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Chronic Pain Treatment With Direct Electrical Nerve Stimulation

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AUTHOR'S KEY POINTS

- Patients with chronic pain who have no demonstrable peripheral nerve abnormality requiring primary surgical release but who have complete relief of symptoms with peripheral nerve block, some improvement in symptoms with transcutaneous nerve stimulation, and no exacerbation of symptoms with transcutaneous nerve stimulation are candidates for treatment with implantable electrical nerve stimulation.
- Nerve blocks are used to confirm the anatomical location of the pain stimulus.
- An initial screening phase involves peripheral nerve exploration, placement of a stimulating electrode proximal to the site of nerve pain, and external neurolysis if necessary. Electrical stimulation on the day(s) following implantation allows changes in amplitude and rate of nerve stimulation to be made. The screening period lasts 2 to 8 days.
- After the initial screening, an electrical implantable pulse generator, which provides the impulse for electrical stimulation, is inserted. An SE-4 external programmer or a metal-backed Itrel implanted pulse generator with telemetry system is used.
- Results of treatment of patients with chronic, intractable pain are encouraging. There has been a consistent improvement in the level of pain, the use of narcotic analgesics has been reduced, and loss of sleep has been alleviated in most patients treated.

Chronic intractable pain that results from direct damage or repetitive operative insults to peripheral nerves presents a nearly impossible quandary for the treating physician, who often exhausts all possible conservative treatment options without providing any significant improvement of symptoms.

In this chapter, I report my preliminary experience with operative intervention for chronic pain with a program of direct electrical stimulation of involved peripheral nerves. While not universally successful, I have found that the relief of chronic pain gives patients an improved mental outlook,

relief from depression, lasting sleep, release from narcotic addiction, and a general sense of restored psychological well-being.

Pain in the extremity appears to be the result of overwhelming, uninhibited sensory stimuli that embrace the central nervous system such that even minor perceptions such as cold, touch, vibration, and moving impulses stimulate painful awareness.[1,13] The pain pattern is different from the sympathetic overflow associated with reflex sympathetic dystrophy. Sympathetic nerve blocks are not helpful, and laboratory studies to assess increased vasomotor tone such as bone scans and quantitative sweat testing are often unremarkable.[3,4] Local trigger areas may be present, but often there are several sites of painful stimuli. Even the unaffected extremity appears to be in sympathy by having increased irritability of peripheral nerves. In general, one main source of nerve pain can be isolated, and when pain from this source is corrected, the other locations of pain dysfunction often improve.

Melzack and Wall in 1965 proposed the hypothesis that peripheral limb pain is controlled by a gate mechanism in which transmission cells are influenced by outside stimuli and that by blocking the firing of these cells, the experience of pain can be controlled.[7] Large alpha peripheral nerve fibers are believed to inhibit the transmission cell response, while small beta fibers stimulate the cellular response of pain. They proposed that electrical stimulation of large alpha fibers would be effective in reducing pain perception either by inhibiting the activation of the smaller beta fibers directly; by producing blocking nerve interference with sensations in the autonomous zones; or by directly stimulating dorsal column cells in the spinal cord that increase large cell activity, with the result of "closing the gate" to chronic pain (see Chap. 100).

With electrodes implanted on the median and ulnar nerves of patients with traumatic peripheral neuropathy, Sweet and Wall produced a "pleasant tingling sensation" in the patients' fingers that was followed by a subsidence of burning pain.[10,15] Subsequent use of electrical stimulation of the dorsal column of the spinal cord was reported to improve chronic back pain and lower limb pain, and the gate theory of pain relief by electrical stimulation was established.[6,9,15]

CLINICAL EXPERIENCE

In an effort to improve the treatment of patients with chronic neurogenic upper extremity pain, an implantable electrical stimulation system was initiated on a trial basis in 1986 at our institution with the Medtronic SE-4 System* and Medtronic Resume Stimulating Lead (Figs. 105-1, 105-2). In the last 2 years, my colleagues and I have also used the Itrel stimulation system based on cardiac pacemaking technology (Fig. 105-3).

Neurological, anesthesiologic, and orthopedic evaluations of the patient were performed. To qualify for a trial of electrical stimulation, the patient must have failed all conservative modes of pain relief, including pharmacologic agents, supportive splints, and physical therapy (ie, desensitization massage, cryotherapy, contrast baths, ice-heat). A preliminary evaluation with peripheral nerve blocks and transcutaneous electrical nerve stimulation (TENS) was required. To qualify for implantable peripheral nerve stimulation (PNS) the following criteria had to be met:

1. A complete neurological examination, including nerve conduction studies, showed no operatively treatable peripheral nerve abnormality.
2. Complete relief of symptoms was present after peripheral nerve blocks with Xylocaine or Marcaine.
3. There was no exacerbation of symptoms with TENS.

We identified 25 patients who met the criteria for PNS for chronic pain unrelieved by conservative treatment programs. Most of the patients had operative procedures, with an average of 2.6 (range of one to eight) previous operations. There were 11 males and 14 females, with a mean age of 43 years. Presenting symptoms included a shooting or burning pain in the median nerve (9 patients), ulnar nerve (16 patients), and radial nerve (1 patient). One patient had both median and ulnar nerve symptoms. Nerve pain was present an average of 32 months (range, 6 months to 10 years). Direct trauma was the cause in 7 patients, indirect trauma in 11, and repetitive stress in 5; there were 2 elec-

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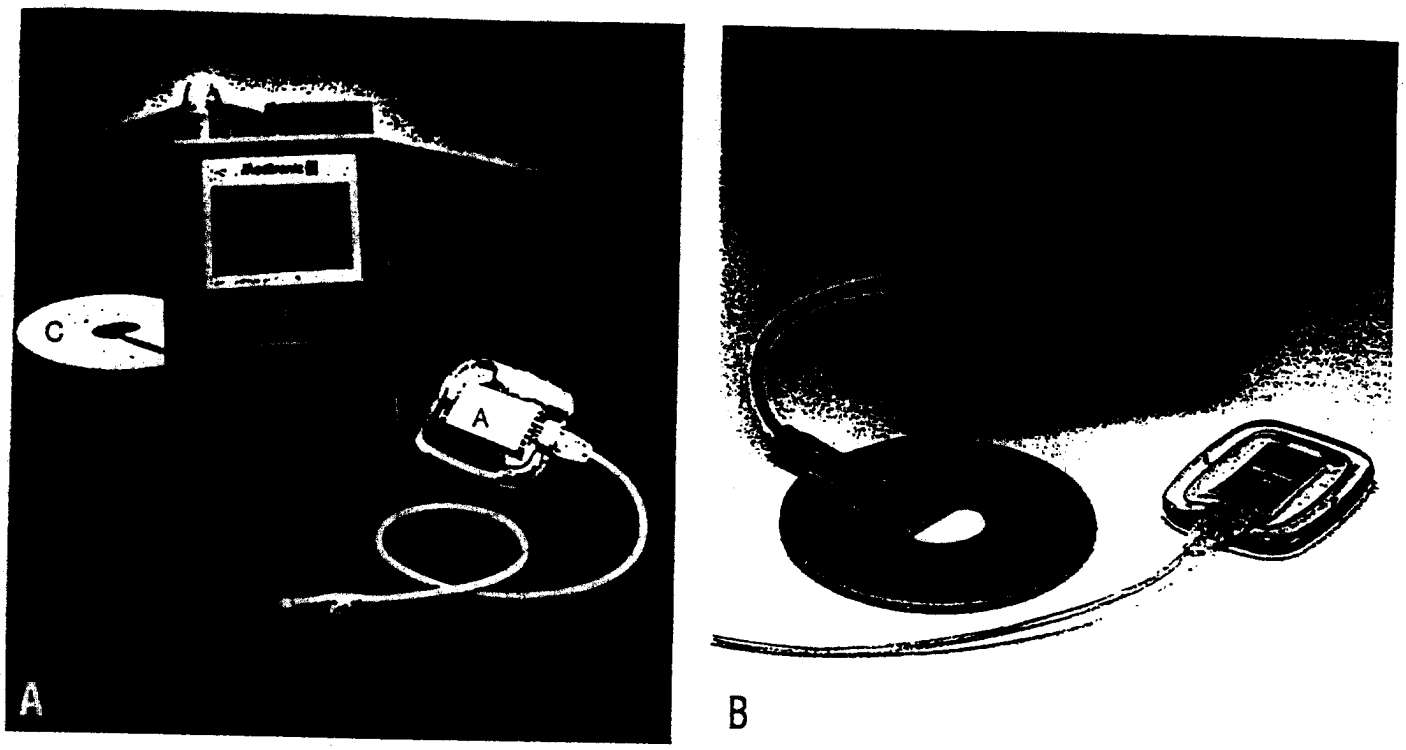

Figure 105–1. *(A) The SE-4 Medtronic transmitter involves an epoxy insulated receiver (A) and a Resume SE-4 electrical stimulator (B) with connecting antenna (C). The receiver is designed to be placed subcutaneous in the trunk or thorax, and the transmitter unit is worn on a belt with the antenna placed over the receiver during the time of electrical stimulation. (B) The X-trel transmitter provides a new alternative to the SE-4. Patient control of amplitude and rate are improved.*

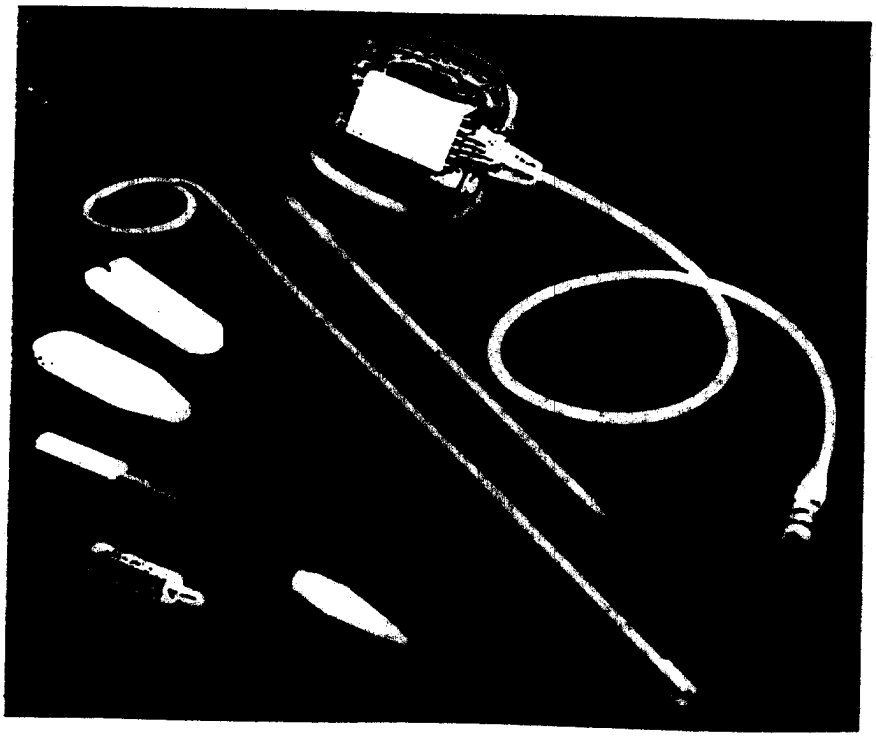

Figure 105–2. *Special equipment is required to insert the SE-4 receiver and connecting leads subcutaneously in the trunk or thorax and connect it to the electrode leads in the shoulder. Note receiver, stylets, and receiver lead passing equipment.*

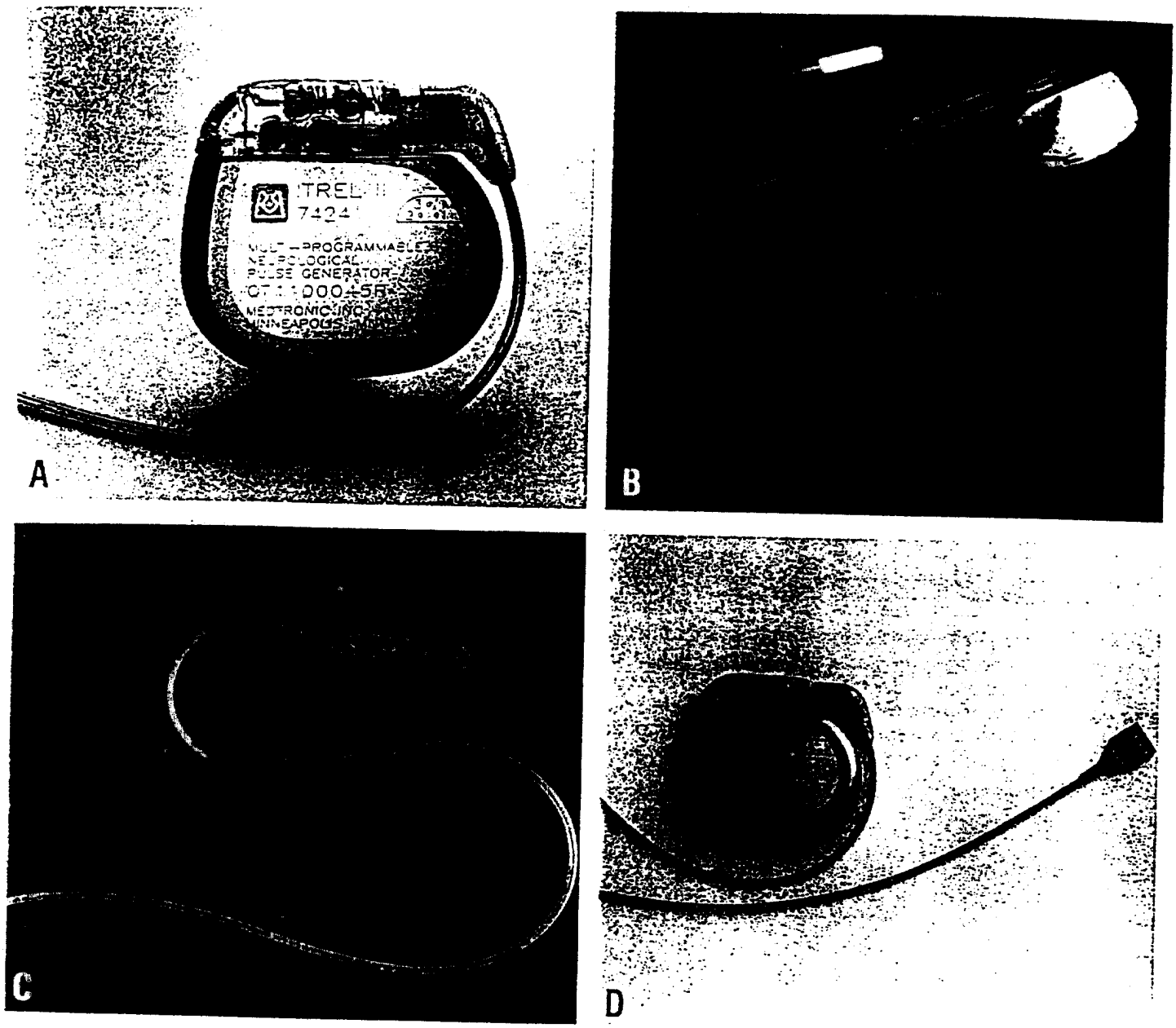

Figure 105–3. The ... system is an implantable pulse generator with an external program that ... pulses amplitude ... and pulse width programmed by an external computer ... (**A**) Itrel implantable pulse generator. (**B**) Itrel and connecting extension lead. (**C**) The ... electrode system is placed percutaneously for direct nerve stimulation. The electrode ... has ... additional ... The electrode connection (bottom) attaches to the Itrel pulse generator. **D** The ... and connecting lead.

trical burns. Postoperative pain was difficult to separate from the original injury but appeared to be at least a contributing factor in 12 of the 25 patients. Many ... patients had a psychiatric examination ... MMPI (Minnesota Multiphasic Personality Inventory), which often suggested personal stress with depression, anxiety, frustration, and anger as a result of chronic pain. No patients were diagnosed with clearly evident psychiatric disease.

Pain was evaluated subjectively by type, location, frequency, and consistency to determine a

ranking on a scale of 0 to 4, with pain of 4 being the most severe. Narcotics for pain relief included codeine, Percodan, Demerol, and Dilaudid. Sleep disturbance was a significant factor in nearly every patient. Some noted extreme difficulty in sleeping more than 2 to 3 hours at a time. Depression and hostility to friends and family was associated with the sleep loss.

The role of workers' compensation and medical/legal claims was difficult to assess, but either or both were believed to be substantial contributing factors in 16 patients. We did not deny treatment to any patient because of continued legal conflicts or unresolved workers' compensation claims.

TECHNIQUE OF ELECTRICAL STIMULATION

After preoperative screening and clinical assessment, a series of two or more nerve blocks was used to confirm the anatomical location of the pain stimulus (or stimuli) and relief of pain. A two-stage operative procedure was discussed with patients and family.

The first stage consisted of a screening phase to determine if PNS would be helpful in providing pain relief. Under general anesthesia, exploration of the involved peripheral nerve was performed. In half of the patients, the only procedure was placement of the stimulation electrode proximal to the site of nerve pain. In the other half, in addition to placement of the electrical stimulation electrode, external neurolysis of the involved peripheral nerve from normal through abnormal tissue was performed (Fig. 105-4*A*). If required, the nerve was transferred to a more suitable vascular bed (Fig. 105-4*B,C*). For example, the ulnar nerve was transferred deep to the flexor–pronator origin in eight patients at the time of PNS implantation. After freeing or transferring the involved nerve, a four-channel electrode was placed proximal to the apparent site of nerve damage (Fig. 105-5*A*). An interval of fascia or muscle was placed between the electrode and the nerve as a soft-tissue barrier to prevent direct contact between the nerve and the electrode (Fig. 105-5*B*). A percutaneous conducting wire was attached to the proximal end of the electrode and passed subcutaneously to exit superiorly above the axilla (Fig. 105-5*C*). The electrode was sutured to fascia or muscle adjacent to the involved nerve with nonabsorbable suture to prevent electrode migration.

Electrical stimulation was tested the next day with a screening unit that allowed changes in the amplitude, rate, and pulse width of electrical stimulation of the involved peripheral nerve. Since the Resume lead contains four electrodes or contacts (Fig. 105-6), the screener allowed us to choose different electrode combinations and polarities (electrode positive of negative charge). The screening period lasted for 2 to 8 days before proceeding with stage two implantation. The patient had control of the screening unit and could alternate the electrode combinations and the rate and amplitude of electrical stimulation.

In stage two, a permanent power source was inserted to provide the impulse for electrical stimulation (Fig. 105-7). An extension connecting wire was attached to the Resume lead and was passed subcutaneously down the chest wall to exit through an incision over the lateral trunk.

The surgeon and patient can choose between two power sources: a system involving an implanted silicone-covered passive radio receiver powered by an external transmitter that uses radio frequency energy (Medtronic SE-4 System) (see Fig. 105-1) or a completely implanted polyurethane insulated Itrel system based on cardiac pacemaker technology (see Fig. 105-3). A recent advance, the X-trel, has replaced the Medtronic SE-4 System (see Fig. 105-1*B*). The SE-4 system provides more variability with external control, allowing the patient to easily change pulse width, signal ramping, and the electrical impulse amplitude and rate, just as he or she can with a TENS unit. The Itrel unit is completely internalized and can be turned on and off with a magnet. Advanced programming capabilities allow external adjustment by a trained technician or nurse using the console programmer. The rate, amplitude, pulse width, and stimulation mode (continuous or cycling with soft start) can be selected and directed to the internal IPG; a printout of the parameters is available. For daily use, most patients simply use the magnetic on/off control. Some patients use the programmer to select different parameters as well as to turn the IPG on and off, but most require

Figure 105–4. *(A) The surgical procedure involves exploration of the involved nerve and neurolysis if appropriate. (B) In half of the ulnar nerve cases, a deep transposition of the nerve beneath the flexor pronator origin was performed. (C) In half of the ulnar nerve cases, the nerve was placed subcutaneously. The electrode is placed proximal to the area of nerve injury and the connecting lead brought out subcutaneously for stage one trial testing.*

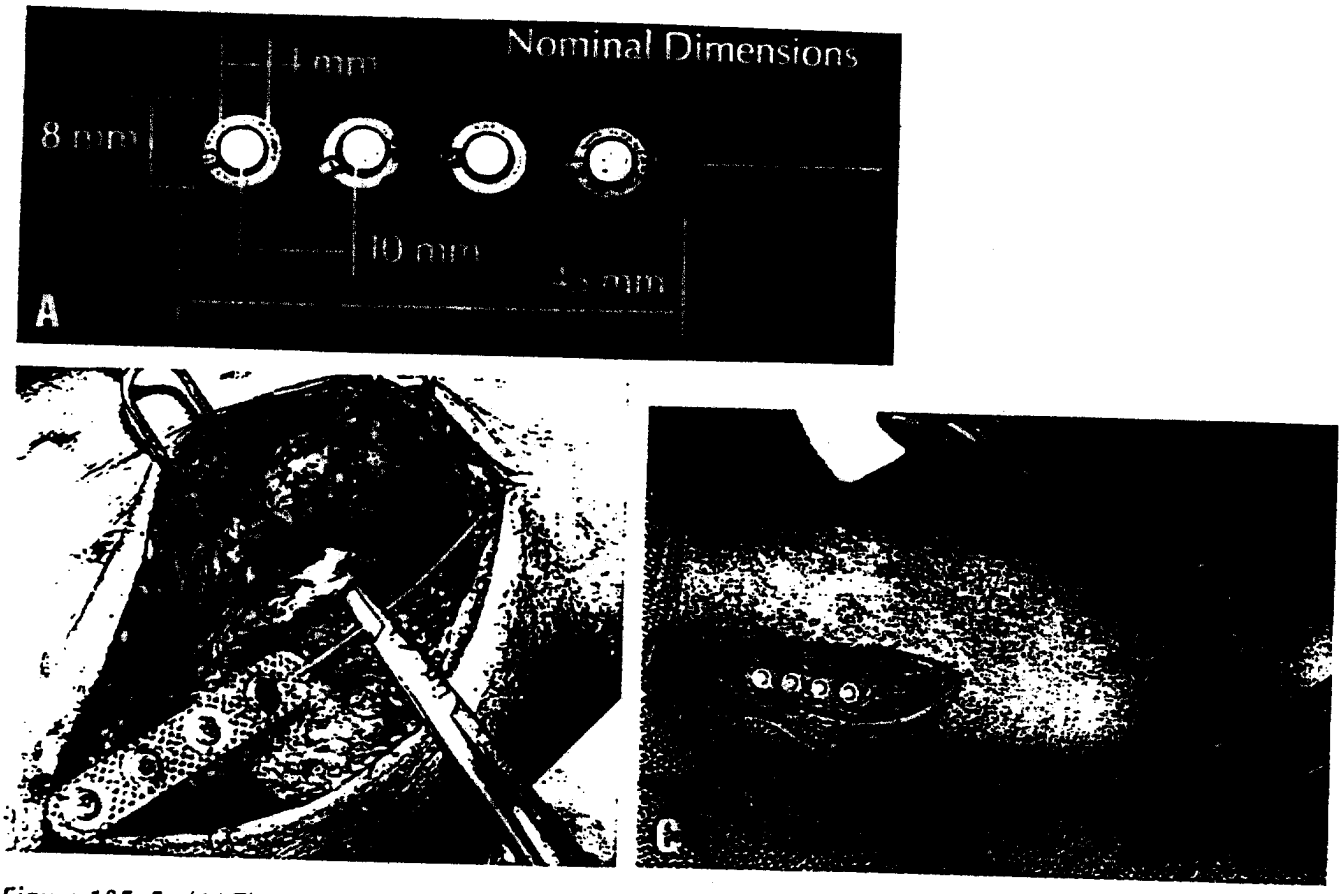

Figure 105–5. *(A) The Medtronic Resome head has four stimulation electrodes (4 mm diameter), which are 10 mm apart. (B) The lead is placed adjacent to the involved nerve, and (C) the extension wires are placed subcutaneously to exit in the superior aspect of the axilla.*

technical assistance to change the parameters and use the console rather than the portable programmer. We caution patients to use the unit intermittently, not to maintain continuous electrical stimulation. We also recommend insertion of the bipolar stimulation system (rather than unipolar) since the bipolar system preserves battery life and is associated with less external electrical noise interference.

No adverse effects on the IPG system have been associated with electrical equipment such as microwave ovens, power tools, or radiofrequency transmission. Caution is recommended with ultrasound and diathermy. *Presence of a cardiac pacemaker is an absolute contraindication to PNS, as is magnetic resonance imaging (MRI).* We have observed a few allergic reactions to leads and lead migration. One patient had pain over the receiver site. Some patients have claimed failure of the electrical stimulation, which can easily be checked by holding an AM radio (small transistor) set at 540 kHz over the electrode leads. The radio will produce a strong buzzing sound when the system is operative. It is not uncommon to discover that the unit has not been properly turned on or that the rate and amplitude of stimulation has been changed.

We have found that an effective pulse amplitude ranges from 1.0 to 2.5 volts, the pulse width from 60 to 120 μsec, and the rate from 30 to 65 pulses/second. Using a higher pulse width lowers the amplitude necessary for effective electrical stimulation.

RESULTS

The criteria for judging the results of electrical stimulation to date are purely subjective and are reported in terms of effective pain relief, absti-

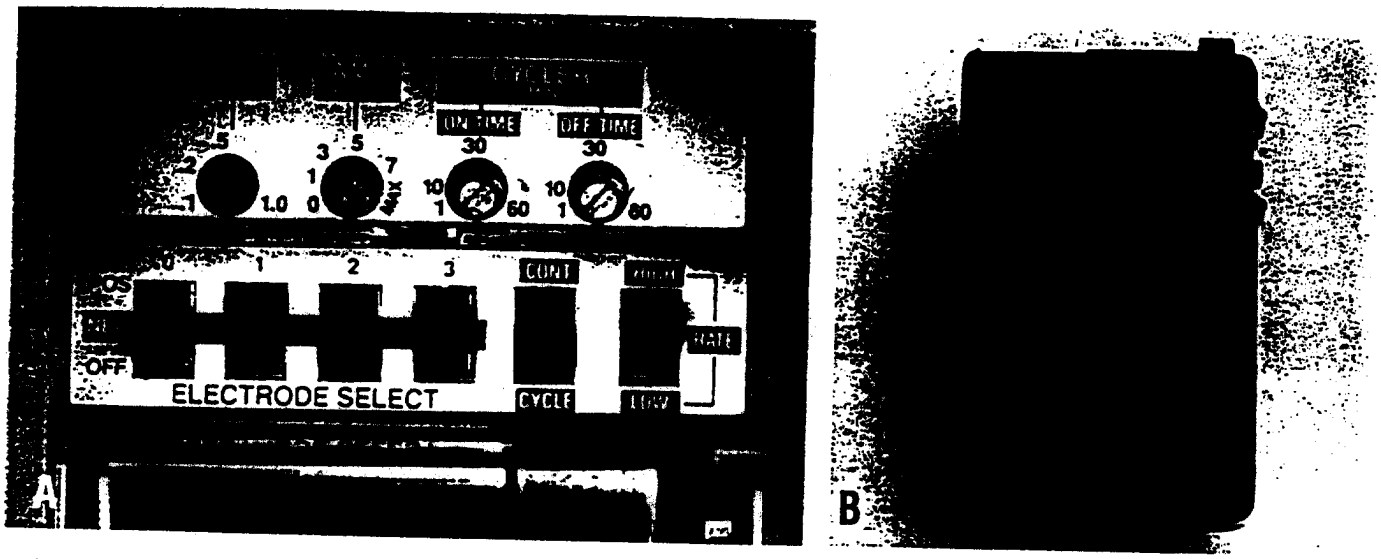

Figure 105–6. *(A) The electrical stimulator selection includes the specific electrodes (0, 1, 2, 3), polarity (positive or negative), and stimulation mode (continuous or cycling). The pulse width (PW) and amplitude (volts) as well as the pulse rate can be adjusted. (B) The X-trel unit also provides choice for special electrodes (0, 1, 2, 3), rate (hi or lo), and stimulation mode (mod 1 or mod 2).*

nence from narcotic pain medication, and the presence of restful sleep. There are no known objective criteria on which to evaluate pain relief. In this study we did not use a control group or blinded study group to which we could compare IENS. It is appropriate, therefore, to report only our observations and to note the following:

1. Of the 25 patients reviewed in this study, 21 (84%) had improvement in their level of pain (Fig. 105-8). Each patient preoperatively had a pain level of 4 to 4+. The level of pain with IENS was reduced to 1 to 2 in 13 patients and to 0 to 1 in 8 patients. Five patients stated that they had complete relief of all pain symptoms. Four patients stated that pain was unchanged, but none reported that pain was worse. Two of the 25 patients reported failure to relieve pain during the screening period, and we removed the electrode and leads under local anesthesia. Two other patients had failure to relieve pain between 6 and 12 weeks after stage

Figure 105–7. *The second stage consists of connecting the electrode lead to the receiver lead (left arrow). The Itrel implantable pulse generator is inserted into a subcutaneous pocket over the lateral trunk, and the receiver leads are tunneled superiorly to the axilla.*

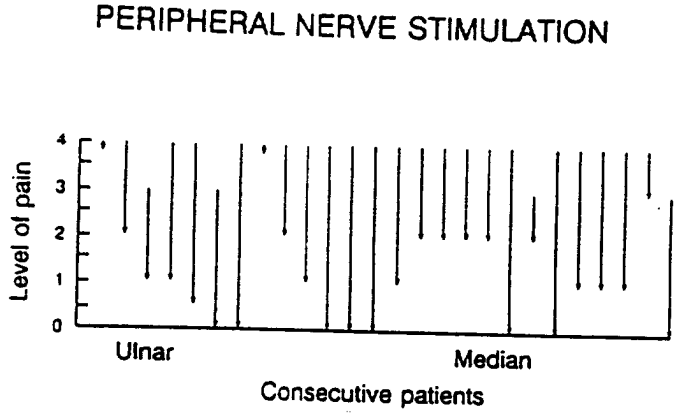

Figure 105–8. *Pain relief. Results of electrical stimulation in 25 patients with a subjective pain level of 1–4. Postoperative improvement is represented by downward arrow.*

two implantation, and the entire system was removed under general anesthesia.

2. Use of narcotic analgesics was eliminated in 80% of patients; only a small group required any kind of opiate for relief of pain on an intermittent basis. Several patients, for example, used codeine at night but not during waking hours.
3. In 18 patients sleep was improved to a restful level for 6 hours or more without the need for hypnotic medication.

The treatment failures were patients for whom failure might have been predicted by the chronicity of their pain and their psychological profiles. One patient had chronic ulnar nerve pain unrelieved by six previous operations (1977, exploration of the ulnar nerve and release of the cubital tunnel; 1980, excision of the medial epicondyle; 1980, ulnar neurolysis and interposition of a Silastic membrane; 1982, ulnar neurolysis and removal of Silastic membrane; 1984, microscopic external and internal ulnar neurolysis; 1986, at our institution, ulnar nerve submuscular transposition and Silastic membrane interposition). In 1987, relief of ulnar nerve pain by electrical stimulation was attempted after ulnar nerve blocks had demonstrated consistent relief of pain. Previously TENS had failed to relieve pain. A trial period of 8 days of electrical stimulation with amplitude, rate, and electrode combinations placed at multiple settings provided no clear evidence of pain relief, and the electrode and lead wires were removed. The patient remains under the care of an anesthesiologist who performs intermittent ulnar nerve blocks every 3 to 4 months. Codeine is required during the intervening periods. Pain management counselling from our psychiatry department has been refused.

A second patient had ulnar nerve pain as the result of a direct blow to the ulnar nerve at work and presented with chronic ulnar nerve pain. She had had cubital tunnel release (1986) and an anterior ulnar nerve transposition with neurolysis (1987) at a neighboring medical facility. At our institution, ulnar neurolysis, revision of the anterior transposition, and an electrical stimulation procedure (SE-4 system with external control) were elected. Good pain relief and withdrawal from narcotics was achieved. At 9 months post-implantation she claimed an allergic reaction to the silicone-covered SE-4 receiver. We changed the SE-4 unit to a metallic-surfaced polyurethane-insulated Itrel unit and again pain relief was achieved. In September 1989, she returned to work as a teaching assistant. She returned after 3 months at work, stating that she had reinjured her elbow and had recurrence of severe, disabling pain. The "allergic reaction" increased at both lead and receiver sites, and in late December 1989 the entire electrical stimulation system was removed. She continues to have mild pain with control by occasional nerve blocks and a supportive splint. While she can work, she claims total disability.

In our experience, most patients have reported a significant improvement in the level of pain with electrical stimulation, but on careful assessment only five reported complete freedom from pain. Eighteen of the 25 patients had enough pain relief to perform almost all daily activities and to sleep soundly without narcotic pain medication. Three patients had moderate pain relief but had some trouble sleeping or working. Four patients, as stated earlier, were failures. Fifteen patients returned to pre-injury functional levels and were able to go back to work. Two patients over the age of 65 years have retired.

Complications related to the electrical stimulation equipment were lead failure in one patient and an unconfirmed receiver (IPG) malfunction in a second patient. The latter had the Itrel IPG replaced with gradual improvement in the level of pain relief.

DISCUSSION

Experience with direct electrical stimulation of peripheral nerves has been limited to several centers in the United States and Europe. Currently, there has been significant interest in using direct electrical stimulation of the spinal cord for low back pain and lower limb pain,[2,5,6,8,9,11,14] but there have been few reports on the treatment of chronic pain in the upper extremity with electrical stimulation.[10,11,14] In 1982 Nashold and associates reported their experience with electrical stimulation in which either an electrode cuff (Avery Laboratory)* was wrapped around the involved nerve, or button electrodes were placed on the involved nerve.[10] Under local anesthesia, areas of pain were localized by percussion and confirmed by both nerve block and intraoperative testing. Of 19 upper extremities, they achieved successful relief of pain in 10 patients (52.6%). They believed that electrode placement under local anesthesia was critical. There was no prescreening process. Nerve mapping to identify the sensory fascicles supplying the painful areas is different from current techniques. In addition, the electrodes were attached directly to the involved peripheral nerve.

Waisbrad and coworkers used the cuff electrode in 19 patients who had chronic pain secondary to traumatic peripheral neuropathy.[14] They reported that 58% had complete relief of pain and that an additional 21% had enough improvement to discontinue analgesics. In their series, nerve blocks were used to assess the relief of specific nerves, and repeat injections were recommended before using electrical stimulation. They used a staged procedure, with the nerve cuff electrode leads brought out subcutaneously during the screening stage. If pain relief was achieved, second-stage implantation of the receiver unit was performed.

Long reports a similar experience with a cuff electrode, indicating long-term pain relief in 50% of patients.[6] Picaza reported up to 86% relief of pain with a cuff electrode, but it is unclear if this figure represents partial or complete relief of symptoms.[11] Adverse effects of the cuff electrode included compression of the nerve, foreign body reaction, and local scarring.[5,8,14] Nashold's group abandoned the cuff electrode in favor of direct electrical stimulation with multiple small button electrodes.

In our series, the technique of nerve stimulation is similar to the program described for spinal cord stimulation. The electrode is placed adjacent to the peripheral nerve and is not wrapped around the nerve as was performed with these earlier electrical stimulation techniques. The peripheral nerve is isolated, a thin barrier of tissue is placed between the nerve and the electrode, and a screening period is used to study the effects of electrical stimulation. A beneficial result can be anticipated when the patient experiences a light, not painful tingling (ie, paresthesias) in the peripheral nerve distribution. Stimulation is recommended for 1 to 2 hours, after which there should be continued pain relief. Patients who have used the stimulation system continuously soon note loss of effectiveness; apparently they build up a tolerance to its beneficial effects.

In our experience, peripheral nerve stimulation has often represented the last avenue of treatment in patients with chronic nerve-related extremity pain. Preliminary results are encouraging, but we are cautious in the interpretation of lasting pain relief. Treatment by electrical stimulation appears to have helped most of our patients live tolerably with chronic pain. Several have had complete pain relief, with subsequent removal of the PNS unit. There have not been any adverse effects of electrical stimulation, and no patients have become worse secondary to treatment.

We do not know the mechanism of pain relief and realize that a significant placebo effect cannot be discounted. More studies are needed to determine if nerve resting action potentials are increased in patients with chronic limb pain and if the electrical stimulation of large afferent nerve fibers provides a stimulus to control hyperactive resting nerve potentials, or sends a blocking signal to the central "gate" of sensory perception. While expensive equipment is required for these techniques, electrical stimulation has been quite beneficial in our experience and that of others.[12] With careful patient selection, we believe that it is an appropriate alternative for the treatment of chronic extremity pain.

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