cited above strongly suggest that the pain relieving effects of clinical PNS are mediated by both central and peripheral mechanisms.

## Recording from Implanted Electrode

Racz et al[9] made electrical recordings from the implanted electrode during the 3 days of trial stimulation on nine patients. The recording system consisted of a Grass P511 amplifier with a Hi Z probe. The recordings revealed unexpected spontaneous activity, as shown in Fig. 16.1. These limited observations are consistent with suggestions that spontaneous nerve activity may be associated with certain pain states and may be causally related to the nociception (afferent) or its sequalae (efferent; swelling, edema, vasoconstriction).

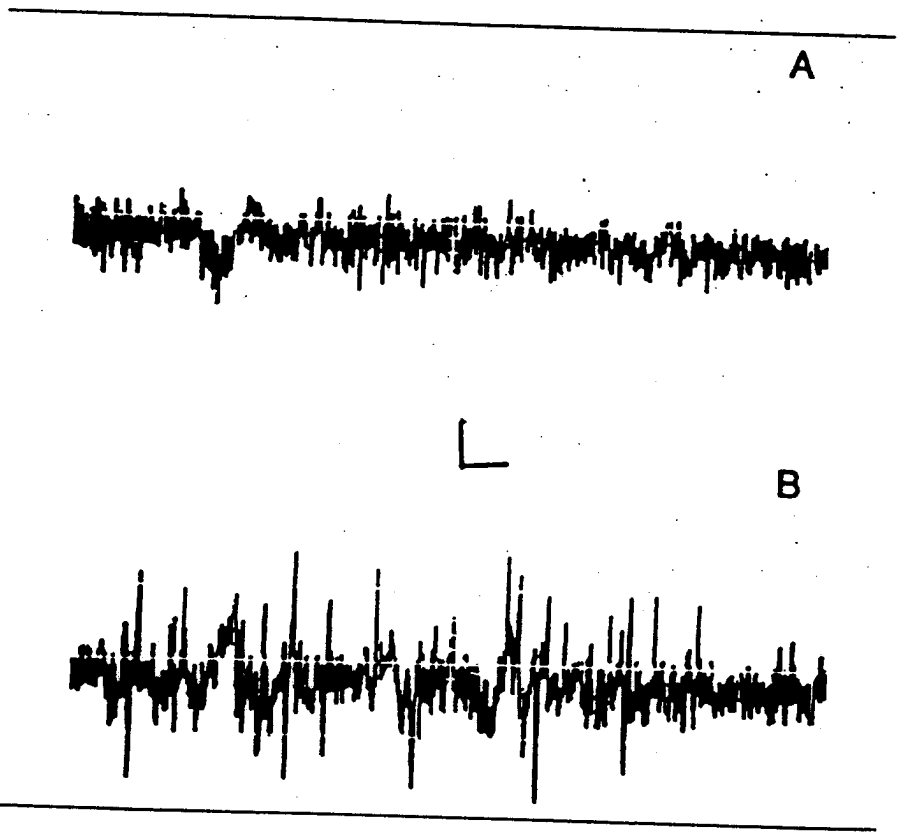


FIGURE 16.1. Recordings of spontaneous activity in the tibial nerve of a patient with foot pain. Note sharp waveforms rising at regular intervals from nearly flat baseline. These waveforms presumably are produced by synchronous activity in a population of axons with homogenous conduction velocity. Vertical scale = 20 $\mu$V; horizontal scale = 20ms in A and 50 ms in B. From Racz et al. [9]

## Patient Selection Criteria

The initial patient selection criteria for PNS are similar to those utilized for any pain control operation. There must be a clear-cut etiology for the pain, and correctable pathology (eg, a nerve entrapment syndrome) should be excluded by appropriate diagnostic studies. Standard conservative treatment measures including physical and exercise therapy, medications, transcutaneous neurostimulation, and nerve blocks should be given a thorough trial. Only patients with intolerable pain despite these efforts are candidates for PNS. Issues of psychiatric pathology, pain-related behavioral factors, and drug abuse must be considered and either excluded or treated prior to surgical intervention.

Virtually all investigators agree that pain in the distribution of a single traumatized peripheral nerve constitutes the best indication for PNS. Some authors have labeled this condition posttraumatic neuralgia, while others have used the terms causalgia or reflex sympathetic dystrophy. Pain characteristic of reflex sympathetic dystrophy that extends outside the territory of a single peripheral nerve is more appropriately treated by spinal cord stimulation if a neuroaugmentative procedure is elected. The use of PNS for sciatica, pain associated with failed low back surgery, cancer pain, idiopathic pain, and pain due to nerve root injury, yielded poor results in earlier series, and these should no longer be indications for this technique.

Many surgeons[2,5] have emphasized the preoperative use of local anesthetic nerve blocks as a selection criteria. If total or near total pain relief is produced on a temporary basis by blockade of a single peripheral nerve, the patient is felt to be a better candidate for PNS. Sweet[3] performed preoperative nerve blocks in 52 patients who subsequently underwent implantations of a peripheral nerve electrode. There were 46 patients who experienced temporary pain relief with an appropriate nerve block. Only 13 of these individuals had sustained pain relief with electrical stimulation of the same peripheral nerve. Of the six patients whose pain was not relieved by nerve block, a single long-term success was observed. It appears that pain relief with nerve blockade does not ensure a favorable response to PNS, but continued pain despite a technically adequate nerve block makes it very unlikely that electrical stimulation of the same nerve will be successful. A local anesthetic block of a single peripheral nerve should be performed preoperatively in patients under consideration for PNS. They should be excluded as surgical candidates if their pain is not stopped temporarily.

Pain reduction with a trial of transcutaneous nerve stimulation (TNS) has also been felt by some to be predictive of success with PNS. This was evaluated in detail by Picaza et al.[10] Thirty patients responded preoperatively to TNS. There were 16 long-term successes in this group with PNS, and 14 failures. Seven patients did not benefit from TNS. Three of these were helped by PNS while four were not. This experience indicates that patients whose pain is not lessened by TNS may be less likely to succeed with PNS, but this should not in itself exclude a patient as a candidate for PNS.

Recent series[2,3,10] have emphasized the use of externalized lead wires for a temporary trial of PNS before permanent electrode placement and connection to a radiofrequency receiver or an internal pulse generator is performed. This type of screening requires an initial surgical procedure, but it does avoid the extra cost and potential morbidity of a permanent electrode system if there is no benefit during a 2 to 8 day trial interval. An approach of this type is warranted and serves to eliminate some patients who will not be helped by PNS.

Racz et al[9] reported outcomes of 24 implants placed in 23 patients. Since that report, additional implants have been done. The total number done at this center now exceeds 180. Outcomes of 125 implants will be presented.

Electrodes were placed on the following nerves: median, ulnar, posterior tibial, peroneal, radial, or sciatic. Criteria for implant include that the patient is suffering from intractable pain secondary to peripheral nerve damage or reflex sympathetic dystrophy (RSD), and more conservative therapies have failed.

## Surgical Procedures

The surgical implant is done in two phases with the patient under general anesthesia. Phase 1 involves surgical implant of the stimulation electrode followed by a 3-day evaluation period. Patients who

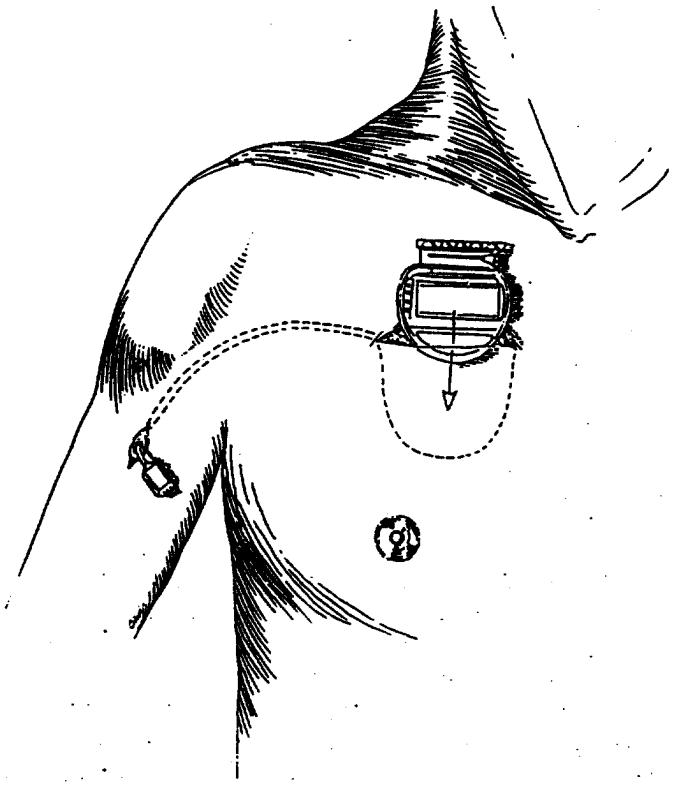

FIGURE 16.4 The pulse generator is implanted in the upper chest wall when the upper extremity is involved. From *Peripheral Nerve Stimulation Surgical Technique Notebook*, Medtronic, Inc. Reproduced with permission.

pulses/s; cycling, time on 64 seconds, and time off, 2 minutes, soft-start on. The appropriate amplitude is found by increasing the stimulus intensity by 0.25-V increments until the patient reports a perception of stimulation. Optimal settings are further fine-tuned by increasing or decreasing the pulse width.

## Results

A number of groups reported their experience with PNS in the late 1970s and early 1980s. There was then little published information on this procedure over the next 10 years. Recently, several surgeons have revitalized interest in PNS by describing results that seem comparable or superior to those of the early investigators.

As is often the case with pain procedures, it is difficult or impossible to compare series because of differences in patient selection criteria, follow-up intervals, and outcome assessment. The experience from eight major studies on PNS will be summarized.

Sweet,[3] who performed the first peripheral nerve electrode implantations, described his initial experience in 1976. A total of 69 patients were treated, 47 of whom had posttraumatic neuralgias. The overall long-term success rate was 25%. A successful outcome required a patient to be off all but mild analgesics and to have returned to productive activity. Sweet observed higher success rates with stimulation of primarily sensory nerves, such as the superficial radial nerve. The poorest results were with sciatic nerve stimulation, particularly for pain associated with prior low back surgery. There were eight infectious complications in his series, with no instances of secondary nerve injury.

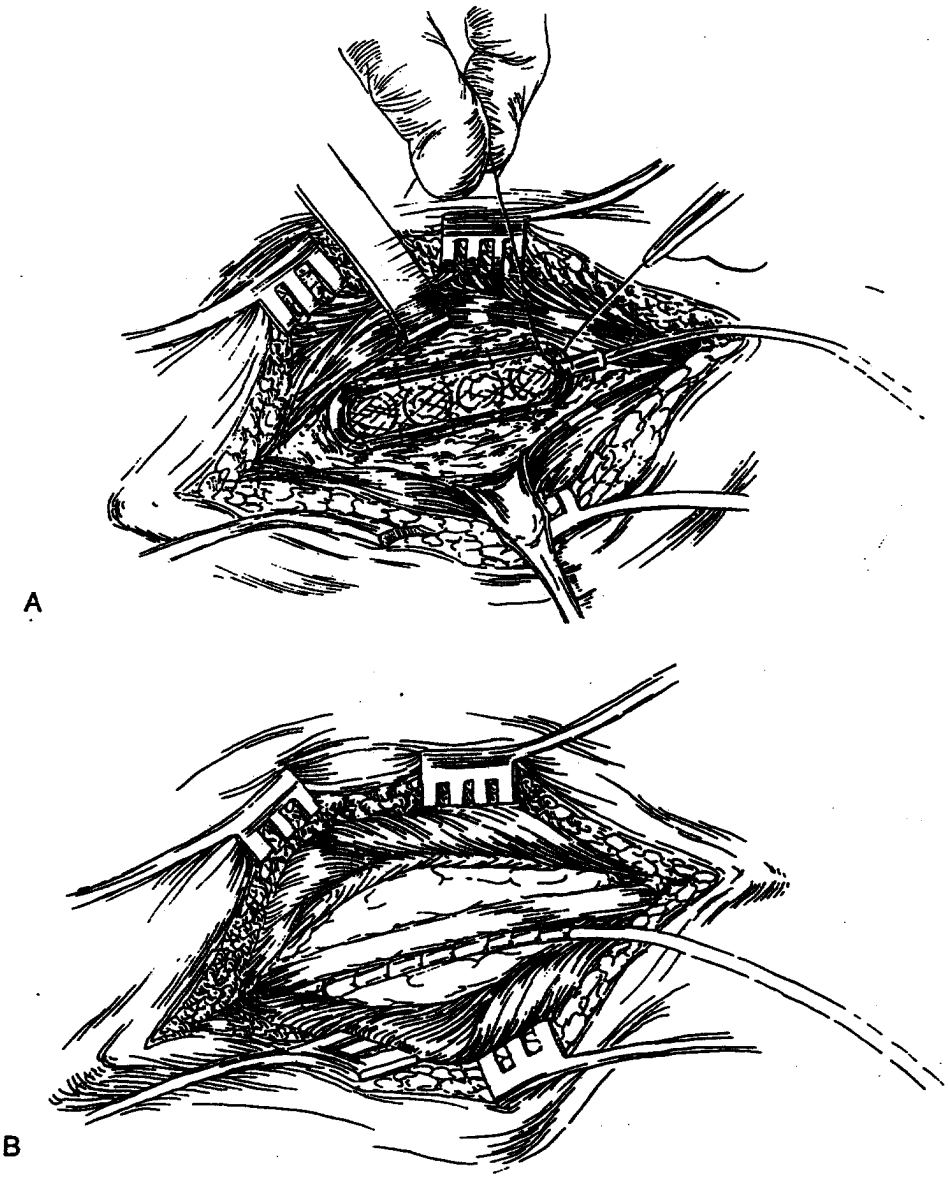


FIGURE 16.3. Electrode implant. (A) fascia is sutured over the electrode and electrode is sutured in place; (B) nerve is allowed to fall into place over the electrode. From *Peripheral Nerve Stimulation Surgical Technique Notebook*, Medtronic, Inc. Reproduced with permission.

in the lower quadrant of the abdomen, below the beltline, when saphenous nerve stimulation is used; or in the thigh approximately over the Hunter's canal area when tibial nerve stimulation is used. When the generator is placed in the upper chest wall (in the general area where pacemakers are implanted), a single nonabsorbable suture is placed through the plastic portion of the generator and the deep fascia overlying the pectoralis muscle to prevent migration. With the lower abdominal implant, care is taken to prevent the generator from contacting the iliac crest and from compressing the iliohypogastric nerve.

The usual initial settings of the Itrel unit are as follow: amplitude, 0.75 to 1.25 V; pulse width, 190 to 400 microseconds; pulse rate, 65 to 85

benefit from the implant enter phase 2 that involves total implant of the apparatus including the battery-powered pulse generator.

Usually a site proximal to the injury is selected for electrode placement (Fig. 16.2). A longitudinal incision is made and dissection to the neurovascular bundle completed. Then a section of nerve approximately 5 to 6 cm long is dissected completely free of surrounding tissue. A flap created from adjacent fascia is placed over the electrode to prevent direct contact between the electrode and the nerve (Fig. 16.3A). The electrode is placed directly under the nerve and sutured in place (Fig. 16.3B,C). Sutures pass through the periphery of the electrode supporting matrix into muscle fascia. The nerve is allowed to return to normal position in such a way that it passes directly over the electrode. Several soft tissue elements are sutured loosely over the nerve to maintain close contact between the nerve and the electrode. The electrode lead is externalized through a small stab wound. The electrode is then connected to a temporary electrical stimulator (standard screener model #7431, Medtronic).

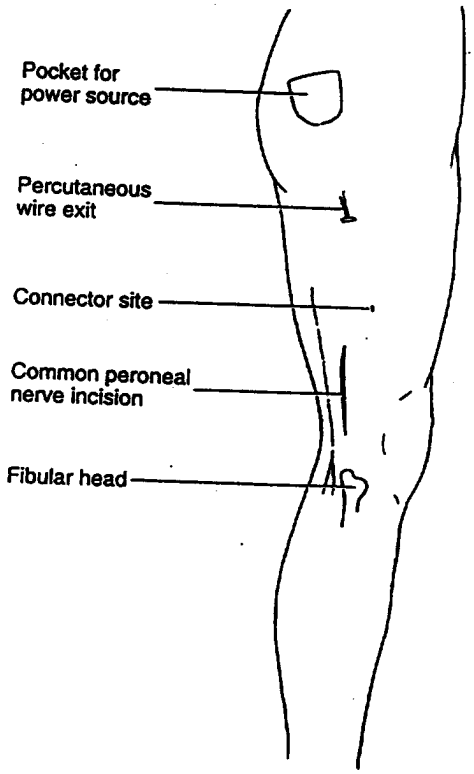


FIGURE 16.2. Incision sites for peripheral nerve stimulator implant. From *Peripheral Nerve Stimulation Surgical Technique Notebook*, Medtronic, Inc. Reproduced with permission.

## Electrode Stimulation Requirements

The implanted electrode has four separate contact points numbered 0, 1, 2, and 3. Any combination of two electrodes may be used for stimulation. When the patient awakens from anesthesia, temporary stimulation is begun. The usual initial settings follow: rate, 65 to 80 pulses/s; voltage, 0.8 to 1.2 V; pulse width, 400 to 500 microseconds. Pattern of stimulation, stimulus duration, and voltage, and contact points through which the stimulation is applied are varied as necessary to get the desired response. The settings are considered to be satisfactory when the patient reports a fine tingle in the distribution of the nerve that is being stimulated and there is complete resolution of pain. Stimulation via contact points 0 and 3, at opposite extremes of the electrode, usually give the best results.

Temporary stimulation is evaluated for 3 days. During this time, pain from the surgical incision usually is present. However, the patient's ability to move extremities previously immobilized by pain can be quite striking. Also, it can be quite remarkable that patients who have been unable to sleep restfully, sometimes for years, may report the ability to sleep all night. If the patient as well as the physicians are satisfied with the response to nerve stimulation (ie, satisfactory pain relief), a permanent Itrel (Medtronic) programmable signal generator is implanted under general anesthesia.

## Permanent Pulse Generator Implantation

The externalized wires are removed and wires to connect the electrode to the implanted pulse generator are tunneled subcutaneously. The pulse generator is implanted in the upper chest wall when the upper extremity is involved (Fig. 16.4);

Campbell and Long[11] in 1976 also reported on a group of 33 patients undergoing PNS, with follow-up intervals from 3 to 68 months. They considered an excellent result to be one in which the patient used no narcotic analgesics, experienced subjective pain relief greater than 50%, resumed normal activities, and had improvement in sleep habits and depression. A partial success designated a patient who met "some" of these criteria. Electrodes were implanted in 14 patients with posttraumatic neuralgias of the brachial plexus, median nerve, or ulnar nerves. There were nine excellent results and 3 partial successes in this group, for an overall response rate of 86%. An additional 19 patients were implanted with sciatic nerve electrodes, primarily for metastatic disease and for sciatica associated with prior low back surgery. There were 4 partial successes in this group and 15 failures. Complications were limited to one infection and one idiosyncratic reaction to the implanted material.

In a later communication, Long et al[12] observed that 7 of 8 patients who were treated with excellent results from ulnar and median nerve electrodes found the need for stimulation diminished after approximately 1 year. They were subsequently able to obtain satisfactory relief with infrequent stimulation.

Picaza et al[10] summarized their early experiences with PNS in 1978. They implanted 69 patients and reported in detail on 37 patients who had follow-up for 12 to 46 months. There were 18 patients with "significant" relief (greater than 50% reduction in pain intensity and/or duration), and 19 patients with "insignificant relief" (less than 50% reduction), for a long-term success rate of 50%. Their series included a wide variety of pain syndromes, but they observed that pain secondary to peripheral nerve or cord injuries responded more favorably, while those related to postoperative lumbar disk surgery or arthropathies did worse.

Picaza et al[10] noted a higher incidence of nerve injury as a consequence of implantation than have other authors. There were four instances of tenderness at the electrode site and progressive motor-sensory deficits that they attributed to neuroma formation. Twenty patients were reoperated on for various reasons. There were two instances of sepsis and four cases in which a thick capsule had formed between the nerve and the electrode, which they termed a "fibroneuroma."

Law et al[13] implanted 22 patients with peripheral nerve electrodes, all of whom had posttraumatic neuralgia. Their experience as of 1980 involved an average follow-up of 25 months, with a range of 9 to 88 months. There were 13 successful outcomes (59%) defined as patients who were using only their stimulation for pain relief. They had a single case of sepsis with no instances of nerve injury in their operative series. One-half of their patients, however, required repeat surgery to reposition electrodes or to change electrode stimulation combinations for maximal effectiveness.

Nashold,[14] another pioneer in neuroaugmentative pain surgery, summarized his experience with PNS in 1982. There were 35 implanted patients with follow-up intervals of 4 to 9 years. In addition to the long follow-up times, his series is distinguished by its unusually stringent criteria for defining a favorable outcome. To be considered a surgical success, patients had to have experienced a subjective decrease in their pain of 90% or more, be off all analgesic medications, increase their physical activity, and continue to use their stimulation for pain control.

There were 10 of 19 (53%) successful outcomes for upper extremity nerve implants, and 5 of 16 (31%) for sciatic nerve implantation. Nashold et al[14] found, as have others, that the results of sciatic nerve stimulation were significantly poorer than those for other nerves, particularly in cases of sciatica associated with prior low back surgery. Their operative complications were limited to one instance of median nerve constriction secondary to electrode placement, and two superficial wound infections that did not require hardware removal. Their initial patients were implanted with a silastic cuff electrode, but in more recent cases they advocated the use of button electrodes adhered around the epineurium in a pattern determined by the patient's response to intraoperative stimulation under local anesthesia.

The preceding series all utilized circumferential cuff electrodes (with the partial exception of Nashold et al[14]) in combination with implanted radiofrequency receivers with external radiofrequency transmitters that could not alter electrode polarities or combinations short of surgical revision. Over

the past 5 years, several groups have reexamined the merits of PNS using equipment originally designed for spinal cord stimulation. This involves the placement of a multicontract electrode parallel to rather than around the nerve, and connecting it to an internal pulse generator or a radiofrequency receiver, either of which can be programmed externally to change electrode combinations or polarities. (Resume electrode and Itrel II pulse generator, Medtronic, Inc., Minneapolis, Minnesota.) In addition, lead wires from the electrode can be externalized for a period of days to permit a trial period of nerve stimulation before a permanent system is implanted. These new techniques, combined with a better understanding of optimal patient selection gained from earlier investigations, may yield improved surgical outcomes.[15]

Cooney[16] reported an additional 25 patients treated with implantation of a longitudinally oriented peripheral nerve electrode, and a programmable internal pulse generator or a radiofrequency receiver. All patients had upper extremity pain symptoms secondary to nerve injury. There was complete pain relief in 5 patients and a greater than 50% pain reduction in an additional 16 patients (84% improvement rate). Two patients had inadequate pain relief during the initial 2 to 8 day screening process, and the remaining 2 patients were considered to be failures at a later date. The follow-up interval was not specified. Complications were limited to technical malfunctions of the stimulating equipment in two patients.

Hassenbusch and coworkers[17] at the Cleveland Clinic have described 23 patients undergoing electrode implantation for what they term stage III reflex sympathetic dystrophy associated with symptoms located entirely or mostly in the distribution of a single peripheral nerve. Patients were followed at least 1 year with varying adjustments made in stimulus parameters and patterns of stimulation. There was "mild-marked" relief of pain in 22 of 23 patients. No operative complications were described.

In a period spanning 1987 to 1992, 125 implants were placed in 117 patients. The follow-up period to date ranges from less than 1 to 53 months. Follow-up information for 16 patients is not available at this writing. Demographic information about the patients is presented in Table 16.1. Over half of the patients were female. The averages of the males and females were equal, although the upper bound of the age range was higher and the lower bound was lower for the female patients.

TABLE 16.1. Patient information.

| | |
|---|---|
| Total number of patients | 117 |
| Total number of implants | 125 |
| Number of patients with 2 implants | 8* |
| Number of Males | 48 |
| Average (range) age 38 (23–63) years | |
| Number of Females | 69 |
| Average (range) age 38 (14–69) years | |

In over half of the male patients the initial injury was work related (Table 16.2). Work-related injury was also the most common source of injury, excluding "other," in female patients. Prior treatments were similar for males and females (Table 16.3). Sympathetic ganglion block was the most common prior treatment. The incidence of prior surgery was higher in females than in males. Two-thirds of the implants were done on an upper extremity (Table 16.4). Of the eight patients receiving double implants, all were on nerves of the same limb with the exception of one patient whose implants were on the same nerve of opposite limbs (Table 16.4).

All patients responded positively to trial stimulation and progressed to phase 2 (implant of battery generator). Patients reported that sleep was more restful and lasted longer beginning the night after the trial stimulation was started. Opioid use was reduced or not needed after implant in patients taking opioids before surgery. Of the 101 patients available for long-term follow-up, 78 had good to excellent relief for up to the maximum follow-up period of 53 months. Other outcome data are presented in Table 16.5. The device was removed from 3 patients whose pain was resolved. It was removed from 11 patients whose pain relief was not sustained and from 1 patient who had minimal pain relief and did not like the PNS. Table 16.6 shows the time from implant to when 73 patients

TABLE 16.2. Source of injury.

| | Work | Surgery | Other* | Unknown |
|---|---|---|---|---|
| Male | 25 | 6 | 16 | 1 |
| Female | 20 | 14 | 26 | 9 |

*Includes: electrical shock; fracture; puncture; venipuncture; gun shot; fall; sports; sprain; accident; hyperextension; crush.

TABLE 16.3. Prior treatment for RSD.

| Type of treatment | Male | Female |
|---|---|---|
| Sympathetic blocks | 43 | 64 |
| Intravenous regional anesthesia (reserpine/guanethidine) | 17 | 30 |
| Epidural blocks | 9 | 13 |
| Spinal cord stimulator | 5 | 11 |
| TNS | 12 | 11 |
| Physical therapy | 23 | 25 |
| Surgery | 15 | 35 |

TABLE 16.5. PNS Patient report of outcome (%)

| | Males | Females |
|---|---|---|
| Good to excellent pain relief | 71.8 | 80.5 |
| Minimal pain relief | 12.8 | 4.9 |
| Implant no longer needed (explant) | 15.4 | 14.5 |
| Increased activity level | 66.67 | 67.7 |
| Presently employed | 51.3 | 30.6 |
| Sleep improvement | 61.5 | 66.1 |
| Pleased with outcome | 76.9 | 82.3 |

Subjects: 39 male, 62 female.

required additional treatment (eg, drug prescription or change of prescription) for their pain. It is common for patients to require sympathetic blocks the first year following implant to treat "sympathetic storms" if they occur. Usual practice is to do a local anesthetic sympathetic block followed by a neurolytic block.[18] The general tendency over time for patients who gain long-term benefit from PNS is for the patients to progressively improve and then become less reliant on PNS.

Some patients presented with poorly localized pain complaints (whole body RSD) whose medical history indicated that the trigger was a peripheral nerve injury. Initially the patient's pain was localized to the injured limb, but over time became progressively more diffuse. Following PNS implant on the affected nerve, the pain regressed in the same fashion as it had progressed.

TABLE 16.4. Location of implant.

| | Male | Female |
|---|---|---|
| Upper extremity | | |
| R. ulnar | 11 | 12 |
| R. median | 9 | 12 |
| R. radial | 2 | 1 |
| L. ulnar | 7 | 12 |
| L. median | 5 | 9 |
| L. radial | 2 | 2 |
| Lower extremity | | |
| R. peroneal | 1 | 2 |
| R. post. tibial | 7 | 9 |
| L. peroneal | 1 | 5 |
| L. post. tibial | 5 | 10 |
| L. sciatic | 0 | 1 |
| Includes the following double implants: | | |
| R. peroneal/post. tibial, $n=2$ | | |
| R. ulnar/median, $n=1$ | | |
| L. peroneal/post. tibial, $n=3$ | | |
| L. ulnar/median, $n=1$ | | |
| L. median/R. median, $n=1$ | | |

One problem that sometimes limited the therapeutic benefit of the PNS implant was the therapeutic benefit itself. When the patients felt better and increased their activity, their movement sometimes changed the juxtaposition of the nerve and the electrode or broke a wire connecting the electrode and signal generator. Twenty-seven patients required reoperation to repair broken leads or to reoppose the nerve and electrode. The electrode with the in-line connector (Medtronic Model 3587) has a greater tendency to fracture than does the electrode with the braided wire connector (Medtronic Model 3586) that is now used.

While all 117 patients whose medical progress was reviewed progressed through phases 1 and 2, 5 of the 180 implants done by Racz et al[18] did not (ie, showed no benefit from trial stimulation). Overall, this suggests that criteria used by this team to select patients for PNS was highly predictive, but not foolproof, and that the phase 2 approach to implant has merit. One patient judged to be a candidate for PNS refused the treatment. Subsequently the affected limb was amputated and the patient developed phantom limb pain. Based on their experience, Racz et al speculate that the PNS implant may have obviated the need for amputation.

As indicated, implants generally were done proximal to the injury site. However, the implant was distal to the injury site in three patients, all of whom benefited from PNS (one patient for nearly 5 years).

TABLE 16.6. Latency to additional treatment (mo).

| | <1 | 2 | 3 | 4 | 5 | 6–12 | >12 |
|---|---|---|---|---|---|---|---|
| Number of patients | 22 | 3 | 7 | 7 | 4 | 22 | 8 |

$N=73$.

In evaluating these results, one must take into consideration that this is a very difficult series of patients with which to deal. Most of the patients have had pain for a long period of time, have had multiple treatments that had failed, and many were referred from long distances. The latter makes long-term follow-up difficult. There must be good communication between the referring physician and the referral center. An example of the importance of this is one patient whose limb was splinted by the referring physician following PNS implant. This led to scarring around the electrode, making reoperation difficult, and ultimately the patient's limb was amputated. The referring physician should clearly understand that a treatment goal is to increase activity and therefore anything that limits activity is counterproductive. Despite the odds against success, the great majority of our patients treated to date have gained some benefit from PNS implant; in some the pain is resolved and a large number have sustained substantial pain relief.

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