SPINAL CORD STIMULATION ELECTRODE DESIGN:
PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL
COMPARING PERCUTANEOUS AND LAMINECTOMY ELECTRODES—PART I: TECHNICAL OUTCOMES

OBJECTIVE: The clinical use of spinal cord stimulation for treatment of chronic intractable pain has been increasingly successful because of recent technical improvements, particularly the development of multiple-contact electrodes supported by programmable implanted pulse generators. Contemporary electrodes can be placed percutaneously in some cases and require a limited laminectomy in other cases.

METHODS: We performed a prospective, randomized, controlled trial comparing two prototypical electrode designs, using a computerized system that allows direct patient interaction and quantitative measurements. A series of 24 patients with chronic lumbosacral pain syndromes first underwent testing with percutaneous four-contact electrodes and then underwent implantation, at the same spinal level, of one of two different electrode configurations; 12 patients received a new percutaneous four-contact electrode of the same design and 12 received an insulated four-contact array, which was implanted via laminectomy.

RESULTS: The insulated array performed significantly ($P = 0.0005–0.0047$) better than the temporary percutaneous electrode for the same patients, according to all three measures tested (ratings of paresthesia coverage of pain, coverage calculated from patient drawings, and amplitudes), at the “usage” amplitude for the three standard bipoles examined. The insulated array also performed significantly ($P = 0.0000–0.026$) better than the permanent percutaneous electrode in terms of coverage ratings and amplitude requirements. Low back coverage ratings were significantly better for the insulated array than for the temporary percutaneous electrode, and scaled amplitudes necessary for low back coverage were significantly better for the permanent percutaneous electrode than for the temporary electrode. In comparison with the percutaneous temporary electrode, at subjectively identical stimulation intensities, the permanent insulated array required significantly lower amplitude.

CONCLUSION: We can immediately infer from these technical data that the use of an insulated array, in comparison with a percutaneous electrode, would double battery life. Extended follow-up monitoring will be required to assess the extent to which the technical advantages we observed for the insulated array might be associated with improved clinical outcomes.

KEY WORDS: Electrical stimulation, Failed back surgery syndrome, Low back pain, Spinal cord stimulation

S pinal cord stimulation (SCS) is a reversible “augmentative” technique (to be distinguished from “anatomic” or “ablative” techniques) for pain management. Minimally invasive techniques are most consistent with this treatment approach. The earliest SCS electrodes were insulated arrays that required laminectomy (albeit very small exposures with local anesthesia). To screen candidates for this procedure, electrodes that could be placed percutaneously were developed in the 1970s. These minimally invasive electrodes were quickly adapted for long-term use (19, 30). Long-term clinical comparisons demonstrated some differences in long-term migration rates, because the percutaneous electrodes retain the
potential to move longitudinally, but these differences are generally less pronounced with contemporary designs (23, 26).

We previously observed that insulated arrays had additional technical advantages when used for the treatment of low back and lower extremity pain. They eliminated certain stimulation-evoked, uncomfortable, side effects and, for patients undergoing implantation for those reasons, they provided better coverage at lower amplitudes, in terms of both absolute units (voltage) and units scaled to the range from perception to discomfort (24). Those observations were recorded for selected patients in an uncontrolled case series, and it was not clear whether they could be generalized to all patients undergoing SCS. Therefore, we performed a prospective randomized study to compare the two designs.

PATIENTS AND METHODS

Patient Selection

Patients with lumbosacral root injury pain, commonly known as “failed back surgery syndrome” (persistent or recurrent pain after lumbosacral spinal surgery), were included in the study, on the basis of the following criteria. The first criterion was a chief complaint of radicular pain, as opposed to axial low back pain; eligible patients described their midline or axial low back pain as being less than or equal to their radiating hip, buttock, or lower extremity pain. The second criterion was an objective basis for the complaint of pain, beyond the history of prior low back surgery. One or more of the following was required: 1) recent abnormal diagnostic imaging results (e.g., myelogram demonstrating lumbar arachnoid fibrosis), 2) a neurological deficit consistent with the patient’s pain complaints and history, and/or 3) a well-documented history of surgery for appropriate indications (e.g., old imaging studies clearly demonstrating a large disc herniation, operative notes describing free disc fragments, or prior examinations demonstrating objective neurological findings).

Patient Exclusion Criteria

Unexplored Treatment Alternatives

SCS is routinely reserved for patients for whom alternative therapy has been exhausted or is associated with an unacceptable potential benefit/risk ratio, in comparison with SCS. For example, repeated low back surgery might be considered as an alternative for some patients with failed back surgery syndrome, although overall it compares unfavorably with SCS (17, 22). In this study, as in routine practice, conservative alternatives (e.g., transcutaneous electrical nerve stimulation, standard medications, and physical medicine and rehabilitation programs) were exhausted before SCS was considered.

Psychological Contraindications

Patients with major psychiatric illnesses or abnormal illness behavior were excluded (4). According to routine reimbursement requirements, psychological assessments were performed, including standardized psychological testing. Patients with overriding issues of secondary gain were excluded, pending resolution of those issues. Inappropriate or exaggerated pain behavior (including Waddell functional signs in examinations) led to exclusion (29). Patients exhibiting inappropriate medication use (drug-seeking behavior or excessive/escalating use despite an absence of benefit and harmful side effects) were excluded, pending successful detoxification.

Coexisting Pain Problems or Neurological Disease

Patients with other chronic pain problems were excluded, as were those with coexisting spinal cord injuries, peripheral neuropathy, or lower extremity nerve injuries. The former could confound interpretation of the pain problem under study, and the latter could interfere with the neural mechanisms of SCS.

Medical Contraindications

As in routine clinical practice, patients with medical illnesses (e.g., sepsis or coagulopathy) that would substantially increase the procedural risks were excluded from the study.

Technical Contraindications

Patients who had previously undergone posterior spinal surgery at or above the thoracolumbar junction would not be amenable to percutaneous electrode placement and so could not undergo the trial required for this protocol.

Technical Methods

Placement of a temporary, percutaneous, four-contact electrode for a therapeutic trial was performed for all patients, to establish the degree to which the patient experienced paresthesia coverage of pain and reported pain relief. As in routine clinical practice, 50% pain relief with SCS (as determined with standard, analog, self-reported, rating methods) was the minimal criterion for the next stage of implantation. These ratings were accepted as valid only in the context of appropriate (stable or reduced) analgesic use and physical activity commensurate with physical condition and reported pain relief during a trial period lasting 3 to 7 days.

A four-contact percutaneous electrode with a 9-mm intercontact separation (Medtronic 3487A; Medtronic, Inc., Minneapolis, MN) was used for all percutaneous trials. The temporary electrode was initially positioned, under fluoroscopic guidance, in the radiological midline with a T12-L1 or L1-L2 interlaminar Tuohy needle and was tested at longitudinal positions from T12 to T8 (inclusive). Bipolar test stimulation was delivered at representative contact combinations along the length of the electrode, to establish placement with respect to the physiological midline. A single cathode with a single anode immediately caudal was the standard test configuration (e.g., −/+00) (11). Acceptable midline placement was defined in terms of an amplitude threshold for bilateral pares-
trode positions spanned the level of the T9 approached the discomfort amplitude. Typical optimal elec- cephad electrode was used as a cathode and the amplitude sia would radiate around to the umbilicus when the most positioned just below the point at which stimulation paresthe- coverage was not achieved at any level, then the electrode wasceptual threshold to the discomfort amplitude. If low back the lowest amplitude with respect to the range from the per- was chosen as the level affording coverage of the low back at metric zone. Each was adjusted to the amplitude necessary to cover the low back, as assessed by the patient, for calculation of coverage (overlap) with respect to the pain map. In addition, coverage was rated by the patient for each setting, using a 100-mm visual analog scale.

The 10 combinations with the highest coverage ratings for each configuration were retested in greater detail, to allow additional quantitative measurements of performance. Each was adjusted to the perceptual threshold, bilateral paresthesia threshold, usage amplitude, and discomfort amplitude; in addition, each was adjusted to the amplitude necessary to elicit paresthesiae in the low back, which was assessed as a specific area of interest common to all patients in the study. This allowed scaling of the amplitude necessary to cover the low back in the range from the perceptual threshold (defined as 0) to the discomfort amplitude (defined as 100) (12, 13). The threshold for low back coverage was not necessarily below the discomfort amplitude; in such cases, the patient was considered to have indicated that there was no low back coverage.

The permanent electrode was positioned at the same radiographic level as the temporary electrode for each patient. If placed via laminectomy, then the electrode (Medtronic 3587A) was introduced via enlargement of the interlaminar space below the intended level and then advancement of the elect rode cephalad in direct contact with the dura, beneath an intact neural arch. (In some cases, a laminectomy over the entire length of the electrode might be required; this was not the case for any of our patients.) As with the temporary electrode, the right/left position of the electrode was established not only radiographically but also physiologically, via intraoperative testing of the conscious patient under local anesthesia. All permanently implanted systems used a Medtronic 3470 (X-trel) pulse generator; the same device was used to test the temporary electrodes. The permanently im- planted systems were adjusted in precisely the same way as the temporary electrodes, using the same protocols with computerized equipment. The study protocol described herein was approved in advance by our institutional review board for studies involving human subjects. Figure 1 illustrates the electrodes used in this study, and Table 1 presents their specifications.

### Statistical Methods

We used simple descriptive and standard paired and unpaired t test statistics (comparison of means) to examine the differences between the Pisces-Quad (Medtronic) and Resume (Medtronic) electrodes. Data for the 10 top-rated usage thresh- olds (rating, coverage, and amplitude) and scaled amplitudes for low back coverage (percentage of the perceptual threshold to discomfort amplitude range) were compared. All reported P values are two-sided.

An analysis of variance was also performed, because of the presumed high level of intrapatient correlation and the small patient sample size. Patient and device identifiers were entered into the model as separate variables. This allowed us to control for the variance inherent in repeated measurements by individual patients and to account for the variance at different device settings, as well as the interdevice variance.

![FIGURE 1. Plain antero-posterior x-rays of the spine, showing percutaneous (A) and insulated (B) electrodes placed successively, at the same spinal level, in the same patient.](image)
For randomization, an outside biostatistician generated a consecutively numbered series of opaque envelopes containing opaque cards; the inner card indicated the next patient assignment. Each envelope was opened only after the investigator had obtained signed witnessed consent for the study.

RESULTS

The study population of 24 patients was derived from a group of 26 consecutive eligible patients who were screened for implantation. All patients reported coverage of most, if not all, of their pain distribution (including low back pain) with the temporary electrodes, but only 24 met the clinical criteria for permanent implantation. Accordingly, those 24 patients proceeded to randomization, followed by implantation of the assigned electrode. Twelve patients were assigned to each group. The following three categories of technical outcome measures were considered: 1) patient ratings of coverage; 2) calculated measures of coverage, derived from graphic data entered by the patients; and 3) quantitative amplitude comparisons.

The permanent insulated array performed significantly (\( P = 0.0005 - 0.0047 \)) better than the temporary percutaneous electrode for the same patients, according to all three measures tested (coverage rating, coverage calculation, and amplitude), at usage amplitude at the three standard bipoles examined. As demonstrated in Table 2, coverage ratings and the calculated coverage were significantly greater; voltage requirements were significantly lower. The permanent percutaneous electrode did not differ significantly from the temporary percutaneous electrode with respect to coverage measures, but patients adjusted the permanent percutaneous electrode to a 35% higher voltage.

The permanent insulated array also performed significantly better than the permanent percutaneous electrode for the randomized control group. As demonstrated in Table 2, patient ratings of coverage were 43% higher (\( P = 0.026 \)) and the calculated coverage was 30% greater (\( P = 0.11 \), not significant).

<table>
<thead>
<tr>
<th>Variable and permanent electrode type</th>
<th>Permanent electrode</th>
<th>Temporary electrode</th>
<th>Permanent/temporary electrode ratio (%)</th>
<th>( P )-value</th>
<th>No. of observations</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage rating (0–100)</td>
<td></td>
<td></td>
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<tr>
<td>Percutaneous</td>
<td>47</td>
<td>52</td>
<td>90</td>
<td>NS</td>
<td>31</td>
<td>12</td>
</tr>
<tr>
<td>Insulated pad</td>
<td>67</td>
<td>47</td>
<td>143</td>
<td>0.0006(^{b})</td>
<td>33</td>
<td>12</td>
</tr>
<tr>
<td>Ratio (%)</td>
<td>143</td>
<td>90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( P )-value</td>
<td>0.026(^{b})</td>
<td>0.52</td>
<td></td>
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<tr>
<td>Calculated coverage (0–100)</td>
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<tr>
<td>Percutaneous</td>
<td>43</td>
<td>36</td>
<td>119</td>
<td>NS</td>
<td>31</td>
<td>12</td>
</tr>
<tr>
<td>Insulated pad</td>
<td>56</td>
<td>38</td>
<td>147</td>
<td>0.0034(^{b})</td>
<td>33</td>
<td>12</td>
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<tr>
<td>Ratio (%)</td>
<td>130</td>
<td>106</td>
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<td></td>
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<tr>
<td>( P )-value</td>
<td>0.11</td>
<td>0.91</td>
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<tr>
<td>Voltage (V)</td>
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<tr>
<td>Percutaneous</td>
<td>2.7</td>
<td>2.0</td>
<td>135</td>
<td>0.0047(^{b})</td>
<td>39</td>
<td>12</td>
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<tr>
<td>Insulated pad</td>
<td>1.4</td>
<td>2.5</td>
<td>56</td>
<td>0.0005(^{b})</td>
<td>35</td>
<td>12</td>
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<tr>
<td>Ratio (%)</td>
<td>52</td>
<td>125</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>( P )-value</td>
<td>0.0000(^{b})</td>
<td>0.18</td>
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</table>

\(^{a}\) Unpaired \( t \) tests demonstrated significant advantages for the permanent insulated pad electrode in comparison with the permanent percutaneous electrode and in comparison with the temporary percutaneous electrode. Coverage of pain by paresthesia was greater, according to rating and graphic methods, and the voltage requirements were lower. Power requirements were significantly higher for the permanent electrode than for the temporary percutaneous electrode. These data represent the three bipolar combinations of adjacent contacts (cathode cephalad) that are routinely used for test stimulations to establish electrode positions. All data were recorded at the usage amplitude (broadest coverage at a subjectively comfortable intensity). NS, not significant.

\(^{b}\) Significant.
The permanent insulated array required a significantly lower amplitude (Resume, 1.44 ± 0.89 V; Pisces-Quad, 2.68 ± 0.96 V; \( P = 0.0000 \), unpaired \( t \) test). On the basis of these amplitude settings, the expected battery life for an implanted pulse generator (Medtronic Itrel 3), assuming 12 hours of daily usage at a rate of 60 pulses/s (with a 500-μs pulse width and a simple, bipolar, 700-Ω load), would be 80 months for the insulated array and 40 months for the percutaneous electrode, i.e., a twofold difference.

Detailed testing at multiple amplitude thresholds for the 10 combinations each patient had rated highest (among the 50 tested at the usage amplitude) yielded the results detailed in Table 3. The low back coverage rating was significantly better for the insulated array than for the temporary percutaneous electrode (\( P = 0.05 \)), and the scaled amplitude necessary for low back coverage was significantly better for the permanent percutaneous electrode than for the temporary electrode (\( P = 0.0032 \)). Analysis of variance, to account for additional differences attributable to repeated measures by individual patients, demonstrated no significant differences. There were no significant differences in the therapeutic ratios (discomfort/amplitude/perceptual threshold). Low back coverage was achieved with the insulated array for a significantly greater fraction of the 10 best contact combinations tested in comparison with the percutaneous temporary electrode for the same patients (72 versus 53%, \( P = 0.05 \)) but not in comparison with the permanent percutaneous electrode for the control group.

**DISCUSSION**

**Electrode Comparisons**

The results of this prospective randomized trial confirmed certain previous observations from uncontrolled case series, i.e., insulated arrays implanted via laminectomy demonstrated technical advantages, compared with percutaneous electrodes. Amplitude requirements were lower, and comparisons of standardized bipolar contact geometries at usage amplitudes demonstrated that patient ratings of coverage, as well as calculated coverage, were significantly greater. These improved technical results might be expected to produce greater pain relief (18).

The insulated array has potential advantages that are demonstrable with finite-element computer modeling. Because its contacts are closer to the spinal cord, modeling predicts reduced recruitment of lateral structures, i.e., dorsal roots (8). This can allow thoracic electrode placement (where cerebrospinal fluid thickness is greatest) without the evoking of segmental radicular side effects.

Our results also indicated that permanent electrodes generally compared favorably with temporary electrodes. Not only the patients who received a different (insulated array) electrode but also those who received the same (percutaneous) electrode design demonstrated significantly better results with at least one of the measures in our second test protocol, i.e., detailed, five-threshold testing of the 10 best combinations among the 50 tested previously. This detailed testing was limited to the clinically manageable group of best contact combinations; we did not exhaustively test all 50 combinations. To the extent that we have been unable to completely reject the null hypothesis that the permanent percutaneous electrode is equivalent to the temporary electrode, we cannot consider the permanent percutaneous electrode as a control for the insulated array in the manner originally proposed.

Our prior observations of performance advantages for insulated arrays were in an enriched population, i.e., the subgroup of patients with stimulation-evoked side effects, consis- 

| TABLE 3. Exhaustive testing results* |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Variable and permanent electrode type | Permanent electrode (%) | Temporary electrode (%) | Permanent/temporary electrode ratio (%) | \( P \) value | No. of observations | No. of patients |
| Low back coverage rating | | | | | | |
| Percutaneous | 66 | 63 | 105 | NS | 53 | 12 |
| Insulated pad | 68 | 62 | 110 | 0.05 | 55 | 12 |
| Low back scaled amplitude | | | | | | |
| Percutaneous | 49 | 61 | 80 | 0.0032 | 87 | 12 |
| Insulated pad | 53 | 60 | 88 | NS | 84 | 12 |
| Therapeutic range | | | | | | |
| Percutaneous | 1.66 | 1.77 | 94 | NS | 118 | 12 |
| Insulated pad | 1.69 | 1.84 | 92 | NS | 120 | 12 |

* The 10 best contact combinations identified by patient ratings during exhaustive testing of all 50 combinations were tested at five amplitude thresholds, ranging from first perception to discomfort. This allowed calculation of the therapeutic range (discomfort/perception) and the scaled amplitude (percentage of the discomfort to perception range), necessary to achieve low back coverage. Paired and unpaired \( t \) tests demonstrated significant advantages for the permanent electrodes (percutaneous or insulated array), compared with the temporary electrode (always percutaneous). There were no significant differences between the two permanent electrodes in these measures. NS, not significant.

* Significant.
tent with recruitment of small fibers in the ligamentum flavum (Fig. 2) (24). With the current randomized study population, we observed significant advantages for permanent electrodes of both designs (one identical to the temporary electrode and the other different). This might be attributable to the patients, who might be better at adjusting the device or might simply draw and rate its effects differently. If this were the case, then we might expect all permanent electrodes in all of our studies to be better than temporary electrodes; in fact, we observed in two prior studies (with the same design as this study) that permanent systems with dual percutaneous leads were equivalent to or significantly worse than temporary single leads (15). Alternatively, the improved performance of the permanent electrode might be attributable to the physicians, who might place the percutaneous electrode more effectively in an individual patient the second time. The strict clear technical guidelines we used should have precluded this and, inasmuch as symmetry scores and absolute amplitude thresholds were not significantly different, we apparently followed these guidelines successfully.

The therapeutic ratio (discomfort amplitude/perceptual threshold) was greater than that observed previously by Barrolat et al. (2), using the same (Resume) electrode. This might be related to our testing methods, in which the patients directly controlled the amplitude, rather than having a third party at the controls. With the ability to decrease the amplitude directly and immediately, our patients might demonstrate higher discomfort thresholds.

Stimulation amplitude requirements were, as expected, significantly higher for the percutaneous electrode than for the insulated array. The insulation and the larger cross-section of the array, which positions the contacts closer to the spinal cord, explain this finding. The reduced amplitude requirement is clearly important if an implanted battery, requiring periodic surgical replacement, is to be used. Surgical replacement is the most important long-term maintenance cost for these implants (which constitute the majority of implants used throughout the world), and this is thus an important factor in the cost-effectiveness of this therapy (3). On the basis of our observations, a twofold difference could be calculated; this would translate directly into a twofold difference in ongoing health care costs. As in our routine clinical practice, however, all of the patients in this study received radiofrequency-coupled implants. Improved battery life for the external transmitter is an advantage even for these patients, but only in terms of everyday operational costs to the patient and not in terms of health care costs (as usually tabulated) or the need for additional procedures.

Insulated arrays are less subject to migration than are percutaneous electrodes. Because of their shape, they are immobilized once they become encapsulated in fibrous tissue. Percutaneously inserted catheters, however, are anchored some distance from the electrode contacts; they retain the potential to move longitudinally, as frequently observed in some series (26). We did not observe any migrations during this short-term study, but assessment of migration will require extended follow-up monitoring.

Study Limitations

SCS for treatment of chronic intractable pain involves multiple technical and clinical issues. This study addresses the most common clinical application (low back and leg pain) and the most commonly used electrodes, but the conclusions are necessarily limited, in the following ways.

Acuity

Long-term technical results have not been addressed here. To what extent is coverage of low back and leg pain (particularly the former) maintained chronically? This study addressed only the short-term effects of SCS, early after implantation; follow-up technical measurements have not been
collected systematically and longitudinally. Repeated observations during an extended period might yield different results. Postoperative incisional pain might have compromised our short-term testing of the more invasive insulated electrode.

**Clinical Outcome Assessments**

Long-term clinical results have not been addressed here. To what extent are low back and leg pain relieved chronically? Is the insulated electrode clinically superior? Relief of pain was not assessed beyond the trial period in this study. Pain relief is assumed to be correlated with the technical outcomes reported here; that is, relief is assumed to result from coverage (17). A meaningful assessment of this hypothesis will require extended clinical follow-up monitoring by disinterested third parties, which is ongoing. Previous clinical series that addressed this as a primary focus reported sustained benefits for the majority of this patient population (5, 18, 28).

**Clinical Scope**

This study addressed low back and leg pain as a chief complaint and was limited to thoracic electrode placement. Other potential applications of these electrode arrays (e.g., treatment of upper extremity pain) have not been addressed here. Because they are less technically demanding than the treatment of back and leg pain, such applications might follow the same principles but in a less sensitive manner (2).

**Limited Testing of Electrode Designs**

This was a comparative study of two prototypical electrode designs that have been available since the 1970s. A number of other designs have been developed, introducing variables that, to varying degrees, are beyond the scope of this study. The methods described here might be useful in addressing the following factors.

**Electrode Geometry.** When we consider electrode designs in axial cross section, as demonstrated in Figure 2, then we note that this study distinguished between two prototypical geometries, i.e., planar contacts backed by (and slightly displaced ventrally by) an insulating paddle and uninsulated cylindrical contacts. Our results might be expected to apply to designs with these cross sectional configurations, but there are variations of these basic designs (for example, arrays with contacts at the edges) to which our results might not apply (9).

**Contact Geometry.** When we consider electrode designs in plan (anteroposterior) view, as presented in Figure 1, then we note that this study addressed prototypical linear electrodes with four contacts in a single column; such electrodes have been available since the middle 1970s but have never been characterized as in this study. A number of other contact arrangements have been described in the past two decades, notably two-dimensional arrays (for implantation via laminotomy) and their percutaneous counterparts (electrodes inserted in tandem or in triplicate). These arrangements allow adjustments of right/left symmetry and configurations of anodes and cathodes to alter current distribution in the spinal cord, which might substantially affect performance (1, 9, 14).

This study addressed only systems with midline contacts positioned on or very near the anatomic midline of the spine and spinal cord (as defined with imaging and operative findings) and the physiological midline (as defined with stimulation). Contacts positioned off the midline, and therefore closer to the dorsal roots, might be expected to perform differently.

**Contact Spacing.** This study was limited to longitudinal intercontact (center-to-center) spacings of no less than 9 to 10 mm. The effects we observed might be more or less prominent with different intercontact spacings. These spacings might be as little as 4 mm for some designs and might be as much as the maximal span of the electrode, i.e., nominally 30 mm in this study and twice that value for some designs (8).

Closely spaced contacts (≤7 mm, center to center) have been reported to have particular advantages in the clinical treatment of lumbosacral pain problems (1, 14, 27). An increasing number of literature reports of computerized, finite-element, modeling studies support this (6, 7, 10).

**Contact Area.** This study was limited to contact areas of 11 to 12 mm². As is the case for intercontact spacing, available contact areas in contemporary designs range from nominally one-half of to twice these values (8).

**Number of Contacts.** This study was limited to electrodes with four contacts; contemporary systems have as many as 16 (1, 14). Ordinarily, in electrodes with so many contacts, most contacts are inactive at any given moment; therefore, this study, with up to four simultaneously active contacts, might be representative of typical practice, at least for longitudinal midline electrodes.

**Limited Testing of Spinal Levels**

We limited this controlled trial to the optimal spinal level defined for each patient in longitudinal mapping with a temporary percutaneous electrode. The optimal spinal level for an insulated plate electrode might be different. For example, because its contacts are slightly closer to the spinal cord, an insulated plate electrode might allow thoracic electrode placement at more cephalad levels, without evoking segmental radicular side effects (8). The ultimate performance of an insulated array might exceed that demonstrated here. Different study methods (e.g., the use of longer electrodes with more contacts) would be required to address this.

**Limited Testing of Stimulation Parameters**

To isolate the study variable, namely electrode design, other variables were fixed or limited in scope, as follows.

**Contact Combinations.** Although we exhaustively tested all 50 combinations for four-contact electrodes, we did so at only one amplitude, to keep the task manageable for our patients. Our pairwise comparisons of contact combinations were limited to the three prototypical bipolar pairs in common clinical use (11). We tested only the 10 best-rated combinations at all five amplitude settings, again to keep the task manageable. More extensive testing and more exhaustive statistical com-
parisons might have revealed additional differences between the electrodes; patient compliance might have been a problem, however, and we might have increased the number of possible statistical comparisons to a level necessitating special correction (e.g., Bonferroni methods).

Pulse Parameters. We limited testing to 60 pulses/s, with a 500-microsecond pulse width. Although there is no evidence that results would differ with other pulse parameters, this remains to be addressed.

Pulse Sequences. For more than a decade, computerized equipment and now commercially available systems have allowed sequential and even simultaneous stimulation deliveries with different stimulation parameters and/or contact combinations (1, 9, 16, 21, 25). These capabilities, which are broadly (and often inappropriately) referred to as “multichannel” stimulation capabilities, increase the range of possible variables. This study does not address such variables. There have been no comparative studies addressing any of those variables with blinded, controlled, scientific methods.

Sample Size

Our sample of 12 patients for each phase of the study, with each providing 10 best combinations for analysis, was adequate for detection of differences of 0.4 standard deviations (e.g., approximately 10 percentage points for rating or coverage) with a statistical power (1 – β) of 80%, at the 0.05 level of significance (two-sided test). Our failure to detect other differences might reflect a Type II error, which a larger sample size would address. Arguably, our sample was adequate for the detection of clinically important technical differences. Although it was adequate for the demonstration of some technical advantages for the insulated array (Resume), the sample size in this study might not be adequate for the detection of clinical differences in long-term follow-up monitoring.

CONCLUSIONS

This prospective randomized trial demonstrated performance advantages for insulated arrays implanted via laminectomy, in comparison with percutaneous electrodes; this finding is consistent with our earlier observations in a nonrandomized pilot study. With the use of identical bipolar contact combinations, rated and calculated coverages at the usage amplitude were significantly better and amplitude requirements were lower for the insulated array design. When we broadened this strictly controlled, technical comparison to a clinically manageable study of the best contact combinations, the advantages of the insulated array were less clear; both designs demonstrated improvements, compared with the temporary configuration, and only the amplitude advantage was consistently maintained. This might reflect the time and sampling constraints of this short-term study. This was strictly a technical comparison; we plan ongoing clinical follow-up monitoring to assess any differences in treatment outcomes.

GLOSSARY


Array

A two-dimensional arrangement of stimulating contacts, either 1) prefabricated on insulated backing as a paddle or plate and implanted via laminotomy or laminectomy or 2) created via insertion of percutaneous electrodes in parallel. Most commonly (and of necessity, if placed percutaneously), the contacts are arranged longitudinally in columns, e.g., two or more columns of N contacts (2 × N); however, an array might contain any number of columns, even 1 × N. A prefabricated paddle or plate might have contacts in, for example, a diamond pattern or rows (8).

Channel

A pulse generator output that is independent of other outputs, particularly with respect to amplitude (voltage or current). A true multichannel stimulator allows simultaneous delivery of different amplitudes to different contacts. (A programmable multicontact stimulator that allows rapid sequential delivery of pulses to different contacts approaches this but is not, strictly speaking, a multichannel device.)

Contact

An electrically conductive point or surface from which current passes into tissue. Contemporary electrode arrays have multiple contacts.

Electrode

An assembly of electrically conductive contacts and wires, with insulating spacers, catheters, and backing material. The term is most often used to refer to the “business end” of the assembly, where contacts deliver stimulation current to tissue. (The term is sometimes used to refer simply to a stimulating contact, but electrodes include insulation and other materials.)

Lead

A linear arrangement of conductors and insulators (wires and their circumferential insulation) between stimulating contacts and connectors. The term is sometimes used to refer to the entire electrode, particularly for percutaneous catheter designs.

Paddle

A flat, essentially two-dimensional, insulated electrode or array. Because it cannot be inserted percutaneously (via a needle), it is implanted in the spinal canal via laminotomy or laminectomy.

Plate

See Paddle.
REFERENCES


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COMMENTS

It was very important to me to read a good study on this topic reported by experienced authors. In practice, I prefer to use laminectomy-type electrodes because of the need for minimal manipulation to obtain good positioning and the opportunity to gain access to a larger contact area for electrode placement. I think that only neurosurgeons should perform such procedures to treat patients’ chronic pain, and I am glad to learn of additional evidence in support of my opinion.

Yücel Kanpolat
Ankara, Turkey

This important and timely study was conducted with appropriate patient selection and screening criteria in a prospective, randomized comparison of the use of percutaneous versus laminectomy electrodes for spinal cord stimulation (SCS). The comparison was based on the technical aspects of SCS for pain—namely, rating of paresthesia coverage of the painful area, coverage calculated from patient drawings, and required stimulation amplitude. The authors point out that their study is not an outcome study and that its results pose fundamental questions concerning electrode design and patterns of SCS. Clearly, if this study can be extended, which I suggest, durable, high-quality data may definitively answer the question regarding the potential superiority of laminectomy electrodes for the production of pain relief by administering SCS.

Kim J. Burchiel
Portland, Oregon

I enjoyed reading this article, in which the authors, including one of the leading people in the field as the senior author, report the results of their well-designed study. In a sense, the results are not quite unexpected, considering that a plate electrode, which for unknown reasons the authors refer to as
an insulated array, provides an electrical field preferentially acting on the dorsal aspect of the spinal cord that is more extensive than a percutaneously implanted one. The findings are thus in accordance with what can be inferred from the theoretical model described by Holsheimer. Moreover, it is a general experience and a recommended strategy to replace a percutaneously implanted electrode with a plate electrode if there are problems with retaining and occasionally also producing adequate paresthesia coverage. The implantation of a plate electrode through a laminotomy is, from a surgical point of view, a minor intervention; when performed with the patient under only local anesthesia, however, it is a distressing experience for most patients. Therefore, robust data are required to justify that approach as the first choice; if that is the case, then it would be logical also to use a laminotomy electrode with temporary, percutaneous extension for trial stimulation. I, for one, am not convinced by the results of this study to the extent that I am prepared to change my first-choice electrode to one that necessitates open surgery. To me, the strongest argument in favor of plate electrodes is the lower stimulation amplitude required and thus the considerably increased battery life of the implanted pulse generators, which have entirely replaced the radiofrequency antenna-transmitted energy (Medtronic Xtrex Neurostimulator; Medtronic, Inc., Minneapolis, MN).

The principal findings reported in this article are that, apart from lower voltage requirements, the plate electrodes provided better paresthesia coverage than the permanent percutaneous ones as assessed by both the patients’ drawings and their subjective, qualitative evaluations. The difference for the patient-rated coverage was statistically significant, and the calculated coverage was not. That finding is surprising to me, because in my experience it is virtually always possible to produce paresthesiae that cover the painful area. To retain paresthesiae over time is another problem. Moreover, there was no difference between the two types of electrodes in enabling paresthesia coverage of the lower back, which in fact remains a major technical problem with SCS. This issue may be a pseudo problem, however, considering that no one has convincingly demonstrated that pain confined to the axial, lower part of the back can be relieved effectively by this treatment. In this study, patients with such pain were excluded; therefore, I find it difficult to understand how the presence of paresthesia in that region was studied. It also is not clear to which region of the lower back the authors refer and why the ambiguous term low back pain is included as a key word.

The study protocol for the trial period was indeed very elaborate and must have required a high degree of patient compliance. The trial period was short at 3 to 7 days. I wonder how it was possible to test all 50 different combinations of polar couplings, considering that the patient must change body position (e.g., sitting, standing up) and wait for at least 5 minutes to be able to evaluate the distribution and character of the paresthesia with each coupling. To reliably assess a possible pain-relieving effect with one selected coupling providing optimal paresthesia coverage requires at least several additional days. The limited time allotted to the test stimulation could have been the reason why the permanent percutaneous electrodes performed better than the temporary ones. Of course, it is most desirable and of utmost importance that the most reliable and practical methods of selecting patients for SCS be developed and that the best technology for maintaining long-term efficacy be used. At the same time, however, neurosurgeons should strive to minimize the invasiveness of the surgical intervention and the discomfort caused to the patient. Are laminotomy electrodes the solution? 

Bjorn A. Meyerson
Stockholm, Sweden

The Esther A. & Joseph Klingenstein Fund is pleased to announce its Fellowship Awards in the Neurosciences for 2003. The purpose of these awards is to support young investigators, in the early stages of their careers, who are engaged in basic or clinical research that may lead to a better understanding of the etiology, treatment, and prevention of epilepsy. The Klingenstein Fund recognizes that to accomplish these goals it is necessary to encourage a variety of approaches. These include studies at the molecular and cellular levels as well as research into the integrative function of the nervous system and clinical investigations. Up to 10 Klingenstein Fellows will be appointed in 2003, and each will receive an award of $150,000 over 3 years. Applicants must hold the Ph.D. and/or M.D. degree and must have completed all research training, including postdoctoral training. The deadline for applications is December 6, 2002. For additional information, write or call the Klingenstein Fund, 787 Seventh Avenue, 6th Floor, New York, NY 10019-6016. Tel: 212/492-6181.