Automated, Patient-Interactive, Spinal Cord Stimulator Adjustment: A Randomized Controlled Trial

OBJECTIVE: Programmable, multi-contact, implanted stimulation devices represent an important advance in spinal cord stimulation for the management of pain. They facilitate the technical goal of covering areas of pain by stimulation-evoked paresthesiae. Adjustment after implantation requires major investments of time and effort, however, if the capabilities of these devices are to be used to full advantage. The objective of maximizing coverage should be met while using practitioners’ time efficiently.

METHODS: We have developed a patient-interactive, computerized system designed for greater ease and safety of operation, compared with the standard external devices used to control and adjust implanted pulse generators. The system automatically and rapidly presents to the patient the contact combinations and pulse parameters specified by the practitioner. The patient adjusts the amplitude of stimulation and then records drawings of stimulation paresthesiae (for comparison with pain drawings), followed by visual analog scale ratings for each setting. Test results are analyzed and sorted to determine the optimal settings. We compared the automated, patient-interactive system with traditional, practitioner-operated, manual programming methods in a randomized controlled trial at two study centers, with 44 patients.

RESULTS: The automated, patient-interactive system yielded significantly ($P < 0.0001$) better technical results than did traditional manual methods, in achieving coverage of pain by stimulation paresthesiae (mean 100-point visual analog scale ratings of 70 and 46, respectively). The visual analog scale ratings were higher for automated testing for 38 patients, higher for manual testing for 0 patients, and equal (tied) for 6 patients. Multivariate analysis demonstrated that the advantage of automated testing occurred independently of practitioner experience; the advantage was significantly greater, however, for experienced patients. The rate of testing (number of settings tested per unit time) was significantly ($P < 0.0001$) greater for the automated system, in comparison with the rate with a human operator using traditional, manual, programming methods (mean of 0.73 settings/min versus 0.49 settings/min). The automated system also identified settings with improved estimated battery life (and corresponding anticipated cost savings). No complications were observed with automated testing; one complication (transient discomfort attributable to excessive stimulation) occurred with manual testing.

CONCLUSION: Automated, patient-interactive adjustment of implanted spinal cord stimulators is significantly more effective and more efficient than traditional manual methods of adjustment. It offers not only improved clinical efficacy but also potential cost savings in extending implanted battery life. It has the additional potential advantages of standardization, quality control, and record keeping, to facilitate clinical research and patient care. It should enhance the clinical application of spinal cord stimulation for the treatment of chronic intractable pain.

KEY WORDS: Pain drawing, Paresthesia mapping, Personal computer, Spinal cord stimulation
In the past 35 years, implanted electrical stimulation devices have been increasingly used for the management of chronic intractable pain. Spinal cord stimulation (SCS) has been the most common application of this technique. Electrodes are implanted over the spinal cord, in the dorsal epidural space, and are connected to a pulse generator with external controls for the practitioner and the patient (11). SCS, like transcutaneous electrical nerve stimulation, peripheral nerve stimulation, and thalamic stimulation, elicits paresthesiae; for pain relief, it has proved to be necessary that these paresthesiae overlap the distribution of pain (13, 15, 22). Figure 1 illustrates this concept.

The major determinants of the distribution of paresthesiae are the positions of the stimulating cathode(s) and anode(s) over the spinal cord. Therefore, electrodes with multiple contacts have been developed, complemented by programmable pulse generators that allow noninvasive selection among the contacts. SCS has become significantly more effective in clinical practice because of these technical improvements (15, 19). As the number of contacts increases, however, the number of possible cathode and anode assignments increases disproportionately. There are 50 bipolar combinations for an array of four contacts and 6050 for an array of eight contacts. If these are to be tested thoroughly and to full advantage for each patient, then increasing amounts of practitioner time are required to determine the most effective combination. Specialized technical training places even greater time demands on practitioners. The potential advantages of these new devices are compromised by these demands.

Traditionally, the practitioner has manually selected each new anode and cathode assignment or pulse parameter, and for each such setting the patient has adjusted or guided adjustment of the amplitude of stimulation, with the process being repeated for each new setting. With an appropriately designed control system, however, the practitioner should be able to specify a sequence of settings and then the patient should be able to work through the sequence, adjusting the amplitude for each setting and recording the effects without full-time supervision or skilled assistance. With a given amount of practitioner time, a larger number of adjustments should be possible. The data recorded in the course of these adjustments may be analyzed for determination of the optimal settings for each patient; they may also be collected for multiple patients for research purposes. Because there is no human operator to introduce bias and because the order of stimulus presentation is easily randomized, this process lends itself to scientific analysis.

In the past 16 years, a series of publications have described a patient-interactive, computerized method for adjustment of implanted, radiofrequency-coupled, spinal cord stimulators (5, 14, 16, 17, 20). Testing of more than 400 patients has demonstrated consistent safety and efficacy for this patient-controlled method in routine clinical settings, with benefits regarding the efficiency, the rapidity, and ultimately the efficacy of SCS (16, 17, 20). This method has also facilitated quantitative comparisons of the performance of different electrode designs (18). This method has not been applicable to internally powered, implanted pulse generators (IPGs), however, which comprise the great majority of implants.

This randomized controlled trial compares a new automated system, applicable to IPGs, with the manual methods that practitioners have hitherto used in routine clinical practice. We compare the two methods with respect to 1) efficacy, 2) safety, and 3) efficiency.

PATIENTS AND METHODS

Device Description

We have developed a computerized, patient-interactive system (Polaris; Stimsoft, Inc., Columbia, MD) that supports the adjustment of IPGs (Itrel 3 and Synergy; Medtronic, Inc., Minneapolis, MN). Functional requirements were derived from the aforementioned reports, and the system was completely and independently redesigned. Practitioner and patient user interfaces were developed for a handheld Windows CE pen tablet (PenCentra 200; Fujitsu, Inc., San Jose, CA) driving a telemetry module (Polaris; Stimsoft; Benchmark Electronics, Inc., Minneapolis, MN; Medtronic), which in turn controls the IPG.

The practitioner user interface automates the process of testing many individual stimulator settings. Unlike a conventional programmer, which allows only one setting to be selected for assessment by the patient, the system allows a series of settings to be preset for patient assessment. It then automatically and sequentially programs the stimulator with each of the pulse parameters and electrode polarity combinations selected by the practitioner. After testing, it sorts the results and presents them to the practitioner, who selects and prescribes the final settings.

The patient user interface presents graphical diagrams and simple verbal instructions. It leads the patient through a tuto-
rial, which teaches the operation of the pen tablet system, and instructs the patient to draw the area(s) of pain. It then presents, one by one, the series of stimulator settings defined by the practitioner. As demonstrated in Figure 2, for each of these settings the patient increases the amplitude to the desired level, draws the area of paresthesiae produced by stimulation, and then enters a rating of the overlap of pain by paresthesiae. The system records this information and calculates additional derivative information, such as drawings of the overlap of pain by paresthesiae and the estimated battery life.

Patient Population and Study Centers

Study patients were derived from a clinical population for which SCS had already been selected, by standard clinical criteria, as the best medical therapy. All patients had already undergone implantation of low thoracic, dorsal, epidural electrodes and IPGs for the treatment of low back and leg pain (the most common application of SCS). The patients were enrolled consecutively as they presented for SCS programming, in an outpatient clinical setting. Some had recently received implants and others had undergone implantation years earlier. Patients were excluded if they could not read and understand written English or if they had excessive difficulty manipulating a pen or stylus.

Two centers were selected, to ensure variations in both patient populations and practitioner experience. One center was a major teaching hospital with more than two decades of extensive published experience with SCS, using the same IPGs as in this study. The other center was a private pain treatment center with multiple physicians and multiple offices, with a smaller, ongoing, SCS experience representative of such centers. At both centers, the implanting physicians designated additional practitioners (nurses, physician assistants, or technicians) to perform the SCS adjustments, with supervision, as is their routine practice. In addition, as is routine practice, the local center augmented its staff with an individual designated by the IPG manufacturer to perform the manual adjustments.

Randomized Controlled Trials

Each patient underwent both manual and automated testing, in random order. In manual testing, the practitioner programmed each test condition using a standard, commercially available programmer (Model 7432; Medtronic). The amplitude was then adjusted either by the practitioner, using the same programmer, or by the patient, using a handheld programmer (Model 7434 Itrel EZ or 7435 Synergy EZ; Medtronic).

In automated testing, the practitioner programmed the test protocol, which included the entire sequence of test conditions, into the automated system. The patient completed the built-in system tutorial and then proceeded with amplitude adjustments for each test condition, using the automated system. A handheld programmer remained accessible to the patient as a backup system. Body position was kept constant during the trials. Patients remained seated, to control for any postural effects.

The amplitude for each test condition was the “usage” level, i.e., the voltage that achieved the broadest paresthesia coverage for which the stimulation remained comfortable to the patient (3, 8, 9, 17, 20). After the amplitude had been set, the patient either marked a 100-mm visual analog scale (VAS) on paper to indicate the overlap of pain by stimulation paresthesiae (manual method) or marked the VAS and drew the area of stimulation paresthesiae using the pen tablet computer (automated method) (Fig. 2).

At least 10 settings were tested with each method, with additional testing of up to 50 settings at the discretion of the patient and the practitioner. The order in which settings were tested was at the discretion of the practitioner with the manual method; the order was not predetermined, and the practitioner was thus free to choose settings as guided by reported coverage. The order of testing was randomized for the automated method. Test times were recorded for each method. The practitioner recorded any difficulties encountered with either system.

![FIGURE 2. Automated system screens. A, the patient controls stimulation by manipulating a vertical bar graph (which resembles a thermometer) either directly with the stylus or indirectly using on-screen pushbuttons. B, a pain drawing overlay, modified from the 50-year-old Palmer pain drawing used in the McGill pain questionnaire, appears on the 640- × 480-pixel color display. This serves as a template not only for pain drawings but also for drawings of stimulation paresthesiae. C, a VAS is used by the patient to estimate the overlap of area(s) of pain by stimulation paresthesiae.](image-url)
One-half of the patients were tested first with the manual method and one-half with the automated method; the order was randomized. For each patient, the order was determined by opening the next in a series of opaque envelopes that contained equal numbers of cards specifying manual testing first or automated testing first. The sealed envelopes had been shuffled repeatedly, to randomize order, and then numbered consecutively.

To avoid bias, the baseline setting for each patient’s implant was recorded before the beginning of the trial and was not revealed to the practitioner. The practitioner could not refer to the patient’s prior test results, if any, or first use the automated system and then, knowing the results, perform a manual testing session for the same patient. No such precautions were necessary for the automated system; it presented the test settings in random order and was not subject to bias resulting from knowledge of previous outcomes.

Independent Study Variables

Contact Combinations

All 50 bipolar combinations for four contacts were available for testing with the manual and automated methods. This represented exhaustive testing for Itrel 3 IPG systems, which support four contacts. For Synergy IPG systems, which support four to eight contacts, a subset of four was selected for testing if eight were implanted. Larger electrode configurations can be divided into subsets of contacts; for such large arrays, local testing of a subset at a specific spinal level is typical practice (1, 2, 9, 10, 19). Exhaustive testing of eight contact arrays (with 6050 possible contact polarity combinations) is not feasible with any method (manual or automatic) because of time requirements.

Pulse Parameters

Pulse width and rate (or frequency, the reciprocal of the interpulse interval) were held constant for both manual and automated testing for each patient. The clinical investigator established pulse parameters consistent with individual requirements, beginning with default values and observing an allowed range of values for the study, based on typical values used in clinical practice. The default pulse width was 450 microseconds (allowed range, 100–450 μs), and the default rate was 60 pulses/s (allowed range, 40–100 pulses/s).

Clinical Center and Practitioner Experience

For each study center, the experience of the practitioner performing the programming was assessed as the total number of stimulators programmed in the 2-year period preceding the study. This was dichotomized as high or low; programming of 20 or more stimulators in the preceding 2 years was categorized as high and smaller values as low.

Patient Experience

In some cases, patients were undergoing formal programming, comparing multiple settings, for the first time after implantation, although all had undergone at least preliminary adjustment at the time of implantation, establishing some degree of coverage of pain areas by stimulation paresthesiae. In other cases, patients returning for clinical follow-up evaluations requested reprogramming to improve coverage. Patients in both categories were enrolled consecutively as they presented, and the duration of patient experience was recorded.

Dependent Study Variable: Patient Ratings

The 100-mm VAS is an established measure used in clinical pain practice and research to record patient ratings (7, 21). Pain ratings and drawings with computer graphic tablets and methods have been validated against pen-and-paper methods (6, 12, 17, 23). It has been demonstrated for a number of years that pain relief with SCS is strongly correlated with patient ratings of the overlap of the painful areas by stimulation paresthesiae (3, 8, 13, 15, 22). Therefore, we chose the VAS rating of overlap as the primary outcome measure, or dependent variable, in this study.

Statistical Methods

The primary statistical result for this study was the mean difference in VAS ratings of overlap between the highest-rated manual setting and the highest-rated automated setting. For numeric accuracy and to avoid possible bias introduced by the modality of data collection, the pen tablet computer-collected data were used as the standard data for each setting. The mean differences were compared with a two-tailed, paired, Student’s t test. The VAS ratings were transformed with an arc-sine transformation, to satisfy the assumptions of the t test. All enrolled patients were included in this analysis (intent to treat). The sample size of the study was chosen to yield 90% power to detect an effect size of 0.75 with a two-sided 5% α level test. Patients were enrolled equally from the two participating centers. The analysis was paired, but for design purposes we assumed no correlation between results for the same patient. This assumption yielded a conservative sample size.

To account for the effects of practitioner experience and center (and other possible confounders), linear regression methods were used (analysis of covariance). The difference in VAS ratings for each patient was modeled as a function of categorical covariates based on the center and degree of experience, to assess their effects and independence. If statistically significant effects were observed for the center and experience, then the overall effect would be taken to be that produced by this adjusted analysis.

Clinically significant end points were the determination of identical prescription settings with the two adjustment methods for all patients or the determination of a statistical difference (α = 0.05) in patient VAS ratings for the best setting for each adjustment method. As secondary outcome measures, the mean differences in the rate of testing and in overall adjustment times were compared, again using a two-tailed,
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FIGURE 3. Representative patient data from the present study, displayed by the automated system as an overlay of pain drawing and stimulation drawing data, with the associated amplitude setting and patient rating, for a single contact combination. This screen is displayed to the system operator. This patient has drawn bilateral lower buttock and lower extremity pain (magenta in the original color display) superimposed on the right side, using the right-side contacts in a two-column array.

Paired, Student’s $t$ test, with each patient acting as his or her own control.

RESULTS

Forty-four patients were enrolled, 22 from each center. Thirty-one patients were female and 13 were male. Thirty-seven patients were Caucasian and 7 were African American. Ages ranged from 21 to 85 years, averaging 48.4 ± 11.8 years (mean ± standard deviation). Patient experience ranged from 0.08 to 10 years, averaging 2.2 ± 2.6 years. Practitioner experience was low (<20 cases programmed) in 10 cases and high in 34 cases. Of 44 implants, 29 were Synergy (6 with four-contact electrodes and 23 with eight-contact or dual four-contact electrodes) and 15 were Itrel 3. Twenty-six implants used Resume insulated electrodes (Medtronic) and 18 used Pisces-Quad percutaneous catheters (Medtronic).

The primary outcome measure, namely the 100-pointVAS rating of overlap, was significantly higher ($P < 0.0001$, paired Student’s $t$ test) for the automated method than for the manual method (VAS ratings of 69.5 ± 26.3 and 46.3 ± 31.8, respectively; a 1.50-fold difference and an absolute difference of 23.2 ± 22.0 points [mean ± standard deviation]). Comparisons of data for individual patients demonstrated that the VAS rating was higher for automated testing for 38 patients, higher for manual testing for 0 patients, and equal (tied) for 6 patients. Of the six ties, three occurred at maximal ratings and one at a minimal rating. Figures 3 and 4 show representative data.

Stepwise linear regression modeling predicted a small amount of the difference in scores on the 100-point VAS scale, on the basis of other variables. Higher manual VAS scores were significantly ($P < 0.0001$) associated with smaller differences; this accounted for 0.4 points of the 23.2-point difference. Patient years of experience were significantly ($P = 0.04$) associated with larger differences (2.1 VAS points/yr experience, after accounting for other baseline differences), and pulse rate was marginally ($P = 0.06$) associated with larger differences (0.19 points/1 pulse/s). No associations were observed with other independent variables, including practitioner experience.

The rate of testing averaged 0.73 settings/min for automated testing, compared with 0.49 settings/min for manual testing (a 1.49-fold difference, $P = 0.0001$, paired Student’s $t$ test). The number of settings tested totaled 2154 and averaged 49.0 ± 5.1 for the automated method. Forty-two patients completed all 50 possible settings; one completed only 35 and another 19. The number of settings tested manually totaled 440 and averaged 10 ± 0. Overall adjustment times averaged 67.3 ± 18.5 minutes for the automated method versus 22.3 ± 8.2 minutes for the manual method (a 3.0-fold difference).

The implant battery life associated with each setting was calculated. The longest time for each patient averaged 156.8 months for the automated method versus 94.2 months for the manual method (a 1.67-fold or 62.6-mo absolute difference; $P = 0.003$, paired Student’s $t$ test). The battery life calculated for each patient’s highest-rated setting averaged 41.2 months for the automated method versus 47.7 months for the manual.
method (a 0.86-fold or –6.5-mo absolute difference; \(P = 0.13\), not significant, paired Student’s \(t\) test).

There was a single instance of inadvertent excessive stimulation causing significant patient discomfort, which occurred during a manual testing session (after the patient had successfully completed her automated testing session). The practitioner turned off the IPC, waited until the patient composed herself, and then programmed the patient’s chosen final setting (an automated setting).

Four of the 44 patients were inadvertently tested with pulse widths or rates that differed between sessions, because of practitioner error in entering these values into the manual programmer and/or the automated system. Exclusion of these four patients from the statistical analysis had no effect on the results.

**DISCUSSION**

This study demonstrates the superiority of automated testing over manual methods, with respect to the efficacy and efficiency (settings per unit time) of testing. It should be noted that the number of settings tested was nearly fivefold greater for the automated method, in threefold greater time. Therefore, although it was more efficient, automated testing proved superior at least in part because of more-thorough testing. This occurred at the choice of the practitioners performing the study; they were under no time or sample size constraints, except for the requirement to test at least 10 settings with each method. This supports the study hypothesis that automated methods are more user-friendly and rewarding than manual methods, from the perspective of both users (the practitioner and the patient). The practitioner’s effort is limited to setup and supervision; the intensity of supervision decreases as the patient demonstrates competence in using the system. The patient, who is empowered to adjust the system autonomously and more efficiently, is motivated to complete the task (as noted for 42 of 44 patients).

The study might have been designed to require that a larger number of settings be tested manually and/or that more time be spent on manual testing. It was evident from the study data, however, that manual testing of 10 settings represented the limit of compliance; this value was never exceeded. At the observed testing rates, had it been required that manual testing time be extended to equal automated testing time and had the practitioners and patients complied, manual testing still would have been incomplete and the outcome still would have favored the automated method.

In this study, time spent by the practitioner in automated testing was tabulated as including the time spent by the patient in completing the tutorial. This automated process required a minimum of 7 minutes, including a fixed display time for a video, followed by an interactive session that (like actual adjustment) varied in duration, as determined by the patient. This process does not require supervision by the practitioner; the patient’s stimulator is not used and need not be connected (or even implanted yet). The time spent by the practitioner could have been reduced by this amount. Such a reduction would further increase the calculated efficiency of the automated method, to approximately twice the manual rate. With additional experience, each patient may be expected to use the automated system even more efficiently and each practitioner may be expected to become more efficient than observed in this study. Ultimately more significant to the practitioner and the patient, however, is the reduced level of supervision required for ongoing testing after the patient has learned to use the automated system. We did not attempt to measure the intensity of effort of the supervising practitioner during this phase of automated testing; it was usual, however, for the practitioner to attend to other duties as possible. Ultimately, the amounts of practitioner effort were comparable for the two methods.

The ability to test SCS settings automatically, systematically, and exhaustively (limited by patient time, motivation, and energy more than by practitioner resources) is very useful in clinical practice. This has been observed for more than 400 patients with the use of a similar prototypical system in a routine clinical setting (20). Some patients are more demanding than others, and some are more motivated than others; their needs can be met with automated testing, and the patient and practitioner can be assured that adjustments have been optimized to the desired degree. If coverage of a patient’s areas of pain is suboptimal, to an extent that the practitioner might consider surgical revision of the implant, then thorough testing is important (before revision); automated testing facilitates this and documents it fully. Programmable multicontact systems have reduced the frequency of surgical revision (19), and automated methods may be expected to contribute to further reductions.

This study is limited to short-term measurements of technical outcomes, namely coverage of areas of pain by stimulation paresthesiae. Achieving the best subjective result by this measure is standard clinical practice; it has been demonstrated in more than three decades that this is a necessary condition for pain relief and that it determines long-term clinical results (3, 8, 13, 15, 22). Programmable multicontact systems have improved technical as well as clinical results (1, 15). It follows that the automated adjustment methods described here should improve the ultimate clinical results, but demonstration of this idea is beyond the scope of this study.

This study addressed the major determinant of technical and clinical outcomes, namely the locations of the stimulating cathodes and anodes (3, 8, 15). Pulse width and rate were held constant. These parameters are routinely adjusted with the same methods, posing a problem comparable to the problem we studied, although the number of choices for each parameter is smaller than the number of contact combinations in this study. The advantages of automated, patient-interactive methods may be expected to apply to the adjustment of these parameters as well.

Implant battery life was calculated for each setting tested, and we observed a substantial potential advantage for the settings identified with the automated method (a 1.67-fold or
Conversely, the battery life calculated for each patient be achieved at the expense of clinically suboptimal settings. However; savings might be achieved at the expense of clinically suboptimal settings. Conversely, the battery life calculated for each patient's highest-rated setting was lower for the automated method (0.86-fold or −6.5-mo absolute difference).

This finding is consistent with previous reports indicating that, as indicated by clinical and technical outcome measures, patients prefer settings that require higher power (e.g., multiple active contacts and higher pulse rates) (17, 19). In this study, automated methods were more effective than manual methods in identifying preferred settings (1.5-fold greater coverage) but yielded increased power requirements (1.16-fold). The quotient of these two values (coverage/power), i.e., 1.50/1.16 = 1.29, indicates that automated methods are “cost-effective” by this measure (i.e., a little extra power affords much more coverage).

SCS has been established as cost-effective by a variety of measures and despite the associated expense (in comparison with treatment alternatives) (4). Automated methods may be expected to enhance this advantage. If IPG replacement or primary stimulator implantation is assumed to cost $10,000 to $25,000, then automated methods might be projected to save several thousand dollars. Ultimately, clinical outcome studies will be necessary to establish the actual magnitude of these savings.

SCS can be and is routinely adjusted to (or very close to) uncomfortably strong amplitudes, to maximize the area of coverage, during the optimization of settings for pain relief (3, 14). The automated system has been designed to minimize such discomfort, by allowing direct patient control without the delays associated with a human intermediary. The system introduces shortcuts (e.g., the amplitude may be immediately decreased to any desired level) as well as safeguards (the amplitude may not be increased as rapidly). In general, the automated system has been designed to make adjustments easier and safer, in comparison with conventional manual methods. This study confirms this, in that there were no instances of inadvertent uncomfortable stimulation with the automated system, whereas there was one such instance with the manual method.

Are any patients more likely to benefit from automated methods than others? It might be expected that initial programming for patients who had recently undergone implantation would be more beneficial, but this was not the case in our study; in fact, more experienced patients derived significantly more benefit. Within our study population, which consisted of consecutive patients presenting to the clinic for initial or follow-up programming, most of the benefit could not be predicted. Although the manual scores were somewhat predictive of a difference (higher manual scores predicted slightly smaller differences), the magnitude of this effect was quite small, accounting for 0.4 points of the 23-point difference on the 100-point VAS scale. The effects of the other two statistically significant predictors were also small (i.e., 2 points/1 yr of patient experience and 0.2 points/1 pulse/s). Most of the overall benefit was independent of these variables and thus was attributable to the automated method itself.

Although we have demonstrated the superiority of automated, patient-interactive methods, have these methods achieved the optimal results? In cases in which we exhaustively tested the available contact combinations, we can claim to have achieved full optimization, i.e., the 15 patients with four-contact Itrel stimulators and the 6 patients with four-contact Synergy stimulators, for whom no additional combinations are possible. For the patients with eight-contact Synergy systems, we optimized the setting for the chosen four-contact subset. A highly motivated patient and practitioner might test many more of the 6050 contact combinations but, even assuming that automated methods permit a testing rate twice that of manual methods, complete testing would require 100 hours. As we accumulate data for these more complex systems, we hope to acquire the expertise to optimize settings more elegantly than by exhaustive testing.

CONCLUSIONS

Patient-interactive, automated adjustment of implanted spinal cord stimulators is significantly more effective and more efficient than traditional manual methods of adjustment. It offers the additional potential advantages of standardization, quality control, and record keeping, to facilitate clinical research and patient care, and it offers potential savings in battery life. It enhances the clinical application of SCS for the treatment of chronic intractable pain.

DISCLOSURE

This research study was supported by Stimsoft, Inc. RBN is a Johns Hopkins University faculty member; he is also president of Stimsoft and serves as a member of the company's board of directors. Under a licensing agreement between Stimsoft and the Johns Hopkins University, RBN is entitled to a share of royalties received by the University for the sale of certain products. RBN and members of his family own the majority of Stimsoft stock. The University has agreed to this arrangement, which is managed in accordance with its policies regarding conflicts of interest.

REFERENCES

Spinal Cord Stimulator Adjustment

North et al. present a well-designed study evaluating the efficacy of a patient-interactive, computerized system for programming spinal cord stimulators. Previous studies have evaluated similar systems for programming radiofrequency-coupled spinal cord stimulators, but this technology has not been previously available for use in systems driven by implanted pulse generators. Current spinal cord stimulators typically include leads with either four or eight contacts, translating into a potential 50 or 6050 bipolar combinations, respectively. The process of selecting the appropriate electrode combination can be an arduous, time-consuming process for the practitioner. The present study demonstrates the efficacy of using a computer program to sequentially test a series of preselected combinations. The authors demonstrate that this automated system was capable of testing settings approximately 1.5 times faster than manual testing. Even more striking was the fact that the visual analog scale rating of paresthetic overlap was significantly higher for the automated method than the manual method. Interestingly, the advantage occurred independently of practitioner experience.

Although the automated system was capable of faster testing, it reviewed five times the number of programs compared with the manual method. Thus, the overall testing time was actually longer. However, this system obviates the need for the practitioner or his designee to be present throughout the testing session. Although the current automated system is capable of fully testing the 50 potential bipolar combinations of a four-contact lead, time constraints would make thorough testing of an eight-contact lead impractical. We may hope that future advances in this technology will incorporate some form of programming algorithm as opposed to exhaustive testing.

Kim J. Burchiel
Louis A. Whitworth
Portland, Oregon

Spinal cord stimulators have been used increasingly in the past few decades in the treatment of chronic pain. At the Istituto Nazionale Neurologico “Carlo Besta” of Milan, since 1974, we have implanted these stimulators in more than 1000 patients, and time-consuming standard manual programming sessions are well known by all members of my staff. We all welcome a user-friendly, patient-interactive automated system for testing the effects of different stimulation parameters. The authors, in their multicentric study, have provided an elegant and well-designed demonstration of the superiority of this new computerized, automated, patient-interactive adjustment system over the traditional manual method of adjustment. The method they used is easily reproducible, and their results can be promptly verified by others. In addition, their method will certainly be helpful to assess the efficacy of other automated systems. Automated, computerized methods should also be introduced and applied to the other fields in which chronic stimulation of the central system has proved useful, such as in the treatment of movement disorders. This article, stressing the usefulness of well-designed automated stimulation parameter adjustment systems, may contribute to their diffusion with the ultimate goal of an easy, standardized, and safe testing modality that can allow the practitioner to use the capabilities of these devices to full patient advantage.

Giovanni Broggi
Milan, Italy

This article by North et al. describes a computerized, patient-interactive system for adjustment of dorsal column stimulators in patients experiencing intractable pain. The authors attempted to solve the problems and understand the interaction by an objective method regarding the stimulation
parameters, relief of pain, and occurrence of dysesthesia. Several methods were proposed to score the pain, including verbal, numeric, and/or visual rating scales. Continuous assessment of pain by use of such scales must be carried out by an independent observer, and measurement of subjective pain experience requires a reliable, easy, consistent, and valid method. During the test stimulation period, many parameters and responses from the patient may constitute a complex situation to evaluate. The manual methods for testing may be time consuming, and interpretation of such a trial may be extremely difficult. Conversely, computerized and automated methods may be used only in patients capable of full cooperation. The authors show the advantages of their computerized and automated testing method over manual methods; such methods will increase the efficacy and the beneficial effect of dorsal column stimulation.

Yücel Kanpolat  
Ali Savas  
Ankara, Turkey

It is well known to all of us who have experience with spinal cord stimulation that the programming of four-polar electrodes, not to mention eight-polar arrays, is a very tedious and time-consuming task. Therefore, any means for making this procedure more efficient and simple are welcome. North et al. present an attractive system for screening stimulator settings that minimizes the active participation of the physician. This patient-interactive system is apparently designed for programming the permanently implanted system, but in most cases, the major effort in exploring the different polar combinations and stimulus parameters is made during the course of trial stimulation. Generally, the stimulator setting found to be optimal can then be used for the permanently implanted system. For a long time, we have used a form with all the 50 different polar combinations listed, and most patients learn to manage the polar settings on the external stimulator and to make notes about the covering of paresthesia. The advantage of this approach is that the testing can be done without time limitation at home, and the patient may then also try the chosen contact combinations when sitting, walking, reclining, etc. It only remains for the physician to optimize the polar setting with fine tuning of the pulse width. For obvious reasons, this method is not applicable to a permanently implanted system, and it also lacks the precision and quantitative documentation provided by the system developed by North et al. I assume that no technical problems would arise in adapting that system to the trial stimulation phase. In fact, that would be very useful for preliminary identification of a few contact combinations with good paresthesia covering, which the patient could then experiment with at home.

The study by North et al. is professionally designed and performed, and there is no reason to question the reliability of the outcome. However, it should be noted that the testing was performed on patients who already had experience with stimulation (mean, >2 yr) and knew how an optimal setting should feel to obtain maximal pain relief; that is not the case when stimulation is applied in naive patients.

The efficacy of the system is to a large extent evaluated in terms of time required related to number of settings assessed: 2.2 min per setting with manual testing and 1.3 min per setting with the automated method. It is my experience that such speedy testing procedures may be unreliable, because, as we all know, even a very minute change of body posture may influence the intensity and distribution of paresthesia. One may also ask whether a short time given to the patient to experience a certain stimulation setting as a base for the definitive programming does not increase the likelihood that later reprogramming will be required. As far I can see, the study by North et al. does not provide data on the long-term clinical efficiency of the final stimulator setting selected by the automated versus the manual method.

Björn Meyerson  
Stockholm, Sweden

Congress of Neurological Surgeons/American Association of Neurological Surgeons Joint Section Chairmen

Cerebrovascular Surgery: Robert Harbaugh, Lebanon, New Hampshire
Disorders of the Spine and Peripheral Nerves: Nevin G. Baldwin, Lubbock, Texas
History of Neurological Surgery: Michael Schulder, Newark, New Jersey
Neurotrauma and Critical Care: M. Ross Bullock, Richmond, Virginia
Pain: Jaimie Henderson, Cleveland, Ohio
Pediatric Neurological Surgery: Thomas G. Luerssen, Indianapolis, Indiana
Stereotactic and Functional Neurosurgery: Douglas Kondziolka, Pittsburgh, Pennsylvania
Tumors: James T. Rutka, Toronto, Ontario, Canada