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General STIM

Chapter 15

• Charles D. Ray

Spinal Cord and Peripheral Nerve Stimulation for Management of Peripheral Pain

Fascination with the therapeutic uses of electricity dates to ancient times. In the first century A.D., electric fish were used to numb aches and pains associated with headache and gout (Ray, 1975a). In more recent times, Benjamin Franklin used electrostatic generators to treat a variety of medical maladies, especially pain. Numerous stimulating or shocking devices were touted as panaceas in the early 1800s, but their use declined with the development of drugs and the abhorrence of device quackery.

The now classic gate control theory of Melzack and Wall (1965) reintroduced the use of electrical stimulation for pain control by providing a rationale for its effects. The first practical implanted stimulation device for pain control was devised by Shealy and co-workers in 1967. Stimulation of the dorsal column of the spinal cord proved to be a successful method for addressing certain cases of severe, chronic pain of the lower extremities. By the early 1970s, the method was being adopted widely and uncritically. After the initial wave of poor results that inevitably followed—due to improper patient selection criteria and fragile equipment—the therapy fell into disfavor. Nevertheless, some investigators deeply involved in the clinical application of electrical stimulation continued to experience good to excellent results in patients considered unsalvageable by other therapeutic means (Burton, 1975; Campbell and Long, 1976; Nielson et al, 1975; North et al, 1978; Ray, 1975a, 1975b).

By the latter part of the 1970s, it had become apparent that about half of the patients treated by stimulator implants would receive lasting relief of approximately 50% of their prestimulation pain, regardless of the intensity or duration of the pain (Burton, 1975; Burton et al, 1977). Since then, development of specific patient selection criteria and improvements in neurostimulation devices and techniques have contributed to enhanced safety and efficacy of neurostimulation for the treatment of chronic, intractable pain.

This chapter addresses two types of neurostimulation for chronic, intractable pain: spinal cord stimulation and peripheral nerve stimulation. Both therapies use implantable electrodes to superimpose a pattern of paresthesia within the painful area to block pain signals. In the case of spinal cord stimulation, electrodes are implanted along the dorsal column of the spinal cord at a position corresponding to the painful area. Peripheral nerve stimulation is helpful for very localized pain involving no more than two nerve roots. The electrodes are placed on the involved nerve distribution branch to achieve very targeted relief. For each type of neurostimulation therapy, the electrode-bearing leads are connected to a stimulus-pulse source, which provides the power for stimulation.

Each of these therapies, when properly applied to the appropriate patient, is safe and effective. They offer alternatives differing from all other therapeutic modes and should be considered before destructive and irreversible procedures or more costly regimens are chosen (Fig. 15–1).

SPINAL CORD STIMULATION

Neuroanatomy of the Two Pain Systems

Activation of normally present inhibitory circuits is probably the principal mode of operation for neurostimulation control of pain (and other stimulation-treatable disorders). There are two pain systems of humans, each of which passes through the substantia gelatinosa of the dorsal spinal cord, the site of the inhibitory spinal gate in the gate control theory. The first pain system is a rapid, direct skin and lining structure or surface-activated, somatotopically specific system. Its constituents include primary afferent small A-delta and C fiber (pain, itching, thermal) input into the marginal cells and substantia gelatinosa of the dorsal spinal cord.

Integrative and filtering effects take place in the dorsal spinal cord that exercise considerable control over what is transmitted upstream. The next-order neurons in this system for conveying localizing pain information cross and ascend in the lateral neospinothalamic tract, passing through the medial lemniscus to terminate in the ventrobasal thalamus. Higher order neurons ascend to the postcentral gyrus of the cortex. Some of the descending system connects principally through the dorsolateral corticospinal system to the spinal segment of pain origin. The overall effect of the oligosynaptic somatotopic lateral pain system is localization, fast withdrawal, and protection against injury.

Stimulating peripheral nerves, dorsal columns, and the contralateral posterolateral sensory-specific thalamus produce localized tingling that can inhibit the experience of pain in the same somatotopic area. This paresthesia effect has been shown to be mediated by an organization involving gate control at the segmental level (Kerr, 1980; Krainick et al, 1980). There is further evidence that this tingling pain-

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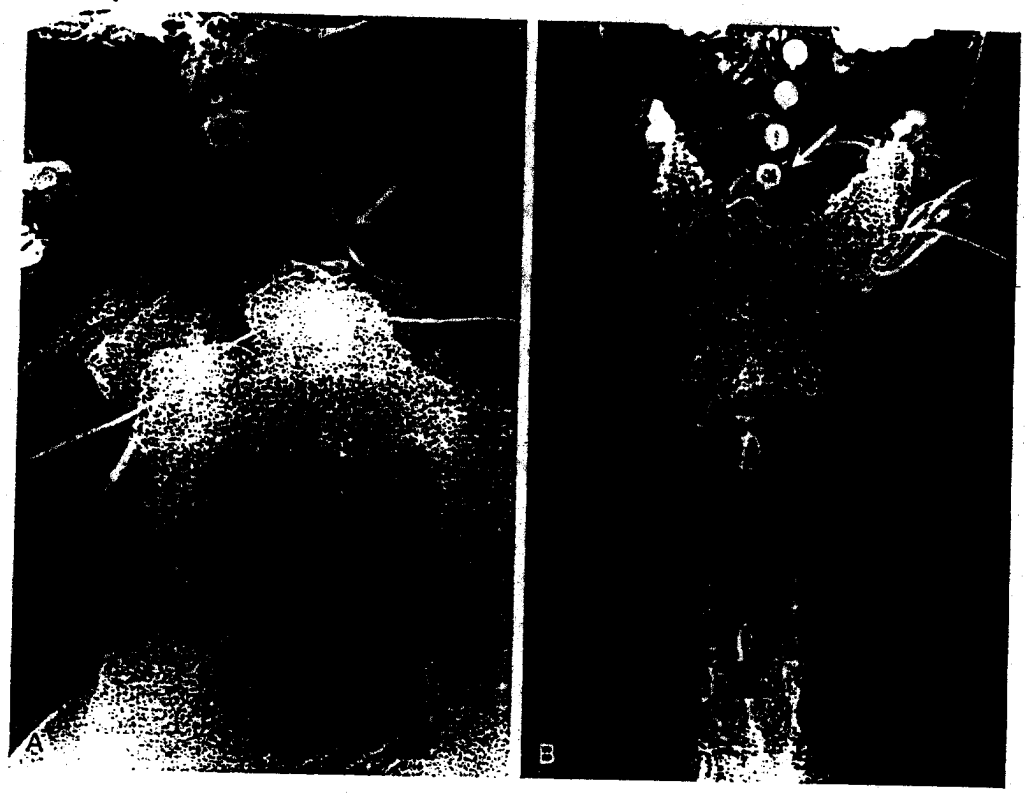

FIGURE 15–1. Anteroposterior *(A)* and lateral *(B)* views of Resume SCS lead (Medtronic, Inc.) in the cervical spine.

suppression effect arises in part from a signal modification (so-called jamming) and is not mediated by the endogenous opioids. For example, the effect is not modified by injection of the narcotic antagonist naloxone (Freeman et al, 1983; Horowitz et al, 1976; Liebeskind et al, 1982; Ranck, 1975).

The second pain system is a slow, indirect, deep structure–activated nonsomatotopic system. Its pathway is one of primary afferent small fiber input, similar to the first system, and local polysynapses to neurons that cross to ascend in the ventral paleospinothalamic tract. Fibers pass upward through the mesencephalic reticular system with its connections to the hypothalamus and limbic system. Bulbar reticular neurons also connect to the periaqueductal gray and the medial and intralaminar thalamus. Further rostral to these structures are connections to the hypothalamus, limbic system, and cortex. This complex system is involved in nondiscriminative aspects of pain as well as motivational and affective states. The system is enkephalin and opiate activated and, when disturbed, is likely the major source of chronic pain in humans (Ray et al, 1981).

Stimulation in the medial, intralaminar, nonspecific thalamic and periaqueductal gray system in humans leads to a reduction in chronic, agonizing pain; there is also an accompanying rise in the intraventricular endorphin content (Akil, 1978). Naloxone reverses these effects. Unlike stimulation of the first system, no somatotopic (tingling) sensations are produced. Thus, the second of the two pain inhibitory systems may be loosely characterized as primarily a chemical-like or opioid system, whereas the other is primarily signal like in function.

Possible Mechanisms of Pain Relief

It is unclear precisely what mechanisms are responsible for the pain relief afforded by electrical stimulation of the spinal cord. In many patients, pain relief begins about 15 minutes after the stimulation is initiated and persists for a half-hour to 2 hours or more after the stimulation is turned off (North, 1991). The prolonged pain relief following cessation of stimulation implies the activation of some neurochemical processes, but the specific processes have not yet been identified. Spinal cord stimulation is known to produce an increase in cerebrospinal fluid levels of substance P and to be associated with serotonin release in the dorsal horn (Linderoth et al, 1992). The extracellular concentration of gamma-aminobutyric acid in the lumbar dorsal horns has been found to increase significantly after 30 minutes of spinal cord stimulation (SCS) in rats (Linderoth et al, 1994, 1993). This finding is particularly notable given the known role of gamma-aminobutyric as an inhibitory neurotransmitter in the central nervous system.

Another possible inhibitory mechanism for SCS is frequency-related conduction block occurring at branch points of primary afferents, with collaterals to the dorsal horn (Campbell et al, 1990). Abram (1993) has postulated that the analgesia resulting from spinal stimulation is associated with both stimulation of large fiber ascending tracts and blockade of spinothalamic pathways. Detailed studies of neural excitation patterns in anesthetized monkeys by Chandler and associates (1993) suggest that spinal cord stimulation reduces pain by inhibiting the firing of spinothalamic tract cells that are activated by small-fiber afferents, while the paresthesias associated with the stimulation result from activation of spinothalamic tract cells that are excited by large-fiber afferents.

In any case, there is little evidence that electrical stimulation applied anywhere in the central nervous system directly produces more than transient inhibition. Thus, whether electrical stimulation for pain control functions either by signal

inhibition or by neurochemically mediated pain inhibition processes, or both, *it is a reversible method.* In addition, it is a nondrug, nondestructive method with relatively few side effects. When side effects do occur, they are usually eliminated or greatly minimized by reducing the stimulus parameters. The majority of selected patients with implanted stimulators continue to enjoy good to excellent results for several years (De La Port et al, 1983, 1993; Krainick et al, 1980; Kumar et al, 1991; Lazorthes et al, 1983; Lifson et al, 1985; Long et al, 1981; North et al, 1993; Ray et al, 1982; Siegfried and Lazorthes, 1982). With recent improvements in the major components of SCS systems, the major reasons for failures, when they occur, are faulty patient selection, incorrect lead placement, inappropriate use of the devices, or misinterpretation of results.

Recent Experience with Spinal Cord Stimulation

North and associates (1993) have reviewed their experience over two decades with 320 patients who underwent implantation of temporary or permanent spinal cord stimulators, or both. Of the 205 patients available for follow-up interview by a disinterested third party (mean follow-up time of 7.1 ±4.5 years), 171 had received permanent implants. Of these, 52% reported at least 50% continued pain relief. Sixty percent reported that they would be willing (knowing what they know now) to repeat the implantation procedure. Additionally, the majority of patients reported improvements in lifestyle and reduced use of analgesics.

In an earlier study, North and colleagues (1991) reported on a series of 62 patients followed for an average of 2.14 years after implantation to treat failed back syndrome, lumbar arachnoid fibrosis, spinal cord injuries, and peripheral pathology or stump pain. A majority of patients reported at least 50% sustained relief of pain, and indicated to a disinterested third party that they would go through the procedure again for the same result. Superposition of stimulation paresthesias upon a patient's topography of pain was found to be a statistically significant predictor of successful relief of pain (Fig. 15–2).

De La Porte and Van de Kelft (1993) have reviewed their experience with SCS for 78 failed back syndrome patients, of whom 64 underwent permanent implantation following a 1-week period of trial stimulation. At a mean follow-up period of 4 years, 55% continued to experience at least 50% pain relief, and 90% were able to reduce their medication. LeDoux and Langford (1993) reported on a series of 32 failed back syndrome patients, of whom 26 received permanent implants. At least 50% pain reduction was reported by 74% of their patients at the 2-year follow-up. Electrode migration was the most common complication in this series.

Kumar and co-workers (1991) reported on their experience with 121 patients over 10 years, with pain of widely varied benign organic etiology. Patients were followed for from 6 months to 10 years, with a mean follow-up of 40 months. Lower extremity pain secondary to arachnoiditis or perineural fibrosis seemed to respond favorably. Good results were also obtained with lower extremity pain due to multiple sclerosis and advanced peripheral vascular disease. Paraplegic pain, phantom-limb pain, midline back pain without radiculopathy, pain due to cauda equina injury, and pain due to primary bone or joint disease seemed to respond less well. Overall, 40% of patients were able to control their pain by SCS alone.

FIGURE 15–2. Resume lead in the epidural space about T9.

Reports of smaller patient series have shown SCS to be a procedure of potential benefit for pain relief in postherpetic neuralgia (Meglio et al, 1989a, 1989b), traumatic paraplegia (Buchhass et al, 1989), idiopathic Raynaud's disease and reflex sympathetic dystrophy of the upper limbs (Robaina et al, 1989), and deafferentation pain (Sanchez-Ledesma et al, 1989). Overall, more than 50 articles are now in the literature reporting on the use of SCS for syndromes ranging from multiple sclerosis to reflex sympathetic dystrophy, with results fairly consistently showing that approximately half of the patients receiving permanent stimulator implants experience at least 50% pain relief over the long term.

Patient Selection

In selecting patients for neurostimulation, one must first ascertain that the problem cannot be appropriately treated by, or has not responded to, other standard means. Next, in overall importance for good results, the following must be determined:

A. Psychosocial criteria (Daniel et al, 1985; Long, 1979; Ray, 1981)
   1. Assurance that the pain is not a manifestation of disordered thinking—there is an objective basis for the complaint (e.g., myelographically documented lumbar arachnoid fibrosis).
   2. Motivation and cooperation by the patient.
   3. Freedom from drug habituation or drug-seeking behavior.
   4. Absence of impending legal actions, unsettled compensation disputes, or other sources of secondary gain.
   5. Absence of major marital, familial, social, or occupational conflict.

B. Clinical criteria
   1. Location and distribution of pain: The topography of the pain must be amenable to overlap by stimulation paresthesias. Trial placement of a temporary electrode to demonstrate relief addresses this issue.
   2. Provokability of the pain: Some mechanical maneuver (e.g., joint movement or direct pressure over the painful area) should reliably provoke or augment the pain, and some other mechanical state (rest, positioning, exercise) should reliably relieve it.

C. Technical criteria
   1. Location of the stimulus site: The technical detail of greatest importance is electrode location. Uncertain or random placement of an electrode almost invariably produces useless results.
   2. Stimulus parameters: The most important parameter is the amplitude or strength of the pulses. Pulse frequency and pulse width may also affect the results and patient comfort.

D. Less important considerations for lasting results
   1. The cause of pain (distribution being considerably more important). North (1993) lists the following specific indications in decreasing order of frequency of application and reported success rates:
      a. Lumbar arachnoid fibrosis (arachnoiditis) or failed back syndrome with radiculopathic pain, ideally predominating over axial low back pain, in particular mechanical pain (North et al, 1991).
      b. Peripheral vascular disease, with ischemic pain (Broseta et al, 1986).
      c. Peripheral nerve injury, neuralgia, or causalgia (including reflex sympathetic dystrophy).
      d. Phantom limb or stump pain (Krainick et al, 1980).
      e. Spinal cord lesions, with well-circumscribed segmental pain (North et al, 1993).
   2. The duration of pain (months or years).
   3. The extent of disability caused by the pain.

Types of Leads

Leads can be categorized according to whether they are for temporary use only or implanted for long-term use. Among leads for definitive implant, models with either percutaneously inserted wire-type or surgically implantable plate-type electrodes exist. Finally, among plate-type electrodes arrayed on a paddle, models with either in-line or a mix of in-line and lateral electrodes are available (Fig. 15–3).

A temporary screening lead can provide a cost-effective way to conduct a stimulation trial with a patient to determine whether SCS therapy may be successful. During trial screening, the physician and patient can determine what configuration of electrodes and settings of stimulation parameters are effective in "covering" the painful area, and can determine appropriate lead positioning. These factors are among the most crucial in obtaining a successful outcome.

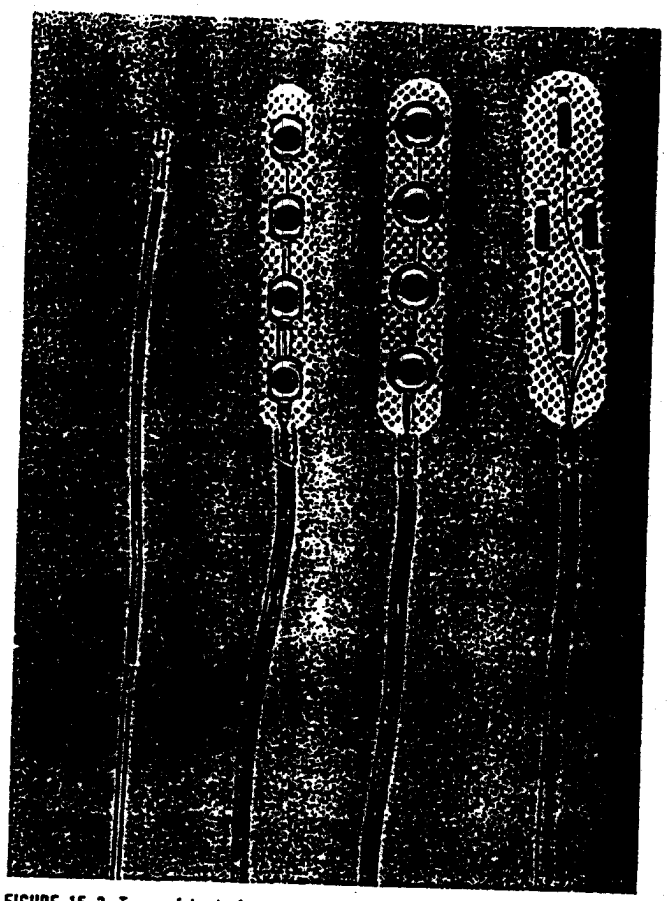

FIGURE 15–3. Types of leads from left to right: percutaneously inserted lead with wire-type electrodes and three surgically implantable leads (Medtronic, Inc.).

Temporary screening leads are typically of the wire type, with several electrodes arranged linearly along the distal end of the electrode. The lead is inserted percutaneously using a Touhy needle, as described later. Temporary screening leads are available that replicate the capabilities of definitive-implant percutaneous leads (such as the Verify screening lead, which replicates the capabilities of the Pisces-Quad, both from Medtronic Neurological, Minneapolis, Minnesota). The screening lead can be left in place for up to 10 days, which is usually sufficient for evaluation of the SCS therapy. If desired, most leads used for definitive implant can be used for the trial stimulation period as well, by means of adapters available from the manufacturer. North (1993) reports that it has been the practice of his group to conduct a minimum 3-day trial with a temporary percutaneous electrode, after which time the electrode is discarded to minimize the risk of infection.

Leads with plate-type electrodes are placed epidurally by a laminotomy procedure, which is described later. The distal end of these electrodes consists of a flat paddle containing several electrodes placed either in a linear or diamond pat-

tern. The paddle-shaped end has the advantage of providing greater stability in the epidural space, reducing the likelihood of treatment failure due to lead migration. In the event that previous epidural scarring, spinal stenosis, or an abnormally small epidural space is encountered, the same electrode configuration and surface area as a standard paddle-shaped lead can be obtained in a smaller size. Models with widths as small as 6.6 mm and with a thickness of 1.37 mm are available (Resume TL, Medtronic Neurological, Minneapolis, Minnesota). For patients with bilateral or a broad area of pain, leads with a diamond pattern of oval-shaped electrodes on the paddle (e.g., SymMix, Medtronic Neurological, Minneapolis, Minnesota) produce stimulation across the patient's midline to optimize broad or bilateral coverage of painful areas.

Stimulation Systems

There are two types of stimulation systems: fully implantable pulse generators, and radiofrequency systems (sometimes called external systems) involving an implanted receiver and an external power source. Fully implanted pulse generators, containing long-lasting (3 to 10 years) lithium batteries, have the advantages of improved patient acceptance and compliance. These systems are turned on and off by an external magnet; parameters are reprogrammed using an external, physician-operated control unit. Radiofrequency systems have the advantage of not requiring surgery when the battery has reached the end of life. Patients requiring high-amplitude stimulation (as determined during the clinical trial) would benefit most from a radiofrequency system. Most leads can be adapted to attach to either type of stimulator system, using connectors supplied by the manufacturers (Fig. 15–4).

Although most SCS systems are designed to power quadripolar leads, systems accommodating eight electrodes are also available to provide broad or bilateral coverage (e.g., Neuromed's Dual Quattrode system and Medtronic's Mattrix system). The Mattrix system uses a fully selectable dual-channel system powered by an external radiofrequency transmitter configured to function either as a single channel (1 × 8) or a true dual channel (2 × 4) system. Changes in electrode combinations and polarities of electrodes may be made externally, as desired. This selectability not only may shorten the duration of the trial period but also may prevent long-term loss of effectiveness in some cases.

Surgical Procedures

Before undertaking the procedure, the surgeon and the nurse or technician who will follow the patient should be familiar with the manufacturer's literature and audiovisual materials. It is worthwhile to visit a clinical center where implants are being performed on a regular basis.

Before the insertion of any of the electrodes discussed here, the patient should completely understand the potential risks and benefits of the procedure. It is helpful to require that the patient and closest relatives view an audiovisual education program covering these matters (Ray, 1980). Because pain is a subjective sensory experience, patients must have their electrode inserted using local (and vocal, or verbal, reassurance) anesthesia. Patients must be convinced that the procedure will be almost painless and that they will be informed of everything before it happens, that is, there will be no surprises.

FIGURE 15–4. Components of the X-Trel system (Medtronic, Inc). A—Antenna, B—External Control Unit, C—Extension Lead, D—Receiver.

CHOICE OF LEAD TYPE

The percutaneous type of lead has the advantage of being inserted through a Touhy needle passed via a small incision. On the other hand, it is sometimes easily or spontaneously dislodged, with a loss of stimulation. Also, the smallness of the electrode surface can make this type of lead less beneficial for permanent implant.

The author has found that the results using larger surface electrodes (plate-type leads) have more than compensated for the apparent increased complexity of implantation. However, because percutaneous electrodes are appropriate for temporary screening purposes (North, 1993), the practitioner will do well to become proficient at both of the insertion procedures described here.

With either type of lead, the technical detail of greatest importance in successful use of SCS is electrode location. If this is not correct, all else fails to compensate.

LEAD INSERTION TECHNIQUE: PERCUTANEOUS TYPE

Whether a percutaneous lead is inserted for the stimulation trial or following the decision to do a definitive implant, the insertion technique is the same.

Oral diazepam, 10 mg, is given when the patient is called to the operating room, and a single-dose, broad-spectrum antibiotic is administered while the patient is in the preanesthetic holding area. Intravenous diazepam and fentanyl is used in conjunction with the local anesthetic, as needed. Moderate analgesia and mild sedation will not interfere with the patient's ability to cooperate; control of the pain is not the objective of this phase of the technique. Percutaneous electrode insertion requires an image-amplifying fluoroscope. The patient lies prone on the fluoroscopic table, with a pillow under the abdomen to promote slight forward flexion. Technical details described here were developed for use with the Neurological Pisces system (Medtronic Neurological, Minneapolis, Minnesota) but are basically applicable to other similar epidural wire-type implant systems (Ray, 1981a, 1981b).

A short (3 cm) axial incision is made, passing over the dorsal processes of the T12 and L1 vertebral levels (or about T6 for cervical electrode placement). A Touhy needle introduces the lead through the interlaminar ligament, entering the epidural space beneath the fluoroscopic shadow of the spinous process of the T11 vertebral level. A careful two-handed technique is used to push the needle into the space. If the ligament is slightly calcified, the hub of the needle is tapped with an instrument (scissors or large hemostat) to drive it gently into the epidural space. Entry into this space is detected by a slight decrease in insertion pressure. An arterial guide wire is then passed into the posterior epidural space. Some wire-type electrodes, such as the Pisces, may be bent about 20 degrees, 1 cm below the tip, to permit guiding the electrode through the epidural space (somewhat as one would guide a cardiac catheter) by rotating the external portion of the stylet during insertion. This is carefully followed on the fluoroscopic image.

The midline of the spinal cord may be significantly displaced from the apparent anatomical midline; one must follow the patient's reports of the location of the tingling to determine appropriate electrode positioning. Intraoperative test stimulation is begun. If possible, the patient should be given the stimulator unit so that he or she may alter the stimulus energy, keeping it comfortable as the testing progresses. Because the negative electrode is about four times more effective than the positive electrode in depolarizing nerves, one usually connects the superior of the bipolar pair of electrodes to the negative terminal of the stimulator.

The physician moves epidural electrode(s) until a good pattern of tingling is obtained, beginning with the rate setting high (above 100 pulses per second). The pulse width is set fairly wide (0.5 msec). Changes in pulse width often produce a change in the distribution of stimulation. Amplitude changes are gradual, preferably under the control of the patient. One searches for an effect (location) of the tingling and absence of radicular stimulation or tingling in an uninvolved area. Having achieved good location, the lead is anchored in the deep tissue using a device provided by the manufacturer or a Hemoclip that is carefully applied so that it does not damage the insulation.

If the physician is conducting a trial of stimulation with the percutaneous lead, extension wires are brought out through a stab wound made far enough away from the posterior wound so that these wires, and not the lead, pass through the skin. The wounds are closed. Over the next several days (usually 1 week or less) trial stimulation is then carried out, searching for the pain-masking effect and optimal setting of the stimulus parameters.

If the trial is completed and the percutaneous lead is being placed for definitive implant, the physician will then proceed to subcutaneous tunneling of the extension and the implantation of the power source.

LEAD INSERTION TECHNIQUE: PADDLE-TYPE

Paddle-type leads have plate electrodes with significantly larger effective surface areas than the percutaneously inserted wire-type electrodes. Furthermore, the paddle-type spinal cord stimulation electrodes are insulated on the side away from the dura, bringing more stimulus energy to their ventral surface. This description is based on extensive personal experience, and the unit described here is the Resume electrode system of Medtronic Neurological, Minneapolis, Minnesota. Other plate electrode systems use similar implantation techniques.

The procedure is performed under a combination of epidural and local anesthesia, and preoperative diazepam and antibiotics are administered (as discussed earlier). The patient is placed prone using lateral chest rolls. The spinous process of the T10 vertebral level is identified by counting down the spine from the C7 level. A linear wheal is raised in the midline skin overlying the spinous processes of T9–T10 or T10–T11 using bacteriostatic saline (0.9% benzyl alcohol preservative is an excellent nonburning preanesthetic) to prevent the pain from subsequent injection of the local 1% procaine or lidocaine. The deeper fascia is injected with either of the latter two local anesthetics. An 8-cm, 22-gauge needle then is used to strike the lamina, where about 10 ml of anesthetic is injected; the anesthetic diffuses along muscle/fascial planes to block most of the posterior sensory branches. Some caution is required so as not to puncture the lung or the dura. The region around the costovertebral joint capsule is also infiltrated to accommodate the placement of a retractor. The paraspinous deep fascia on the opposite side is also injected. A total of about 60 ml is used and will be refreshed as needed.

In a personal communication, Krainick of Mainz, Germany has described the use of an epidural catheter inserted in the upper lumbar level and then maneuvered upward to the level of the incision (T9–T10 vertebral body) under fluoroscopic control. Small volumes of dilute bupivacaine can be administered through this catheter. Krainick reports that the local epidural block provides adequate anesthesia for that level and some degree of analgesia below, but the patient can clearly feel tingling paresthesias in the legs while remaining pain free at the incision wound (Krainick, 1986). The author routinely uses 10 to 15 ml of 0.5% bupivacaine, injected into the epidural space just cephalad to the planned incision site, via a Husted needle. No epidural catheter is required.

The insertion technique for plate electrode units requires a hemilaminotomy at the T9 or T10 vertebral level on the painful side. The electrode assembly (four plates) is simply slipped into the epidural space (Fig. 15–5).

A small laminotomy 8 to 10 mm wide and 8 to 12 mm long is performed very close to the lateral base of the T9 or T10 spinous process. The ligamentum flavum is usually

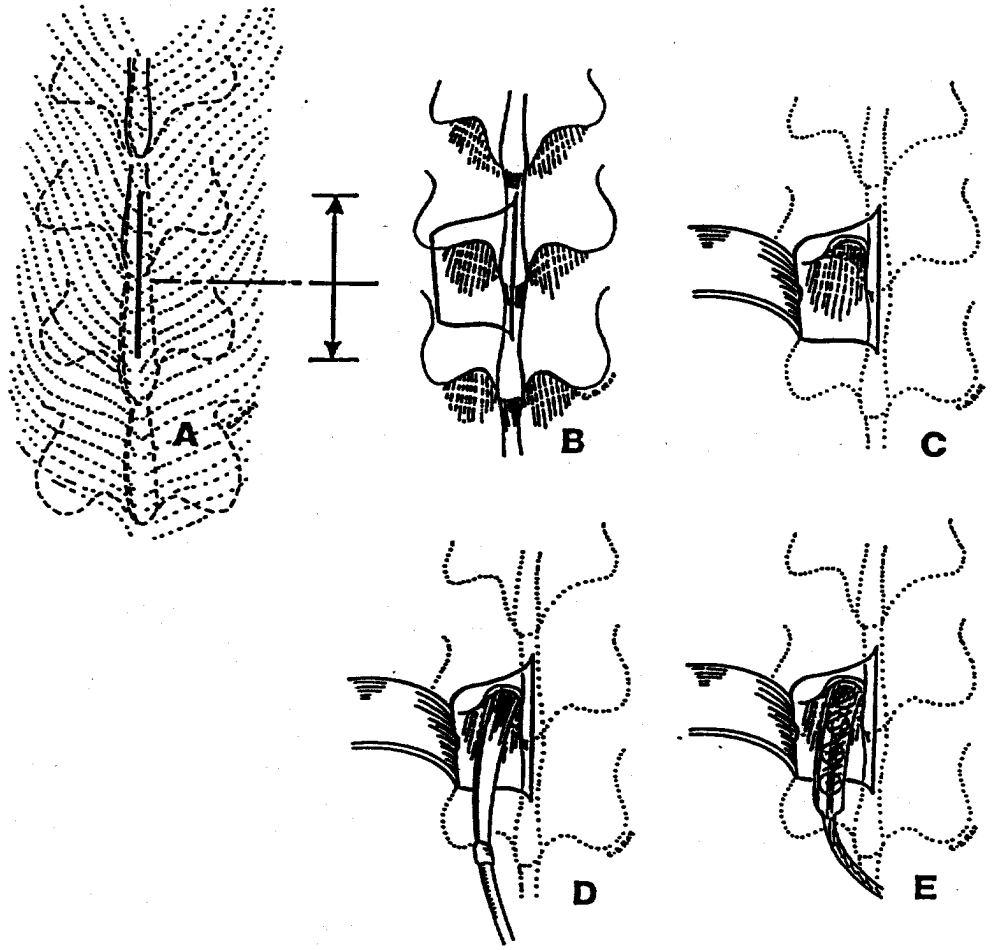

FIGURE 15–5. Diagrams showing technique for implantation of plate-type SCS electrode. *A*, Exposure under local anesthesia for left-sided pain. Area outlined is to be exposed during the procedure. *B*, Laminotomy. The skin, muscle, and other tissues are retracted, prying against the pars and costovertebral joint capsule. *C*, Curved dissector passed to provide tract for the electrode. *D*, Electrode passed into the epidural space, angulated slightly to cross the midline. *E*, The platinum electrode surfaces face the dura.

removed (unless the space is large). The patient is warned that the ensuing manipulations in the epidural space might be uncomfortable. A Penfield No. 3 dissector is passed cephalad in the epidural space, followed by a curved plastic dissector. These clear a path through possible epidural adhesions. The laminotomy must be wide enough to permit some medial and lateral movement of the electrode as it is slipped into place. The electrode passes from the painful side toward the midline and may even cross it slightly. The location is determined by test stimulation, and the electrode is moved about as needed. The patient should operate the amplitude control of the stimulator unit as the electrode is repositioned. Close interaction between the surgeon and patient is essential. The sole task at that moment is to find a position where the tingling covers all of the painful areas with no unwanted stimulation, (e.g., radicular burning or stimulation) into uninvolved areas. The testing is not performed to determine if the stimulation has any effect on the old pain problem (Fig. 15–6).

In some cases, the painful area cannot be covered well, especially in the deep midline low back. Sometimes, it may be necessary to extend the laminotomy into the lower lamina and slip the electrode into the epidural space in the caudal direction. At times, the search for the best placement may be frustrating, especially if this takes a long time and the patient begins to suffer from increasing pain. In any case, a poor location of stimulation paresthesias during on-table testing will *not* improve later; it must be correct the first time. The trial period and methods used are essentially identical with those for the percutaneously inserted systems.

Trial Period

It is usually advisable to wait at least a day after the insertion of the electrodes before beginning trial stimulation; the sensitivity of the fresh wound often causes a distortion of the perceived paresthesias. Over the next 3 to 7 days, the patient tries the device while keeping a diary of electrode combinations (with polarities and electrode configurations used), stimulus parameters, sensations produced, latency and persistence of effectiveness, degree of pain relief, and physical activity level. Nurses' notes are checked for consistency with the patient's observations and for medications required. The patient should once again review audiovisual or other teaching materials (Ray, 1980). Time must also be spent answering questions. Patients must be taught when, how, and why to alter the parameters of stimulation and the effect of these on outcome. If need be, the patient can be sent out of the hospital for several days before deciding whether or not the system should be internalized. Appropriate skin care must be carefully maintained.

When the results show subjective and objective improvement in pain behavior, reported pain level, physical activity, and reduced need for medication, the system will be internalized. Several authors believe that unless the improvement is

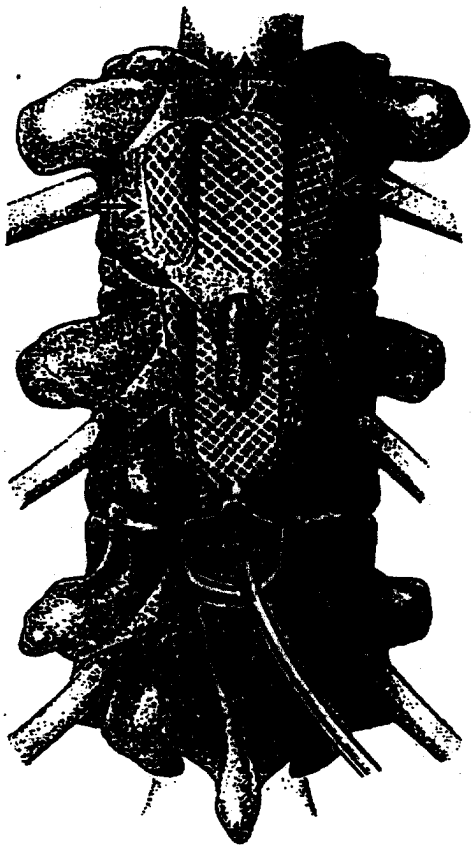

FIGURE 15–6. Laminotomy for placement of surgically implanted SCS lead. The laminotomy should be wide enough to permit some medial and lateral movement of the lead within the epidural space.

at least 50% better than the preimplant state, the results are, or will become, poor and the system should not be implanted (Burton, 1975; Burton et al, 1977; Long, 1979; Nielson et al, 1975; Ray et al, 1982; Siegfried and Lazorthes, 1982).

Internalization of Implanted Stimulators

If a percutaneous lead has been inserted, the negative electrode (as selected between the two electrodes during the trial period) is marked by tying a knot in the percutaneous extension or by placing a Hemoclip on it. This should be done about 1 cm beyond the point of emergence from the skin. Of course, multielectrode units are coded and need not be marked. In all cases, final selection of the combination should be written in the daily clinical record before internalization. In implantable stimulators with the capability of having electrode combinations changed after implantation, there is less need for such notation.

The location of the subcutaneous pocket for the receiver or implantable pulse generator is selected after ascertaining the patient's wishes. The author typically places the pocket on the anteroinferior chest wall or in the subclavicular space. In these protected locations, the receiver is supported against the ribs and cannot rotate or migrate into deeper fat. Abdominal area placements are also common. The pocket should have between 5 and 10 mm of overlying fat.

The technique of internalization has been well described elsewhere (Ray, 1981a, 1981b); the manufacturer's surgical procedure manual should also be reviewed. Internalization of the receiver is almost always performed under general anesthesia. A one-dose preoperative antibiotic is again given. The passage of interconnecting lead wire must be planned with some care. A small intermediate or passing incision may be required for long lead wires. Pockets adequate to accommodate the connector and redundant lead wires must also be planned. Percutaneous extensions are cut off (after being previously marked, if necessary.) Routine preparation is followed by draping the patient with a self-adherent plastic sheet. The midline incision is reopened, and the cut ends of the extensions are brought through. The receiver or pulse generator is implanted in its pocket; its leads are then passed, being careful not to traverse muscle, and are also brought out through the posterior midline wound. The leads are connected and sealed as specified in the manufacturer's instructions. Throughout this procedure, one must be careful not to injure the insulation, leads, or connectors.

Postoperative instructions are given to the patient (or responsible relatives) so that all important details are well understood. With percutaneously inserted spinal cord stimulation implants, patients should be reminded not to bend excessively, especially to the side away from the pocket location, for the first 2 months after implantation. This allows the tissues to heal in position around the electrodes and lead, reducing the likelihood of displacement. This admonition is rarely needed for patients implanted with paddle-type leads. Before leaving the hospital, the patient must completely understand techniques of care of the skin overlying the implant and care of any external components of the system. Good descriptive material is available from the manufacturers.

The proper and continuous use of such life-modifying implanted devices is not to be taken lightly by the physician in charge of the case. Personal visits are required at least twice within the first year, yearly thereafter, and by correspondence as often as needed. Most device adjustments for optimization of parameters can be performed by well-trained nurses or technicians at follow-up.

Complications

The most common complication is loss of effectiveness because of mechanical failure (of the lead or insulation) or because of some undetermined physiological change. Other complications rarely occur in experienced hands (Bishop, 1980; Lazorthes and Verdie, 1983). In nearly 700 implants performed by the author's group for 15 years, a system has had to be removed on only four occasions for infection, and never for spinal cord compression or cerebrospinal fluid leakage. The effective lifetime for a spinal implant is about 3 to 7 years, at which time the most likely failure is mechanical breakage of the lead or insulation around the wire or battery depletion. The recently developed totally implantable pulse generators may continue to function for 5 to 10 years.

Effectiveness and Outlook

It is the author's conclusion that the techniques presented here are valid and serve a definite role in the management

of selected patients with severe chronic pain. Others (such as Kallgren, 1994) agree that spinal cord stimulation is one of the safest and most effective procedures available for the management of chronic pain. Alternative surgical procedures, such as dorsal root entry zone (DREZ) lesioning, can be effective for relief of chronic pain (e.g., pain secondary to brachial plexus avulsion [Thomas and Kitchen, 1994] and differentiation pain [Ianoco et al, 1992]), and can be applied in situations in which SCS is not applicable, such as the treatment of trigeminal neuralgia (Chen, 1993). However, because DREZ lesioning is a destructive procedure, it is irreversible. Complications of DREZ lesioning, including sensory loss, motor weakness, and new pain, have been reported in substantial percentages in some series of patients (Kumagai et al, 1992). In contrast, SCS is a nondestructive procedure that can be performed on a trial basis, as described. The applications of SCS should continue to expand with the development of more widespread understanding and acceptance of the methods.

PERIPHERAL NERVE STIMULATION FOR FOCUSED PAIN AREAS

When pain is highly focused, involving not more than two nerve roots, peripheral nerve stimulation may be an appropriate intervention. This neuroaugmentation technique is used less commonly than SCS, but the principles involved are the same. Gybels and Van Calenbergh (1990) report an 81% success rate in a carefully selected group of patients at follow-up (mean 4.3 years, range 1.1 to 7.6 years). Patients with intractable pain secondary to peripheral nerve damage or reflex sympathetic dystrophy are the best candidates for this therapy. Indications include direct or indirect nerve trauma, reflex sympathetic dystrophy, causalgia, repetitive stress, and postherpetic neuritis. Other patient selection criteria for peripheral nerve stimulation are the same as for spinal cord stimulation.

The most common peripheral nerves to be treated with peripheral nerve stimulation are ulnar, median, radial, tibial, and common peroneal nerves. In the 1960s, surgical technique for peripheral nerve stimulation involved the placement of cuffs proximal to the injury on the nerve. Direct contact between the electrodes lowered the long-term success rates. Today, both percutaneous and plate-type leads are used in peripheral nerve stimulation. The injured nerve is separated from the lead by using intramuscular septum or split fascia. A special-purpose peripheral nerve stimulation lead has been developed (On-Point, Medtronic Neurological, Minneapolis, Minnesota) to provide greater lead stability and facilitate implantation and anchoring. This paddle-type lead, designed to fit in small spaces, has a skirt of mesh polyester for suturing to the fascia (Fig. 15–7).

As with spinal cord stimulation, patients being considered for peripheral nerve stimulation must meet the standard selection criteria and undergo preoperative evaluation to determine the exact location and extent of the nerve damage. Implantation of a peripheral nerve stimulation system involves lead placement, trial screening, and system implantation. Some clinicians use transcutaneous electrical nerve stimulation (TENS) devices for trial screening (Gybels and Van Calenbergh, 1990).

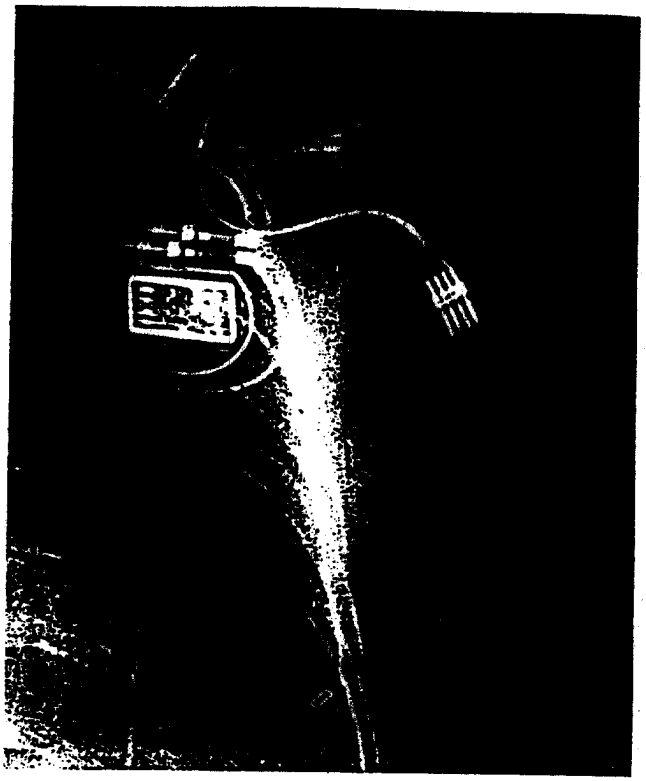

FIGURE 15–7. Peripheral nerve electrode on the ulnar nerve. Transmitter and receiver in the left upper anterior chest wall. (Resume TL lead and Itrel spinal cord stimulation system, by Medtronic, Inc.)

Unlike SCS lead placement, peripheral lead placement is performed under general anesthesia. The lead is placed beneath the involved nerve proximal to the nerve damage and anchored with sutures. Techniques specific to the nerve involved may vary. For example, a consideration in a lead implant involving the ulnar or median nerve is that the elbow should be flexed and extended several times to ensure that there is no undue stress on the lead. Manufacturers' surgical technique manuals provide details pertinent to each implant location (Lewis and Racz, 1992).

Once optimal positioning is achieved, a harvested fascial flap is sewn between the nerve and electrode plate to prevent direct contact. Care should be taken to ensure that the lead body does not rub against the nerve. Percutaneous wires are tunneled subcutaneously and connected to an external temporary power source for a trial of stimulation that may last one or more days. The goal of the trial screening is to determine that the area of pain is covered by the paresthesia and that an acceptable level of pain relief is obtained.

If the patient experiences at least 50% pain relief during the screening trial, the system can be implanted under general anesthesia. The site where the power source will be implanted is identified, and a pocket is formed. Chest or abdominal wall locations are common sites, with the selection dependent on the lead location. An extension is tunneled subcutaneously from the pocket to the lead incision site, and then connected to both the lead and the power source. Incisions are closed and dressed.

The power source should be programmed in the recovery room when the patient is responsive. Because parameter settings are a function of the resistance between the lead and

stimulated nerve, movement of the extremity may cause positional sensitivity. Patients can compensate by adjusting the amplitude. Early and aggressive physical therapy is recommended. Return of function and strength is proportional to the patient's use of the limb. Following removal of the sutures, activities are unrestricted.

CONCLUSIONS

Both spinal cord stimulation and peripheral nerve stimulation are neuroaugmentation techniques that contribute significantly to the clinician's armamentarium against chronic, intractable pain. It is the author's conclusion that the techniques presented here are valid and serve a definite role in the management of selected patients with severe chronic pain. Others (e.g., Kallgren, 1994) agree that spinal cord stimulation is one of the safest and most effective procedures available for the management of chronic pain.

Alternative surgical procedures, such as DREZ lesioning, can be effective for relief of chronic pain (e.g., pain secondary to brachial plexus avulsion [Thomas and Kitchen, 1994] and differentiation pain [Ianoco et al, 1992]), and can be applied in situations in which SCS and peripheral nerve stimulation are not applicable, such as the treatment of trigeminal neuralgia (Chen, 1993). However, because DREZ lesioning is a destructive procedure, it is irreversible. Complications of DREZ lesioning including sensory loss, motor weakness, and new pain have been reported in substantial percentages in some series of patients (Kumagai et al, 1992). In contrast, SCS and peripheral nerve stimulation are nondestructive procedures that can be performed on a trial basis, as described. The applications of SCS and peripheral nerve stimulation should continue to expand with the development of more widespread understanding and acceptance of these methods.

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